BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Pharmaceutical Sciences
M.Pharm - Master of Pharmacy
New Syllabus

BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY)

A GRADE AWARDED BY GOVT OF INDIA
A+ GRADE REACCREDITATION BY NAAC

Faculty of Pharmaceutical Sciences
Master of Pharmacy

M.Pharm. (PCI Syllabus)

PROGRAMME STRUCTURE & SYLLABUS
CBCS

w.e.f. 2019-20
M.Pharm. CBCS 19-20

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FACULTY OF PHARMACEUTICAL SCIENCES

MASTER OF PHARMACY (M.PHARM.)

M. Pharm. (PCI Syllabus)

Choice-Based Credit System

Programme Structure and Syllabus

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M.Pharm. CBCS 2019-20

Bharati Vidyapeeth (Deemed to be University), Pune

Bharati Vidyapeeth, the parent organization of this University is one of the largest educational organizations in the country. It has 180 educational units under its umbrella including 80 Colleges and Institutes of conventional and professional disciplines.

The Ministry of Human Resource Development, Government of India on the recommendations of the University Grants Commission accorded the status of "Deemed to be University" initially to a cluster of 12 units of Bharati Vidyapeeth. Subsequently, 17 additional colleges / institutes were brought within the ambit of Bharati Vidyapeeth University wide various notifications of the Government of India. Bharati Vidyapeeth (Deemed to be University), commenced its functioning on 26th April, 1996.

Constituent Units of Bharati Vidyapeeth (Deemed to Be University)

1. BVDU Medical College, Pune.
2. BVDU Dental College & Hospital, Pune
3. BVDU College of Ayurved, Pune
4. BVDU Homoeopathic Medical College, Pune
5. BVDU College of Nursing, Pune
6. BVDU Yashwantrao Mohite College of Arts, Science & Commerce, Pune.
7. BVDU New Law College, Pune
8. BVDU Social Sciences Centre (M.S.W.), Pune
9. BVDU Yashwantrao Chavan Institute of Social Science Studies & Research, Pune.
10. BVDU Centre for Research & Development in Pharmaceutical Sciences & Applied Chemistry, Pune
11. BVDU College of Physical Education, Pune.
12. BVDU Institute of Environment Education & Research, Pune
13. BVDU Institute of Management & Entrepreneurship Development, Pune
14. BVDU Poona College of Pharmacy, Pune
15. BVDU College of Engineering, Pune
16. BVDU Interactive Research School in Health Affairs (IRSHA), Pune
17. BVDU Rajiv Gandhi Institute of Information Technology & Biotechnology, Pune
18. BVDU College of Architecture, Pune
19. BVDU Abhijit Kadam Institute of Management & Social Sciences, Solapur
20. BVDU Institute of Management, Kolhapur
21. BVDU Institute of Management & Rural Development administration, Sangli
22. BVDU Institute of Management & Research, New Delhi
23. BVDU Institute of Hotel Management & Catering Technology, Pune
24. BVDU Yashwantrao Mohite Institute of Management, Malakapur-Karad
25. BVDU Medical College & Hospital, Sangli
26. BVDU Dental College & Hospital, Mumbai
27. BVDU Dental College & Hospital, Sangli
28. BVDU College of Nursing, Sangli
29. BVDU College of Nursing, Navi Mumbai

The status of university was given to a cluster of these colleges and institutes in appreciation of the high level of their academic excellence and for their potential for further growth.

During the last 20 years or so, the University has achieved higher pinnacles of academic excellence and has established its reputation to such an extent that it attracts students not only from various parts of India but also from abroad. According to a survey conducted by Association of Indian Universities, this University is one among the top ten Universities in the country preferred by the overseas students for admissions. At present, there are more than 850 overseas students from 47 countries on the rolls of constituent units of this University.

During the last 20 years, there has been tremendous academic expansion of the University. It now conducts in all 305 courses in its constituent units, of them 108 are Post Graduate, 45 are Under Graduate and 55 Diploma level courses. 12 Fellowship and 5 certificate courses. All the professional courses which the University conducts such as those of Medicine, Dentistry, Engineering etc., have approval of the respective statutory councils, viz., Medical Council of India, Dental Council of India, All India Council for Technical Education etc.

The University is a throbbing center of research activities and has launched Ph.D. programmes in 77 subjects and M.Phil in 3 subjects. It has also introduced quite few innovative academic programmes such as Masters in Clinical Optometry, M.Tech. in Nano Technology etc.

The University's performance and achievements were assessed by the "National Assessment and Accreditation Council" and it was reaccredited with a prestigious "A" grade in 2011. Some programmes of the constituent units such as College of Engineering at Pune, Management Institute in Delhi and others have also been accredited by "National Board of Accreditation". Three constituent units of Bharati Vidyapeeth (Deemed to be University), are also the recipients of ISO 9001-2001 certifications.

BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY)

POONA COLLGE OF PHARMACY, PUNE

Bharati Vidyapeeth's Poona College of Pharmacy was established in 1981. This college has got approval and recognition of All India Council of Technical Education, New Delhi, Pharmacy Council of India, New Delhi and Bharati Vidyapeeth (Deemed to be University). Earlier the college was affiliated to University of Poona and Maharashtra University of Health Sciences. Now it is a constituent unit of Bharati Vidyapeeth (Deemed to be University). The College conducts B.Pharm, M.Pharm (in Pharmaceutics, Pharm. Chemistry, Pharmacology, Pharmacognosy and Quality Assurance Techniques). The college is housed in beautiful building and located in our bewitching teaching complex at Erandwane, Paud Road, Pune. The excellence which this college has achieved during these years in Pharmacy education is mainly due to its experienced and qualified teaching faculty and the infrastructural facilities of high quality provided in the college. The college has excellent library with modern books on pharmacy. The college also provides hostel facilities on a limited scale to our students both boys and girls.

As soon as the college came under the ambit of Bharati Vidyapeeth (Deemed to be University), the syllabus of B.Pharm and M.Pharm Course was revised and upgraded with the help of eminent experts in the pharmacy and the same was approved by University Authorities. While doing so the guidelines given by UGC, AICTE, Pharmacy Council of India, and the societal needs have been taken into consideration.

VISION:

To be recognized as a premier pharmacy institution of academic excellence.

MISSION STATEMENT:

1) To produce competent pharmacists catering to the needs of Industry, Academia, Research and Society.
2) To create a centre of excellence for education and research in the field of pharmac utical sciences.
3) To contribute our humble share to ensure the wellbeing and to reduce the suffering of mankind.

PROGRAMME EDUCATIONAL OBJECTIVES (PEO)

1) To provide a comprehensive pharmaceutical education leading to B. Pharm. Degree.
2) To integrate pharmacy knowledge and skills with pharmaceutical research so as to increase inclination for higher studies and research.
3) To develop pharmacists to contribute effectively in the social health care system.
4) To provide hands on training through state of art infrastructure to meet challenges of pharmacy profession.
5) To inculcate leadership and entrepreneurship capabilities in future pharmacists.

PROGRAMME OUTCOMES (POS)

On completion of the B. Pharm. program, a student will be able to:

1. Demonstrate knowledge of the basic pharmaceutical sciences and the ability to acquire, manage and use current information for problem solving.
2. Describe the synthesis, formulation, analysis and pharmacological aspects of drugs and pharmaceuticals.
3. Identify the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines.
4. Observe record, analyze, criticize, organize, improvise and manage documents, data and information related to pharmaceutical products and practices.
5. Develop problem-based learning approach and analytical thinking in his/her academic and professional life.
6. Demonstrate the ability to plan and implement professional activities.
7. Act efficiently as a leader in the diverse areas of the profession.
8. Write, interpret and communicate effectively and scientifically.
9. Apply the knowledge and skills gained through education to gain recognition in professional circle and society.
10. Partnering with other health care communities to provide innovative solutions.
11. Create awareness in society about the effective and safe use of medicines.
12. Demonstrate eco-friendly products and processes to maintain public health.
13. Imbibe ethical practices and moral values in personal and professional endeavors.
14. Tackle future challenges through lifelong learning.

CHAPTER –I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity

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7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours.Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The Course Content hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the Course Content hours shall be multiplied by 1/2. Similarly, the Course Content hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2.Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments,Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits

are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9.Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Quality Assurance	MQA
5.	Pharmaceutical Regulatory Affairs	MRA
6.	Pharmaceutical Biotechnology	MPB
7.	Pharmacology	MPL
8.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

Table 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wK	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affairs	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650

Table 3: Course of study for M. Pharm. (Industrial Pharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wK	Marks
Semester I					
MIP101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP102T	Pharmaceutical Formulation Development	4	4	4	100
MIP103T	Novel drug delivery systems	4	4	4	100
MIP104T	Intellectual Property Rights	4	4	4	100
MIP105P	Industrial Pharmacy Practical I	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPH201T	Advanced Biopharmaceutics and pharmacokinetics	4	4	4	100
MPH202T	Scale up and Technology Transfer	4	4	4	100
MPH203T	Pharmaceutical Production Technology	4	4	4	100
MPH204T	Entrepreneurship Management	4	4	4	100
MPH205P	Industrial Pharmacy Practical II	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650

Table 4: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./w K	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC102T	Advanced Organic Chemistry - I	4	4	4	100
MPC103T	Advanced Medicinal Chemistry	4	4	4	100
MPC104T	Chemistry of Natural Product	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650

Table 5: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wK	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650

Table 6: Course of study for M. Pharm. (Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./wK	Marks
Semester I					
MRA101T	Good Regulatory Practices	4	4	4	100
MRA102T	Documentation and Regulatory Writing	4	4	4	100
MRA103T	Clinical Research Regulations	4	4	4	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biological & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA105P	Regulatory Affairs Practical I	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA205P	Regulatory Affairs Practical II	12	6	12	150
	Seminar/ Assignment	7	4	7	100
	Total	35	26	35	650

Table 7: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wK	Marks
Semester I					
MPB101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB102T	Microbial and cellular Biology	4	4	4	100
MPB103T	Bioprocess Engineering and Technology	4	4	4	100
MPB104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB105T	Pharmaceutical Biotechnology Practical I	12	6	12	150
	Seminar / Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPB201T	Proteins and protein formulation	4	4	4	100
MPB202T	Immunotechnology	4	4	4	100
MPB203T	Bioinformatics and Computer Technology	4	4	4	100
MPB204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB205T	Pharmaceutical Biotechnology Practical II	12	6	12	150
	Seminar / Assignment	7	4	7	100
	Total	35	26	35	650

Table 8: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wK	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology I	4	4	4	100
MPL103T	Pharmaceutical and Toxicological Screening Methods I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105T	Pharmacology Practical I	12	6	12	150
	Seminar / Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmaceutical and Toxicological Screening Methods II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Experimental Pharmacology Practical II	4	4	4	100
MPL205T	Pharmacology Practical II	12	6	12	150
	Seminar / Assignment	7	4	7	100
	Total	35	26	35	650

Table 9: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wK	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacology I	4	4	4	100
MPG103T	Photochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105T	Pharmacognosy Practical I	12	6	12	150
	Seminar / Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPG201T	Medical Plant Biotechnology	4	4	4	100
MPG202T	Advanced Pharmacology II	4	4	4	100
MPG203T	Indian System of Medicine	4	4	4	100
MPG204T	Herbal Cosmetics	4	4	4	100
MPG205T	Pharmacognosy Practical II	12	6	12	150
	Seminar / Assignment	7	4	7	100
	Total	35	26	35	650

Table 10: Course of study for M. Pharm. III Semester (Common for all Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research methodology and biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	35	21

*Non University Exam

Table 11: Course of study for M. Pharm. IV Semester (Common for all Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final presentation	3	3
	Total	35	20

Table 12: Semester Wise Credits Distribution

Semester	Credit Points
I.	26
II.	26
III.	21
IV.	20
Co-curricular activities (attending conference, scientific presentations and other scholarly activities)	Minimum = 02 Minimum = 07*
Total Credit Points	Minimum = 95 Minimum = 100*

*Credit Points for Co-Curricular Activities

Table 13: Guidelines for Awarding Credit Points for Co-Curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar / Conference/ Workshop /Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/ Workshop /Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from eachM.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 16.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted by the respective university except for the subject with asterix symbol

(*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables 14: Schemes for internal assessments and end semester

(Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPH 102T	Drug Delivery System	10	15	1Hr	25	75	3Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1Hr	25	75	3Hrs	100
MPH 104T	Regulatory Affair	10	15	1Hr	25	75	3Hrs	100
MPH 105T	Pharmaceutics Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MPH 201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1Hr	25	75	3Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
MPH 203T	Computer Aided Drug Delivery Systems	10	15	1Hr	25	75	3Hrs	100
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1Hr	25	75	3Hrs	100
MPH 205P	Pharmaceutics Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 15: Schemes for internal assessments and end semester and end semester (Industrial Pharmacy-MIP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MIP 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MIP 102T	Pharmaceutical Formulation Development	10	15	1Hr	25	75	3Hrs	100
MIP 103T	Novel drug delivery systems	10	15	1Hr	25	75	3Hrs	100
MIP 104T	Intellectual Property Rights	10	15	1Hr	25	75	3Hrs	100
MIP 105T	Industrial Pharmacy Practical -I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MPH 201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1Hr	25	75	3Hrs	100
MPH 202T	Scale up and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
MPH 203T	Pharmaceutical Production Technology	10	15	1Hr	25	75	3Hrs	100
MPH 204T	Entrepreneurship Management	10	15	1Hr	25	75	3Hrs	100
MPH 205P	Industrial Pharmacy Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 16: Schemes for internal assessments and end semester

(Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPC 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPC 102T	Advanced Organic Chemistry – I	10	15	1Hr	25	75	3Hrs	100
MPC 103T	Advanced Medicinal Chemistry	10	15	1Hr	25	75	3Hrs	100
MPC 104T	Chemistry of Natural Products	10	15	1Hr	25	75	3Hrs	100
MPC 105T	Pharmaceutical Chemistry Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MPC 201T	Advanced Spectral Analysis	10	15	1Hr	25	75	3Hrs	100
MPC 202T	Advanced Organic Chemistry II	10	15	1Hr	25	75	3Hrs	100
MPC 203T	Computer Aided Drug Design	10	15	1Hr	25	75	3Hrs	100
MPC 204T	Pharmaceutical Process Chemistry	10	15	1Hr	25	75	3Hrs	100
MPC 205P	Pharmaceutical Chemistry Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 17: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MQA 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MQA 102T	Quality Management Systems	10	15	1Hr	25	75	3Hrs	100
MQA 103T	Quality Control and Quality Assurance	10	15	1Hr	25	75	3Hrs	100
MQA 104T	Product Development and Technology Transfer	10	15	1Hr	25	75	3Hrs	100
MQA 105T	Pharmaceutical Quality Assurance Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MQA 201T	Hazards and Safety Management	10	15	1Hr	25	75	3Hrs	100
MQA 202T	Pharmaceutical Validation	10	15	1Hr	25	75	3Hrs	100
MQA 203T	Audits and Regulatory Compliance	10	15	1Hr	25	75	3Hrs	100
MQA 204T	Pharmaceutical Manufacturing Technology	10	15	1Hr	25	75	3Hrs	100
MQA 205P	Pharmaceutical Quality Assurance Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 18: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs-MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MRA 101T	Good Pharmaceutical Practices	10	15	1Hr	25	75	3Hrs	100
MRA 102T	Documentation and Regulatory Writing	10	15	1Hr	25	75	3Hrs	100
MRA 103T	Clinical Research Regulations	10	15	1Hr	25	75	3Hrs	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals a& Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	10	15	1Hr	25	75	3Hrs	100
MRA 105T	Pharmaceutical Regulatory Affairs Property Rights	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	10	15	1Hr	25	75	3Hrs	100
MRA 202T	Regulatory Aspects of Herbal &Biologicals	10	15	1Hr	25	75	3Hrs	100
MRA 203T	Regulatory Aspects of Medical Devices	10	15	1Hr	25	75	3Hrs	100
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	10	15	1Hr	25	75	3Hrs	100
MRA 205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 19: Schemes for internal assessments and end semester examinations (Pharmaceutical Biotechnology-MPB)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPB 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPB 102T	Microbial And Cellular Biology	10	15	1Hr	25	75	3Hrs	100
MPB 103T	Bioprocess Engineering and Technology	10	15	1Hr	25	75	3Hrs	100
MPB 104T	Advanced Pharmaceutical Biotechnology	10	15	1Hr	25	75	3Hrs	100
MPB 105T	Pharmaceutical Biotechnology	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MPB 201T	Proteins and protein Formulation	10	15	1Hr	25	75	3Hrs	100
MPB 202T	Immunotechnology	10	15	1Hr	25	75	3Hrs	100
MPB 203T	Bioinformatics and Computer Technology	10	15	1Hr	25	75	3Hrs	100
MPB 204T	Biological Evaluation of Drug Therapy	10	15	1Hr	25	75	3Hrs	100
MPB 205P	Pharmaceutical Biotechnology Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 20: Schemes for internal assessments and end semester examinations (Pharmacology-MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPL 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPL 102T	Advanced Pharmacology –I	10	15	1Hr	25	75	3Hrs	100
MPL 103T	PharmacologicalToxicological screening Methods-I	10	15	1Hr	25	75	3Hrs	100
MPL 104T	Cellular and Molecular Pharmacology	10	15	1Hr	25	75	3Hrs	100
MPL 105T	Experimental Pharmacology- I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MPL 201T	Advanced Pharmacology II	10	15	1Hr	25	75	3Hrs	100
MPL 202T	Pharmacologiacal and Toxicological Screening Methods – II	10	15	1Hr	25	75	3Hrs	100
MPL 203T	Principles of Drug Discovery	10	15	1Hr	25	75	3Hrs	100
MPL 204T	Clinical research and pharmacovigilance	10	15	1Hr	25	75	3Hrs	100
MPL 205P	Experimental Pharmacology II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 21: Schemes for internal assessments and end semester examinations (Pharmacognosy-MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPG 101T	Modern Pharmaceutical Analytical Techniques	10	15	1Hr	25	75	3Hrs	100
MPG 102T	Advanced Pharmacology –I	10	15	1Hr	25	75	3Hrs	100
MPG 103T	Phytochemistry	10	15	1Hr	25	75	3Hrs	100
MPG 104T	Industrial Pharmacognostical Technology	10	15	1Hr	25	75	3Hrs	100
MPG 105T	Pharmacognosy Practical I	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650
Semester II								
MPG 201T	Medicinal Plant Biotechnology	10	15	1Hr	25	75	3Hrs	100
MPG 202T	Advanced Pharmacognosy –II	10	15	1Hr	25	75	3Hrs	100
MPG 203T	Indian system of medicine	10	15	1Hr	25	75	3Hrs	100
MPG 204T	Herbal Cosmetics	10	15	1Hr	25	75	3Hrs	100
MPG 205P	Pharmacognosy Practical II	20	30	6Hrs	50	100	6Hrs	150
-	Seminar/ Assignment							100
	Total							650

Tables 22: Schemes for internal assessments and end semester examinations

(Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics	10	15	1Hr	25	75	3Hrs	100
	Journal club				25			25
	Discussion/ Presentation (Proposal Presentation)				50			50
	Research Work					350	1 Hr	350
	Total							525
Semester IV								
-	Journal club				25			25
-	Discussion/ Presentation (Proposal Presentation)				75			75
-	Research Work and Colloguium					400	1Hrs	400
-								500

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 23: Scheme for awarding internal assessment: Continuous mode Theory

Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 24: Guidelines for the allotment of marks for attendance

Percentage of Attendance	theory	Practical
95-100	8	10
90-94	6	7.5
85-89	4	5
80-84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular courseincluding internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However, his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 25. The exact dates of examinations shall be notified from time to time.

Table – 25: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and II	November /December	May / June
II and IV	May / June	November /December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfils the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 26.

Table – 26: Letter grades and grade points equivalent to percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

*A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$\mathrm{SGPA} = \frac{\mathrm{C1G1} + \mathrm{C2G2} + \mathrm{C3G3} + \mathrm{C4G4}}{\mathrm{C1} + \mathrm{C2} + \mathrm{C3} + \mathrm{C4}}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example, if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$\text{SGPA} = \frac{\text{C1G1} + \text{C2G2} + \text{C3G3} + \text{C4} * \text{ZERO}}{\text{C1} + \text{C2} + \text{C3} + \text{C4}}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\text{CGPA} = \frac{\text{C1S1} + \text{C2S2} + \text{C3S3} + \text{C4S4}}{\text{C1} + \text{C2} + \text{C3} + \text{C4}}$$

where C1, C2, C3,... is the total number of credits for semester I,II,III,…. and S1, S2, S3,….is the SGPA of semester I,II,III,…. .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	=	CGPA of. 7.50 and above
First Class	=	CGPA of 6.00 to 7.49
Second Class	=	CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation I Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Outcomes

1. 1Comprehend the basic concepts of UV-Visible, IR and NMR spectroscopic techniques and Mass spectrometry,
2. Explain instrumentation and their functions of UV-Visible, IR and NMR spectroscopy techniques and Mass spectrometry
3. Apply the chromatographic and electrophoresis separation for analysis of drugs.
4. Describe Immunological assays and X-ray crystallographic techniques
5. Interpret UV-Vis, IR, NMR and Mass spectra
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

THEORY **60 HOURS**

1. 11 hrs
   a) **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy.
   b) **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
   c) **Spectrofluorometric:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer
   d) **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.

2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double 11hrs

resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Masss spectroscopy. 11hrs

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: 11 hrs
   a) Paper chromatography
   b) Thin Layer chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gaschromatography
   f) High Performance Liquid chromatography
   g) Affinity chromatography

5. a. **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: 11 hrs
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   b. **X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X- ray diffraction.

6. **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays. 5 hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS (MPH 102T)

Objectives

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

Course Outcomes

1 Understand concept of sustained, controlled release formulations and 3D printing in pharmaceuticals
2. Identify different types of rate-controlled drug delivery systems.
3. Compare various Gastroprotective drug delivery systems.
4. Describe ocular drug delivery system, barrier of drug permeation and methods to overcome barriers.
5. Discuss formulation and evaluation aspects of transdermal drug delivery system.
6. Formulate and evaluate protein and peptide drug delivery system and understand concept of vaccine.

THEORY **60 Hrs**

1. Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine:Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. — 10 hrs

2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals. — 10 hrs

3. Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. — 10 hrs

4. Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 06 hrs

5. Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. 10Hrs 10 hrs

6. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. 08 hrs

7. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. 06 hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS (MPH 103T)

Objectives

Upon completion of the course, student shall be able to understand

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic Drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

Course Outcomes

1. Understand concepts of pre-formulation studies of various dosage forms.
2. Identify the importance of API in the development of branded and generic products.
3. Compare the regulatory aspects associated with calibration and validation of processes and equipments.
4. Describe concept of cGMP and industrial management.
5. Know compression, compaction and consolidation parameters.
6. Understand optimization and pilot plant scale up techniques.

THEORY **60 HRS**

1. a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. 10 Hrs
   b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

2. Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. 10 Hrs

3. cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost 10 Hrs

control, industrial and personal relationship. Concept of Total Quality Management.

4. Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. 10 Hrs

5. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test. 10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS (MPH 104T)

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

Course Outcomes

1. Illustrate the concepts of innovator and generic drugs.
2. Identify the regulatory guidance and guidelines for filing and approval of drug products.
3. Design Dossiers for submission to regulatory agencies in different countries.
4. Assess regulatory requirements for conducting clinical trials.
5. Plan pharmacovigilance activities.
6. Discuss post approval regulatory requirements for actives and drug products.

THEORY **60 Hrs**

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12hrs
   b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.

2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. 12hrs

3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). 12hrs

4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. 12hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I (MPH 105P)

Course Outcomes

1. Understand dissolution of sustained and controlled release formulation.
2. Compare dissolution profile of prepared formulation with marketed formulation.
3. Estimate effect of particle size and binder concentration on dissolution of tablet.
4. Compute micromeritic properties of powders and granules.
5. Study formulation and development of transdermal patch.
6. Study Heckel, Higuchi and Peppas's plot.

Content

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV
7. spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) (MPH 201T)

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

Course Outcomes

1. Apply the concept of drug targeting in the treatment of various diseases.
2. Understand formulation and evaluation of nanoparticles and liposomes.
3. Compare micro capsule and micro sphere-based systems.
4. Study formulation and evaluation of transdermal and pulmonary systems.
5. Apply nucleic acid based therapeutic delivery for management of hereditary disorders and cancer.
6. Compute the biopharmaceutics and pharmacokinetic parameters.

THEORY **60 Hrs**

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. — 12 Hrs

2. Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. — 12 Hrs

3. Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. — 12 Hrs

4. Pulmonary Drug Delivery Systems :Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. — 12 Hrs

5. Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.
   Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. — 12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Course Outcomes

1. Understand the various mechanisms of absorption of drug.
2. Identify the physiological, physicochemical and dosage form-related factors affecting drug absorption from different dosage forms
3. Design a dosage form on the basis of biopharmaceutical considerations and to understand its effect on In Vitro Drug Product Performance
4. Study different various pharmacokinetic models and their significance in interpreting various pharmacokinetic parameters
5. Establish in vitro-in vivo correlation for different drug products and Design protocols for bioavailability and bioequivalence studies
6. CO6: Understand the pharmacokinetic basis of modified-release and targeted drug delivery.

THEORY **60 Hrs**

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. **12hrs**

2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product. **12hrs**

3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein- binding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked to transporters. **12hrs**

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. **12hrs**

5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. **12hrs**

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Objectives

Upon completion of this course it is expected that students will be able to understand,

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence (AI) and Robotics
8. Computational fluid dynamics(CFD)

Course Outcomes

1. Understand concepts of computational modeling for the drug disposition.
2. Identify the importance of computers in the market analysis.
3. Know the computers in preclinical studies
4. Learn artificial intelligence and robotics in drug development.
5. Apply various pharmaceutical techniques in pharmaceutical formulation.
6. Understand computer aided biopharmaceutical characterization of formulation.

THEORY **60 Hrs**

1.	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12hrs
2.	Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12hrs
3.	Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in	12hrs

Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

4. a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations
   b. Computer simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
   c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems — 12hrs

5. Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. — 12hrs

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH 204T)

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

Course Outcomes

1. Understand key ingredients used in cosmetics and cosmeceuticals.
2. Know key building blocks for various formulations.
3. Study regulatory and biological aspects for cosmeceuticals.
4. Identify different design of cosmeceutical products.
5. Understand the challenges in formulating herbal cosmetics.
6. Formulate and evaluate various cosmetics and cosmeceuticals.

THEORY **60 Hrs**

1.	Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12hrs
2.	Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12hrs
3.	Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.	12hrs

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.
Controversial ingredients: Parabens, formaldehyde liberators, dioxane

4. Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. 12hrs

5. Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. 12hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II (MPH 205P)

Course Outcomes:

1. Understand dissolution improvement approach of poorly soluble drug using solid dispersion technique.
2. Prepare and evaluate nanocarrier systems (niosomes& liposomes).
3. Study preparation methods of microcapsule.
4. Demonstrate pharmacokinetic and IV-IVC data analysis by Winonlin software.
5. Describe importance of design of experiment and quality by design for pharmaceutical development.
6. Prepare and evaluate microspheres and spherules.

Content

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

INDUSTRIAL PHARMACY(MIP)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Outcomes

1. Comprehend the basic concepts of UV-Visible, IR and NMR spectroscopic techniques and Mass spectrometry,
2. Explain instrumentation and their functions of UV-Visible, IR and NMR spectroscopy techniques and Mass spectrometry
3. Apply the chromatographic and electrophoresis separation for analysis of drugs.
4. Describe Immunological assays and X-ray crystallographic techniques
5. Interpret UV-Vis, IR, NMR and Mass spectra
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

THEORY **60 HOURS**

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 11hrs

   IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   Flame emission spectroscopy and Atomic absorption

   spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 11hrs

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy — 11hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: — 11hrs

   a) Paper chromatography b) Thin Layer chromatography

   c) Ion exchange chromatography d) Column chromatography

   e) Gas chromatography f) High Performance Liquid chromatography

   g) Affinity chromatography

5. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: — 11hrs
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Immunological Assays: Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. — 5hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 102T)

Objectives

On completion of this course it is expected that students will be able to understand-

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

Course Outcomes

1. Understand concepts of pre-formulation studies of various dosage forms.
2. Identify the role of pharmaceutical additives in formulation development.
3. Compare in vitro and in vivo correlation.
4. Describe concept of design of experiment in product development.
5. Know concept of solubility and methods to enhance solubility.
6. Understand stability protocols, report and ICH guidelines.

THEORY **60 Hrs**

1. Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. 12Hrs

2. Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development. 12Hrs

3. Solubility: Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. 12Hrs

4. Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations. 12Hrs

5. Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH 12Hrs

effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. he Theory and Practice Of rd ndustrial Pharmacy, 3 ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms:tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3 ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3 CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

Objective

On completion of this course it is expected that students will be able to understand,

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

Course Outcomes

1. Understand concept of sustained, controlled release formulations and 3D printing in pharmaceuticals
2. Identify different types of rate-controlled drug delivery systems.
3. Compare various Gastroprotective drug delivery systems.
4. Describe ocular drug delivery system, barrier of drug permeation and methods to overcome barriers.
5. Discuss formulation and evaluation aspects of transdermal drug delivery system.
6. Formulate and evaluate protein and peptide drug delivery system and understand concept of vaccine.

THEORY **60 Hrs**

1. Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.
   Carriers for Drug Delivery: Polymers / co-polymers- introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers. — 12Hrs

2. Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems — 12Hrs

3. Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. — 08Hrs

4. Sub-Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects. 04Hrs

5. Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions. 12Hrs

6. Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

7. Biotechnology in Drug Delivery Systems: Brief review of major areas- recombinant DNA technology, monoclonal antibodies, gene therapy. 06Hrs

8. New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 06Hrs

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS (MIP 104T)

Objectives

On completion of this course it is expected that students will be able to understand,

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

Course Outcomes

1. Understand regulatory audit process.
2. Study regulatory guidelines of drug and drug product.
3. Compare different regulatory agencies.
4. Describe regulatory requirement for contract research organization.
5. Know trademark, patent, IPR and types of IPR.
6. Study regulations associated with biosimilars.

THEORY **60 Hrs**

1.	Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.	12 Hrs
2.	Role of GATT, TRIPS, and WIPO	12 Hrs
3.	Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.	12 Hrs
4.	Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	12 Hrs
5.	Regulatory requirements for contract research organization. Regulations for Biosimilars.	12 Hrs

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

INDUSTRIAL PHARMACY PRACTICAL - I (MIP 105P)

Course Outcomes

1. Demonstrate data analysis by UV and HPLC analysis.
2. Learn to quantify the drug from different spectroscopic methods.
3. Understand the different approaches to find out the solubility and stability of different dosage forms.
4. Study formulation and development of various dosage forms including tablets, capsules and liposomes,TDDS and semisolid dosage forms.
5. Understand dissolution improvement approach of poorly soluble drug using solid dispersion technique.
6. Learn to carry out electrophoresis of various peptide drug delivery system.

Course Content

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation.
9. Stability studies of drugs in dosage forms at 25 RH.C, 60% RH and 40 C, 75%
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 201T)

Objectives

On completion of this course it is expected that students will be able to understand,

1. The basic concepts in Biopharmaceutics and pharmacokinetics.
2. The use of raw data and derive the pharmacokinetic models and
3. parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
4. To critically evaluate Biopharmaceutics studies involving drug product equivalency.
5. To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutics parameters.

Course Outcomes

1. Understand the various mechanisms of absorption of drug.
2. Identify the physiological, physicochemical and dosage form-related factors affecting drug absorption from different dosage forms
3. Design a dosage form on the basis of biopharmaceutical considerations and to understand its effect on In Vitro Drug Product Performance
4. Study different various pharmacokinetic models and their significance in interpreting various pharmacokinetic parameters
5. Establish in vitro-in vivo correlation for different drug products and Design protocols for bioavailability and bioequivalence studies
6. Understand the pharmacokinetic basis of modified-release and targeted drug delivery.

THEORY **60 Hrs**

1. Drug Absorption from The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. — 12 Hrs
2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic

Factors Affecting Drug Bioavailability, Rate- Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product

3. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. 12 Hrs

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution. 12 Hrs

5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies. 12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B.J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

SCALE UP AND TECHNOLOGY TRANSFER (MIP 202T)

Objectives: On completion of this course it is expected that students will be able to understand,

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

Course Outcomes

1. Understand the basics of Pilot plant design and Analyze layout designing of various pharmaceutical manufacturing facility
2. Importance of Technology transfer from R & D to pilot plant to plant scale and process scale up for various dosage forms
3. Familiarize with the scope, importance, and types of validation
4. Impart theoretical knowledge and training to perform validation/qualification of pharmaceutical process, facility, and utilities.
5. Understand the various Process validation for pharmaceutical manufacturing
6. Familiarize with Industrial safety: Hazards

THEORY **60 Hrs**

1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations. 12 Hrs

   Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

2. Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification. 12 Hrs

3. Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. 12 Hrs

4. Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control — 12 Hrs

5. Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution. — 12 Hrs

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 203T)

Objectives

On completion of this course it is expected that students will be able to understand,

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

Course Outcomes

1. Understand the manufacturing technologies of tablet, Capsules, Parenteral and disperse systems
2. Understand and analyze the design and functioning of equipment's and processes employed in pharmaceutical manufacturing of tablet, Capsules, Parenteral and disperse systems
3. Understand the principles and applications of advanced technologies like Lyophilization, Spray drying, pelletization, spheronizers, marumerisers, etc.
4. Perform the troubleshooting / problems encountered during manufacture of pharmaceutical Products
5. Learn Packaging Technology with various packaging materials, machinery, labeling, package printing for different dosage forms
6. Study various air handling systems and water treatment process techniques and its maintenance required in pharmaceutical manufacturing.

THEORY **60 Hrs**

Improved Tablet Production: Tablet production process, unit

1. operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques.Problems encountered. — 12 Hrs
2. Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. — 12 hrs
3. Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments. — 12 Hrs
4. Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered. — 12 Hrs

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

5. Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI. 12 Hrs

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy,.Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation in Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

ENTREPRENEURSHIP MANAGEMENT (MIP 204T)

Objectives: On completion of this course it is expected that students will be able to understand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies and Networking

Course Outcomes

1. Understand the scope of entrepreneurship in pharmaceutical business and role of enterprise in national and global economy.
2. Study the concepts of entrepreneurial competency
3. Understand the concept of growth strategies and networking
4. Understand the concept of enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis, etc.
5. Know about the Joint venture, co-ordination and feasibility study
6. Focus on the new project proposal to find its feasibility as new enterprise project

THEORY **60 Hrs**

1. Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management. — 12 Hrs

2. entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role. — 12 Hrs

3. Launching and Organising an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation. — 12 Hrs

4. Growth Strategies and Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study. — 12 Hrs

5. Preparing Project Proposal To Start On new Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation. 12 Hrs

REFERENCES

1. Akhauri, M.M.P. (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

INDUSTRIAL PHARMACY PRACTICAL - II (MIP 205P)

Course Outcomes

1. Understand dissolution improvement approach of poorly soluble drug using solid dispersion technique.
2. Compare dissolution profile of prepared formulation with marketed formulation.
3. Demonstrate pharmacokinetic and IV-IVC data analysis by Winonlin software.
4. Study formulation and development of various dosage forms including tablets, capsules, suspensions, emulsions, injections, enteric coated tablets
5. Demonstrate freeze dryer and develop freeze dried formulation
6. Demonstrate Spray dryer and develop spray dried formulation

Content

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.

PHARMACEUTICAL CHEMISTRY(MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

Objectives After completion of course student is able to know about chemicals and excipients

1. The analysis of various drugs in single and combination dosage forms
2. Theoretical and practical skills of the instruments

Course Outcomes

1. Comprehend the basic concepts of UV-Visible, IR and NMR spectroscopic techniques and Mass spectrometry,
2. Explain instrumentation and their functions of UV-Visible, IR and NMR spectroscopy techniques and Mass spectrometry
3. Apply the chromatographic and electrophoresis separation for analysis of drugs.
4. Describe Immunological assays and X-ray crystallographic techniques
5. Interpret UV-Vis, IR, NMR and Mass spectra
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

THEORY **60 Hrs**

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. — 10 hrs
   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. — 10 hrs

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10hrs
   a. Thin Layer chromatography
   b. High Performance Thin Layer Chromatography
   c. Ion exchange chromatography
   d. Column chromatography
   e. Gas chromatography
   f. High Performance Liquid chromatography
   g. Ultra High Performance Liquid chromatography
   h. Affinity chromatography
   i. Gel Chromatography

5. a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X Ray Crystallography: Production of X rays, Different X ray methods, Bragg 's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. 10 hrs

6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 hrs
   b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)

Objectives: - Upon completion of course, the student shall be to understand

- The principles and applications of reterosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

Course Outcomes

1. Describe and apply retrosynthesis
2. Mechanize and apply various named reactions
3. Conceptualize the disconnection approach and develop new synthetic routes for small molecules
4. Employ various catalyst in organic reaction
5. Synthesize heterocyclic compound
6. Carry the synthesis of compounds by blocking competing groups

THEORY **60 Hrs**

1. Basic Aspects of Organic Chemistry: 12 hrs

    1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
    2. Types of reaction mechanisms and methods of determining them,
    3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions

a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
c) Rearrangement reaction

2. Study of mechanism and synthetic applications of following named Reactions: 12 hrs

    Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction.

3. Synthetic Reagents & Applications: 12 hrs

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: carbamates and amides

4. **Heterocyclic Chemistry:** 12 hrs

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline , Mercaptopurine and Thioguanine.

5. Synthon approach and retrosynthesis applications 12 hrs

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA)
ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
iii. Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

Objectives

At completion of this course it is expected that students will be able to understand

1. Different stages of drug discovery
2. Role of medicinal chemistry in drug research
3. Different techniques for drug discovery
4. Various strategies to design and develop new drug like molecules for biological targets
5. Peptidomimetics

Course Outcomes

1. Explain different stages of drug discovery
2. Describe role of medicinal chemistry in drug research
3. Apply different techniques for drug discovery
4. Design and develop new drug like molecules for biological targets
5. Synthesize new peptidomimetic drugs
6. A detailed understanding of the processes involved in the design, development and discovery of medicinal compounds.

THEORY **60 Hrs**

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs
   Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2. Prodrug Design and Analog design: 12 Hrs
   a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
   b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
   c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3. a) Medicinal chemistry aspects of the following class of drugs — 12 Hrs

   Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

   a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.
   b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4. Rational Design of Enzyme Inhibitors Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors. — 12 Hrs

5. Peptidomimetics Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones. — 12 Hrs

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

Objectives

At completion of this course it is expected that students will be able to understand-

1. Different types of natural compounds and their chemistry and
2. medicinal importance
3. The importance of natural compounds as lead molecules for new drug discovery
4. The concept of rDNA technology tool for new drug discovery General methods of structural elucidation of compounds of natural origin
5. Isolation, purification and characterization of simple chemical constituents from natural source

Course Outcomes

1. Categorize different types of natural compounds on the basis of chemistry
2. Describe importance of natural compounds as lead molecules for new drug development
3. Conceptualize rDNA technology tool for new drug discovery
4. Elucidate the structure of natural compounds
5. Isolate, purify and characterize constituents from natural source
6. Explain the uses of different natural products in treating the diseases

THEORY **60 Hrs**

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs — 12 Hrs
   a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
   b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
   c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
   d) Neuromuscular Blocking Drugs: Curare alkaloids
   e) Anti-malarial drugs and Analogues
   f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

2 a) Alkaloids — 12 Hrs

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

3 a) Terpenoids 11 Hrs

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).

b) Vitamins Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

4. a). Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation 12 Hrs

b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

5. Structural Characterization of natural compounds 13 Hrs

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.

9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I (MPC 105P)

Course Outcomes

1. Analyze the samples by employing advanced instruments
2. Perform important named reactions
3. Characterize medicinally important compounds for their structures
4. Estimate the elements and groups present chemical compounds of any origin
5. Ascertain the physical properties of compounds
6. Determine the presence of degraded products

Content

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen-schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

ADVANCED SPECTRAL ANALYSIS (MPC 201T)

Objectives

At completion of this course it is expected that students will be able to understand-

1. Interpretation of the NMR, Mass and IR spectra of various organic compounds
2. Theoretical and practical skills of the hyphenated instruments
3. identification of organic compound

Course Outcomes

1. Calculate absorption max using woodward fieser rules
2. Describe concepts of hyphenated instruments techniques, Thermal analysis and radio immunoassay
3. Interpret IR, NMR and Mass spectra of organic compounds
4. Apply analytical techniques for characterization of drugs
5. Apply chromatographic techniques for analysis of Pharmaceuticals
6. Select suitable methods of analysis for analysis of Pharmaceuticals

THEORY **60Hrs**

1.	UV and IR spectroscopy: Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.	12hrs
2.	NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	12hrs
3.	Mass Spectroscopy Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.	12hrs
4	Chromatography: Principle, Instrumentation and Applications of the following: a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography	12hrs
5	a). Thermal methods of analysis Introduction, principle, instrumentation and application of DSC, DTA and TGA.	12hrs

b). Raman Spectroscopy Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY - II (MPC 202T)

Objectives

Upon completion of course, the student shall able to understand

1. The principles and applications of Green chemistry
2. The concept of peptide chemistry.
3. The various catalysts used in organic reactions
4. The concept of stereochemistry and asymmetric synthesis

Course Outcomes

1. Able to utilize the green synthesis approaches for drug synthesis
2. Understand the application peptide synthesis reaction for development of pharmaceuticals
3. Conceptualize the catalyst used for pharmaceutical medicinal synthesis
4. Should be able to understand utilization of varoius catalyst in organic reaction
5. Able to apply asymmetric and stereochemical synthetic approaches for drug development
6. Able to use the photochemical method for the synthesis of drugs

THEORY **60 Hrs**

1. Green Chemistry: 12 hrs

   a. Introduction, principles of green chemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
   d. Continuous flow reactors: Working principle, advantages and synthetic applications.

2. Chemistry of peptides **12** hrs
   a. Coupling reactions in peptide synthesis
   b. Principles of solid phase peptide synthesis, t-BOC and
   c. FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

d. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
e. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over- activation and side reactions of individual amino acids.

3. Photochemical Reactions 12 hrs

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

4. Catalysis: 12 hrs

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
f. Phase transfer catalysis - theory and applications

5. Stereochemistry & Asymmetric Synthesis 12 hrs

a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.
b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

C**OMPUTER AIDED DRUG DESIGN (MPC 203T)**

Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Course Outcomes

1. Explain the role of CADD in drug discovery
2. Apply different CADD techniques in drug design
3. Apply different CADD techniques in drug design
4. Work efficiently with molecular modeling softwares
5. Employ in silico virtual screening protocols
6. Calculate molecular properties and correlate with biological activities

THEORY **60 Hrs**

1. Introduction to Computer Aided Drug Design (CADD) History, different techniques and applications. 12 hrs
   Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2. Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations 3D-QSAR approaches and contour map analysis.Statistical methods used in QSAR analysis and importance of statistical parameters. 12 hrs

3. Molecular Modeling and Docking 12 hrs

   a) Molecular and Quantum Mechanics in drug design.
   b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

4 Molecular Properties and Drug Design 12 rs

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
c) Homology modeling and generation of 3D-structure of protein.

5. Pharmacophore Mapping and Virtual Screening Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. 12 hrs

In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

Objectives

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of apis and intermediates
- The various unit operations and various reactions in process chemistry

Course Outcomes

1. Understand various unit operations and various reactions in process chemistry.
2. Apply knowledge on the development and optimization of a scale up synthetic route/s.
3. The pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients and new chemical entities for the drug development phase.
4. Develop synthetic routes that are safe, cost-effective, environmentally friendly & efficient.
5. Analyse the outcome of organic reactions using a basic understanding of the general reactivity of functional groups and mechanism.
6. Evaluate the principles and applications of modern chemical instrumentation, experimental design, and data analysis.

THEORY **60 Hrs**

1. Process chemistry 12 hrs

Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process.

Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities

2 Unit operations 12 hrs

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c) Distillation: azeotropic and steam distillation
d) Evaporation: Types of evaporators, factors affecting evaporation.
e) Crystallization: Crystallization from aqueous, non- aqueous solutions factors affecting crystallization, nucleation. Principle and general

methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3 Unit Processes - I 12 hrs

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

4 Unit Processes - II 12 hrs

1. Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
2. Fermentation: Aerobic and anaerobic fermentation. Production of
   a. Antibiotics; Penicillin and Streptomycin,
   b. Vitamins: B2 and B12
   c. Statins: Lovastatin, Simvastatin
3. Reaction progress kinetic analysis
   d. Streamlining reaction steps, route selection,
   e. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5 Industrial Safety 12 hrs

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
b) Fire hazards, types of fire & fire extinguishers
c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-
d) 14001(Environmental Management System), Effluents and its management

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill

5. Polymorphism in Pharmaceutical Solids. Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

PHARMACEUTICAL CHEMISTRY PRACTICALS – II (MPC 205P)

Course Outcomes

1. Conducts experiments using oxidation, reduction and nitration reactions
2. Synthezize important active pharmaceutical ingredients comparatively
3. Anayse the structure & purity by using advanced instrumental data
4. Compute different physicochemical properties
5. Design new medicinally important molecules by computational tools
6. Employ advanced synthetic techniques including microwave and parallel synthesis

Content

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. NaBH4 reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Outcomes

1. Comprehend the basic concepts of UV-Visible, IR and NMR spectroscopic techniques and Mass spectrometry,
2. Explain instrumentation and their functions of UV-Visible, IR and NMR spectroscopy techniques and Mass spectrometry
3. Apply the chromatographic and electrophoresis separation for analysis of drugs.
4. Describe Immunological assays and X-ray crystallographic techniques
5. Interpret UV-Vis, IR, NMR and Mass spectra
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

THEORY **60 Hrs**

1. 10 hrs
   a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, 10 hrs

Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 hrs
   - Thin Layer chromatography
   - High Performance Thin Layer Chromatography
   - Ion exchange chromatography
   - Column chromatography
   - Gas chromatography
   - High Performance Liquid chromatography
   - Ultra High Performance Liquid chromatography
   - Affinity chromatography
   - Gel Chromatography

5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 hrs
   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 hrs
   b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA:

Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

QUALITY MANAGEMENT SYSTEMS (MQA 102T)

Objectives

At completion of this course it is expected that students will be able to understand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

Course Outcomes

1. To understand the importance of quality and ISO management systems
2. To understand the tools for quality improvement
3. To study Quality evaluation of pharmaceuticals
4. To understand Stability testing of drug and drug substances
5. To understand the Quality evaluation of pharmaceuticals
6. To study the Statistical approaches for quality

THEORY **60 Hrs**

1. Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality — 10 hrs

   Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

   Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.

   Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

2. Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence — 10 hrs

and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

3. Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self-inspection. 10 hrs
   Quality systems: Change Management/ Change control.
   Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

4. Drug Stability: ICH guidelines for stability testing of drug substances and drug products. 10 hrs
   Study of ICH Q8, Quality by Design and Process development report
   Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

5. Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability. 10 hrs

6. Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking. 10 hrs

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001

5. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to
- Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

Course Outcomes

1. To understand the importance of quality and ISO management systems
2. To understand the tools for quality improvement
3. To study Quality evaluation of pharmaceuticals
4. To understand Stability testing of drug and drug substances
5. To understand the Quality evaluation of pharmaceuticals
6. To study the Statistical approaches for quality

THEORY **60 Hrs**

1. Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q- series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines. — 11 hrs
2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. — 12 hrs
3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias). — 12 hrs

4 Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. 12 hrs

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. 12 hrs

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

Objectives

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

Course Outcomes

1. To understand the new product development process
2. To understand the necessary information to transfer technology from R&D
3. To understand the Pharmaceutical dosage form and their packaging requirments
4. To study the different principles of Drug discovery and development
5. To study concept of pilot plant scale up
6. To understand the new product development process- SUPAC and BACPAC

THEORY **60 Hrs**

1. Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational Course Content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA. 12 Hrs

2. Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development. **12** Hrs

3. Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges. 12 Hrs

4. Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials,

Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packing materials.

5. Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit. 12 Hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way ‘Pure and applied Pharmacy’ by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL - I (MQA 105P)

Course Outcomes

1. Understand the analysis of Pharmacopoeial compounds in bulk and in their formulations
2. To study case studies on Total Quality Management, Six sigma and CAPA
3. To perform preformulation studies for tablets and parenterals
4. To perform experiments based on HPLC, GC and other analytical instruments
5. To perform testing of related and foreign substances in drugs and raw materials
6. To perform IPQC testing of pharmaceuticals

Content

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
    1. Total Quality Management
    2. Six Sigma
    3. Change Management/ Change control. Deviations,
    4. Out of Specifications (OOS)
    5. Out of Trend (OOT)
    6. Corrective & Preventive Actions (CAPA)
    7. Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an idea to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Course Outcomes

1. Understand various environmental hazards, including air, water, soil, and chemical risks.
2. Explain the sources and characteristics of air-based and chemical hazards.
3. Apply fire prevention and protection measures in pharmaceutical industry settings.
4. Analyze safety regulations and assess potential risks in diverse industrial processes.
5. Develop comprehensive safety management plans for pharmaceutical environments.
6. Evaluate the effectiveness of workplace self-protective measures and safety programs.

THEORY **60Hrs**

1. Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, 12 hrs
   a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources
   Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

2 Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system. 12 Hrs

3 Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen 12 Hrs

displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

4	Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.	12 Hrs
5	Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.	12 Hrs

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

PHARMACEUTICAL VALIDATION (MQA 202T)

Objectives

At completion of this course, it is expected that students will be able to understand

8. The concepts of calibration, qualification and validation
9. The qualification of various equipments and instruments
10. Process validation of different dosage forms
11. Validation of analytical method for estimation of drugs
12. Cleaning validation of equipments employed in the manufacture of pharmaceuticals

Course Outcomes

1. Define calibration, qualification, and validation concepts and their importance.
2. Apply qualification processes to various pharmaceutical equipment and instruments.
3. Understand the principles of process validation and documentation requirements.
4. Analyze and validate analytical methods in accordance with ICH guidelines and USP.
5. Develop strategies for cleaning validation and computerized system validation.
6. Evaluate the economic significance and ethical considerations of intellectual property in the pharmaceutical industry.

THEORY **60 Hrs**

1. Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. — 10hrs

   Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).
2. Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. — 10hrs
   Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.
3. Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test — 10hrs

apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

4. Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.
   Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. — 10hrs

5. Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).
   Validation of facilities in sterile and non-sterile plant.
   Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP — 10 Hrs

6. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. — 10 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.

7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

AUDITS AND REGULATORY COMPLIANCE (MPA 203T)

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

Course Outcomes

1. Understand the cGMP Regulations and their significance in quality assurance.
2. Conduct audits for vendors and production departments, such as bulk pharmaceutical chemicals and packaging material
3. vendors.
4. Evaluate the auditing process for microbiological laboratories, focusing on manufacturing processes, product information,
5. and critical areas.
6. Develop checklists for auditing critical systems in Quality Assurance and Engineering departments, such as HVAC, water systems, and ETP.
7. Assess the importance of auditing in pharmaceutical industries.
8. Prepare comprehensive auditing reports based on the outcomes of various audits.

THEORY **60 Hrs**

1.	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12Hrs
2	Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation	12Hrs
3	activities, Transitioning to quality system approach, Audit checklist for drug industries. Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12Hrs

4	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12Hrs
5	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

Objectives

At completion of this course it is expected that students will be able to understand,

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non-sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Course Outcomes

1. Understand legal requirements and licenses for pharmaceutical manufacturing compliance.
2. Differentiate between aseptic and non-sterile manufacturing processes for effective production planning.
3. Apply principles of process planning and scheduling to develop production plans.
4. Analyze various packaging methods such as blister packs, bubble packs, and foil/plastic pouches in terms of their suitability for different pharmaceutical products.
5. Designing a pharmaceutical manufacturing facility layout involves creating a layout that adheres to Good Manufacturing Practices (GMP).
6. Assess the impact of Quality by design (QbD) and Process Analytical Technology (PAT) on quality improvement and cost reduction.

THEORY **60 Hrs**

1. Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control. 12Hrs

2. Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). 12Hrs

Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment.

3. Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). 12Hrs

   Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

   Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

4. Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material. 12Hrs

5. Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing 12Hrs

costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3 ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms:nd tablets Vol. I-III, 2ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4^{TH} ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS (MQA 205P)

Course Outcomes

1. Apply different techniques like Flame photometer, HPLC, TLC, colorimetric for analysis
2. Apply QbD and PAT principles to a real-life pharmaceutical case study.
3. Evaluate the effectiveness of a method for drug analysis during the validation process.
4. Compare the validation requirements for different types of pharmaceutical testing equipment, such as Dissolution Testing Apparatus, Friability Apparatus, and Disintegration Tester.
5. Apply principles of plant layout design to both sterile and non-sterile environments.
6. Analyze the checklist for Bulk Pharmaceutical Chemicals vendors, tableting production, sterile production area and water for injection to ensure quality control.

Content

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO2 using Colorimetric method
7. Qualification of following Pharma equipment a.Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

PHARMACEUTICALREGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (MRA 101T)

Objectives

At completion of this course it is expected that students will be able to understand,

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

Course Outcomes

1. Discuss key regulatory and compliance elements with respect to good manufacturing practices
2. Describe key regulatory and compliance elements with respect to good laboratory practices
3. Recommend key regulatory and compliance elements with respect to good automated laboratory practices
4. Outline key regulatory and compliance elements with respect to good distribution practices
5. Plan and design appropriate quality management systems
6. Outline good regulatory practices in the healthcare and related industries

THEORY **60 Hrs**

1. Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs. 12hrs

2. Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards 12hrs

3. Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards. 12hrs

4. Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards — 12hrs

5. Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents. — 12hrs

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Objectives

Upon completion of the course the student shall be able to,

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

Course Outcomes

1. Identify various documents required in pharmaceutical industry
2. Outline the basics of dossier compilation and submission
3. Design audits for the pharmaceutical industry
4. Plan and implement inspections in the pharmaceutical industry
5. Discuss aspects of product life cycle management
6. Plan the follow ups after regulatory submissions and post approval document requirements

THEORY **60 Hrs**

1. Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF). 12 Hrs

2. Dossier preparation and submission: Introduction and overview of dossiers, Course Contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of ubmission. Submission in Sugam system of CDSCO. 12 Hrs

3. Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation 12 Hrs

and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485

4. Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good anufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA). 12 Hrs

5. Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard 12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications

12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

Course Outcomes

1. Describe phases of clinical trials
2. Prioritize ethics in clinical trials
3. Identify regulations governing clinical trials
4. Outline ICH and other guidelines related clinical research
5. Explain USA & EU regulations related to clinical trials
6. Explain Indian regulations related to clinical trials

THEORY **60 Hrs**

1. Clinical Drug Development Process 12hrs

- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation

2. Ethics in Clinical Research: 12hrs

- Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
    - Ethical principles governing informed consent process
    - Patient Information Sheet and Informed Consent Form
    - The informed consent process and documentation

3. Regulations governing Clinical Trials 12hrs

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical
- Studies

FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

4. Clinical Research Related Guidelines 12hrs
    - Good Clinical Practice Guidelines (ICH GCP E6)
    - Indian GCP Guidelines
    - ICMR Ethical Guidelines for Biomedical Research
    - CDSCO guidelines

GHTF study group 5 guidance documents

Regulatory Guidance on Efficacy and Safety ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,

- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population
- General biostatics principle applied in clinical research

5. USA & EU Guidance USA: FDA Guidance 12hrs
   - CFR 21Part 50: Protection of Human Subjects
   - CFR 21Part 54: Financial Disclosure by Clinical Investigators
   - CFR 21Part 312: IND Application
   - CFR 21Part 314: Application for FDA Approval to Market a New Drug
   - CFR 21Part 320: Bioavailability and bioequivalence requirements
   - CFR 21Part 812: Investigational Device Exemptions
   - CFR 21Part 822: Post-market surveillance
   - FDA Safety Reporting Requirements for INDs and BA/BE Studies
   - FDA Med Watch
   - Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use
- EU MDD with respect to clinical research
- ISO 14155

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application:
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDruga ndCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (MRA 104T)

Objectives

Upon the completion of the course the student shall be able to:

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

Course Outcomes

1. Describe Acts and Rules related to biological, herbals, food and neutraceuticals in India
2. Explain regulatory requirements and approval procedures for biological, herbals, food and neutraceuticals in India
3. List Indian Pharmacopoeial standards and other standards for various products
4. Discuss bioavailability and bioequivalence requirements
5. Outline different types of intellectual property rights
6. Design the regulatory requirements for approval process of herbals, biologicals, food and neutraceuticals in India

THEORY **60 Hrs**

1. Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 12hrs
    - Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
    - Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

    Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

2. Regulatory requirements and approval procedures for Drugs & Cosmetics 12hrs
Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

- Format and Course Contents of Regulatory dossier filing Clinical trial/ investigations

1. Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards — 12hrs

2. Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO
   Guidelines for Drug testing in animals/Preclinical Studies
   Animal testing: Rationale for conducting studies, CPCSEA Guidelines
   Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research — 12hrs

3. Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs — 12hrs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL - I (MRA 105P)

Course Outcomes

1. Write SOPs, and analytical reports
2. Recommend documentation for in process and finished products
3. Plan and prepare for clinical trial applications
4. Prepare regulatory requirements checklist for conducting clinical trials
5. Describe the procedure for registering for different Intellectual Property Rights in India
6. Discuss the features and applications of SUGAM portal of CDSCO

Content

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labelling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II

REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

Objectives

Upon completion of the course, the student shall be able to know

- process of drug discovery and development and generic product development
- regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

Course Outcomes

1. Discuss cosmetics regulations in regulated and semi-regulated countries.
2. Identify various regulatory approval process and registration procedures for API and drug products in US, EU Market.
3. Assess regulatory considerations and legislation for import, manufacture, distribution, and sale of cosmetics in European Union & Australia.
4. Assess regulatory considerations for manufacturing, packaging, and labelling of pharmaceuticals in Japan
5. Understand regulatory submissions as per WHO and other committees across the globe
6. Study regulatory requirements for registration of drugs and post approval requirements for Asean countries and CIS (Commonwealth Independent States) countries.

THEORY **60 Hrs**

1. USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. — 12hrs

2. European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files ASMF) system in EU, Course Content and approval process of IMPD,Marketing — 12hrs

Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

3. Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan — 12hrs

4. Emerging Market: Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana) — 12hrs

5. Brazil, ASEAN, CIS and GCC Countries: — 12hrs
   ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.
   CIS (Commonwealth Independent States): Regulatory pre- requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE
   Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Objectives

- Upon the completion of the course the student shall be able to:
- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Course Outcomes

1 Understand the regulation requirements for newly developed biologics and biosimilars.
2. Know the pre-clinical and clinical development considerations of biologics.
3. Assess the regulations, guidelines, principles, and data requirements for the development of biologics in India.
4. Study laws, regulations and guidance on development and approval of biologics and biosimilars in US.
5. Evaluation, development, regulatory approval of biologics along with their stability, safety, advertising, labelling and packing in EU
6. Understand Quality, safety and legislation for herbal products in India, USA and European Union

THEORY **60 Hrs**

1. India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP. 12hrs

2. USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics 12hrs

3. European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU 12hrs

4. Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network) 12hrs

5. Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union. 12hrs

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies;Wei Wang, Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Objectives

Upon completion of the course, the student shall be able to know

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

Course Outcomes

1. Understand classification, process of development, ethical, and quality considerations of medical devices.
2. Assess regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN countries.
3. Study Quality System Regulations of Medical Devices
4. Understand the in vitro diagnostics, classification and approval process for European Union
5. Discuss registration procedures, Quality System requirements and clinical
6. Study USFDA - Quality System Requirements 21 CFR Part 820, labeling requirements 21 CFR Part 801

THEORY **60 Hrs**

1. Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.
   IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). 12hrs

2. Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device 12hrs

3. USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process. 12hrs

4. European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process.
   Basics of In vitro diagnostics, classification and approval process 12hrs

5. ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation.
   IMDRF study groups and guidance documents. 12hrs

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S.Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Objectives

Upon completion of the course, the student shall be able to

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Course Outcomes

1. Know the regulatory Requirements for nutraceuticals
2. Understand the regulation for registration and labeling of nutraceuticals and food supplements in USA and Europe
3. Assess global aspects, NSF Certification, NSF Standards for Food and Dietary Supplements
4. Understand Good Manufacturing Practices for Nutraceuticals
5. Understand Regulations for import, manufacture and sale of nutraceutical products in India
6. Compare Recommended Dietary Allowances (RDA) of Nutraceuticals in India in USA and Europe.

THEORY **60 Hrs**

1. Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market. 12hrs

2. Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals. 12hrs

3. India : Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India. 12hrs

4. USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S 12hrs

5. European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe. 12hrs

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_ STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL - II (MRA 205P)

Course Outcomes

1. Prepare submission to FDA, EMA and MHRA using eCTD software
2. Compare clinical trial application requirements of US, EU and India of Biologics
3. Understand registration requirement comparison study in 5 emerging markets (WHO, BRICS, China and South Korea, Asian countries)
4. Prepare checklists for 510k and PMA for US market
5. Develop STED Application for Class III Devices
6. Develop Clinical Investigation Plan for Medical Devices

Content

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

PHARMACEUTICAL BIOTECHNOLOGY (MPB)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPB 101T)

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Outcomes

1. Comprehend the basic concepts of UV-Visible, IR and NMR spectroscopic techniques and Mass spectrometry,
2. Explain instrumentation and their functions of UV-Visible, IR and NMR spectroscopy techniques and Mass spectrometry
3. Apply the chromatographic and electrophoresis separation for analysis of drugs.
4. Describe Immunological assays and X-ray crystallographic techniques
5. Interpret UV-Vis, IR, NMR and Mass spectra
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

THEORY **60 Hrs**

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 12hrs
   IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
   b. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   c. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 12hrs

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy — 12hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: — 12hrs
   a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

5. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: — 12hrs

   a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

   b) X ray Crystallography: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder diffration technique, Types of crystals and applications of X-ray diffraction.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

MICROBIAL AND CELLULAR BIOLOGY (MPB 102T)

Objective

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

Course Outcomes

1. Elaborate the importance of microorganisms in health and industry.
2. Summarize the principles of cemtral dogma of moleular biology
3. Undustrand the criticals of cell biology, cell structure and function
4. Elaborate cell cycle, regulation and its implications
5. Devise measures of microbial and cellular clutures growth and dynamics
6. Employ steps for prevention and management of infectious diseases.

THEORY **60Hrs**

1. Microbiology 12hrs

   Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomycetes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications

2. Molecular Biology: Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation. 12hrs

   Gene regulation

   Gene copy number, transcriptional control and translational control.

   RNA processing

   Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids-types purification and application. Phage genetics, geneticorganization, phage mutation and lysogeny.

3 Cell structure and function 12hrs

Cell organelles, cytoskeleton & cell movements, basic aspectsof cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics,secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Celljunctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – thelife and death of cells in tissues.

Cell Cycle and Cytoskeleton

Cell Division and its Regulation, G-Protein CoupledReceptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, IntermediateFilaments.

Apoptosis and Oncogenes

Programmed Cell Death, Tumor cells, carcinogens & repair.

Differentiation and Developmental Biology

Fertilization, Events of Fertilization, In vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application.

5. Principles of microbial nutrition 12hrs

   Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

   Growth of animal cells in culture

   General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In-vitro screening techniques- cytotoxicity, anti-tumor, anti-viral assays.

6. Microbial pathology 12hrs

   Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.

REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB 103T)

Objectives

- At the completion of this subject it is expected that students will be able to, Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

Course Outcomes

1. Understand basics and design of fermentation technology
2. Scale up and scale down processing of fermentation technology
3. Bioprocessing of the industrially important microbial metabolites
4. Regulation governing the manufacturing of biological products
5. Understand and conduct fermentation process kinetics.
6. Bioprocessing of the industrially important microbial metabolites in R & D organizations.

THEORY **60 Hrs**

1. Introduction to fermentation technology 12hrs
   Basic principles of fermentation
   Study of the design and operation of bioreactor
   Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.
   Types of bioreactor
   CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application
   Computer control of fermentation process
   System configuration and application

2 Mass transfer 12hrs
   Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.
   Rheology

Rheological properties of fermentation system and their importance in bioprocessing.

3 Scale up of fermentation process 12hrs

Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

Cultivation and immobilized culture system

Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

Introduction to immobilization

Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering

4 Scale down of fermentation process 12hrs

Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

Isolation and screening Primary and secondary, maintenance of stockculture, strain improvement for increased yield.

5 Bioprocessing of the industrially important microbial metabolites 12hrs

a) Organic solvents – Alcohol and Glycerol
b) Organic acids - Citric acids, Lactic acids,
c) Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP
d) Antibiotics - Penicillin, Streptomycin, Griseofulvin,
e) Vitamins - B12, Riboflavin and Vitamin C

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids Regulation governing the manufacturing of biological products.

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB 104T)

Objective

At the completion of this subject it is expected that students will be able to

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

Course Outcomes

1. Understand latest technology development in technique, tools
2. Identify appropriate sources of enzymes.
3. Understand and perform rDNA technology, gene manipulation
4. Understand the overview of pharmacogenomics
5. Learn the regulatory approval process for new drugs, biologics, devices,
6. Understanding the use of biotechnology tools and techniques on drug and vaccine development

THEORY **60 Hrs**

1. Enzyme Technology 12hrs

   Classification, general properties of enzymes, dynamics of enzymatic activity,sources of enzymes, extraction and purification, pharmaceutical,therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase,amylase and trypsin.

2. Genetic Engineering 12hrs

   Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection andscreening, expression in E.coli and yeast.

   Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences.

   Gene library and cDNA

   Applications of the above technique in the production of,

   - Regulatory proteins - Interferon, Interleukins
   - Blood products - Erythropoietin
   - Vaccines - Hepatitis-B
   - Hormones - Insulin

3 Therapeutic peptides 12hrs

Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

Transgenic animals

Production of useful proteins in transgenic animals and gene therapy.

Human Genome

The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes

4 Signal transduction 12hrs

Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.

Oncogenes

Introduction, definition, various oncogenes and their proteins.

5. Microbial Biotransformation 12hrs

Biotransformation for the synthesis of chiral drugs and steroids.

Microbial Biodegradation

Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein,

Applications of microbes in environmental monitoring.

Biosensors

Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.

REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I (MPB 105P)

Course Outcomes

1. Characterize DNA and RNA
2. Illustrate techniques involved in DNA manipulation
3. Sterility test for pharmaceutical preparations
4. Whole cell immobilization engineering
5. Replica plating
6. Design, observe, record, compute, analyse and interpreted experimental data

Content

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

PROTEINS AND PROTEIN FORMULATIONS (MPB 201T)

Objective

At the completion of this course it is expected that students will be able to understand,

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

Course Outcomes

1. Elaborate the methods of purification of Proteins used in lab and industry.
2. Summarize the principles of Peptides in drug development
3. Understand the basics of protein identification and characterization
4. Elaborate on Protein based formulations
5. Applications of protein engineering in drugs development protein sequencing
6. Promote novel applications and critical thinking

THEORY **60 Hrs**

1. Protein engineering 12hrs
   Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.

2. Peptidomimetics 12hrs
   Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

3. Proteomics 12hrs
   Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.
   2-Dimensional gel electrophoresis
   Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments

4. Protein formulation 12hrs

Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre- formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

5. Methods of protein sequencing 12hrs
   Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

REFERENCES

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

IMMUNOTECHNOLOGY (MPB 202T)

Objective

After this course, the students will be able to: -

1. Understand the techniques like immunodiagnostic tests,
2. Characterization of lymphocytes, purification of antigens and antibody, etc.
3. Access health problems with immunological background;
4. Develop approaches for the immune intervention of diseases

Course Outcomes

1. Understand basics of thechniques like immunodiagnostic tests
2. Characterization of lymphocytes, purification of antigens and antibody proteins MABs
3. Understand the Health problems with immunological background, autoimmune diseases
4. Elaborate on approaches for the immune intervention of diseases
5. Undustrand the basics of protein identification and characterization
6. Understand Applications in diagonistics and Biosimillars

THEORY **60 Hrs**

1. Fundamental aspects of immunology 12hrs

   Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.

   Types of immune responses, anatomy of immune response. Overview of innate and adaptive Immunity.

   Humoral Immunity

   B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

   Cell mediated Immunity

   Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

2. Immune Regulation and Tolerance 12hrs

   Complement activation and types and their biological functions, cytokines and their role in immune response.

   Hypersensitivity

   Hypersensitivity Types I-IV, Hypersensitivity reactions and Treatment Autoimmune diseases

3. Vaccine technology 12hrs

Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.

Stem cell technology

Stem cell technology and applications to immunology

4. Hybridoma Technology 12hrs

Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.

5. Immunological Disorder 12hrs

Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

Immunodiagnosis

Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.

REFERENCES

1. J. Kubey, Immunology – an Introduction.
2. S.C. Rastogi, Immunodiagonstics, New Age International.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB 203T)

Objectives

Upon completion of this course it is expected that the students will be able to understand,

1. Use of computers in developing a new drug
2. Biological concepts for bioinformatics
3. Proteins and their diversity
4. Various gene finding methods
5. Searching the biological databases
6. Target searching
7. Various methods of drug designing

Course Outcomes

1. Understand the general concept behind use of computers in developing a new drugs
2. Elaborate on Biological concepts for bioinformatics
3. Understand the diversity in protein and DNA sequences
4. Demonstrate on the Data mining and searching biological databases
5. Learn the biological target searching and evaluation
6. Learn various techniques of in sillico drug designing

THEORY **60 Hrs**

1. Introduction to Bioinformatics 12hrs
   Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics, Biological Database
   Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

2. Sequence analysis 12hrs
   Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

3. Protein informatics 12hrs
   Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small

peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

Protein structure prediction

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

Docking

Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

4. Diversity of Genomes 12hrs

Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.

Completed Genomes

Bacterium, Nematode, Plant and Human

Evolution of Genomes

Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

Phylogenetic analysis

Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

5. Target searching and Drug Designing 12hrs

Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.

REFERENCES

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors

3. T. E. Creighton, Protein Structure and Molecular Properties, W. H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB 204T)

Objective

At the completion of this subject it is expected that students will be able to,

- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs in vitro and in vivo

Course Outcomes

1. Understand about the general concept of standardization of biologicals
2. Elaborate on significance and application of transgenic and knockout animals
3. Understand biological medicines in development of various diseases
4. Understand the overview of Biological assys and high throughput screening
5. Learn the biological evaluation of drugs in vitro and in vivo
6. Bio-medicines for diseases, therapeutics and products catagory

THEORY **60 Hrs**

1. Biological Standardization 12hrs
   General principles, Scope and limitation of bio-assay, bioassay of some official drugs.
   Preclinical drug evaluation
   Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity.
   Guidelines for toxicity studies
   Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

2. Pyrogens 12hrs
   Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.
   Microbiological assay
   Assay of antibiotics and vitamins.
   Biological evaluation of drugs
   Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).

3. Biologic Medicines in Development for various diseases - By Therapeutic Category 12hrs
   - Genetic Disorders

- Eye related Disorders
- Digestive Disorders
- Diabetes/Related Conditions
- Cardiovascular Disease
- Cancer/Related Conditions
- Blood Disorders
- Autoimmune Disorders
- Infectious Diseases
- Neurologic Disorders
- Skin Diseases
- Organe Transplantation

Biologic Medicines in Development for various diseases – by Product Category

- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)
- Interferons
- Growth Factors
- Gene Therapy
- RNA Interference

4. Regulatory aspects: drugs, biologics and medical devices an introduction to the regulations and documents necessary for approval of a medical product. 12hrs
   Regulatory consideration
   Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.
   New Drug Applications for Global Pharmaceutical Product Approvals

5. Bioavailability 12hrs
   Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability.
   Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.
   Pharmacokinetics
   Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

REFERENCES

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical Pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - II (MPB 205P)

Course Outcomes

1. Transformation of E. coli rDNA technology
2. Recombinant Protein expression and analysis
3. Database searching and data mining, data curation
4. Sequence analysis methods and tools
5. Gene anotation and phylogenetic analysis
6. RT-PCR – working, programming analysis and interpretation

Content

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Objectives

After completion of course student is able to know about,

6. Chemicals and Excipients
7. The analysis of various drugs in single and combination dosage forms
8. Theoretical and practical skills of the instruments

Course Outcomes

1. Comprehend the basic concepts of UV-Visible, IR and NMR spectroscopic techniques and Mass spectrometry,
2. Explain instrumentation and their functions of UV-Visible, IR and NMR spectroscopy techniques and Mass spectrometry
3. Apply the chromatographic and electrophoresis separation for analysis of drugs.
4. Describe Immunological assays and X-ray crystallographic techniques
5. Interpret UV-Vis, IR, NMR and Mass spectra
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

THEORY **60 Hrs**

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10hrs
   IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
   Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double 10hrs

resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10hrs
   j) Thin Layer chromatography
   k) High Performance Thin Layer Chromatography
   l) Ion exchange chromatography
   m)Column chromatography
   n) Gas chromatography
   o) High Performance Liquid chromatography
   p) Ultra High Performance Liquid chromatography
   q) Affinity chromatography
   r) Gel Chromatography

5. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10hrs
   Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
   X ray Crystallography: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10hrs
   Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I (MPL 102T)

Objectives

Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Course Outcomes

1. Elaborate the mechanism of drug actions at cellular and molecular level.
2. Summarize the pharmacological effects of drugs.
3. Aprraise pharmacotherapy correlating the pathophysiology of diseases.
4. Recommend drugs for the treatment of diseases based on safety and efficacy.
5. Devise measures for prevention of adverse effects and drug interactions.
6. Employ steps for prevention and management of lifestyle diseases.

THEORY **60 Hrs**

1. Genera Pharmacology 12hrs

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects

2. Neurotransmission 12hrs

a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters-
c. Adrenaline and Acetyl choline).
d. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].
e. Non adrenergic non cholinergic transmission (NANC). Co- transmission Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems
Autonomic Pharmacology
Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3. Central nervous system Pharmacology General and local anesthetics 12hrs
Sedatives and hypnotics, drugs used to treat anxiety.
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.
Narcotic and non-narcotic analgesics.

4. Cardiovascular Pharmacology 12hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.

Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs

5. Autocoid Pharmacology 12hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.

13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(MPL 103T)

Objectives

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

Course Outcomes

1. Appraise the regulations and ethical requirements for the use of experimental animals.
2. Describe the various animals used in the drug discovery process, good laboratory practices in maintenance and handling of experimental animals
3. Elaborate the screening methods involved in the drug discovery process.
4. Elucidate newer techniques like transgenic and alternatives to animal experimentation for preclinical studies.
5. Integrate and apply the learnings of preclinical screening to drug discovery process.
6. Appreciate and correlate the preclinical data to humans.

THEORY **60 Hrs**

1. Laboratory Animals 12hrs
   Common laboratory animals: Description, handling and applications of different species and strains of animals.
   Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals.
   Maintenance and breeding of laboratory animals.
   CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods

2. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12hrs
   General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12hrs

   Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents.
   Gastrointestinal drugs: anti ulcer, anti -emetic, anti- diarrheal and laxatives.

4. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12hrs
   Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods.

5. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12hrs
   Iimmunomodulators, Immunosuppressants and immunostimulants
   General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin
   Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

Course Outcomes

1. Understand the structure and functions of cells, cell cycles and gene therapy.
2. Elaborate the cell signalling in molecular mechanisms of drug action.
3. Demonstrate the applications of molecular biology techniques in pharmacology.
4. Apply pharmacogenomics and proteomics techniques in pharmacology.
5. Justify the use of immunotherapeutics in clinical practices
6. Appraise the use of cell culture techniques.

THEORY **60 Hrs**

1. Cell biology 12hrs
   Structure and functions of cell and its organelles
   Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing
   Cell cycles and its regulation.
   Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.
   Necrosis and autophagy.

2. Cell signaling 12hrs
   Intercellular and intracellular signaling pathways.
   Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
   Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and triacylglycerol.
   Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3. Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, 12hrs

Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.
Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

4. Pharmacogenomics 12hrs

Gene mapping and cloning of disease gene.
Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism
Genetic variation in drug transporters
Genetic variation in G protein coupled receptors
Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics
Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutic in clinical practice

5. a.Cell culture techniques 12hrs

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.
Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry

b. Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I (MPL 105P)

Course Outcomes

1. Demonstrate effects of drugs on various systems using in vivo experiments.
2. Employ appropriate laboratory technique for preclinical studies.
3. Estimate drugs in formulations and biological fluids using analytical techniques.
4. Illustrate the molecular mechanism of action of drugs.
5. Relate in vitro, ex vivo and in vivo evaluation techniques in drug discovery process.
6. Analyze and interpret the preclinical data using software's.

Content

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV
    1. spectrophotometry
    2. Experiments based on HPLC
    3. Experiments based on Gas Chromatography
    4. Estimation of riboflavin/quinine sulphate by fluorimetry
    5. Estimation of sodium/potassium by flame photometry
    6. Handling of laboratory animals.
1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.

20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel‘s Text book of quantitative chemical analysis -Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers’ medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY - II (MPL 201T)

Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Course Outcomes

1. Elaborate the mechanism of drug actions at cellular and molecular level.
2. Summarize the pharmacological effects of drugs.
3. Appraise pharmacotherapy correlating the pathophysiology of diseases.
4. Comprehend the recent advances in treatment of diseases.
5. Describe measures for prevention of adverse effects and drug interactions.
6. Recommend drugs for the treatment of diseases based on safety and efficacy.

THEORY **60 Hrs**

1. Endocrine Pharmacology 12hrs
   Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones
   Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.
   Drugs affecting calcium regulation

2. Chemotherapy 12hrs
   Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

3. Chemotherapy 12hrs
   Drugs used in Protozoal Infections
   Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology
   Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
   Immunosuppressants and Immunostimulants

4. GIT Pharmacology 12hrs
   Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology
Biological and circadian rhythms, applications of chronotherapy in various diseases like
cardiovascular disease, diabetes, asthma and peptic ulcer

5. Free radicals Pharmacology 12hrs

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant
Recent Advances in Treatment:
Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

(MPL 202T)

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Course Outcomes

1. Explain the various types of toxicity studies.
2. Appreciate the ethical and regulatory requirements for toxicity testings.
3. Demonstrate the practical skills required to conduct the preclinical toxicity studies.
4. Illustrate the importance and applications of toxicokinetic studies.
5. Integrate and apply the regulatory toxicological studies for drug discovery process.
6. Relate the preclinical safety pharmacology to clinical trials.

THEORY **60 Hrs**

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) 12hrs
   Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP)
   History, concept and its importance in drug development

2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. 12hrs
   Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
   Test item characterization- importance and methods in regulatory toxicology studies

3. Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) 12hrs
   In vivo carcinogenicity studies

4. IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. 12hrs

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay.
Tier2- GI, renal and other studies

5. Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. 12hrs
Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

Course Outcomes

1. Explain the various stages of drug discovery
2. bioinformatics in drug discovery
3. Explain various targets for drug discovery
4. Explain various lead seeking method and lead optimization
5. Appreciate the importance of SBDD and LBDD
6. Apply the concept of prodrug in drug discovery and design

THEORY **60 Hrs**

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. 12hrs
   Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2. Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. 12hrs
   Protein structure
   Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

3. Rational Drug Design 12hrs
   Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based

approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

4. Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them. 12hrs

5. QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design 12hrs

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systemsand communication in Pharmacovigilance

Course Outcomes

1. Explain the regulatory requirements for conducting clinical trial
2. Interpret the types of clinical trial designs
3. Categorize the responsibilities of key players involved in clinical trials
4. Formulate safety monitoring, reporting and close-out activities
5. Describe the principles of Pharmacovigilance
6. Assess the adverse drug reaction reporting systems in community and communication in Pharmacovigilance

THEORY **60 Hrs**

1. Regulatory Perspectives of Clinical Trials: 10 hrs
   Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and Course Content of an Informed Consent Process Ethical principles governing informed consent process

2. Clinical Trials: Types and Design 10 hrs
   Experimental Study- RCT and Non RCT,
   Observation Study: Cohort, Case Control, Cross sectional
   Clinical Trial Study Team
   Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3. Clinical Trial Documentation- Guidelines to the preparation of documents, 10 hrs
   Preparation of protocol, Investigator Brochure, Case Report Forms,
   Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT
   Adverse Drug Reactions: Definition and types. Detection and reporting

methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

4. Basic aspects, terminologies and establishment of pharmacovigilance 10 hrs
History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

5. Methods, ADR reporting and tools used in Pharmacovigilance 10 hrs
International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

6. Pharmacoepidemiology, pharmacoeconomics, safety pharmacology 10 hrs

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II (MPL 205P)

Course Outcomes

1. Evaluate the effects of agonists and antagonists on isolated tissue experiments
2. Understand the various phases of drug discovery
3. Analyze the effect of drugs on CVS.
4. Demonstrate the practical skills required to conduct the preclinical toxicity studies.
5. Sensibilise the society about ADR monitoring
6. Appreciate correlation of pharmacology with molecular docking studies

Content

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Outcomes

1. Comprehend the basic concepts of UV-Visible, IR and NMR spectroscopic techniques and Mass spectrometry,
2. Explain instrumentation and their functions of UV-Visible, IR and NMR spectroscopy techniques and Mass spectrometry
3. Apply the chromatographic and electrophoresis separation for analysis of drugs.
4. Describe Immunological assays and X-ray crystallographic techniques
5. Interpret UV-Vis, IR, NMR and Mass spectra
6. Select and apply suitable instrumental analytical techniques to asses purity and safety of pharmaceuticals for the benefit of society

THEORY **60 Hrs**

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 12 hrs
   a) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
   b) Spectrofluorometric: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   c) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.1 12 hrs

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 12 hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 12 hrs
   a) Thin Layer chromatography
   b) High Performance Thin Layer Chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Ultra High Performance Liquid chromatography
   h) Affinity chromatography
   i) Gel Chromatography

5. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: 12 hrs
   a) Paper electrophoresis
   b) Gel electrophoresis
   c) Capillary electrophoresis
   d) Zone electrophoresis
   e) Moving boundary electrophoresis
   f) Iso electric focusing

   X ray Crystallography: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 12 hrs
   Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

ADVANCED PHARMACOGNOSY - I (MPG 102T)

Objectives

Upon completion of the course, the student shall be able to know the,

- advances in the cultivation and production of drugs
- various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

Course Outcomes

1. Explain the advances in the cultivation and production of drugs.
2. Explain various phytopharmaceuticals and their source, their utilization, and medicinal values.
3. Comprehend various nutraceutical herbs and their benefits.
4. Outline drugs of marine origin.
5. Describe recent advances in research of marine drugs.
6. Understand the pharmacovigilance of drugs of natural origin.

THEORY **60 Hrs**

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In- situ conservation of medicinal plants. 12hrs

2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. 12hrs

3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following
   i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric. 12hrs

4. Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. 12hrs
   a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
   b) Limonoids – i) d-Limonene ii) α – Terpineol
   c) Saponins – i) Shatavarins
   d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
   e) Phenolic acids- Ellagic acid
   f) Vitamins
   g) Tocotrienols and Tocopherols
   h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, taxol
   i) Miscellaneous

5. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. 12hrs

REFERENCES (Latest Editions of)

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy-Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products-Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.
14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
16. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

PHYTOCHEMISTRY (MPG 103T)

Objectives

Upon completion of the course, the student shall be able to know the,

- different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery
- phytochemical fingerprinting and structure elucidation of phytoconstituents.

Course Outcomes

1. Understand the separation of the active constituents obtained from natural sources by the different methods of separation. (Chromatography).
2. Identify and understand the different methods to evaluate these components and learn the concept to deal with the side effects of some components (if any).
3. Outline the Herbal Drug discovery and development.
4. Explain the Optimization of Lead Compounds Demonstrate the complete management of extraction, Isolation, and Phytochemical analysis of Natural Products
5. Outline the Phytochemical documentation
6. Outline the Phytochemical documentation

THEORY **60 Hrs**

1. Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs: 12Hrs
   a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids.
   b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin. Steroids: Hecogenin, guggulosterone and withanolides
   c) Coumarin: Umbelliferone.
   d) Terpenoids: Cucurbitacins

2. Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source: artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. 12Hrs

3. Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of 12Hrs

fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4. Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. 12Hrs

5. Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) 12Hrs
   a. Carvone, Citral, Menthol
   b. Luteolin, Kaempferol
   c. Nicotine, Caffeine iv) Glycyrrhizin.

REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)

Objectives

By the end of the course the student shall be able to know,

- the requirements for setting up the herbal/natural drug industry.
- the guidelines for quality of herbal/natural medicines and regulatory issues.
- the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

Course Outcomes

1. Understand the separation of the active constituents obtained from natural sources by the different methods of separation. (Chromatography).
2. Identify and understand the different methods to evaluate these components and learn the concept to deal with the side effects of some components (if any).
3. Outline the Herbal Drug discovery and development.
4. Explain the Optimization of Lead compounds
5. Demonstrate the complete management of extraction, Isolation, and Phytochemical analysis of Natural products
6. Outline the Phytochemical documentation

THEORY **60 Hrs**

1. Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals. — 12 Hrs
2. Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS.
   Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000. — 7. Hrs
3. Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs. — 12 Hrs
4. Testing of natural products and drugs: Herbal medicines - clinical laboratory testing. Stability testing of natural products, protocols. — 12 Hrs

5. Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents — 12 Hrs

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

PHARMACOGNOSY PRACTICAL - I (MPG I05P)

Course Outcomes

1. Understand the spectroscopical methods of analysis of pharmacopoeial compounds of natural origin and their formulations.
2. Understand and explain various chromatographic methods of analysis.
3. Demonstrate methods of extraction.
4. Interpret monograph analysis.
5. Formulate and standardize different dosage form.
6. Developing the fingerprint of selected medicinal plants extracts.

Content

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

Objectives

Upon completion of the course, the student shall be able to,

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

Course Outcomes

1. Understand the concept of plant genetic engineering and molecular biology.
2. Demonstrate the plant tissue culture techniques for the production of Genetically modified plants.
3. Explain the hairy root culture for the production of different primary and secondary metabolites
4. Elaborate Plant fermentation technology.
5. Differentiate methods of cloning and their applications
6. Apply the concept of PCR in plant genome analysis.

THEORY **60 Hrs**

1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. 12 Hrs

2. Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. 12 Hrs

3. Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of 12 Hrs

medicinal agents. Precursors and elicitors on production of secondary metabolites.

4. Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis. 12 Hrs

5. Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest. 12 Hrs

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II (MPG 202T)

Objectives

Upon completion of the course, the student shall be able to know the,

- validation of herbal remedies
- methods of detection of adulteration and evaluation techniques for the herbal drugs
- methods of screening of herbals for various biological properties

Course Outcomes

1. Validation of Herbal remedies
2. Illustrate the methods for the detection of adulterants.
3. outline the techniques available for evaluation of herbal drugs
4. Elaborate methods for biological screening of herbal drugs.
5. Understand the concept of ethnobotany and ethno pharmacology.
6. Create the analytical profile of some herbal drugs

THEORY **60 Hrs**

1. Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues. 12 Hrs

2. Adulteration and Deterioration: Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. 12 Hrs

3. Ethnobotany and Ethno pharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethno pharmacology in drug evaluation, Reverse Pharmacology. 12 Hrs

4. Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. 12 Hrs

6. Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, 12 Hrs

Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

INDIAN SYSTEMS OF MEDICINE (MPG 203T)

Objectives

After completion of the course, student is able to

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

Course Outcomes

1. Understand basic principle of various Indian system of medicine.
2. Explain the clinical research of traditional medicine
3. Illustrate c GMP of the traditional system of medicine.
4. Elaborate Formulation development and standardization of various traditional formulations.
5. Describe the Safety monitoring of herbal medicines and Quality control and quality assurance concepts involved in the traditional system of medicine.
6. Differentiate the concepts of AYUSH, ISM, CCRAS, CCRS, CCRH, and CCRU.

THEORY **60 Hrs**

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine — 12 Hrs
   Different dosage forms of the ISM.
   Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

2. Naturopathy, Yoga and Aromatherapy practices — 12 Hrs
   a) Naturopathy - Introduction, basic principles and treatment modalities.
   b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
   c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.
3. Formulation development of various systems of medicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations. — 12 Hrs

4. Schedule T – Good Manufacturing Practice of Indian systems of medicine — 12 Hrs
   Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments,

standard operating procedures, health and hygiene, documentation and records.

Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.

5. TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU — 12 Hrs

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy: An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG 204T)

Objectives

After completion of the course, student shall be able to,

- understand the basic principles of various herbal/natural cosmetic preparations
- current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

Course Outcomes

1. Understand the basic principles of herbal cosmetics.
2. Explain Regulatory Provisions related to the manufacturing of cosmetics including and Import, Export policies of Herbal/natural cosmetics.
3. Describe Raw product analysis and Herbal cosmeceutical development and standardization.
4. Elaborate on Possible interactions between chemicals and Herbs.
5. Illustrate concepts of Quality control and quality assurance of herbal cosmetics
6. Classify Toxicological and allergen screening techniques.

THEORY **60 Hrs**

1. Introduction: Herbal/natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics. 12 Hrs

2. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. 12 Hrs

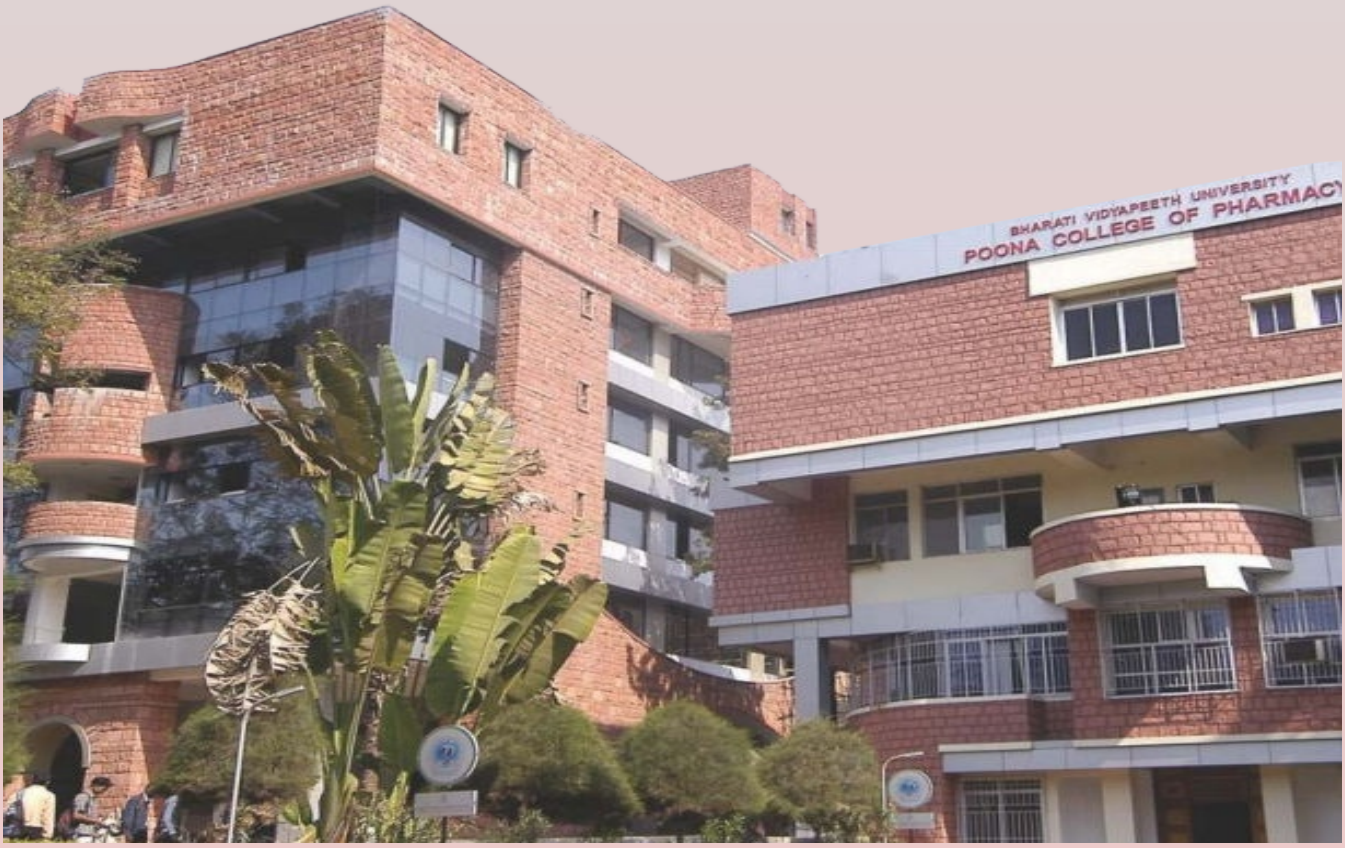
3. Herbal Cosmetics: Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following:
   Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails. 12 Hrs

4. Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. 12 Hrs

5. Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act. 12 Hrs

REFERENCES (Latest Editions of)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.



Bharati Vidyapeeth
(Deemed to be University) Pune, India
Poona College of Pharmacy
Erandwane, Pune - 411 038
Website: https://www.bvuniversity.edu.in/pcp
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BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY), PUNE

Faculty of Pharmaceutical Sciences
M.Pharm - Master of Pharmacy
Old Syllabus

BHARATI VIDYAPEETH
DEEMED UNIVERSITY, PUNE, (INDIA)

(Established u/s 3 of UGC Act, 1956 vide notification No. E9-95-U.3 of Government of India)

A GRADE UNIVERSITY STATUS AWARDED BY M.H.R.D., GOVT. OF INDIA
REACCREDITED WITH 'A' GRADE BY NAAC

FACULTY OF PHARMACEUTICAL SCIENCES

MASTER OF PHARMACY (M.Pharm.)

CHOICE BASED CREDIT AND GRADING SYSTEM

COURSE STRUCTURE & SYLLABUS

w.e.f. 2012-13

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w.e.f. 2012-13

BHARATI VIDYAPEETH DEEMED UNIVERSITY PUNE

Faculty of Pharmaceutical Sciences

Master of Pharmacy (M.Pharm.)

CHOICE-BASED CREDIT AND GRADING SYSTEM 2012 -13

INTRODUCTION

Bharati Vidyapeeth, the parent body of Bharati Vidyapeeth University was established on 10th May, 1964, by Dr. Patangrao Kadam with the objective of bringing intellectual awakening and all sided development of the people of our country through dynamic education.

Bharati Vidyapeeth is a leading educational institution in the country, which has created a history by establishing within a span of 48 years, 171 educational institutions imparting education from the pre-primary stage to post graduate stage. Our colleges and institutions of higher education impart education in different disciplines including Medicine, Dentistry, Ayurved, Homemopathy, Nursing, Arts, Science, Commerce, Engineering, Pharmacy, Management, Social Sciences, Law, Environmental Science, Architecture, Hotel Management and Catering Technology, Physical Education, Computer Science, Library Science, Information Technology, Biotechnology and Agriculture.

The Department of Human Resource Development, Government of India on the recommendation of University Grants Commission accorded the status of University initially to twelve units of Bharati Vidyapeeth. Subsequently, 17 additional colleges/ institutes were brought within the ambit of Bharati Vidyapeeth University vide various notifications of the Government of India. Bharati Vidyapeeth University commenced its functioning on 26th April 1996.

Constituent Units of Bharati Vidyapeeth University

1. Bharati Vidyapeeth Medical College,Pune
2. Bharati Vidyapeeth Dental College & Hospital, Pune
3. Bharati Vidyapeeth College of Ayurved,Pune
4. Bharati Vidyapeeth Homoeopathic Medical College, Pune
5. Bharati Vidyapeeth College of Nursing, Pune
6. Bharati Vidyapeeth Yashwantro Mohite College of Arts, Science and Commerce, Pune
7. New Law College, Pune
8. Social Sciences Centre (M.S.W.) Pune
9. Poona College of Pharmacy, Pune
10. College of Engineering, Pune
11. Institute of Management Enterprenurship Development, Pune
12. Yashwantrao Chavan Institute of Social Sciences Studies & Research, Pune.
13. Research and Development Centre in Pharmaceutical Science & Applied Chemistry, Pune
14. College of Physical Education, Pune
15. Bharati Vidyapeeth's Institute of Environmental Education & Research, Pune
16. Rajiv Gandhi Institute of Information Technology and Biotechnology, Pune
17. Interactive Research School in Health Affairs (IRSHA), Pune
18. R & D Center in Pharm. Sciences & Applied Chemistry, Pune
19. Bharati Vidyapeeth's Institute of Management and Research, New Delhi
20. Bharati Vidyapeeth's College of Architecture, Pune
21. Bharati Vidyapeeth's Institute of Hotel Management and Catering Technology, Pune.
22. Bharati Vidyapeeth's Yashwantrao Mohite Institute of Management, Kolhapur
23. Bharati Vidyapeeth's Institute of Management & Rural Development Administration, Sangli.
24. Bharati Vidyapeeth's Abhijit Kadam Institute of Management and Social Sciences, Solapur

25. Bharati Vidyapeeth's Medical College & Hospital, Sangli
26. Bharati Vidyapeeth's Dental College & Hospital, Mumbai.
27. BVDU Dental College & Hospital, Sangli
28. BVDU College of Nursing, Sangli
29. BVDU College of Nursing, Navi Mumbai

ACCREDITATION:

The National Assessment and Accreditaion Council (NAAC) have Re-accreditated Bharati Vidyapeeth Deemed University and all its constituent units with A grade.

Poona College of Pharmacy

Poona College of Pharmacy was established in 1981. This college has got approval and recognition of All india Council of Technical Education, New Delhi, and Pharmacy Council of India, New Delhi. Earlier the college was permanently affiliated to University of Pune Now it is a constituent unit of Bharati Vidyapeeth Deemed University. The college conducts B.Pharm, M.Pharm (Pharmaceutics, Pharm. Chemistry, Pharmacology, Pharmacognosy, Pharmaceutical Biotechnology and Quality Assurance Techniques), Pharm.D, Pharm.D (Post Baccalaurate) and Ph. D. programs. The college is housed in beautiful building and located in our bewitching teaching complex at Erandvane, Pune. The excellence which this college has achieved during these years in pharmacy education is mainly due to its experienced and qualified teaching faculty and the insfrastructural facilities of high quality provided in the college. The college has excellent library with modern books on pharmacy. The college also provides hostel facilities on a limited scale to our students both boys and girls.

As soon as the college came under the ambit of Bharati Vidyapeeth Deemed University, the syllabus of B.Pharm and M.Pharm. Courses was revised and upgraded with the help of the eminent experts in the pharmacy field and the same was approved by the University authorities. While doing so the guidelines given by UGC, AICTE, Pharmacy Council of India, and the societal needs have been taken into consideration.

Accreditation

In appreciation of it's academic excellence, availability of excellent infrastructural facilities and the potential it has for further growth, the National Board of Accreditation (NBA) has re accreditated the B.Pharm. program of this college. Similarly, the National Assessment and Accreditaion Council (NAAC) has also re-accreditated Bharati Vidyapeeth Deemed University, and this college.

Receiving the re- accreditation from both the accrediting national authorities is a remarkable achievement of this college.

GUIDELINES FOR CHOICE-BASED CREDIT AND GRADING SYSTEM:

The University Grants Commission (UGC), the National Assessment and Accreditation Council (NAAC), the Distance Education Council (DEC) and even the National Knowledge Commission (NKC) have time and again come out with recommendations for improving the quality and effectiveness of higher education provisions in the country. The ministry of Human Resource Development at the Central level and the Ministry of Higher & Technical Education, Govt. of Maharashtra have also repeatedly stressed on the need for universities to adopt measures to improve the quality of education imparted by the universities. Thus the need to develop a Choice-Based Credit System (CBCS) in tune with global trends and the adoption of a sound grading system for reflecting learner performance.

Advantages of the Credit System

- Represents a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning, not in teaching.
- Helps to record course work and to document learner workload realistically since all activities are taken into account - not only the time learners spend in lectures or seminars but also the time they need for individual learning and the preparation of examinations etc.
- Segments learning experience into calibrated units, which can be accumulated in order to gain an academic award.
- Helps self-paced learning. Learners may undertake as many credits as they can cope with.
- Affords more flexibility to the learners allowing them to choose inter-disciplinary courses, programmes, etc.
- Respects 'Learner Autonomy'. Allows learners to choose according to their own learning needs, interests and aptitudes.
- Makes education more broad-based. One can take credits by combining unique combinations.
- Facilitates Learner Mobility. Offers the opportunity to study at different times and in different places. Credits earned at one institution can be transferred to another.
- Is beneficial for achieving more transparency and compatibility between different educational structures.

ACADEMIC REGULATIONS FOR MASTER OF PHARMACY (M. Pharm.) PROGRAMME

Bharati Vidyapeeth University, Pune offers Master of Pharmacy (M.Pharm.) course at the Poona College of Pharmacy, Pune in the following specializations:

1) Pharmaceutics
2) Pharmaceutical Chemistry
3) Pharmacology
4) Pharmacognosy
5) Quality Assurance Techniques
6) Pharmaceutical Biotechnology

1.0 Duration :

The duration of Master of Pharmacy (M.Pharm.) course will be of 24 months, divided into four semesters, each semester of 6 months duration.

2.0 Eligibility for admission to M.Pharm. course :

The candidate seeking admission to M.Pharm. course must have :

1) Passed B.Pharm. degree examination of any statutory/recognized University with atleast 60% of aggregate marks or equivalent grade (55 % for S.C./S.T., teacher and sponsored candidates.
2) As per the AICTE guideline, few seats are reserved for the candidates having qualified GPAT score and atleast 60% marks at the B.Pharm. examination.
3) The candidate must have appeared at All India Entrance Test conducted by Bharati Vidyapeeth University.

3.0 Admission to M.Pharm. course :

The admissions to this course will be given strictly on the basis of merit obtained by the candidates in the relevant categories in the All India Entrance Test conducted by Bharati Vidyapeeth University.

4.0 Annual intake and allotment of seats :

A. The annual intake for each specialization is as follows :

1.	Pharmaceutics	-	18
2.	Pharmaceutical Chemistry	-	18
3.	Pharmacology	-	10
4.	Pharmacognosy	-	10
5.	Quality Assurance Techniques	-	18
6.	Pharmaceutical Biotechnology	-	10

B. The seats will be allotted to the different categories (that is SC/ST/GPAT etc.) of the candidates as per the rules of AICTE & Bharati Vidyapeeth University.

5.0 A.I.C.T.E. fellowship :

Only those candidate who have a qualified GPAT score and who have obtained atleast 60 % marks at B.Pharm. examination will be considered eligible for A.I.C.T.E. fellowships.

6.0 Fees:

The tuition fees, other fees and deposits like library and laboratory deposits will be as prescribed by the University from time to time.

7.0 Grant of terms :

The student who have satisfactorily completed the prescribed requirements of the course, appeared in all the internal assesements and has kept at least 75 % attendance at theory classes and practicals (if any) separately for each subject will be granted terms.

8.0 Syllabus :

The syllabi of the subjects for Semester-I and II are given at the end of rules and regulations.

9.0 Structure of the M. Pharm Programme

9.1 Each academic year consists of two semesters. Every branch of the M.Pharm. programme has a curriculum and course content (syllabi) for the subjects recommended by the Board of Studies and approved by the Academic Council.

9.2 The programme details are as follows:

I. First semester programme containing theory & practical subjects which are as per the respective specialization.

II. The core subjects in the semester are based on the respective specializations.

III. An assignment on the research paper published in journals on the subjects related to the field of specialization shall be allotted to the students to develop research and analytical skills to analyze various facets of the given research topic.

IV. The candidate has to present seminar on the chosen/ allotted topics during the 1st, 2nd 3rd and 4th semesters.

V. 3rd & 4th semester shall be devoted for the project work for the respective specialization.

VI. During the 3rd semester a candidate has to present an end semester seminar on proposed project work, literature survey and methodology of the project work.

VIII. The 4th semester consists of seminar followed by submission of project dissertation and viva-voce.

9.3 Project dissertation has to be submitted by each student individually. The general guidelines for evaluation of M. Pharm. thesis/ project work shall include the following:

I. Whether the objectives of the project work has been clearly identified and defined.

II. Whether it is relevant to the respective field.

III. Whether it is likely to make a significant contribution to the advancement of the knowledge or its usefulness from commercial viability.

IV. Whether the investigator possesses the necessary expertise to accomplish the work.

V. Whether the investigator has published/ submiited and presented any papers in the relevant field.

VI. Any other aspects which may be considered relevant.

10.0 CREDIT BASED SYSTEM

The studies and examinations of the M. Pharm course shall be on the basis of Marks cum Credit system but semester -wise and final evaluation shall be by grading system.

10.1 The course content of the individual subjects - theory and practicals – is expressed in terms of a specified number of credits. The number of credits assigned to a subject depends on the number of contact hours (lectures) per week.

10.2 In general, credits are assigned to the subjects based on the following contact hours per week per semester.

One credit for each Lecture hour.

One credit for two hours of practical.

10.3 The curriculum of M. Pharm programme is designed to have a total of 100 credits for the award of M. Pharm degree. A student is deemed to have successfully completed a particular semester's programme of study when he / she earns all the credits of that semester i.e., he /she has no 'F' grade in any subject of that semester.

11.0 MEDIUM OF INSTRUCTION

The medium of instruction (including examinations and project reports) shall be English.

12.0 REGISTRATION

Every student has to register himself/herself for each semester individually at the time specified by the College / University.

13.0 Scheme of Examination: CONTINUOUS ASSESSMENT AND EXAMINATIONS

13.1 The assessment of the student's performance in each course will be based on continuous internal evaluation and semester-end examination. The marks for each of the component of assessment are based on the assessment procedure shown in the Table 1:

Table 1: Assessment Procedure

S. No.	Component of assessment	Marks allotted/ Grade	Type of Assessment	Scheme of Examination
1	Theory	40	Continuous evaluation	(i) One mid semester examinations shall be conducted for 30marks each. (ii) 5 marks are allotted for assignments. (iii) 5 marks are allotted for attendance
		60	Semester end evaluations	The semester-end examination in theory subjects will be for a maximum of 60 marks.
		100		
2	Practicals	40	Continuous evaluationto	(i) 10 marks are allotted for record work andday day performance and viva voce of the student in each lab throughout the semester. The candidate shall lose the marks for the practical classes she/ he remains absent. (ii) One examination for a maximum of 30 marks shall be conducted at the middle of the semester
		60	Semester end evaluations	The semester-end practical examination will be for a maximum of 60 marks.
	Total	100		
3	Seminars	Grade O/A/B/F	Seminar	**Seminar 1:** During the 1st semester the candidate has to present end semester seminar on selected topics which shall be evaluated by the departmental committee. **Seminar 2:** During the 2nd semester the candidate shall present the end semester seminar on selected topics which shall be evaluated by the departmental committee. **Seminar 3:** During the 3rd semester the candidate shall present the end semester seminar on proposed project work, literature survey and methodology of the project work which shall be evaluated by the departmental committee. **Seminar 4 :** During the 4th semester the candidate shall present the end semester seminar on the dissertation work of the project This shall be evaluated by the departmental committee.
5	Project work	300	Project evaluation	**Viva Voce** The dissertation work of the project shall be evaluated on the basis of the performance and presentation skills on parameters like Preface, Objectives, general introduction, Drug profile, Review of literature, Plan of work, Methodology/experimental work and investigations, Interpretation and analysis of data, Results and Discussion.The candidate has to present the seminar before the committee comprising of External and Internal Examiners on the project work which shall be followed by viva voce which shall be evaluated for a maximum marks of 300.

* BVDU shall appoint examiners for conduct of the examination.

14.0 REAPPEARANCE

14.1 A Student who has secured 'F' Grade in any theory course / Practicals of any semester shall have to reappear for the semester end examination of that course / Practicals.

14.2 A student who has secured 'F' Grade in Project work shall have to improve his report and reappear for viva – voce Examination of project work at the time of examination to be conducted as scheduled by the University.

15.0 ATTENDANCE REQUIREMENTS

15.1 A student whose attendance is less than 75% in all the courses put together in any semester will not be permitted to attend the end - semester examination and he/she will not be allowed to register for subsequent semester of study. He /She has to repeat the semester along with his / her juniors.

16.0 GRADING SYSTEM

16.1 Based on the student performance during a given semester, the final letter grade will be awarded at the end of the semester in each course. The letter grades and the corresponding grade points are as given in Table 2.

Table 2: Grades & Grade Points

Grade	Grade points	Absolute marks
O	10	91 and above
A+	9	81- 90
A	8	71-80
B+	7	61-70
B	6	51- 60
C	5	50 only
F	-	Less than 50

16.2 A student who earns a minimum of 5 grade points (C grade) in a course is declared to have successfully completed the course, and is deemed to have earned the credits assigned to that course. However, a minimum of 50 marks is to be secured at the semester end examination of theory / practical courses in order to pass in the theory / practical course.

16.3 Seminar :

The student will have to give one seminar in each Semester.

Evaluation of Performance in Seminar :

The performance of student in seminars will be evaluated by the Seminar Evaluation committee. The grades will be awarded for the performance in each seminars as follows :

"O" - 80 % or above marks

"A" - 60 % but less than 80 % marks

"B" - 50 % but less that 60 % marks

"F" - Less than 50 Marks

The student will be considered to have passed in seminar provided he/she has obtained atleast "B" Grade. The failed candidate will have to give the seminar again in the same semester. If a student fails to secure minimum "B" Grade in the seminar at the second attempt, he/she will be required to give the seminar again in the next semester.

The grade awarded to the student in the seminar will be shown separately in his statement of marks of the concerned semester.

18.0 GRADE POINT AVERAGE

18.1 A Semester Grade Point Average (GPA) for the semester will be calculated according to the formula:

$$SGPA = \frac{\sum [C \times G]}{\sum C}$$

Where,

C = number of credits for the course,

G = grade points obtained by the student in the course.

18.2 Semester Grade Point Average (SGPA) is awarded to those candidates who pass in all the subjects of the semester.

18.3 To arrive at Cumulative Grade Point Average (CGPA), a similar formula is used considering the student's performance in all the courses taken in all the semesters completed up to the particular point of time.

$$CGPA = \frac{\sum [C \times G]}{\sum C}$$

Where,

C = total number of credits for the course,

G = grade points obtained by the student in the entire course.

18.4 The requirement of CGPA for a student to be declared to have passed on successful completion of the M. Pharm programme and for the declaration of the class is as shown in Table 3.

Table 3: CGPA required for award of class

Distinction	**e" 8.0***
First class	**7.0 -7.9**
Second class	**6.0 -6.9**
Pass	**5.0- 5.9**

19.0 **ELIGIBILITY FOR AWARD OF THE M. Pharm. DEGREE**

19.1 **Duration of the programme**:

A student is ordinarily expected to complete the M Pharm. programme in four semesters of two years. However a student may complete the programme in not more than four years including study period.

19.2 However the above regulation may be relaxed by the Vice Chancellor in individual cases for cogent and sufficient reasons.

19.3 Project dissertation has to be submitted on or before the last day of the course. However, it can be extended up to a period of 6 months maximum, with the written permission of the concerned guide.

19.4 A student shall be eligible for award of the M. Pharm degree if he / she fulfil all the following conditions.

a) Registered and successfully completed all the courses and projects.

b) Successfully acquired the minimum required credits as specified in the curriculum corresponding to the branch of his/her study within the stipulated time.

c) Has no dues to the Institute, hostels, Libraries etc, and

d) No disciplinary action is pending against him / her.

19.5 The degree shall be awarded after approval by the Academic Council.

RULES

1. With regard to the conduct of the end-semester examination in any of the practical courses of the programme, the University shall appoint one examiner from the institute in addition to an external examiner in the said subject.
2. In respect of all theory examinations, the paper setting shall be done by an internal and external paper setter having a minimum of five years of teaching experience. The panel of paper setters for each course is to be prepared by the Board of Studies of the department concerned and approved by the Academic Council. The paper setters are to be appointed by the Vice Chancellor on the basis of recommendation of the Controller of Examinations
3. The theory papers of end-semester examination will be evaluated by two examiners, internal and external.
4. Panel of examiners of evaluation for each course is to be prepared by the Board of Studies of the department concerned and approved by the Academic Council.
5. The examiner for evaluation should possess post graduate qualification and a minimum of five years teaching/ industrial experience.
6. The appointment of examiners for evaluation of theory papers will be done by the Vice Chancellor on the basis of recommendation of Controller of Examinations from a panel of examiners approved by the Academic Council.
7. Project work shall be evaluated by three examiners at the semester end examination. One examiner shall be internal and the two shall be external.
8. The attendance marks (maximum 5) shall be allotted as follows:

Percentage of attendance	Marks
76% to 84%	1
85% to 89%	2
90% to 94%	3
95% to 99%	4
100%	5

9 . Exemption :

A student who has obtained atleast 50 % marks in theory paper/s and/or practicals shall be exempted at his/her option from appearing for the same. The benefit of the exemption so earned will be available for 2 consecutive years only, since his/her first appearance at that examination.

11. A.T.K.T.

A student will be promoted from First Semester to Second Semester and from Second Semester to third Semester irrespective of number of subjects in which he/she failed in the first and second semester examination.

A candidate is allowed to continue his/her research work and submit the dissertation in accordance with the relevant regulation, but the result of the dissertation will not be declared until he/she has cleared the First , Second and Third Semester Examinations.

A candidate who has failed to pass M.Pharm. Fourth Semester Examination is required to keep minimum one fresh Semester and resubmit the revised dissertation, give a seminar and appear for viva-voce examination.

10. Dissertation :

Every student before appearing for the M.Pharm. Fourth Semester Examination is required to submit 5 typewritten copies of the dissertation duly certified by the Guide to the University for evaluation through the Principal of the College. The topic for the dissertation shall be assigned to him/her by the Guide. The student will be allowed to submit his/her dissertation not before 23 months since his registration. However he/she will submit the same within a period one month after the end of the Fourth Semester**.**

11. Extra Credits:

A student can enrol for extra credits over and above the total 100 credits prescribed for the course with following options:

a. Attend and appear for the exam of the opted extra credits.
b. Only attend the classes for the opted extra credit.

The extra credit course can be selected from within the institute or any other institute of Bharati Vidyapeeth Deemed University offering courses for Faculty of Pharmaceutical Sciences.

SCHEME OF INSTRUCTION : M.PHARM CBCS

SEMESTER-I

Sr.No	Theory	No.of hrs./week	Credits
1	Advanced Pharmaceutical Analysis	04	04
2	Research Methodology and Bioscreening	04	04
3	Advanced Core subject-I	04	04
4	Elective-I	04	04
	Total	**16**	**16**
Sr.No	**Practicals**	**No.of hrs./week**	**Credits**
1	Advanced Pharmaceutical Analysis Practical	06	03
2	Advanced Core subject-I Practical	06	03
3	Seminar- I	-	03
	Total	**12**	**09**
	Grand Total	**28**	**25**

SEMESTER-II

Sr.No	Theory	No.of hrs./week	Credits
1	Advanced Core Subject -II	04	04
2	Advanced Core Subject -III	04	04
3	Elective-II	04	04
4	Elective-III	04	04
	Total	**16**	**16**
Sr.No	**Practicals**	**No.of hrs./week**	**Credits**
1	Advanced Core-II	06	03
2	Seminar-II	-	06
	Total	**06**	**09**
	Grand Total	**22**	**25**

SEMESTER-III

Sr.No	Theory	No.of hrs.	Credits
1	Seminar-III	-	06
2	Assignment on Research Paper	--	06
	Total	**-**	**12**

SEMESTER-IV

Sr.No	Theory	No.of hrs.	Credits
1	Seminar-IV	-	06
2	Dissertation work	-	22
3	Viva-voce	-	10
	Total	**-**	**38**

SEMESTER WISE DISTRIBUTION OF CREDITS FOR M. PHARM

Semester	Theory		Practical/ Seminar/ Assgnment Credits		Total Credits
	Hours	Credits	Practical Hours	Credits	
M. Pharm. I Semester	16	16	12	09	25
M. Pharm. II Semester	16	16	06	09	25
M. Pharm. III Semester				12	12
M. Pharm. IV Semester				38	38
	Total				**100**

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM) PHARMACEUTICS

SEMESTER I -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	5	5	60	100
2	Advanced Pharmaceutics-I	30	5	5	60	100
3	Research Methodology and Bioscreening	30	5	5	60	100
4	Elective-I	30	5	5	60	100
	TOTAL					**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmaceutics-I	10	30	60	100
3	Seminar I	-	-	Letter Grade O/A/B/F	Letter Grade O/A/B/F
	Total				**200**
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutics-II	30	5	5	60	100
2	Advanced Pharmaceutics-III	30	5	5	60	100
3	Elective-II	30	5	5	60	100
4	Elective-III	30	5	5	60	100
	TOTAL					**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutics-II	10	30	60	100
2	Seminar II	-	-	Grade O/A/B/F	Grade O/A/B/F
	Total				**100**
	Grand Total Semester II (Theory+ Prtactical)				**500**

SEMESTER III

S.No	Name of the Subject	End sem	Grand total
1	Seminar III (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	Letter Grade O/A/B/F	Letter Grade O/A/B/F
2	Assignment on Research Paper	Letter Grade O/A/B/F	Letter Grade O/A/B/F

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	Letter Grade O/A/B/F	-	Letter Grade O/A/B/F
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications /abstracts of the author, mode of presentation)		150	150
3	Viva – Voce		150	150
	TOTAL			**300**
	Grand total Semester I to IV = 600 + 500 + 300 = 1400			

SCHEME OF EXAMINATION FORMASTER OF PHARMACY (M.PHARM)
PHARMACEUTICAL CHEMISTRY

SEMESTER I -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1.	AdvancedPharmaceutical Analysis	30	5	5	60	100
2.	Research Methodology and Bioscreening	30	5	5	60	100
3.	Advanced Pharmaceutical Chemistry -I	30	5	5	60	100
4.	Elective-I	30	5	5	60	100
	TOTAL					400

SEMESTER I –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmaceutical Chemistry-I	10	30	60	100
3	Seminar I	-	-	Letter Grade O/A/B/F	Letter Grade O/A/B/F
	Total				**200**
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutical Chemistry-II	30	5	5	60	100
2	Advanced Pharmaceutical Chemistry-III	30	5	5	60	100
3	Elective-II	30	5	5	60	100
4	Elective-III	30	5	5	60	100
	TOTAL					**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Chemistry-II	10	30	60	100
2	Seminar II	-	-	Grade O/A/B/F	Grade O/A/B/F
	Total				**100**
	Grand Total Semester II (Theory+ Prtactical)				**500**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	Letter Grade O/A/B/F	Letter Grade O/A/B/F
2	Assignment on Research Paper	Letter Grade O/A/B/F	Letter Grade O/A/B/F

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	Letter Grade O/A/B/F	-	Letter Grade O/A/B/F
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications/ abstracts of the author, mode of presentation)		150	150
3	Viva – Voce		150	150
	TOTAL			300

Grand total Semester I to IV = 600 + 500 + 300 = 1400

MASTER OF PHARMACY (M.PHARM) PHARMACOLOGY

SEMESTER I -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	5	5	60	100
2	Research Methodology and Bioscreening	30	5	5	60	100
3	Advanced Pharmacology-I	30	5	5	60	100
4	Elective-I	30	5	5	60	100
	TOTAL					**400**

SEMESTER I –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmacology - I	10	30	60	100
3	Seminar I	-	-	Letter Grade O/A/B/F	Grade Letter O/A/B/F
		Total			**200**
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmacology -II	30	5	5	60	100
2	Advanced Pharmacology -III	30	5	5	60	100
3	Elective-II	30	5	5	60	100
4	Elective-III	30	5	5	60	100
	TOTAL					**400**

SEMESTER II –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmacology -II	10	30	60	100
2	Seminar II	-	-	Grade O/A/B/F	Grade O/A/B/F
	Total				**100**
	Grand Total Semester II (Theory+ Prtactical)				**500**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on proposed Project Work, Literature Survey, Plan of Work, Methodology)	Letter Grade O/A/B/F	Letter Grade O/A/B/F
2	Assignment on Research Paper	Letter Grade O/A/B/F	Letter Grade O/A/B/F

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	Letter Grade O/A/B/F	-	Letter Grade O/A/B/F
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications/ abstracts of the author, mode of presentation)		150	150
3	Viva – Voce		150	150
	TOTAL			300

Grand total Semester I to IV = 600 + 500 + 300 = 1400

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM) PHARMACOGNOSY

SEMESTER I -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	5	5	60	100
2	Research Methodology and Bioscreening	30	5	5	60	100
3	Advanced Pharmacognosy - I	30	5	5	60	100
4	Elective-I	30	5	5	60	100
	TOTAL					**400**

SEMESTER I –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmacognosy-I	10	30	60	100
3	Seminar I	-	-	Letter Grade O/A/B/F	Letter Grade O/A/B/F
	Total				**200**
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmacognosy-II	30	5	5	60	100
2	Advanced Pharmacognosy-III	30	5	5	60	100
3	Elective-II	30	5	5	60	100
4	Elective-III	30	5	5	60	100
	TOTAL					**400**

SEMESTER II –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmacognosy-II	10	30	60	100
2	Seminar II	-	-	Grade O/A/B/F	Grade O/A/B/F
	Total				**100**
	Grand Total Semester II (Theory+ Prtactical)				**500**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	Letter Grade O/A/B/F	Letter Grade O/A/B/F
2	Assignment on Research Paper	Letter Grade O/A/B/F	Letter Grade O/A/B/F

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	Letter Grade O/A/B/F	-	Letter Grade O/A/B/F
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications/abstracts of the author, mode of presentation)		150	150
3	Viva – Voce		150	150
	TOTAL			300
	Grand total Semester I to IV = 600 + 500 + 300 = 1400			

SCHEME OF EXAMINATION FORMASTER OF PHARMACY (M.PHARM) QUALITY ASSURANCE

SEMESTER I -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	5	5	60	100
2	Research Methodology and Bioscreening	30	5	5	60	100
3	Quality Assurance Techniques -I	30	5	5	60	100
4	Elective-I	30	5	5	60	100
	TOTAL					**400**

SEMESTER I –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Quality Assurance Techniques -I	10	30	60	100
3	Seminar I	-	-	Letter Grade O/A/B/F	Letter Grade O/A/B/F
	Total				200
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Quality Assurance Techniques -II	30	5	5	60	100
2	Quality Assurance Techniques -III	30	5	5	60	100
3	Elective-II	30	5	5	60	100
4	Elective-III	30	5	5	60	100
	TOTAL					**400**

SEMESTER II –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Quality Assurance Techniques -II	10	30	60	100
2	Seminar II	-	-	Grade O/A/B/F	Grade O/A/B/F
	Total				**100**
	Grand Total Semester II (Theory+ Prtactical)				**500**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	Letter Grade O/A/B/F	Letter Grade O/A/B/F
2	Assignment on Research Paper	Letter Grade O/A/B/F	Letter Grade O/A/B/F

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	Letter Grade O/A/B/F	-	Letter Grade O/A/B/F
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology / experimental work and investigations, interpretation and analysis of data, results and discussions, publications/abstracts of the author, mode of presentation)		150	150
3	Viva – Voce		150	150
	TOTAL			300

Grand total Semester I to IV = 600 + 500 + 300 = 1400

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM)
PHARMACEUTICAL BIOTECHNOLOGY

SEMESTER I -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	5	5	60	100
2	Research Methodology and Bioscreening	30	5	5	60	100
3	Advanced Pharmaceutical Biotechnology-I	30	5	5	60	100
4	Elective-I	30	5	5	60	100
	TOTAL					**400**

SEMESTER I –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmaceutical Biotechnology -I	10	30	60	100
3	Seminar I	-	-	Letter Grade O/A/B/F	Letter Grade O/A/B/F
	Total				**200**
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	Mid Sem	Assign-ment	Atten-dance	End Sem	Grand Total
1	Advanced Pharmaceutical Biotechnology-II	30	5	5	60	100
2	Advanced Pharmaceutical Biotechnology-III	30	5	5	60	100
3	Elective-II	30	5	5	60	100
4	Elective-III	30	5	5	60	100
	TOTAL					**400**

SEMESTER II –PRACTICAL

S.No.	Name of the subject	Day to day Assessment	Mid Sem Exam	End Sem	Grand total
1	Advanced Pharmaceutical Biotechnology-II	10	30	60	100
2	Seminar II	-	-	Grade O/A/B/F	Grade O/A/B/F
	Total				**100**
	Grand Total Semester II (Theory+ Prtactical)				**500**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1.	Seminar III (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	Letter Grade O/A/B/F	Letter Grade O/A/B/F
2.	Assignment on Research Paper	Letter Grade O/A/B/F	Letter Grade O/A/B/F

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	Letter Grade O/A/B/F	-	Letter Grade O/A/B/F
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/experimental work and investigations, interpretation and analysis of data, results and discussions, publications/abstracts of the author, mode of presentation)		150	150
3	Viva – Voce		150	150
	TOTAL			300

Grand total Semester I to IV = 600 + 500 + 300 = 1400

CREDIT BASED SYSTEM FOR M. PHARM IN PHARAMCEUTICAL REGULATORY AFFAIRS (PRA)

Scheme of Instruction :

SEMESTER-I

Sr.No	Theory	Hrs./week	Credits
1	Advanced Pharmaceutical Analysis	04	04
2	PHARAMCEUTICAL REGULATORY AFFAIRS I	04	04
3	Research Methodology and Bioscreening	04	04
4	Elective-I	04	04
	Total	**16**	**16**

Sr.No	Practicals	Hrs./week	Credits
1	Advanced Pharmaceutical Analysis Practical	06	03
2	PHARAMCEUTICAL REGULATORY AFFAIRS I Practical	06	03
3	Seminar- I	-	03
	Total	**12**	**09**
	Grand Total: Theory + Practical	**28**	**25**

SEMESTER-II

Sr.No	Theory	Hrs./week	Credits
1	PHARAMCEUTICAL REGULATORY AFFAIRS II	04	04
2	PHARAMCEUTICAL REGULATORY AFFAIRS III	04	04
3	Elective-II	04	04
4	Elective-III	04	04
	Total	**16**	**16**

Sr.No	Practicals	No.of hrs./week	Credits
1	PHARAMCEUTICAL REGULATORY AFFAIRS II Practicals	06	03
2	Seminar-II	-	06
	Total	**06**	**09**
	Grand Total: Theory + Practical	**22**	**25**

SEMESTER-III

Sr. No	Theory	No. of hrs.	Credits
1	Seminar-III	—	06
2	Assignment on Research Paper	—	06
	Total	—	**12**

SEMESTER-IV

Sr. No	Theory	No. of hrs.	Credits
1	Seminar-IV	-	06
2	Dissertation work	-	22
3	Viva-voce	-	10
	Total	**-**	**38**

SEMESTER WISE DISTRIBUTION OF CREDITS FOR M. PHARM

Semester	Theory Total Credits		Practical/ Seminar/ Assignments Credits		
	Hours	Credits	Practical	Hours	Credits
M. Pharm. I Semester	16	16	12	09	25
M. Pharm. II Semester	16	16	06	09	25
M. Pharm. III Semester				12	12
M. Pharm. IV Semester				38	38
Total					**100**

BHARATI VIDYAPEETH DEEMED UNIVERSITY, PUNE

SYLLABUS FOR M Pharm 2012-13

RESEARCH METHODOLOGY AND BIOSCREENING

Theory 4 hours/week

CREDITS 04

UNIT NO. I

i. Meaning of research, purpose of research, types of research (educational, clinical, experimental historical descriptive, basic applied and patent oriented research)- Objective of research
ii. Literature survey: Use of library, books and journals- Medline-Internet, getting patents and reprints of articles as source for literature survey.
iii. Selecting a problem and preparing research proposal for different types of research mentioned above.

UNIT NO. II

i. Methods and tools used in research.
ii. Qualitative studies, Quantitative studies
iii. Sample data organization, Descriptive data analysis.
iv. Limitations and source of error.
v. Inquiries in form of questionnaire, opinioaire or by interview.
vi. Technical report writing/ paper writing/thesis writing. Plagiarism.
vii. Quality By Design: Basic concepts, Process Analytical Techniques.

UNIT NO. III

i. Guidelines and techniques for experiments with animals. Regulatory bodies like CPCSEA, BS, OECD, LD_{50}, ED_{50} determination, Bioassays, Handling of biological waste, handling of radioactive materials.
ii. Bioscreening of following category of drugs:
    a. Cardiovascular System- Antihypertensives, antiarrythmics, antiatherosclerotic.
    b. Central nervous system-Anti psychotics, antidepressants, antiparkinsonian, nootropics, anticonvulsants.
    c. Pain pathways: Analgesics, antiinflammatory.

UNIT NO. IV

i. Biostatistics: Probability distribution, binomial polynomial, distribution, continuous data distribution, probit and logit analysis, linear regression and correlation, significance of correlation and regression, Parametric tests, testing hypothesis, types of errors, Test of significance for correlation co efficient. Non parametric tests, Experimental design (randomization, completely randomized and latin square designs, cross over and parallel design and factorial designs.)

RECOMMENDED BOOKS:

1. Anderson J. Thesis and Assignment writing.
2. Best JV, Kahn JV. Research in education. 7th Ed. Prentice Hall of India. New Delhi.1999
3. Brown L. Effective Business Report Writing.
4. Das P and Das G. Protection of industrial property rights.
5. Davis R M. Thesis project in Science and Engineering.
6. Day R A. How to write and publish a research paper. 5th Ed. ISI Press. Philadelphia. 2006.
7. Furmess E. Spelling for the millions.
8. Halton M. Presentation skills Indian Society for Institute Education.
9. Mcfariane G. A practical introduction to copy right.
10. Menzel D. Writing a technical paper.
11. CPCSEA guidelines WWW.CPCSEA.COM
12. CPCSEA guidelines for laboratory animal facility Indian Journal of Pharmacology. 2003; 35: 257-274.
13. OECD guidelines.
14. Bolton S; Pharmaceutical statistics; Marcel Dekker.
15. Rao NSN, Murthy NS Applied statistics in health care. Jaypee Brothers Medical Publishers. New Delhi.
16. Juran J.M. and Godfrey A.B. Juran's quality handbook; McGraw Hill.
17. Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.

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ADVANCED PHARMACEUTICAL ANALYSIS

(Thoery) (4 Hrs/Week)

UNIT I

1. Spectroscopic methods - Introduction, applications and structure elucidation using UV, IR, NMR, Mass spectrometry with examples.(14h)

UNIT II

2. Separation techniques - Theory, instrumentation, applications of GLC, HPLC, HPTLC,GC-MS,LC-MS, LC-MS-MS. (14h)

UNIT III

3. a. Chiral chromatography, ion pair chromatography, super critical fluid chromatography. (8h)
   b. Immunochemical techniques - Immunoelectrophoresis, immunoprecipitation, ELISA, radioimmuno assays.(6h)

UNIT IV

4. a. Thermal analysis - Theory, instrumentation and applications of thermogravimetric analysis, differential thermal analysis, differential scanning calorimeter.(9h)
   b. XRD techniques: theory, instrumentation and applications (5h)

ADVANCED PHARMACEUTICAL ANALYSIS

(Practical) (6 Hrs/Week) Credits 3

1) Experiments based on UV, FT-IR, HPLC, GC and DSC
2) ELISA test/ LAL test
3) Estimation of drugs in biological fluids.
4) Validation of analytical methods

RECOMMENDED BOOKS :

1) Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2) M.Orchin and H.H.Jaffe - Theory and applications of ultra violot spectroscopy (John Wiley and Sons, N.Y.)
3) Silverstein, Basseler, Morril - Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4) Willard, Merritt, Dean - Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5) J.R.Dyer - applications of Absorption Spectroscopy of Organic compounds (Prentic Hall, London)
6) C.N.R.Rao - Chemical applications of Infra-red spectroscopy (Academic press, N.Y.)
7) Higuchi : Instrumental Methods of Analysis
8) Analytical Chemistry by open learning series
9) R.J. Hamilton-Introduction to High Performance Liquid chromatography, (Chapman and Hall, London).
10) Ewing–Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)

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ADVANCED PHARMACEUTICS- I

Theory 4 hours/week Credits 4

UNIT 1

1. Preformulation studies:

   Physicochemical factors influencing formulation

   Principles and applications of characterization Techniques

   Drug Excipient Compatibilty studies

2. Stability Studies: Basic concepts, Kinetics and ICH guidelines for stability evaluation

UNIT 2

3. Statistical Designs including Factorial and other approaches

4. Dissolution : Theory of dissolution, concept of drug release. Dissolution test apparatus: different designs, factors affecting dissolution rate. Dissolution of different dosage forms: solids, suspensions, topicals, suppositories and controlled release systems.

   Comparison of dissolution profile by model independent (f1 & f2 analysis) and dependant methods IVIVC

UNIT 3

5. Solids : Handling of solids, pharmaceutical granulation, compression and compaction properties of binary mixtures, lubricant sensitivity, characterization of granules and compacts.

6. Pharmaceutical aspects of solubilization and solubilized systems : Solubilization of drugs by following approaches: use of surfactants for solubiliaztion; solid dispersions, cyclodextrin inclusion complexes, cosolvency etc.

UNIT 4

7. Surfactant System: Phase behaviour of surfactants in binary and ternary systems. Factors affecting phase behaviour; Micellization; Micelle structure, shape size factors affecting CMC and micellar size, thermodynamics and kinetics of micelle formation

8. Polymer Science : Types and applications of polymers, methods of polymerization and characterization of polymers. Polymers for controlled release Bioadhesive polymers, stimuli sensitive polymers. Biodegradable polymers, Biodegradation of polymers, enzymatically degradable bonds in synthetic polymers, dendrimers

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ADVANCED PHARMACEUTICS-I

Practical (6 Hrs/week) Credits 3

Experiments based on following concepts :

1) Solids :

   a) Particle size analysis by microscopy and laser diffraction techniques

   b) Compression and compaction : Heckel plot studies, Tensile strength

   c) Mechanical properties of granules

2) Solubilization

   a) Effect of dielectric constant on solubility

   b) Complexation

   c) Ternary phase diagram

   d) Solid dispersions: Preparation and characterization of amorphous and crystalline forms.

3) Polymer science : Rheological and Thermal characterization of polymers.

4) Preparation and characterication of different mesophases of surfactant/ polymers.

5) Dissolution studies of various dosage forms

Recommended books :

1) N.G. Stanley - Wood, Enlargement and compaction of particle solids; Butterworths
2) D. M. Parikh, Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
3) H.G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
4) A. Kitahard and A.Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
5) J.T.Carstensen; Drug stability; Marcel Dekker
6) G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7) A. Martin, P.Bustamante and A.H. Chun; Physical Pharmacy; Waverly
8) Lieberman, Rieser and Banker; Pharmaceutical dosage forms; Disperse system; Marcel Dekker.
9) M.N. Rubinstein, Pharmaceutical Technology, Drug Stability, John Wiley and Sons.
10) Martin Rhodes, Principles of Powder Technology, John Wiley and Sons
11) James J.Wells, Pharmaceutical Preformulation, Ellis Horwood Ltd.
12) P.J.Tarcha, Polymers for Controlled Drugs Delivery, CRC Press.
13) P.H.List and P.C. Schmidt; Pharmaceutical technology, CRS press.
14) Robinson, Novel Drug Delivery System, Marcel Dekker.

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ADVANCED PHARMACEUTICS- II

Theory 4 hours/week Credits 4

Design, development, manufacture and evaluation of the following novel drug delivery systems:

UNIT1:

1. Oral Drug Delivery Systems: Osmotic DDS, Ion exchange controlled DDS, Hydrodynamically balanced DDS
2. Mucosal DDS: Physiological basis of mucosal delivery with reference to oral mucosal, nasal, vaginal and rectal routes. Bioadhesion and bioadhesive polymers, DDS for mucosal administration. In-vitro, ex-vivo and in-vivo evaluation techniques.
3. Microspheres: Methods to obtain microcapsules/ microspheres, their evaluation and applications.

UNIT2:

4. Transdermal DDS: Percutaneous absorption and penetration enhancers, development of transdermal gels, patches with reference to components and evaluation. Iontophoretic and Sonophoretic DDS.
5. Ocular DDS –Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation.
6. Parenteral DDS: CR Injectables, implants etc. development and evaluation

UNIT3:

7. Colloidal DDS: Specialized DDS like micro / nano emulsions, SMEDDS, Multiple emulsions, liposomes, niosomes, polymeric micelles and other vesicular DDS, their design and development into final dosage forms, issues and consideration
8. Nanoparticulate systems such as lipid nanoparticles and polymeric nanopartciles: Methods of preparation, characterization and applications
9. Peptide and protein based DDS: Chemistry and special features of peptide and protein molecules, stability, Challenges in protein/ peptide delivery, Formulation approaches and evaluation of peptide and protein delivery; Routes of delivery, Toxicity, immunogenicity, vaccines and gene based DDS

UNIT4:

10. Pulmonary DDS – Physiological basis and formulation considerations. Design of Pressurized aerosols, Dry powder DDS, Devices for administration and evaluation.
11. Targeted DDS: Concept of drug targeting, need for drug targeting , basis for drug targeting both active and passive. Ligands for targeted delivery, Monoclonal antibodies in targeted delivery, design of targeted DDS for cancer and infectious diseases, brain targeting, Colon targeting approaches and DDS
12. Intrauterine Devices, Intravaginal drug delivery systems

ADVANCED PHARMACEUTICS-II

(Practical) (6 Hrs per week) Credits

Experiments based on follwing concepts.

1) Formulation and evaluation of sustained release tablet formulation.
2) Preparation and characterization of Microcapsules/ Microspheres : at least 2 methods.
3) Preparation and evaluation transdermal films/patches and gel formulation
4) In-vitro permeation studies across skin and nasal mucosa
6) Formulation design and evaluation of

   a) Liposomes b) Multiple emulsion c) Niosomes d) nanosuspension

   e) Osmotic pump f) Ocular insert

RECOMMENDED BOOKS :

1) P. Tyle, drug Delivery Devices, fundamental and applications, Marcel Dekker.
2) Morton rosoff, Controlled release of drugs, VCH Publishers.
3) D.W. Osborne, and A.H. Amann, topical drug delivery formulations, Marcel Dekker.
4) P. Tyle Drug delivery devices, Marcel Dekker
5) Barry, Dermatological formulation, Marcel Dekker
6) Robinson, Novel Drug Delivery systems, Marcel Dekker
7) N.K. Jain, Controlled and Novel Drug delivery, CBS Publisher, New Delhi.
8) P. Johnson and J.G. Lloyd – Jones, Drug Delivery Systems, VCH Publisher
9) P. Tyle and B.P. Ram, Targeted Therapeutic systems, Marcel Dekker
10) C.G. Wilson and N. Washington, Physiological Pharmaceutics, Ellis Horwood Limited
11) H.S. Bean, A.H. Beckett, and J.E. Carless, Advances in Pharmaceutical Sciences vol. 5 Academic Press.
12) R.O. Potts, and R.H. Guy, Mechanisms of Transdermal Drug delivery, Marcel Dekker.
13) T.J. Roseman and S.Z. Controlled release delivery systems, marcel Dekker.
14) A.J. Hickey, Pharmaceutical Aerosol Technology, Marcel Dekker.
15) J. Kreuter, Controlled drug delivery systems, Marcel Dekker
16) K.S.E. Su and S.F. Chang, Nasal systemic drug delivery, Marcel Dekker
17) A.F.Kydonieus, Controlled release technologies : methods, theory and applications vol. I & II, CRC Press inc.
18) Y.W. Chein, Trasdermal controlled systemic medication, Marcel Dekker
19) P.B. Deasy, Microencapsulation and related drug processes, Marcel Dekker.

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ADVANCED PHARMACEUTICS - III

(Theory) (4 hrs/week) Credits

UNIT1:

1. Absorption: Cell membrane, absorption mechanisms, oral drug absorption, pH-partition hypothesis. Factors affecting: physico-chemical, dosage form related, patient related. Drug absorption through other routes, transdermal, nasal, buccal, ocular, and sublingual. In-vitro, in-situ and in-vivo models for drug absorption studies. ABC transporters. Animal Tissue culture Technique for drug absorption studies.
2. Distribution: Tissue permeability of drugs, barriers to distribution of drugs. Factors affecting drug distribution, physicochemical properties of drugs, volume of distribution, Drug - protein binding, drug tissue binding, factors affecting protein drug binding. Kinetics of drug protein binding significance of drug tissue binding.

UNIT2:

3. Metabolism :Drug metabolism organs and enzymes, chemical pathways Phase-I and Phase-II reactions. First pass effect, factors affecting metabolism
4. Excretion:Renal and nonrenal routes of drug excretion, concept of clearance. Factors affecting excretion mainly renal excretion.

UNIT3:

5. Pharmacokinetics : Pharmacokinetics in drug discovery and development, Pharmacokinetics models, Laplace transformations and concept of compartment modeling.

1) One compartment model : intravenous injection, intravenous infusion, First order absorption (Urinary and plasma data)
2) Multicompartment models. Intravenous injection, intravenous infusion, first order absorption, multidosing data.
3) Non-linear Pharmacokinetics Michaelis- Menten kinetics, estimation of K_m and V_m, Area under curve, enzyme induction.
4) Non compartmental analysis - statistical moment theory

6. Integration of Kinetics: Interrelationships between pharmacokinetics parameters and physiological variables.

UNIT4:

7. Application of Pharmacokientic: Multiple dosing, controlled release dosage form, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronipharmacokientics.
8. Bio-availability and Bioequivalence: Study design, protocols and regulatory requirements and statistical consideration in data analysis

RECOMMENDED BOOKS :

1. J.B.Blanchard, R.J. Sawchul and B.B.Brodie, Principle and Perspectives in Drug bioavailability, K. Karger Publication.
2. M. Gibald and Perrier, Pharmacokientices, Marcel Dekker.
3. M.Rawland and T.N. Tozer, Clinical Pharmacokinetics, Waverly Publications
4. P.Jenner and B. Testa, Concepts in drug metablism, Marcel Dekker
5. D.M. Brmhankar and S.B.Jaiswal, Biopharmaceutics and pharmacokientis A Treatise, Vallabh Prakashan.
6. Jean - Pierre Labaune, Hand book of pharmacokinetics, John Wiley & sons.
7. B. Testa, Advances in drug research, Vol. 19, Academic Press.
8. R.E. Notari; biopharmaceutics and clinical Pharmacokinetics; Marcel Dekker.
9. P.G. Welling and F.L.S. Tse; Pharmacokinetics, regulatory- Industrial Academic perspectives, Marcel Dekker.

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ADVANCED PHARMACEUTICAL CHEMISTRY-I

(Theory) (4 h/Week) Credits 4

Unit I

1. Protective groups for –OH, -NH_2, -COOH. Special protective groups for aldehyde / ketone such as oxazolines [A. I. Meyer's reagent] & 1,3- dithianes. Methods for the deprotection of the above groups. Concept of "Umplong". Reactions of 1, 3-dithiane (4h).
2. Homogeneous & heterogeneous reductions / hydrogenations. Metal - ammonia / amines reductions (4h).
3. Catalyzed reactions-: General concept of catalysis, Distinction between catalysis and Induction, Base catalysis, Transition metal catalysis, Catalysis by Enzymes, Enzymes and chiral recognition, Artificial enzymes (4h)

Unit II

4. Name reactions:

Hoffmann degradation, Beckmann rearrangment,Michael addition. Claisen- Schmidt, MPV reduction, Oppanaur Oxidation, Bayer- Villiger reaction, Wolf- Kishner reaction, Claimenson's reaction, Fries reaction, Mannich reaction, Stobbe reaction, Wiitig reaction, Pinacole-pincolone rearrangment, Benzil-benzillic acid rearrangment, Curtius rearrangment.(7h)

5. Fluorinating agents & their use in drug synthesis (2h)
6. Regio- & stereoselective & stereospecific formation of enolate anions, their nucleoplillic & addition reactions. Role of Li, Na, K, Mg, & B metal ions in the regio- & stereoselective &stereospecific formation of enolate anions(4h)

Unit III

7 Chemistry of active methylene compounds(4h)

8 Different methods for the preparation of á-methylene lactones & similar functionalities(2h)

9 Pericyclic reactions. HOMO & LUMO. Conservation of orbital symmetry. Woodward rules for allowed & disallowed motions. Stereo specificity of these reactions(5h)

Unit IV

10 Heterocyclic Chemistry : IUPAC Nomenclature and name reactions such as Knorr and Paal-Knorr pyrrole synthesis,Fischer indole synthesis, Modelung indole synthesis, Reissert indole synthesis, Hinsberg thiophene synthesis, Claisen isoxazole synthesis,Robinson- Gabriel synthesis, Guareshi-Thorpe pridine synthesis, The Zincke Reaction (6h)

11 Stereochemistry & it's importance in medicinal chemistry.. Nomenclature & stereochemistry of spiro-compounds. Stereochemistry of allenes & biphenyls (4h)

12 Dynamic stereochemistry, conformations & reactivity in open chain & cyclic systems. Weinstein, Curtin – Hammet principle. Cram's rule & Prelog modification. Topicity & it's significance in dynamic stereochemistry (8h)

ADVANCED PHARMACEUTICAL CHEMISTRY-I

(Practicals) (6 h/week) Credits 3

1. Clemmensen reduction
2. Lithium aluminium hydride reduction
3. Sodium borohydride reduction
4. Claisen-schmidt condensation
5. Oxidation of sulphide to sulfoxides and sulfones with hydrogen peroxide & peracid.
6. Preparation of Wittig reagent & reaction with aldehyde and ketone
7. Resolution of a acidic and basic racemic mixture by diasteriomer formation

8. Synthesis of thiazide & hydrothiazide derivative in a multi step process.
9. Diel's Alder reaction for preparing bicyclo [2.2.1] system.
10. Synthesis of any tripeptide from amino acids.
11. Fischev India Synthesis
12. Grignard reaction.
13. Pinacolone – synthesis

Recommended books:

- R. T. Morrison & R. N. Boyd, "Organic Chemistry". Allyn & Bacon, Inc., Boston, U. S. A.
- H. O. House, W. A. Benjamin, "Modern synthetic Reactions"., Inc., Menlo Park, California, U. S. A.
- E. L. Eliel, "Stereochemistry of Carbon Compounds", McGraw-Hill Book Company, Inc., New York, U. S. A.
- D. Nasipuri, "Stereochemistry of Organic Compounds". Wiley Eastern Limited, New Delhi, India.
- M. B. Smith, "Organic Synthesis", McGraw-Hill, Inc., New York, U. S. A.
- Text book of Organic Chemistry by Vogel.

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ADVANCED PHARMACEUTICAL CHEMISTRY-II

(Theory) (4 h/Week)

UNIT I

1) Enzyme Inhibition -

a. Enzyme structure : primary, secondary, tertiary and quarternary.

b. Enzyme kinetics

c. Enzyme inhibitors - Reversible, Irreversible, Kcat inhibitors, Transition state analogs.

d. Enzyme Inhibitors as drugs - ACE, leukotrienes, Lipoxygenase, Cycloxygenase, Aromatase, Xanthine oxidase, HMG-Co- A , MAO and Cytochrome P-450 Inhibitors. (9h)

2) Drugs binding to nucleic acid :

a. DNA intercalating agents

b. DNA binding and nickling agents

c. Agents interfering with DNA enzymes

d. Inhibitors of the transcribing enzymes

e. Agents interacting with ribosomal RNA and interfering with its function.

Above agents with reference to Antimalarial, anti-cancer, antiviral.(9h)

UNIT II

3) Design and application of prodrugs concept

a. Prodrug concept, hard and soft drugs

b. Classification of prodrugs.

c. Prodrugs of various functional groups like carbonyl, hydroxy, amide, amines.

d. Application of prodrug approach to: pharmaceutical, pharmacokinetic and pharmacodynamic applications.

e. Limitations and drawbacks of prodrug concept

f. Macromolecular carries for drug targetting : types of carries used, methods of drug release, active and passive targetting, polymeric prodrugs and their applications.

g. Twin drugs/Hybrid drugs (14h)

UNIT III

4) Synthon Approach

a. Definition of terms- disconnection, synthon, functional group interconversion (FGI).

a. Basic rules in disconnection

b. Use of synthon approach in synthesis of following compounds:

Trimethoprim, Terfenadine, Ibuprofen, Propanolol, Fentanyl, Ciproflaxacin, Cimetidine, Piroxicam, Rosiglitazone, Diclofenac, Coptopril, Nifedipine .(14h)

Unit IV

5) Drug Discovery

a. Historical perspective, Drug discovery strategies in direct drug design (structure based) and indirect drug design, Target selection and lead identification (Natural product sources, Fermentation / Microbial sources, Synthetic)

b. Drug discovery strategies in structure based drug design: Molecular drug Targets—Introduction, Enzymes, Membrane Transportes,,Voltage- Gated Ion channels, Non- selective cation channels, Direct Ligand –gated Ion channels as drug targets.

c. Lead compound discovery strategies: Introduction, Analog Design, Systematic screening, Exploitation of Biological information, Planned Reasearch and rational approaches.

d. Primary Exploration of Structure –Activity relationship : Molecular variations in homologous series; Molecular variations based on isosteric replacements, Ring transformations.

e. Homo and Heterodimer Ligands: The twin drug approach: Introduction; Homodimers and symmetrical ligands; Heterodimer and dual acting ligands Dimer and symmetrical ligands; Hybrid molecules as ligands of two different receptors., Hybrids as enzyme inhibitors, Hybrids acting at one receptor and one enzyme.(10h)

6) QSAR –

a. Strategies for primary strcture- activity relationship exploration: Introduction, Preliminery considerations, Hit optimization strategies; Application rules-

Minor modification rule, The biological logic rule, the structural logic rule; The right substituent rule, The easy organic synthesis rule, The pharmacological logic rule

b. Parameters - Lipophilicity, electronic, steric factors, Quantitative Models – (Hansch analysis, Free Wilson Analysis, Mixed approach) Other QSAR approaches, Applications of Hansch analysis, Free Wilson analysis. (06)

RECOMMENDED BOOKS:

1. Burger : Medicinal Chemistry (John Wiley & Sons N.Y.)
2. Foye : Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer : Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
4. Ariens : Medicinal Chemistry Series
5. Ellis and West : Progress in Medicinal Chemistry Series
6. Butterworther: Progress in Medicinal Chemistry Series
7. Wilson and Gisvold - Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren : Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9. Comprehensive Medicinal Chemistry - Series -I-VI (Elsevier Pergamon) by Corwin Hansch, Peter G. Sammes and John B. Taylor.
10. Contemporary Drug synthesis (wiley Interscience) by Jie-Jac Li, Douglas S. Jhonson, Drago R. Silskoric and Bruce D. Roth.
11. The Practice of Medicinal Chemistry (Academic Press, Elsevier), 2nd Edition by Camille G. Wermuth.
12. Synthesis of Drug, A synthon approach by Radhakrishnan P. Iyer & Anant v. prabhu, 1st Edition, (1985) Sevak Publications, Mumbai.
13. Hugo Kubingi - QSAR, Hansch Analysis and Related approaches Vol.1
14. Poul Krogsgaand Larsen : A text book of Drug Design and Development First Edi.
15. Thomas J. Perum, C.L.Propst - Computer Aided Drug Design
16. Pandi Veerapandian - Structure Based Drug design
17. Paul S. Charifson - Practical Applications of Computer Aided Drug Design (Murcell & Dekkar Inc. New York)
18. Paul Leff - Receptor Based Drug Design
19. Bernard Testa, Walter Fuhrer - Perspectives in Medicinal Chemistry
20. Hansch Comprehensive Medicinal Chemistry Vol-IV

ADVANCED PHARMACEUTICAL CHEMISTRY- II

(Practicals) (6 h/Week) Credits 3

1) Determination of partition coefficient
2) Determination of PKa value
3) Synthesis of drugs mentioned in the theory using basic operations+
4) like molecular distillation, fractional crystallization, purification by column chromatography & structure confirmation by spectroscopic methods.

5) Synthesis of drugs using synthon approach
6) Asymmetric synthesis
7) Resolution of racemic mixture.
8) Microwave assisted synthesis of drugs.
9) Application of partition coefficient, pKa, steric factors, electronic factors in QSAR studies with example, use of statistical regression analysis.

RECOMMENDED BOOKS:

1. Organic synthesis : Fieser and William Son (CBS publishers)
2. Mann and Saunders, Critical Organic Chemistry (Orient Longman)
3. A.I. Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman).

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ADVANCED PHARMACEUTICAL CHEMISTRY-III

Credits 4

UNIT I (Theory) (4 h/Week)

1) Combinatorial chemistry:

Introduction, Combinatorial approaches, Chemical peptide and small molecule libraries; Applications, methodology, Combinatorial organic synthesis, Assays and screening of combinatorial libraries, Introduction to high throughputs screening (HTS) (8h)

2) Proteins and peptide drugs:

Chemistry, structure and stability. Reactivity of proteins and peptides. Different ways to synthesize these drugs-study of Insulin, Relaxin, Somatostatin, DNAse Interferon.(6h)

UNIT II

3) Chiral technology:

Introduction to chirality and techniques used: Assymmetric synthesis of Diltiazim, Timolol, Vitamins C, Ampicillin, Dextrapropoxyphen, Thienamycin, Citrenalol, Propranolol, Atenolol, Naproxen.

Enatio – selective synthesis of Atorvasation, Fluxitine, Sertraline, Zolmitriptan.

Esomeprazole, Gefitinib, Cetrizine, Fexofenadine, Linezolide, Ciprofloxacin, Risperidone, Ziprasidone.(14h)

UNIT III

4) Recent advances in drugs used in the treatment of:

Cancer, AIDS, cardiovascular disorders, diabetes, hepatitis, immunosuppression, Alzheimers, Parkinson, lipid / cholesterol lowering agents

Synthesis of two drugs from each category describing reaction conditions, mechanism and strategies involved in the synthesis.(14h)

UNIT IV

5) Molecular modeling in drug design

Introduction to Molecular Modelling : Concepts and Methods, Molecular Mechanics - force fields (Potential energy function), Energy Minimization Methods - Steepest, descent, Conjugate gradients, Newton methods (Non mathematical), Conformational analysis, Systematic search, Monte carlo simulations, Molecular dynamics simulations, Ligand design based on 3D structure of receptor/enzyme.(14h)

RECOMMENDED BOOKS:

1. Burger : Medicinal Chemistry (John Wiley & Sons N.Y.)
2. Foye : Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer : Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
4. Ariens : Medicinal Chemistry Series
5. Ellis and West : Progress in Medicinal Chemistry Series
6. Butterworther: Progress in Medicinal Chemistry Series
7. Wilson and Gisvold - Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren : Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9. Comprehensive Medicinal Chemistry - Series -I-VI (Elsevier Pergamon) by Corwin Hansch, Peter G. Sammes and John B. Taylor.
10. Contemporary Drug synthesis (wiley Interscience) by Jie-Jac Li, Douglas S. Jhonson, Drago R. Silskoric and Bruce D. Roth.
11. The Practice of Medicinal Chemistry (Academic Press, Elsevier), 2nd Edition by Camille G. Wermuth.
12. Synthesis of Drug, A synthon approach by Radhakrishnan P. Iyer & Anant v. prabhu, 1st Edition, (1985) Sevak Publications, Mumbai.
13. Hugo Kubingi - QSAR, Hansch Analysis and Related approaches Vol.1

14. Poul Krogsgaand Larsen : A text book of Drug Design and Development First Edi.
15. Thomas J. Perum, C.L.Propst - Computer Aided Drug Design
16. Pandi Veerapandian - Structure Based Drug design
17. Paul S. Charifson - Practical Applications of Computer Aided Drug Design (Murcell & Dekkar Inc. New York)
18. Paul Leff - Receptor Based Drug Design
19. Bernard Testa, Walter Fuhrer - Perspectives in Medicinal Chemistry
20. Hansch Comprehensive Medicinal Chemistry Vol-IV

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ADVANCED PHARMACOLOGY- 1

(Theory 4 hours/week)

Unit No. I

i. Care, handling and breeding techniques of laboratory animals.
ii. Regulations for laboratory animal care.
iii. Ethical requirements.
iv. Knowledge of CPCSEA proformas for performing experiments on animals.
v. Alternatives to animal studies.
vi. Organisation of preclinical screening programmes.
vii. Safety assessment tests, toxicity tests.
viii. OECD guidelines.
ix. Modern techniques
x. Receptor binding assay.
xi. Microarrays
xii. Patch clamp
xiii. High throughput screening

Unit No. II

Preclinical evaluation of following category of drugs:

i. Sedative, hypnotics, anxiolytics.
ii. Antidepressents.
iii. Antipsychotics.
iv. Nootropics.
v. Antiparkinsonian.
vi. Analgesics- antipyretics.
vii. Anti inflammatory.
viii. Anticonvulsants.
ix. Local anaesthetics.
x. CNS stimulants.
xi. Cardiac glycosides.
xii. Antiarrhythmics.
xiii. Antihypertensives.
xiv. Antiatherosclerotics.

Unit No. III

Preclinical evaluation of following category of drugs:

i. Anti ulcer agents, laxative
ii. Bronchodialators.
iii. Diuretics.
iv. Histamine antagonists.
v. Muscle relaxants.
vi. Cholinergic and anticholinergics.
vii. Adrenergic and adrenergic receptor blockers.

Unit No. IV

Preclinical evaluation of following category of drugs:

i. Antidiabetics.

ii. Antithyroid.
iii. Antifertility screening,
iv. Androgens, estrogen, progesterone.
v. *In vitro* testing of drugs.
vi. Animal cell lines and their uses.
vii. Limitation of in vitro testing of drugs.
viii. Transgenic animals and their applications.

RECOMMENDED BOOKS:

1. Ghosh M. N.: Fundamental of Experimental Pharmacology, Scientific Book Agency, Calcutta.
2. Jaju B. P., Pharmacology: A Practice Exercise Book. Japee Brothers, New Delhi.
3. Kulkarni S. K.: Hand Book of Experimental Pharmacology, VallabhPrakashan, New Delhi.
4. Lawrence D. R. and Bacharch A. L.: Evaluation of Drugs Activities, Pharmacometrics, Academic Press.
5. Perry W. L. M.: Pharmacological Experiments on Isolated Preparations, E and S, Livingston, London.
6. Sheth U. K., Dadkar N. K. and Kamat U. G.: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Mumbai.
7. Thomson E. B.: Drug Bioscreening, VCH, New York.
8. Turner R. A.: Screening Methods in Pharmacology, Academic Press, London.
9. Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
10. Sambrook J, Russel D W. Molecular Cloning: A laboratory manual third edition vol. 1, 2. CSHL Press. New York. 2001.
11. CPCSEA guidelines WWW.CPCSEA.COM
12. CPCSEA guidelines for laboratory animal facility Indian Journal of Pharmacology. 2003; 35: 257-274.
13. OECD guidelines.

ADVANCED PHARMACOLOGY- I

(Practical) (6 Hrs/week)

1. Prepration of vaginal smears and examination under microscope.
2. Methods of handling experimental animals.
3. Standard techniques for injection of drugs, collection of blood samples and feeding of animals.
4. Langendorff method.
5. Use of anesthetics and cannulation of veins, arteries and trachea. Working on Physiograph (Students Biopac, PowerLab) setting rat BP and rat/mouse ECG recording. Use of video tracking system.
6. Screening of Analgesics
7. Screening of Anti-inflammatory drugs.
8. Demonstrations of:

   i. Tread mill ii. Run way apparatus iii. Vogel conflict test iv. Light and dark chamber v. Elevated plus maze vi. Conditioned avoidance chamber vii. Catalepsy bar test viii.Actophotometer ix. Radial maze eight arms.

RECOMMENDED BOOKS:

1) Ghosh M. N.: Fundamental of Experimental Pharmacology, Scientific Book Agency, Calcutta.
2) Jaju B. P., Pharmacology: A Practice Exercise Book. Japee Brothers, New Delhi.

3) Kulkarni S. K.: Hand Book of Experimental Pharmacology, VallabhPrakashan, New Delhi.
4) Perry W. L. M.: Pharmacological Experiments on Isolated Preparations, E and S, Livingston, London.
5) Sheth U. K., Dadkar N. K. and Kamat U. G.: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Mumbai.
6) Thomson E. B.: Drug Bioscreening, VCH, New York.
7) Turner R. A.: Screening Methods in Pharmacology, Academic Press, London.
8) Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
9) Trevor B Poole The UFAW Handbook on the care and management of laboratory animals sixth edition. Longman scientific and technical.
10) Foster H L, Small D J, Fox J G. The mouse in biomedical research Experimental biology and oncology. Academic Press.1982.
11) Suckow M A, Weisbroth S H, Franklin C. L. THE LABORATORY RAT. American Collge of laboratory animal medicine. Academic Press.Elsevier. 2006 second edition.
12) Sharp P E. C la Regina M. The laboratory rat. CRC Press. Taylor Francis.1998.
13) Rigalli A, Di Loreto V E. Experimental Surgical Models in the Laboratory Rat. CRC Press. Taylor Francis.2009.

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ADVANCED PHARMACOLOGY-- II

(Theory 4 hours/week)

UNIT NO. I

i. Clinical evaluation of new drugs.
ii. Organization, ethics and protocols for clinical trials.
iii. Principles of therapeutic drug monitoring.
iv. Clinical pharmacology of drugs used in treatment of following diseases:
    a. Hypertension.
    b. Congestive cardiac failure.
    c. Angina pectoris, acute myocardial infarction.
    d. Cardiac arrhythmia.
    e. Atherosclerosis
    f. Peripheral vascular disorders.
    g. Coagulation disorders.

UNIT NO. II

Clinical pharmacology of following class of drugs:

i. Pain management, pain pathways
ii. Opoid analgesics.
iii. NSAID analgesics.
iv. Local anaesthetics .
v. Prostaglandines.
vi. Leukotrienes.
vii. Platelet activating factor.
viii. Immunopharmacology: Current concepts in treatment and research of drug for AIDS.
ix. Drug allergy and hypersensitivity.
x. Immunostimulants and immunomodulants.
xi. In vitro & in vivo tests for immunological investigation.

UNIT NO. III

Clinical pharmacology of drugs used in treatment of following diseases:

i. Gastrointestinal diseases
ii. Peptic ulcer
iii. Nausea vomiting
iv. Diarrhoea
v. Constipation
vi. Renal disease
vii. Acute renal failure.
viii. Chronic renal failure (drug doses in renal impairment).
ix. Respiratory diseases
x. Asthma
xi. Chronic obstructive pulmonary oedema
xii. Pulmonary embolism

UNIT NO. IV

1. Clinical pharmacology of drugs used in treatment of following deseases.
    i. Hepatic disorders:

ii. Cirrhosis
iii. Hepatitis
iv. Diabetis mellitus.
v. Infectious diseases
vi. Neoplastic disorders:
2. General guidelines for rational use of antibiotics.
3. Resistance to antibiotics.
4. General principel of cancer chemotherapy.
5. Toxicity and toxicity amelioration of anticancer drugs.

RECOMMENDED BOOKS:

1. Ananth J; Treatment of Psychiatric Disorders, Japee, New Delhi
2. Balakrishan, K.V., Komar's Manual of Medical Prescriptions, Paras Publications
3. Bennet P N, Brown M J. Clinical Pharmacology.10th Ed. Churchill Livingstone.Elsevier. London 2008.
4. Bickley, L.S., Bates's Guide to Physical Examination and History Taking, Lippincott
5. Chaudhari, Quintessence of Medical Pharmacology; Central Publishers, New Delhi
6. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, McGraw-Hill
7. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
8. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
9. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
10. Howland D H, Mycek M J. Lippincott's Illustrated Reviews. Pharmacology. 3rdEd.B I Publications Pvt. Ltd.2006.
11. Koda and Kimble; Applied Therapeutics: The Clinical Uses of Drugs
12. Kundu, A.K.; Bedside Clinics in Medicine, Academic Publishers, Part-I and II
13. Misbahuddin, M, Chaudhari, M.A., Jalil, A; Community Pharmacology, Japee, New Delhi
14. Oxford Textbook of Medicine, Blackwell Science
15. Panda, U.N., Textbook of Medicine, CBS publisher, New Delhi
16. Patten, J; Neurological Differential Diagnosis, 2nd Edition
17. Relevant Reviews Articles from Medical and Pharmaceutical Literature
18. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
19. Scott, L.T; Basic skills in interpreting laboratory data, American Society of Health System Pharmacist
20. Sharma H L, Sharma K K. Principles of Pharmacology. First Ed. Paras Medical Publisher. Hyderabad. 2008.
21. Tripathi K D. Essentials of Medical Pharmacology. 6th Ed. Jaypee. 2008.
22. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York
23. Walton, J.; Boain's Diseases of Nervous System, Tenth Edition.

'ADVANCED PHARMACOLOGY-- II

(Practical) (6 Hrs/week)

1. Screening of hypnotics, muscle relaxants.
2. Evaluation of i. local anesthetics, ii. anticonvulsants, iii.antiparkinsonian agents, iv. diuretics.v antiulcer agents vii. Mydriatic andmiotic agents.

3. LD_{50} determination.
4. Bio assays of Ach, Histamine, Oxytocin, Adrenaline, Pancuroniuum.
5. Use of HPLC, Spectrophotometer in estimation of drugs.
6. Knowledge of Modern Methods of Molecular Pharmacology like i.radioligand binding assay, ii.patch clamp, iii.ELISAiv.PCR and Gel Documentation.

RECOMMENDED BOOKS:

1) Ghosh M. N.: Fundamental of Experimental Pharmacology, Scientific Book Agency, Calcutta.
2) Jaju B. P., Pharmacology: A Practice Exercise Book. Japee Brothers, New Delhi.
3) Kulkarni S. K.: Hand Book of Experimental Pharmacology, VallabhPrakashan, New Delhi.
4) Perry W. L. M.: Pharmacological Experiments on Isolated Preparations, E and S, Livingston, London.
5) Sheth U. K., Dadkar N. K. and Kamat U. G.: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Mumbai.
6) Thomson E. B.: Drug Bioscreening, VCH, New York.
7) Turner R. A.: Screening Methods in Pharmacology, Academic Press, London.
8) Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
9) Trevor B Poole The UFAW Handbook on the care and management of laboratory animals sixth edition. Longman scientific and technical.
10) Foster H L, Small D J, Fox J G. The mouse in biomedical research Experimental biology and oncology. Academic Press.1982.
11) Suckow M A, Weisbroth S H, Franklin C. L. THE LABORATORY RAT. American Collge of laboratory animal medicine. Academic Press.Elsevier. 2006 second edition.
12) Sharp P E. C la Regina M. The laboratory rat. CRC Press. Taylor Francis.1998.
13) Rigalli A, Di Loreto V E. Experimental Surgical Models in the Laboratory Rat. CRC Press. Taylor Francis.2009.

ADVANCED PHARMACOLOGY- III

(Theory 4 hours/week)

UNIT NO. I

i. Molecular mechanisms of drug action.
ii. Receptor occupancy and cellular signalling system.
iii. G proteins
iv. Cyclic nucleotide
v. Phosphatidyl inositol.
vi. Cytokines
vii. Neuropeptides and their modulation
viii. Neurosteroids
ix. Endothelium derived vascular substances, nitric oxide
x. Phosphodiesterase and protein kinase c enzymes
xi. Arachidonic acid metabolites, COX-2 regulators and their role in inflammation
xii. Pharmacology of atrial peptides
xiii. Reactive oxygen intermediates
xiv. Antioxidants and their therapeutic implications.

UNIT NO. II

Recent trends on different classes of receptors and drugs acting on them:

i. Adrenergic receptors
ii. Cholinergic receptors
iii. Serotonin receptors
iv. Dopamine receptors
v. Histamine receptors
vi. Opiate receptors
vii. Purinergic receptors
viii. Angiotensin receptors
ix. GABA receptors
x. Excitatory amino acid glutamate, aspartate
xi. Kinin

UNIT NO. III

Recent trends on different classes of receptors:

i. Hormone receptors
ii. Gluccocorticoid
iii. Mineralocorticoid
iv. Oestrogen
v. Progesterone
vi. Androgen
vii. Insulin.
viii. Ion channels and their modulators
ix. Calcium
x. Potassium
xi. Sodium

xii. Chloride

Unit No. IV

i. Apoptosis- Pharmacological and clinical implications
ii. Adhesion therapy- cardiac and vascular remodelling
iii. Basic concept of chronopharmacology and their implications to drug therapy
iv. Concept of gene therapy and recent developments in the in the treatment of various hereditary diseases
v. Human genome mapping and its potential in drug research.

RECOMMENDED BOOKS:

1. Avery, G.S., Drug Treatment, Adis Press, Sydney
2. Bacq Z.M., Cepek, Fundamentals of Biochemical Pharmacology
3. Barar, F.S.K., Essentials of Pharmacotherapeutics; S.Chand and Company, New Delhi
4. Bowman, W.C. and Rand, M.J.; Textbook of Pharmacology, Blackwell, Oxford
5. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, Little Brown And Co, Boston
6. Drill, V.A.; Pharmacology in Medicine, McGraw Hill, New York
7. Foreman J C, Johansen T Text book of receptor pharmacology CRC Press New York 1996
8. Goodman and Gilman; Pharmacological Basis of Therapeutics, McGraw Hill
9. Grollman Pharmacology and Therapeutics, Lea and Tebiger, Philadelphia
10. Katzung, B.G; Basic and Clinical Pharmacology, Lange Medical Publisher, USA
11. Melmon, K.L., and Morelli; Clinical Pharmacology: Basic Principle of Therapeutics, McMillan, New York
12. Rang, H.P., Dale, M.N., Pharmacology, Churchill Livingston, UK.

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ADVANCED PHARMACOGNOSY – I

(Theory) (4 Hrs/Week)

CREDITS :04

Unit 1

Study of information retrieval methods of natural products & herbal data base.

Phytochemical & Pharmacological literature review of:

Gymnema sylvestre
Azadirachta indica
Adathoda vasica
Asparagus racemosus
Commiphora mukul
Podophyllum hexandrum
Ocimum sanctum
Canscora decussate
Tylophora asthmatica

Unit 2

Cultivation of medicinal plants; *ex-situ* & *in-situ* cultivation, biodiversity law, WTO & TRIPS agreement. Plant breeders right, Indian & International Patent law applicable to natural products.

Unit 3

Nutraceuticals

Overview- Relationship of Food, Nutrition, Health and Disease, Current status on Relationship of Nutrition and Health Dietary Guidelines/ Food guide Pyramid/Food vs. Drugs; Defining functional Foods, Nutraceuticals and Dietary Supplement, Weight control Products and Medicinal Foods.

Antioxidants & phytochemicals & their role in prevention of specific diseases.

Nutrition laws & regulation; FDA, FPO, MPO, BIS AGMARK.

Unit 4

Marine Drugs: Discovery, Marine Biology, Review of Marine Drugs

RECOMMENDED BOOKS:

1. Introduction to spices, plantation crops, medicinal and aromatic plants: N. Kumar et al, Oxford & IBH Publishing Co. Pvt Ltd., New Delhi, 1997.
2. Herbal Drug Industry: R.D. Chaudhary, Eastern Publishers, New Delhi 1996.
3. Wealth of India, CSIR, New Delhi (Related Volumes).
4. Cultivation & Utilization of medicinal plants: Atal & Kapoor, RRL Jammu.
5. Cultivation & Utilization of aromatic medicinal plants: Atal & Kapoor, RRL Jammu.
6. Various Research Journals on Medicinal Natural Products.
7. Barrett, S. and Herbert, V. 1994. The Vitamoin Pushers. Prometheus Books, Amherst, N. Y.
8. Barrett, S. and Jarvis, W.T. 1993. The health Robbers. Prometheus Books, Amherst, N.Y.
9. G. Gibson and C, Williams Editors 2000 Functional foods woodhad publishers. Co. London.
10. Goldberg, I. Functional foods. 1994. Chapman and Hill, New York.
11. Tyler, V. E. 1993. The Honest herbal. Pharmaceutical Products Press, New York.
12. Shils, ME, Olson, JA, Shike, M. 1994. Modern Nutrition in health and Disease. Eighth edition. Lea and Febiger.
13. Drug & Cosmetic Act, (With latest amendments including Ayurvedic GMP), Govt. Of India.

ADVANCED PHARMACOGNOSY – I

(Practicals) (6 Hrs/Week)

Credits:03

Thin Layer Chromatography: Identification of alkaloids, flavonoids, steroids

HPLC and HPTLC: Separation of some Phytopharmaceuticals: Demonstration

Pharmacognostic Evaluation of crude drugs

Extractive value Determination

Volatile oil extraction – Mentha oil, eucalyptus oil, rose oil

Determination of heavy metals, mycotoxins, pesticidal residues

Spectroscopic analysis of isolated compounds

Flourimetric analysis of isolated compounds

Monograph analysis of crude drugs as per Ayurvedic Pharmacopoeia

Evaluation and standardization of extracts based on WHO guidelines

Evaluation and standardization of herbal formulations

RECOMMENDED BOOKS:

1. Quality Control of Herbal Drugs by Pulok K. Mukharjee, 1st edition, Business Horizons Pharmaceutical Publishers, New Delhi 2002.
2. Indian Herbal Pharmacopoeia Volume 1 and 2, RRL, IDMA, 1998, 2000.
3. Standardization of Botanicals by V. Rajpal, Volume 1 Eastern Publishers New Delhi 2002.
4. PDR for Herbal Medicine 2nd Edition Medicinal Economic Company New Jersey , 2000.
5. Natural Products: a lab guide by Raphael Ikan 2nd Edition Academic Press 1991.
6. Botanicals of Phytocosmetic Desk Ref by Frank S D Amelio Sr CRC Press 1999.
7. Herbal Drug Industry by R. D. Chaudhary, 1st Edition, Eastern Publisher, New Delhi 1996.
8. Trease and Evans Pharmacognosy by WC Evans 15th Edition W.B. Saunders Edinburgh New York.

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ADVANCED PHARMACOGNOSY II

(Theory)(04 Hrs/Week)

Credits:04

Unit 1

Methods of extraction: Types of extracts and standardization

Natural products as lead for new drugs: Approaches to discovery and development of natural products as potential new drugs, selection and optimization of lead compounds for further developments with suitable examples from CNS, anti-cancer, antibiotics and cardiovascular. Stereochemistry, SAR, structural modifications.

Unit 2

Steriods and Flavonoids:

Steroids: Sources, Uses and structural elucidation of cholesterol, ergosterol and stigmasterol.

Phenolics and Flavonoids: Sources, Uses, Chemistry and General methods of structural determination (chemical and spectral analysis) of quercetin, Gymnemic acid, Hesperidine.

Unit 3

Terpenoids and carotenoids:

Terpenoids: Sources, Uses, Chemistry and General methods of structural determination of Terpenoids, Structural elucidation by chemical and spectral analysis of Menthol, Curcumin, Artemisinin and Taxol.

Carotenoids: Sources, Uses, Chemistry and General methods of structural determination of Carotenoids. Structural elucidation by chemical and spectral analysis of Vitamin-A. Chemistry and sources of Lycopene, Bixin and Chlorophyll.

Alkaloids:

General method for structure elucidation. Spectral analysis and structure determination of atropine, morphine, lysergic acid, quinine and camptothecin.

Unit 4

Biosynthetic studies on the following:

Shikimic acid pathway: Atropine and Morphine.

Acetate pathway: Anthraquinone glycosides.

Mevalonic acid pathway: Steroids, Terpenoids and Cardiac glycosides.

Methods of extraction and instrumental elucidation of phytocontituents a general idea.

RECOMMENDED BOOKS:

1. Research in education: John W.Best and James V.Kahn, Prentice Hall of India Pvt. Ltd.New Delhi,1996.
2. Quality Control of Herbal Drugs by Pulok K. Mukharjee,1st edition, Business horizons Pharmaceutical Publishers, New Delhi, 2002.
3. Standardization of Botanicals by V. Rajpal, Vol.1, Eastern publishers, New Delhi,2002.
4. Indian Herbal Pharmacopoeia, Vol.1 and 2, RRL, IDMA, 1998,2000.
5. Cultivation and Utlilzation of medicinal plants: Atal and Kapoor, RRL, Jammu.
6. Cultivation and Utlilzation of aromatic plants: Atal and Kapoor, RRL, Jammu.
7. Various Research Journals on Medicinal Natural Products.
8. PDR for Herbal Medicines. 2nd edition. Medicinal Economic, New Jearsy,2000.
9. Wealth of India, CSIR, New Delhi (Related Volumes).

ADVANCED PHARMACOGNOSY II

(Practicals) (6 Hrs/Week)

Credits: 03

1. Phytochemical screening of plant extracts and drugs.
2. Isolation, separation, purification and identification of important phytoconstituents belonging to different classes:
   a) Starch, Amylose and Amylopectin
   b) Myristicin and trimyristicin from Nutmeg
   c) Eugenol from Clove
   d) Genistein from Soyabean
   e) Lycopene from Tomato
   f) Curcumin from Turmeric
   g) Sennosides from Senna
   h) Glycyrrhizin from Glycyrrhiza
   i) Strychnine and Brucine or quinine or nicotine or piperine or hesperidine.
3. Antimicrobial screening of plant extracts and drugs.
4. Screening of drugs for microbial counts.

RECOMMENDED BOOKS:

1. Cultivation of medicinal and aromatic crops, 1st edition by A.A. Farooqui and B.S. Sreeramu, University Press 2001.
2. Medicinal Plants of India, 1st edition by S.N. Yoganarsimhan, Interline Publishing Pvt, LTD 2000.
3. Medicinal Natural Products (a biosynthetic approach) 1st edition by Paul M. Dewick, John Wiley and Sons Ltd England 1998.
4. Pharmacopoeial methods for Ayurvedic Formulation CCRAS, Govt. of India
5. Ayurvedic pharmacopoeia, Govt. of India
6. Indian Herbal Pharmacopoeia: Both volumes, IDMA

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ADVANCED PHARMACOGNOSY III

(Theory) (04 Hrs/ Week)

Credits: 04

Unit 1

Plant Extract Types, preparation and their importance, methods of standardization of various extracts. Use of chemical and biological markers for standardization.

Isolation and Estimation of phytopharmaceuticals.

Unit 2

Regulatory guidelines for herbal drugs. (Indian and international)

Different methods (including Industrial) for isolation estimation of phytoconstituents from the following drugs (with special emphasis on HPLC and HPTLC)

1. *Acorus calamus*
2. *Aloe barbadensis* - Aloin
3. *Adhatoda vasica* –Vasicin
4. *Andrographis paniculata* – Andrographolide
5. *Azadirachta indica*
6. *Bacopa monieri* – Bacosides
7. *Curcuma longa* –Curcuminoids
8. *Garcinia cambogia* α *– hydroxyl citric acid*
9. *Glycyrrhiza glabra* – Glycyrrhzinic Acid, Derivatives
10. *Gymnema sylvestre* – Gymnemic Acid
11. *Mucuna pruriens* – L Dopa
12. *Phyllanthus amarus* – Phyllanthin
13. *Piper nigrum/ longum* – Piprrine
14. *Picrorrhiza kurroa* – Kutkin
15. *Polygala senga/ tennuifolia/ chinesis* – total triterpenoid Saponins
16. *Psoralea corylifolia* – Psoralin
17. *Tinospora cardifolia* - Cordifolioside
18. *Tribulus terestris* – Total saponins
19. *Valeriana walichii* – Valepotriates
20. *Withania somnifera*- Withanolides
21. *Zingiber officinalis*- Gingerol
22. *Coleus forskolii*- Forskolin
23. *Commiphora mukul*- Guggulosterone
24. *Trigonella foenum graceum*- Saponins
25. *Ocimum sanctum*- Ursolic acid

Shelf life studies, Protocol to study stability of herbal based products, Approaches for both physical, Physicochemical and chemical parameters of assessment at different stages.

Unit 3

Herbal Cosmetics

Raw materials of herbal origin used in cosmetics, oils, waxes, gums, hydrophilic colloids, perfumes, protective agents, bleaching agents, preservatives, anti oxidants.

Formulation aspects of incorporating herbal extracts in various preparations like skin care creams, deodorants, hair care preparations.

Unit 4

Herbal Based Industry

Study of infrastructure, staff requirement, project profile, plant and equipment, processing research and development.

Drug herb interaction, types of interaction examples quality of evidence and significance.

Examples and case study of herbal listed above.

Standardization of ayurvedic formulations.

RECOMMENDED BOOKS:

1. Ayurvedic Formulary of India, Govt. of India, 1962
2. Pharmacognosy : Trease W. C.,Evans G. E. Bailliere & Tindall, London, 14th edition
3. Natural Products :A Lab guide by Raphael Ikhan 2ndEdition academic Press,1991.
4. Botonicals A Phytocosmetic Desk by Frank S D 'Amelio Sr CRC Press, 1999.
5. Indian Herbal Pharmacopoeia, Vol. 1 & 2, RRL, IDMA, 1998, 2000.
6. Quality Control of Herbal Drugs by Pulok K. Mukherjee, 1st edition, Business Horizons Pharmaceutical Publishers, New Delhi 2002.
7. PDR for Herbal Medicines, 2nd Edition, Medicinal Economic Company, New Jersey 2000.
8. Wealth of India, CSIR, New Delhi (Related Volumes).
9. British Herbal Pharmacopoeia, (Vol., 1,2,3) Her Majesty's Services, UK.
10. Various Research Journals on Medicinal Natural products.

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ADVANCED QUALITY ASSURANCE TECHNIQUES I

Theory 4 hours/week

Credits 04

Study of concepts of cGMP and related topics.(14 hours/Unit)

UNIT ONE :

I. Personnel :

1. Qualification, Experience and Training.
2. Key Persons and their responsibilities.
3. Personnel Hygiene and clothing.
4. Legal Aspects and Consultants.

II. Buildings and Facilities :

1. Manufacturing facilities and surrounding areas.
2. Plumbing and drainage systems.
3. Sewage,refuge and disposal of waste.
4. Washing and toilet facilities.
5. Sanitation and maintenance of sanitation system.

III. Equipment :

1. Design,site location and construction.
2. Cleaning,Operation and maintenance of equipments.

UNIT TWO

I. Materials :

1. Purchasing
2. RM/PM/Int./Bulk and Finishing Products
3. Reference and working standards.
4. Miscellaneous and waste materials.

II. Outsourcing :

1. Outsourcing of manufacturing operations.
2. Outsourcing of analytical services.
3. Outsourcing of other services.

UNIT THREE :

I. Quality Management :

1. Concepts of QA/QC/cGMP.
2. Key activities in quality management function as per cGMP guidelines.

II. Post Operational Activities :

1. Distribution :
2. Recalled, Returned Rejected and Recovered Products
3. Product Complaints.

III. Inspection :

WHO guidelines on inspection of Pharma MFG. Facilities.

UNIT FOUR :

I. Manufacturing Operations and Control :

1. Sanitation of Manufacturing Premises.
2. Control of Mix-ups and Cross Contamination.

3. Processing of in process and bulk products.
4. Packaging and labeling operations
5. I.P.Q.C. activities
6. Release of finished products.
7. Process Deviations.
8. Charge in of components.
9. Time Limitation on production.
10. Drug Product Inspections.
11. Expiration dating.
12. Calculation of yields.

II. Sterile Pharmaceutical Activities :

Manufacturing and Q.A. aspects of sterile Pharmaceutical Products.

III. CGMP guidelines for biological products :

Manufacturing and Q.A. aspects of Biological Products.

RECOMMENDED BOOKS :

1. Pharmaceutical Quality Assurance by M.A.Potdar Nirali Prakashan, Pune
2. Current Good Manufacturing Practices for Pharmaceuticals by Prof.M.A.Potdar B.S.Publications Hydrabad.
3. Good Manufacturing Practices by S.H.Wills and J.R.Stoker Marcker and Dekker Incorporations.
4. Selected International, GMP guidelines of various countries like UK, USA, Australia, South Africa.WHO.India. & ICH guide lines.

ADVANCED QUALITY ASSURANCE TECHNIQUES I

Practicals (6 hours/week)

A.) Designing of the following key documents:

1. Site master file
2. SOP on SOP
3. MPCR/BPCR (for sterile and non sterile products)
4. Change control format
5. Product complaint document
6. Internal audit document
7. Product recall document
8. I.P.Q.C document
9. Warehousing documents
10. System suitability test document

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ADVANCED QUALITY ASSURANCE. TECHNIQUES II

Theory 4 hours/week

Credits 04

Pharmaceutical Validation

UNIT-ONE:

I. Introduction to Pharmaceutical Validation:

a) F.D.A guidelines.

b) Definition of process validation and its importance.

c) Scale up of process validation.

d) Organisation of process validation.

II. Master Plans:

a) Validation Master Plan.

b) Calibration Master Plan.

III. Validation of solid dosage forms, tablets and capsules.

UNIT- TWO:

1. Vendor certification.
2. Cleaning validation.
3. Computer system validation.
4. Validation of sterilization process & Injectable formulations.

UNIT- THREE:

1. Prospective, retrospective, concurrent and revalidation.
2. Analytical method validation.
3. Validation of equipment and facilities, HVAC and water systems.

UNIT- FOUR:

1. Process validation and Quality assurance.
2. Validation in contract manufacturing.
3. Harmonization, cGMP and validation.

RECOMMENDED BOOK:

1. Pharmaceutical process validation by Robert Nash and A.H Wacther Marcel and Dekker Inc. Vol. 129
2. Validation of pharmaceutical process (sterile products) by F.J Carleton and J.P Agalloco Marcel and Dekker Inc.
3. Pharmaceutical Q.A by Professor M.A Potdar Nirali Prakashan, Pune.
4. Current good manufacturing practices by Professor M.A Potdar B.S publications, Hyderabd.

ADVANCED QUALITY ASSURANCE TECHNIQUES II

Practical 6 hours/week

A. Validation of following equipment

1. Autoclave
2. Hot air oven
3. Powder mixer (dry)
4. Tablet compression machine
5. Fluidised bed drier

B. Validation of processing area
(developing room description chart and unfolded room diagrams)

C. Cleaning validation of an equipment and facility.

D. Validation of any two analytical instruments.

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ADVANCED QUALITY ASSURANCE TECH.III

Theory 4 hours/week

Credits 04

Principles of Quality Planning and Analysis and its application to Pharma-Industry.

UNIT---ONE

I. Basic concepts of Quality

(1) Historical background
(2) Definitions of Quality
(3) The quality function
(4) Managing quality

II. Quality improvement and cost reduction

(1) Sporadic and chronic problems
(2) Product by Product approach
(3) Introduction to six sigma improvement
(4) Concepts of continuous improvement

UNIT---TWO

I. Quality Control

(1) Definitions of Control
(2) Measurement
(3) Self Control
(4) Six step control procedure

II. Organization for Quality

(1) Evolution of organization for Quality
(2) Co-ordination of Quality activities
(3) Role of upper management and quality director
(4) Role of middle management and workfoce
(5) Concept of teams in organizing quality
(6) Quality project management

UNIT---THREE

I. Developing quality culture

(1) Technology and Culture
(2) Motivation theories of MASLOW and McGregor
(3) Corporate quality culture
(4) Quality goals and their management
(5) Self development and empowerment

II. Quality Assurance

(1) Defination of Q.A.
(2) Quality audits
(3) Human relations in auditing
(4) Reporting audit results and taking corrective actions.

III. Quality in Manufacturing

(1) Lean manufacturing and value stream management
(2) Initial planning for quality
(3) Automated manufacturing

(4) Manufacturing planning
(5) Quality management in manufacturing operations

UNIT---FOUR

I. Inspection test and measurement

(1) Inspection planning
(2) Seriousness Classification
(3) Automated inspection and inspection accuracy
(4) Acceptance sampling and quality indexes
(5) Sampling plan

II. Statistical Process Control

(1) Definitions and advantages of SPC
(2) Statistical control charts
(3) Pre- control
(4) Process capability
(5) Measuring process performance
(6) SPC and quality improvement

Recommanded Books

(1) Quality planning and analysis. By J. M. Juran and F.M. Gryna Tata Mcgraw Hill India. 5th Edition
(2) Improving quality through planned experimentation By Moen.Tata Mcgraw Hill India.
(3) Statistical Process Control By Grant. Tata Mcgraw Hill India.

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY I

(Theory) (4 Hrs/Week)

CREDITS: 04

Unit 1: Molecular and genetic mechanisms, Genes and Chromosomes

Nucleic acids and their structure, DNA replication, Central Dogma of Molecular Biology, Sequencing methods; Enzymatic DNA sequencing; Chemical sequencing of DNA; Automated DNA sequencing; Transcription-structure of mRNA and tRNA-splicng-translation-post transcriptional modifications. Chromosomal organization and morphology in eukaryotes and prokaryotes, exons and introns, mobile and organelle DNAs, nucleosome-structure and spatial organization, histones, transposons

Unit 2: Tools of Genetic Engineering

Restriction Enzymes; DNA ligase, Klenow enzyme, T4 DNA polymerase, Polynucleotide kinase, Alkaline phosphatase; Cohesive and blunt end ligation; Linkers; Adaptors; Labeling of DNA: Hybridization techniques: Northern, Southern and Colony hybridization, Fluorescence *in situ* hybridization; DNA-Protein Interactions-Electromobility shift assay, Cloning Vectors: Plasmids; Bacteriophages; M13 vectors; PUC19 and Bluescript vectors, Phagemids; Lambda vectors; Insertion and Replacement vectors; Cosmids; Artificial chromosome vectors (YACs; BACs); Animal Virus derived vectors-SV-40; vaccinia/bacculo & retroviral vectors; Expression vectors; pMal; GST; pET- vectors; Protein purification; His-tag; GST-tag; MBP-tag etc.; Intein-based vectors; Inclusion bodies; Methodologies to reduce formation of inclusion bodies; Baculovirus and Pichia vectors syste

Unit 3: Cloning Methodologies

Insertion of foreign DNA into host cells; Transformation; Construction of libraries; Isolation of mRNA and total RNA; cDNA and genomic libraries; cDNA and genomic cloning; Expression cloning; Yeast two hybrid system; Phage display; PCR: Primer design; Taq DNA polymerases; Proof reading enzymes; Types of PCR – multiplex, nested, reverse transcriptase, real time PCR, touchdown PCR, hot start PCR, colony PCR, cloning of PCR products; PCR in molecular diagnostics;

Unit 4: Applications of Genetic Engineering

Site specific mutagenesis; rDNA technology for the production of therapeutic protins, production of recombinant insulin, Blood products: Erythropoietin, human serum albumin, Recombinant vaccice: Hepatitis B surface antigen, Regulatory proteins: growth hormones, interferon, Stability of rDNA procucts

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY I

Practicals: 6 hours/week

Experiments: Recombinant DNA Technology lab

1. Analysis of DNA by agarose gel electrophoresis,
2. Isolation of plasmid DNA by Alkali lyses method
3. Isolation of mammalian DNA form blood
4. Restriction enzyme digestion Isolation of genomic DNA from bacteria/animal tissue (to show partial and complete digestion).
5. Isolation of total RNA /poly A mRNA
6. DNA amplification through Polymerase Chain Reaction using random and gene specific primers
7. DNA ligation

Recommended Rules :

1. Lenin's Genesx. Kreb JE, Goldstein E.S., Kilpatrick S.T. (2011) Jores and Bartlett Pyblishers, M.A., USA, Ol 1776
2. Watson J and Stephen (2004) Molecular Biology of the Gene, Dorling Kindersley (India) Pvt. Ltd. New Delhi Tylor and French group New York.
3. Cooper G.M. and Hausman R.E.(2004).The Cell: A Molecular approach, Sinauer Associates, Inc. ASm Press, Washington D.C.

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY II

(Theory) (4 Hrs/Week)

CREDITS: 04

Unit 1: Fundamental concepts of the immune system

Basics of Immunology. Components of cell mediated and humoral immunity. Components of innate and acquired immunity; MHC genes, Antigen processing and presentation; MHC and immune responsiveness and disease susceptibility, different MHC molecules Phagocytosis; Complement and Inflammatory responses; Haematopoesis; maturation of different immune cells. Antigens - immunogens, haptens; Active and passive immunization

Unit 2: Molecular basis of Immune response

Immunoglobulins, class, sub-class and structure, Immunoglobulin superfamily, affinity, avidity. Allotype, Idiotype, Isotype, Antibody genes and antibody diversity, monoclonal and polyclonal antibody, Precipitation, agglutination, opsonization and complement mediated immune reactions; Different immunological techniques - RIA, ELISA, Western blotting, ELISPOT assay, immunofluorescence, and flow cytometry, recombinant DNA and protein based vaccines, adjuvants

Unit 3: Enzyme technology

Dynamics of enzyme activity, enzyme kinetics, sources of enzymes, Pharmaceutical, therapeutic and clinical applications of enzymes. Protein engineering in enzyme improvements, Immobilization of enzymes, methods of immobilizaion, whole cell immobilization and its applications

Unit 4: Bioprocess Engineering:

Kinetics of cell/microbial growth, substrate utilization and product formation; Simplestructured models; Sterilization of air and media; Batch, fed-batch and continuous processes; Aeration and agitation; Mass transfer in bioreactors; Rheology of fermentation fluids; Scale-up concepts; Design of fermentation media; Various types of microbial and enzyme reactors; Instrumentation in bioreactors.

Texts/References:

1. Kuby, RA Goldsby, Thomas J. Kindt, Barbara, A. Osborne Immunology, 6th Edition, Freeman, 2002.
2. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing, 2002.
3. Janeway et al., Immunobiology, 4th Edition, Current Biology publications., 1999.
4. Paul, Fundamental of Immunology, 4th edition, Lippencott Raven, 1999.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY II

Practicals: 6 hours/week

Experiments:

1. cDNA amplification by RT-PCR, form isolated RNA
2. Preparation of competent cells for transformation
3. Bacterial transformation, Selection of recombinant colonies
4. Detection of SNPs in specific DNAs
5. Bacterial fermentation for production of recombinant protein
6. Basic Bioinformatic tools
7. *In silico* analysis of DNA sequences

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY III

(Theory) (4 Hrs/Week)

CREDITS: 04

Unit 1: Control of gene expression and epigenetics

Introduction of DNA into mammalian cells; Transfection techniques; Gene silencing techniques; Introduction to siRNA technology; Micro RNA; Construction of siRNA vectors; Principle and application of gene silencing; Gene knockouts and Gene Therapy; Creation of knockout mice; Disease model; Somatic and germ-line therapy- *in vivo* and *ex-vivo*; Suicide gene therapy; Gene replacement; Gene targeting; Transgenics; cDNA and intragenic arrays; Differential gene expression and protein array.

Unit 2: Introduction to the human genome project and Pharmacogenomics

Physical mapping and sequencing of the genome; Sequence analysis, comparative homologies; Evolutionary changes and single nucleotide polymorphism; Expression: analysis of expressed genes

Unit 3: Animal cells and culture techniques

Characteristics of animal cells: Metabolism, regulation and nutritional requirements for mass cultivation of animal cellcultures; Kinetics of cell growth and product formation and effect of shear force; Product and substrate transport; Micro & macro-carrier culture; Genetic engineering in animal cell culture; Animal cell preservation.

Unit 4: Bioinformatics:

Introduction to Human genome and bioinformatics resources (NCBI, EBI, ExPASy); Sequence and structure of the databases; Sequence analysis (biomolecular sequence file formats, sequence alignment, phylogeny); Online tools and their application, ORF finder, BLAST etc. Genomics and Proteomics (Large scale genome sequencing strategies; Comparative genomics; Understanding DNA microarrays and protein arrays); Molecular modeling and simulations (basic concepts including concept of force fields).

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Syllabus for M. Pharm in PHARAMCEUTICAL REGULATORY AFFAIRS (PRA)

PHARAMCEUTICAL REGULATORY AFFAIRS – I

(Theory) (4 Hrs/Week)

CREDITS :04

Section I

Unit No.1 **14 Hours**

Overview of GMP guidelines with specific reference of World health organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Medicines control council (MCC), Therapeutic goods administration (TGA) and ANVISA Brazil guidelines and Japanese regulation.

Unit No.2 **14 Hours**

International organization for standardization (ISO): Fundamentals of quality management system.

Pharmaceutical management, Material management, Documentation control, Market Complaints and recalls, GMP audits, Pharmaceutical Total Quality System (Quality by Design (QBD).

Section II

Unit No.3 **14 Hours**

ICH Guidelines, overview of QSEM classification and related guidance. Detailed study of stability, analytical validation, impurities, pharmacopeias, specification, quality risk management and pharmaceutical development.

Unit No.4 **14 Hours**

Preparation of Common technical document (CTD) as per ICH guidelines, electronic documentation and e-filing (e-CTD).

Guidelines for reporting adverse drug reaction in various countries.

Management of Clinical trials, role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials.

PHARAMCEUTICAL REGULATORY AFFAIRS – I

Practicals (6 Hrs/Week)

CREDITS :03

1. Preparation stability protocol and stability report.
2. Accelerated stability studies of marketed products as per ICH Guidelines.
3. Dossier preparation as various countries guidelines.
4. Preparation of SOP's for operation of manufacturing and analytical equipments.

Books and References Recommended:

1. Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals
2. Common Technical documents (ICH guidelines).
3. ISO Guidelines
4. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
5. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
6. WHO GMP guidelines
7. www.ich.org
8. www.anvisa.gov.
9. www.picscheme.org
10. www.mhra.gov.uk
11. www.tga.gov.au
13. www.mccza.com
14. www.who.int
15. www.ep.espace.net

PHARAMCEUTICAL REGULATORY AFFAIRS – II
(Theory) (4 Hrs/Week)
CREDITS :04

Section I

Unit No.1 **14 Hours**

Requirements of cGMP with specific reference of USFDA (21 CFR part 210 and 211), European Medicines Agency (EMEA) guidelines.

Unit No.2 **14 Hours**

Requirements for registration of pharmaceutical products into USA with emphasis on para I, II, III & IV filing. Preparation of documents for approval of IND, NDA, ANDA, BLA applications and export registration (USFDA 21 CFR part 310, 312, 314, 320). Biowaivers. Understanding the FDA 505(b)(2) Regulatory Approval Pathway, Hatch-Waxman act.

Section II

Unit No.3 **14 Hours**

Brief Guidance for Industry: CMC related to all dosage forms and Scale - Up and Post approval Changes (SUPAC)-Chemistry, Manufacturing and Controls, In Vitro Release Testing, and In Vivo Bioequivalence Documentation.

Unit No.4 **14 Hours**

Registration of product in European market: New drug product and generic product.
Preparation of dossier of Drug product and Drug master file.

In vitro BA/BE Clinical

Brief Guidance for Industry: Dissolution testing of immediate release solid oral dosage forms.
Guidance for Industry: Extended release oral dosage forms: Development, evaluation and application of In Vitro/In Vivo Correlations.
Guidance for Industry: Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System

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PHARAMCEUTICAL REGULATORY AFFAIRS – II
Practicals (6 Hrs/Week)
CREDITS :03

1. Comparison of dissolution profiles and calculation of F1 and F2 values of tablets of innovator/standard and generic manufacturers.
2. Comparison of In-vitro release and calculation of F1 and F2 values of semisolid preparations of innovator/standard and generic manufacturers.
3. Preparation dossier of a pharmaceutical product.
4. Preparation of MFR, BPR and packaging record for manufacturing of various dosage forms.
5. Dossier preparation for US and European market a) Product without BA and BE, b) Products with clinical data.
6. Evaluation of some Orange Book (OB) patents from PARA IV filing prospective.

Books and References Recommended:

www.emea.europa.eu
www.fda.gov

PHARMACEUTICAL REGULATORY AFFAIRS - III
(Theory) (4 Hrs/Week)
CREDITS :04

Section I

Unit No.1 **14 Hours**

The Drugs and Cosmetics act, 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Good manufacturing practices for homeopathic medicines (Schedule M-I), Requirements of factory premises for manufacture of cosmetics (Schedule M-II), Good manufacturing practices for Ayurvedic, Siddha and Unanni medicines (Schedule T). Regulatory requirements for nutraceuticals. ISI standards of cosmetics.

Unit No.2 **14 Hours**

Requirements for registration of pharmaceutical products into India. Preparation of dossier for product registration as per Indian legislative requirements**.**

Section II

Unit No.3 **14 Hours**

Documentation: Master formula record (MFR), Master formula card (MFC), Batch processing record (BPR), Packaging records, Standard operating procedure (SOP), Site master file, specifications, Certificate of analysis (COA), Material safety data sheet (MSDS), Method of Analysis (MOA), Annual product review, validation protocols, Stability protocol, T- License, forms, maintenance of records in Pharmaceutical industry.

Unit No.4 **14 Hours**

Regulatory requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials (schedule Y).

Regulatory requirements for packaging material– Pharmacopoeial requirements, D & C act & rules, Weight & Measure acts, DCGI / DPCO guidelines, FDA guidelines and various other foreign regulatory guidelines.

Books and References Recommended:

1. Vijay Malik, Law relating to Drugs & Cosmetics.
2. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
3. The Gazettes of India. The Patent Act 1970 and its Latest amendments.

ELECTIVES

1. STERILE PRODUCT FORMULATION AND TECHNOLOGY

(Theory) (4 Hrs/Week)

CREDITS: 04

UNIT 1

1. **Preformulation:** Physico-chemical properties of materials used in parenteral formulations, selection of polymeric components, selection of packaging components.
2. **Formulation of SVP and LVP:** Requirement, components, materials, Pharmacopoeial requirements, special types of parenterals such as suspensions, emulsions, dried forms, sterile diagnostics and radiopharmaceuticals.

UNIT 2

3. **Ophthalmic Products:** Ocular anatomy and physiology relevant to ocular drug delivery, ocular pharmacokinetics, conventional ophthalmic products, ocular inserts.
4. **Sustained Release Parenterals:** Liposomes, and niosomes, polymeric nanoparticles, lipid nanoparticles, implants, loaded erythrocytes.

Delivery systems for Proteins and peptides

UNIT 3

5. Environmental Control: Temperature and humidity control, air handling systems and their validation.
6. Industrial sterilization: large scale sterilization processes, process selection, specifications, development and validation of process and equipments.

UNIT 4

7. Guidelines: Overview of GMP and regulatory guidelines.

RECOMMENDED BOOKS :

1) K.E. Avis, H. A. Liberman and Lachman; Pharmaceutical dosage forms: Parenteral Medications; Vol. 1,2,3, Marcel Dekker.
2) S.J. Turco; Sterile dosage forms : their preparation and clinical application; Lee and Febiger.
3) N.K. Jain; Controlled and novel drug delivery; CBS Publication.
4) J.R.Robinson and H.L.Lee; Controlled drugs delivery : Fundamentals and Applications; Marcel Deker.
5) F. J. Carleton and J. P. Agalloco; Validation of aseptic pharmaceutical processes; Marcel Dekker.
6) L. A Trissel; Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.
7) N.A.Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.

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2. NOVEL DRUG DELIVERY SYSTEMS

(Theory) (4 Hrs/Week)

CREDITS: 04

Design, development, manufacture and evaluation of the following novel drug delivery systems:

UNIT1:

a. Oral Drug Delivery Systems: Osmotic DDS, Ion exchange controlled DDS, Hydrodynamically balanced DDS
b. Mucosal DDS: Physiological basis of mucosal delivery with reference to oral mucosal, nasal, vaginal and rectal routes. Bioadhesion and bioadhesive polymers, DDS for mucosal administration. In-vitro, ex-vivo and in-vivo evaluation techniques.
c. Microspheres: Methods to obtain microcapsules/ microspheres, their evaluation and applications.

UNIT2:

d. Transdermal DDS: Percutaneous absorption and penetration enhancers, development of transdermal gels, patches with reference to components and evaluation. Iontophoretic and Sonophoretic DDS.

e. Ocular DDS –Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation.

f. Parenteral DDS: CR Injectables, implants etc. development and evaluation

UNIT3:

g. Colloidal DDS: Specialized DDS like micro / nano emulsions, SMEDDS, Multiple emulsions, liposomes, niosomes, polymeric micelles, and other vesicular DDS, their design and development into final dosage forms, issues and consideration

h. Nanoparticulate systems such as lipid nanoparticles and polymeric nanopartciles: Methods of preparation, characterization and applications

i. Peptide and protein based DDS: Chemistry and special features of peptide and protein molecules, stability, Challenges in protein/ peptide delivery, Formulation approaches and evaluation of peptide and protein delivery; Routes of delivery, Toxicity, immunogenicity, vaccines and gene based DDS

UNIT4:

j. Pulmonary DDS – Physiological basis and formulation considerations. Design of Pressurized aerosols, Dry powder DDS, Devices for administration and evaluation.

k. Targeted DDS: Concept of drug targeting, need for drug targeting , basis for drug targeting both active and passive. Ligands for targeted delivery, Monoclonal antibodies in targeted delivery, design of targeted DDS for cancer and infectious diseases, brain targeting, Colon targeting approaches and DDS

RECOMMENDED BOOKS :

1) P. Tyle, drug Delivery Devices, fundamental and applications, Marcel Dekker.
2) Morton rosoff, Controlled release of drugs, VCH Publishers.
3) D.W. Osborne, and A.H. Amann, topical drug delivery formulations, Marcel Dekker.
4) P. Tyle Drug delivery devices, Marcel Dekker
5) Barry, Dermatological formulation, Marcel Dekker
6) Robinson, Novel Drug Delivery systems, Marcel Dekker
7) N.K. Jain, Controlled and Novel Drug delivery, CBS Publisher, New Delhi.
8) P. Johnson and J.G. Lloyd – Jones, Drug Delivery Systems, VCH Publisher
9) P. Tyle and B.P. Ram, Targeted Therapeutic systems, Marcel Dekker
10) C.G. Wilson and N. Washington, Physiological Pharmaceutics, Ellis Horwood Limited
11) H.S. Bean, A.H. Beckett, and J.E. Carless, Advances in Pharmaceutical Sciences vol. 5 Academic Press.
12) R.O. Potts, and R.H. Guy, Mechanisms of Transdermal Drug delivery, Marcel Dekker.
13) T.J. Roseman and S.Z. Controlled release delivery systems, marcel Dekker.
14) A.J. Hickey, Pharmaceutical Aerosol Technology, Marcel Dekker.
15) J. Kreuter, Controlled drug delivery systems, Marcel Dekker
16) K.S.E. Su and S.F. Chang, Nasal systemic drug delivery, Marcel Dekker
17) A.F.Kydonieus, Controlled release technologies : methods, theory and applications vol. I & II, CRC Press inc.
18) Y.W. Chein, Trasdermal controlled systemic medication, Marcel Dekker
19) P.B. Deasy, Microencapsulation and related drug processes, Marcel Dekker.

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3. BIOPHARMACEUTICS AND PHARMACOKINETICS

(Theory) (4 Hrs/Week)

CREDITS: 04

UNIT1:

1. Absorption: Cell membrane, absorption mechanisms, oral drug absorption, pH-partition hypothesis. Factors affecting: physico-chemical, dosage form related, patient related. Drug absorption through other routes, transdermal, nasal, buccal, ocular, and sublingual. In-vitro, in-situ and in-vivo models for drug absorption studies. ABC transporters. Animal Tissue culture Technique for drug absorption studies.
2. Distribution: Tissue permeability of drugs, barriers to distribution of drugs. Factors affecting drug distribution, physicochemical properties of drugs, volume of distribution, Drug - protein binding, drug tissue binding, factors affecting protein drug binding. Kinetics of drug protein binding significance of drug tissue binding.

UNIT2:

3. Metabolism :Drug metabolism organs and enzymes, chemical pathways Phase-I and Phase-II reactions. First pass effect, factors affecting metabolism
4. Excretion:Renal and nonrenal routes of drug excretion, concept of clearance. Factors affecting excretion mainly renal excretion.

UNIT3:

5. Pharmacokinetics:Pharmacokinetics in drug discovery and development, Pharmacokinetics models, Laplace transformations and concept of compartment modeling.
6. One compartment model : intravenous injection, intravenous infusion, First order absorption (Urinary and plasma data)
7. Multicompartment models. Intravenous injection, intravenous infusion, first order absorption, multidosing data.
8. Non-linear Pharmacokinetics Michaelis- Menten kinetics, estimation of K_m and V_m, Area under curve, enzyme induction.
9. Non compartmental analysis - statistical moment theory Integration with Kinetics : Interrelationships between pharmacokinetics parameters and physiological variables.

UNIT4:

10. Application of Pharmacokientic: Multiple dosing, controlled release dosage form, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronipharmacokientics.
11. Bio-availability and Bioequivalence: Study design, protocols and regulatory requirements and statistical consideration in data analysis

RECOMMENDED BOOKS :

10. J.B.Blanchard, R.J. Sawchul and B.B.Brodie, Principle and Perspectives in Drug bioavailability, K. Karger Publication.
11. M. Gibald and Perrier, Pharmacokientices, Marcel Dekker.
12. M.Rawland and T.N. Tozer, Clinical Pharmacokinetics, Waverly Publications
13. P.Jenner and B. Testa, Concepts in drug metablism, Marcel Dekker
14. D.M. Brmhankar and S.B.Jaiswal, Biopharmaceutics and pharmacokientis A Treatise, Vallabh Prakashan.
15. Jean - Pierre Labaune, Hand book of pharmacokinetics, John Wiley & sons.
16. B. Testa, Advances in drug research, Vol. 19, Academic Press.
17. R.E. Notari; biopharmaceutics and clinical Pharmacokinetics; Marcel Dekker.
18. P.G. Welling and F.L.S. Tse; Pharmacokinetics, regulatory- Industrial Academic perspectives, Marcel Dekker.

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4. INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT

(Theory) (4 Hrs/Week)

CREDITS: 04

UNIT 1

1. **Pilot plant scale - up, pilot plant design:** tablets, capsules, liquid orals. parenterals, and semisolid preparations.

   Basis requirements for design of product, facility, equipment selection, personnel, Pharmaceutical process validation for various products.

2. **Quality Assurance:** GMP considerations, quality assurance and process control. Total quality management and productivity. ISO 9000 Series salient features.

UNIT 2

3. **Optimization Techniques:** Optimization parameters, classical optimization, statistical design and applied optimization methods.
4. **Production Planning:** Plant site selection, layout and organization of pharmaceutical industries. Vendor development capacity (plant, machine, human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix.

UNIT 3

5. **Machinery Engineering :** Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handling for various pharmaceutical products.
6. **Drugs and Cosmetics Act :** Requirements related to manufacture and sale of drugs.

UNIT 4

7. **Safety :** Industrial hazards due to fire, accident, mechanical and electrical equipment, chemical and pharmaceuticals, monitoring and preventive system.
8. **Effluent Testing and Treatment:** For pharmaceutical industry.
9. **Automation:** Flexible manufacturing system, computer control systems : data acquizition, distributed control and centralized control system. Typical models for solid and liquid manufacturing.

RECOMMENDED BOOKS:

1. P. R. Watt; Tablet machine instruments in pharmaceuticals; John Wiely and Sons.
2. B. Rothery; ISO 14000 and ISO 9000; Gower.
3. G.C. Cole; Pharmaceutical production facilities, design and applications; Taylor and Francis.
4. J.R.Berry and R.A. Nash; Pharmaceutical process validation; Marcel Dekker.
5. S. Bolton; Pharmaceutical statistics; Marcel Dekker.
6. S.H.Will and J.R. Stoker; Good Manufacturing Practices for Pharmaceuticals; Marcel Dekker.
7. R. F. Brewer; Design of Experiments for process improvement and quality Assurance; Narosa.
8. A. Jaiswal; Management of quality control and standardisation; Kanishka Publisher, New Delhi.
9. D.H.Stamatis; Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
10. P. Gilson, G. Green halgh and K. Kerr; Manufacturing management; Chapman and Hall.
11. S.S.Rao; Optimization theory and applications; Wiley Eastern Limited.
12. J.F. Despautz; Automation and validation of information in pharmaceutical processing; Marcel Dekker.
13. J.M. Juran and A..B. Godfrey; Juraris quality handbook; McGraw Hill.
14. S.N. Katju's; Law and drugs; Law Publishers(I) Pvt. Ltd.

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5. PACKAGING TECHNOLOGY

(Theory) (4 Hrs/Week)

CREDITS: 04

Unit 1.

1. **S**tatus and scope in Pharmaceutical Industry
2. **Elements of packaging :** Purpose, types of packaging material: primary and secondary and special types, functions of packaging.
3. Primary Packaging Material:
   a. Glass containers (ampoules, vails and bottles) metals (tins for consmetic powders, tubes for skin and ophthalmic ointments, Aluminium containers and foils), Fibers board and paperboard for bulk packaging in containers and drums).
   b. Containers and laminations of the metal containers Films and Foils- including AL, PVC, used ins trip packaging and blister packaging of tablets, cellulosics and cellophone.
   c. Plastic- polymers and copolymers, electrosetting and thermoforming (Medium and high density polystyrene PET)
   d. Equipment in primary packaging including strip packing, blister packing powder filling , liq filling, aerosol filling, snap on closures.
   e. Sterilization of primary packaging material by gamma irradiation.

Unit 2.

4. a. Secondary Packaging Materials: Folding cartons and set of boxes, Materials of construction, design and specifications-corrugated fiberboard, Packaging inserts- specifications and test methods and quality control.
   b. Cushioning–Cushioning materials, applications for impact, vibrations, temperature and humidity closures, applicatures fasteners and adhesives- cap threads, cap liners, aluminium bands, shrink brands, stoppers and plugs, tapes, adhesives.
   c. Shrink Warp Process

Unit 3.

5. Specifications, quality control tests and methods and evaluation of packaging of materials.
6. Labels and labeling
   a. Direct printing heat transfer, ordinary labels, adhesives
   b. Standards and Quality Control test including dimensions printing and lists such as folding test, gluing, ageing, block vibration and shock for the boxes
   c. Toxicity and safety of printing inks

Unit 4.

7. Sterilization of containers:

   Different methods of sterilization for containers (primary) including autoclaving, dry heat, gas sterilization, ionizing and non-ionizing radiations

8. Quality Control, Stability, Safety and Environmental consideration.

   Law and regulation governing packaging

RECOMMENDED BOOKS:

1. J. F.Hanlon; Handbook of Package Engineering; Mc-Graw Hill book Company.
2. Lockhart H; Packaging pharmaceutical and health care.
3. K. Harburn;Quality Control of Packaging Materials in the Pharmaceutical Industry;. Marcel Dekker.

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7. COSMETICOLOGY

(Theory) (4 Hrs/Week)

CREDITS: 04

Unit 1.

1) **Physiological consideration :** skin, hair, nail and eye - in relation to cosmetic application.
2) **Rheology of cosmetics :** Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

Unit 2.

3) **Manufacturing techniques:** cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.
4) **Evaluation of cosmetics:** Performance, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and antiaging products.

Unit 3.

5) **Clinical safety testing :** Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.
6) **Advances in cosmetics:** Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.
7) **Herbal cosmetics:** Formulation development

Unit 4.

8) **Packaging:** Package development and design for cosmetics including aerosol packs
9) **Regulatory requirements:** Manufacturing and sale of cosmetics

RECOMMENDED BOOKS :

1) J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
2) J.B.Wilkinson and R.J. Moore; Harry's cosmetology; Longman Science and Technical.
3) S.N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4) E.G.Thomssen; Modern cosmetics; Universal Publishing Corporation.
5) M.S.Balsam and E. Sagarin ; Cosmetics, science and technology; John Wiley and Sons.
6) R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox
7) H.R.Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8) W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.
9) C.G.Gebelein, T.C.Cheng and V.C. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
10) L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11) W.A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3, Chapman and Hall
12) Dr. Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

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8. IMMUNOPHARMACOLOGY AND IMMUNOASSAYS

(Theory)(4Hrs/Week)

Unit No. I

1) Basic Principles :
   - i. Cells of the immune system.
   - ii. Non specific immunity
   - iii. The specific immunologic response Antigens and antigen-body binding
   - iv. Immunologlobulines
   - v. The humoral immune response
   - vi. The cellular immune response
   - vii. The control of immune response
   - viii. The complement system
2) Pharmacological aspects of clinical conditions involving immunological mechanism
   - i. Hypersensitivity
   - ii. Delayed hypersensitivity
   - iii. Immunomodulators

Unit No. II

i. Current concepts in therapy and research of drugs for :
ii. Acquired Immuno Deficiency Syndrome (AIDS)
iii. Tissue transplantation (Immunosuppresants and immunoenhancers)
iv. Cancer
v. Vaccines and sera
vi. Antifertility drugs and vaccine
vii. Drug allergy

Unit No. III

i. Methods for (invitro and invivo) evaluation of influencing immune system drugs
ii. Biochemical tests used in immunology laboratory
iii. Radioimmassays (RIA), Enzyme multiplied Immuno assay techniques (EMIT)
iv. Fluoroscencepolarisation Immunoassay (FPIA)
v. Enzyme linked Immunosorbent Assay (ELISA)
vi. Apoenzyme - Reactivation Immunoassay (NIIA)
vii. Substrate labeled flouroscence immunoassay (SLFIA)
viii. Prosthetic group labeled Immunoassay (PGLI)
ix. Immunomodulators of Indigenous origin (plants)

Unit No. IV

Fc Receptors

i. Introduction, structure and function of antibodies, conformation of antibodies, Fc8R family,
ii. Proteins, transcripts and genes: Gene, structure and actions of high affinity Fc receptor for immunoglobulin E.
iii. Fc - receptor mediated killing
iv. Fc- receptor on T and B lymphocytes
v. Immunoglobulin binding factors

RECOMMENDED BOOKS :

1) Kirkwood E and Catriona L. Understanding Medical Immunology (John Wiley and Sons, New Yord)

2) Humphrey J.H. and White R.G. Immunology for students of Medicine (Blackwell Scientific Publication London)

3) Goodman and Gilmans. The pharmacological Basis of Therapeutics (9th Ed.)McGraw Hill 1996.

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9. TOXICOLOGY

(Theory) (4Hrs/Week)

Unit No. I

I) Fundamental Principles :

i. Introduction, Toxicological Evidence, Common household poisons, description of sub disciplines of toxicology, qualitative and quantitative aspects of toxic effects.

ii. Biotransformation : detoxication and bioactivation

iii. Absorption, distribution and elimination of xenobiotics

iv. Toxicokinetics : quantitative aspect Dose time - effect relationships

II) Molecular aspects of toxicology

i. Cytotoxicity - Molecular Mechanism of cell death, Genetic toxicology

ii. Introduction to carcinogenesis

Unit No. II

Organ toxicology

i. Cytopathology general response patterns and Morphological aspects Necrosis and apoptosis: Irreversibility of cell damage and cell death.

ii. Dermatotoxicology: Toxicological, pathology and methodological aspects Respiratory toxicology: toxicological, pathology and methodological aspects.

iii. Respiratory toxicology; pathophysiology, toxicological pathology and mechanisms of toxicity

iv. Gastrointestinal toxicology: toxicological pathology and source of intestinal toxicity

v. Hepatotoxicology : Mechanisms of liver toxicity and methodology aspects

vi. Nephotoxicology : toxicological pathology and biochemical toxicology

vii. Cardiovascular toxicology: Toxicological pathology and methodological aspects

viii. Toxicology of blood: Pathophysiology, Toxicological pathology and mechanism of toxicity

Unit No. III

i. Immunotoxicology:determination of immunotoxic effects and immunotoxicity mechanisms

ii. Endocrine toxicology

iii. General reproductive toxicology

iv. Functional neurotoxicology

v. Neurobehavioural toxicology

vi. Food, nutritional toxicology

Unit No. IV

i. Medical and clinical toxicology

ii. Ecotoxicology

iii. Occupational toxicology

iv. Carcinogenicity mutagenicity; Teratogenicity

RECOMMENDED BOOKS :

1) Niesink R.J.M. de Vries J and Hollingers M.A. Toxicology, Principles and Applications, CRC Press 1996
2) Amdur M.O. Doul J and Klassen C.D. Casarett and Doull's toxicology
3) Gupta P.K. and Salunkhe D.K. Modern toxicology Vol-I, II and III (Metropolitan, New Delhi).

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11 PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

(Theory)(4Hrs/Week)

Unit No. I

Therapeutic Drug Monitoring

Introduction, Necessity of TDM, Criteria for valid TDM, Essentials for effective TDM, Organization of a TDM service, information requirements for TDM, effectiveness of TDM.

Unit No. II

Drug selection, Dosage regimen design, Pharmacokinetics of the Drug, Patient compliance, Evaluation of pateint's response, Measurement of serum drug concentrations, Monitoring serum drug concentrations, Design of dose regimens. Conversion from i.v. infusion to oral dosing. Determination of dose frequently, dosing of drugs in elderly.

Unit No. III

Analytical aspects of TDM, Uses of HPLC and Immunoassays in TDM

Unit No. IV

TDM of selected individual drugs - Aminoglycosides, Carbamazepine, Theophulline Digoxin, Methotrexate, Phenytoin, Aspirin, Lithium, Valproic acid.

RECOMMENDED BOOKS :

1) Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and B.C. Andrew
2) Therapeutic Drug Monitoring and Clinical Biochemistry by Mike Halworth and Nigel Capps.
3) Biopharmaceutics and Pharmacokinetics by RobertE. Notari.
4) Principles and Prescriptives in Drug Bioavailability by S.Karger.
5) Pharmaceutics and Pharmacy Practice by Gilbert S.Banker
6) Remington's Pharmaceutical Sciences
7) Dissolution, bio-availability and bio-equivalence by Abdou
8) Pharma Review by Leon Shargel
9) Current concepts in Pharmaceutical Sciences by James Swarbrick
10) Drug Disposition and Pharmacokientics by Stephen H. Curry
11) Pharmacokinetics by MiloGilbaldi and Donald Perrier 2nded Marcel Dekker Inc. New York 1982.
12) Drug Level monitoring, Analghical Techniques, metabolism and pharmacokinetics.
13) Simkin : Handbook of TDM.
14) Goodman & Gilman's The pharmacological Basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R.W. Ruddon. International Edition.MicGraw Hill.
15) Principles of drug action the basis of pharmacology by goldstein A., Arrow L. and Kalman S.M. 2nd ed. John Wiley & sons. Inc.New York 1974.
16) Clinical pharmacokinetics. Concepts and Applications by rowland M and Tozert.N. 3rd ed. Lea and Febiger Philadelphia, 1995.
17) Pharmacokinetics for pharmaceutical scientists Wagner J.G. Technomic. Inc. Lancaster PA 1993.
18) Integration of pharmacokinetics, pharmacodynamics and Toxico kinetics in Rational Drug Development Plenum, New York, 1993.
19) Applied Pharmacokinetics, Principles of Therapeutic Drug monitoring, by Evans W.E., Schentag J.J. and Jusko W.J. (Eds). 3rd ed. Applied Therapeutics Inc. Vancouvers HA. 1992.

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12 AGROTECHNOLOGY

(Theory) (4 Hrs/Week)

Unit 1.

1. Significance/importance of cultivation of Medicinal and Aromatic plants.

Export potential of Medicinal and Aromatic plants and their derivatives from India.

2. **Cultivation :** Methods of propagation and factors (Endogenous and exogenous) affecting cultivation of Medicinal and Aromatic plants.

Endogenous Factors: Mutation, polyploidy, chemical races, hybridization etc.

Exogenous factors: Soil - physical and chemical properties, organic matter, microorganisms of soil, soil classification and soil management, soil testing.

Influences of altitude temperature, humidity, rainfall /irrigation,

Soil fertility and fertilizers - plant nutrition and their functions, maintainance of soil fertility, types of manure and fertilizers, mode and time of application of fertilizer and manure.

Weeds and weed control

Diseases and Pests of medicinal and Aromatic crops and their control.

Unit 2.

3. Agroproducts marketing and storage:

4. Methodology for assessment of availability of Medicinal and Aromatic plant materials from the forest.

Unit 3.

5. Scientific study of cultivation, collection and preparation for market of followings, along with their products and Byproducts :
   a) Dioscorea
   b) Senna
   c) Isapgol
   d) Neem
   e) Mentha
   f) Solanum
   g) Jasmine
   h) Spirulina

Unit 4.

6. Study of following agro based products :
   a) Starch and its derivatives
   b) Cellulose and its derivatives
   c) Activated carbon
   d) Catechu and catechin
   e) Alginate and its derivatives
   f) Plant products for insect control
   g) Cheese, butter, yoghurt from milk.

RECOMMENDED BOOKS :

1) Wealth of India : CSIR New Delhi
2) A hand book of Agriculture - ICAR, New Delhi
3) Cultivation and utilization of Medicinal plants C.K. Atal and B.M.Kapour RRL, CSIR
4) Cultivation and utulization of Aromatic plants, C.K. Atal and B.M.Kapour RRL, CSIR
5) Spices, plantation crops, Medicinal and aromatic plants. N.Kumar, J.B.M. Md. Abdul Khader, P. Rangaswami, I. Irulappan - Oxford and 1BH Publishing Co.. Pvt. Ltd., New Delhi.
6) Materia Medica: Nadkarni, Kothari.

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12. PHYTOPHARMACEUTICALS

(Theory) (4 Hrs/Week)

Source, phytochemistry (isolation, identification, chemical nature), and physiological activities of following phytopharmaceuticals.

Unit 1.

1) Anticancer: Taxol, other taxanes, Camptothecin, vinblastine, Genistein, Etoposide

Unit 2.

2) Nervous system activities: Hypericin, Valepotriates, Gingkolides

3) CVS activities: Colenol, Streptokinase

Unit 3.

4) Anti-inflammatory : Curcuminoids, Guggulipids, Boswellic acid, Serratiopeptidase.

Unit 4.

5) Miscllaneous: Silymarin, Artemisinin, Omega-3 fatty acids.
Charantin and momordicosides, Resveretrol, Protamine sulphate, prostaglandins.

RECOMMENDED BOOKS :

1) Pharmacognosy : Trease and Evans, Bailliere & Tindall, 14th edth.
2) Pharmacognosy : Kokate,Purohit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3) Biochemistry : Delvin
4) Alkaloids Edited by J.R.F.Manske
5) Various Research Journals on Natural products and therapeutics.

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13 MEDICINAL PLANT BIOTECHNOLOGY

(Theory) (4 Hrs/Week)

Unit 1

1. Introduction to Plant tissue Culture, advantages, applications and limitations.
2. Concepts of totipotency, nutritional requirements and role of growth hormones, types of cultures. Organogenesis, Embryogenesis, Protoplast culture

Unit 2

3. Suspension culture, protocols to evaluate growth and viability of plant cells under *in vitro* conditions. Production of secondary metabolites by plant cells under *in vitro* conditions and strategies to enhance secondary metabolites.
4. Bioreactor management and its comaprision with fermention. Large scale cultivation of plant cells in bioreactor system for the production of bioactive compounds.

Unit 3

5. Gene Transfer in plants concepts and applications. Initiation of Hairy root cultures and their application in production of secondary metabolites. Electroporation, Microprejectiles, Micro and macro injection. Liposomes Ultrasonication.
6. Methods of quality improvement of plants.
   a) Chemodemes b) Hybridisation c) Mutation d) Polyploidy
   Applications of transgenic plants
   a) Resistance to hebicides, insects, fungus and virus, physiological stress
   b) Edible vaccines

Unit 4

7. Localisation of transferred gene in genetically modified plants
   a) Gene mapping
   b) Use of markers
8. Applications of Medicinal Plant Biotechnology in Pharmacy
   a) Cell Immobilisation
   b) Biotransformation
   c) Germplasm conservation

RECOMMENDED BOOKS :

1. Medicinal Plant Biotechnology: A. G. Namdeo
2. Medicinal Plant Biotechnology: Ciddi Veersham
3. Essentials of Molecular Biology: Dovid F.A., George M.M.
4. An introduction to plant tissue culture : M.A.Razdan
5. Plant biotechnology: Samtel
6. Plant tissue culture: Narayanswamy
7. Plant tissue culture: Angela Stafford, Open University press, Buckingham, 1991.
8. Plant tissue culture: Dixon
9. Pharmaceutical Biotechnology: Vyas, Dixit, CBS Publishers, New Delhi, 1998.
10. Pharmcognosy: Trease W.C., Evans g.E., Bailliere & Tindall, 15th edth.

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14. PHARMACEUTICAL MARKETING

(Theory) (4 Hrs/Week)

Unit 1

1) CONCEPT OF PHARMACEUTICAL MARKETING SELLING AND ORGANIZATION STRUCTURE

1. Meaning of Pharmaceutical Marketing and selling
2. Organization structure of Pharmaceutical Marketing dept. Job responsibilities of people involved.
3. Customers in Pharmaceutical Marketing

Unit 2

2) ADVERTISING AND SALES PROMOTION IN PHARMACEUTICAL MARKETING

1. Advertising of Pharma products and Detailing concepts
2. Various sales Promotion Methods its advantages, disadvantages.
3. Medical representative and his role
4. Various strategies to sell Pharmaceutical products

Unit 3

3) DISTRIBUTOR AND RETAILER IN PHARMA BUSINESS

1. Retailer and his importance
2. Distributor and his importance
3. Retail prescription audit

Unit 4

4) INSTITUTIONAL BUSINESS

1. Types of Institutions
2. Promotion activities at Institutions
3. Advantages of Institutional business

5) INTERNATIONAL PHARMA MARKETING MANAGEMENT :

1. International Pharma Market

2. Export Management of Pharmaceuticals

RECOMMENDED BOOKS :

1. Pharmaceutical Marketing by Subba Rao
2. The Fast Track Career- The M.R. S.S. Nadkarni

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15. IPR AND REGULATORY AFFAIRS

(Theory) (4 Hrs/Week)

Unit No.1 14 Hours

Intellectual property rights: Patent, copyrights, design and trademark. Effect of GATT and WTO on commerce of pharmaceuticals. Importance of patent, Application, processing of patent, Indian Patent Act 1970 and its latest amendments, United state patent, world patent processing. Patent term extension.

Unit No.2 14 Hours

Drugs Prices Control Order 1995, Factory Act, Labour Act, Medicinal and Toilet preparation (Excise duties) Act and Rules,

Narcotic Drugs and Psychotropic Substances Act and Rules, 1985 and latest amendments. The drug and Magic remedies (Objectionable advertisements) act and rules, 1954.

Unit No.3 14 Hours

Inspection and quality audit: Self inspection, Internal and External audits. Procedure for inspection of pharmaceutical manufacturing plants. Audits for vendor approvals, Contract manufacturing.

Biostatistics tools techniques, data analysis and presentation.

Unit No.4 14 Hours

Sewage disposal and pollution control from pharmaceutical Industry: Categorization of pharmaceutical industry as per EPA, Solid waste management of the expiry and rejected materials. Biomedical waste (Management and Handling) Rules, 1998.

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16. DRUG REGULATORY AFFAIRS

(Theory) (4 Hrs/Week)

CREDITS :04

Section I

Unit No.1 14 Hours

The Drugs and Cosmetics act, 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Good manufacturing practices for homeopathic medicines (Schedule M-I), Requirements of factory premises for manufacture of cosmetics (Schedule M-II), Good manufacturing practices for Ayurvedic, Siddha and Unanni medicines (Schedule T). Regulatory requirements for nutraceuticals. ISI standards of cosmetics.

Unit No.2 14 Hours

Requirements for registration of pharmaceutical products into USA with emphasis on para I, II, III & IV filing. Preparation of documents for approval of IND, NDA, ANDA, BLA applications and export registration (USFDA 21 CFR part 310, 312, 314, 320). Biowaivers. Understanding the FDA 505(b)(2) Regulatory Approval Pathway, Hatch-Waxman act.

Section II

Unit No.3 14 Hours

Overview of GMP guidelines with specific reference of World health organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Medicines control council (MCC), Therapeutic goods administration (TGA) and ANVISA Brazil guidelines and Japanese regulation.

Unit No.4 14 Hours

Intellectual property rights: Patent, copyrights, design and trademark. Effect of GATT and WTO on commerce of pharmaceuticals. Importance of patent, Application, processing of patent, Indian Patent Act 1970 and its latest amendments, United state patent, world patent processing. Patent term extension.

Books and References Recommended:

1. Vijay Malik, Law relating to Drugs & Cosmetics.
2. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
3. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
4. Common Technical documents (ICH guidelines).
5. ISO Guidelines
6. www.ich.org
7. www.anvisa.gov.
8. www.picscheme.org
9. www.mhra.gov.uk
10. www.tga.gov.au
11. www.mccza.com
12. www.who.int
13. www.patentoffice.nic.in
14. www.ep.espace.net
15. www.uspto.gov
16. www.epa.gov
17. www.emea.europa.eu
18. www.fda.gov.

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17. PROJECT MANAGEMENT

(Theory) (4 Hrs/Week)

CREDITS :04

UNIT ONE:

Pre Planning For Project Management :

1. Importance of project management
2. Organizing for project management
3. Role of project manager
4. Role of clients, customers and others
5. Setting up planning and control system

UNIT TWO:

Project Planning Process :

1. Defining project
2. Creating work breakdown structure
3. Estimating activities

4. Sequencing activities
5. Calculating the critical path
6. Scheduling project
7. Resources planning
8. Preparing planning budgets
9. Approval of projects
10. Setting up a monitoring and control process

UNIT THREE:

Executing The Project

1. Initiating the project
2. Controlling project objectives
3. Reporting on project objectives
4. Controlling changes in the project
5. Conducting project evaluations
6. Managing risks in project management
7. Closing the project

UNIT FOUR:

Heading The Project Team

1. Developing project teams
2. Managing conflicts
3. Communicating effectively
4. Holding effective meetings
5. Making team decisions
6. Using sources of power wisely
7. Making changes
8. Managing performance

Recommended books:

1. Project management ; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. Ltd Year of publication 2008
2. Project management: The managerial process By Clifford F. Gray and Eric W. Larson Publisher: Tata Mc Graw Hill Third edition
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
4. Project management By Jeffery K. Pinto Publisher: Prentice-Hall Year of publication 2007

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18 PHARMACEUTICAL PLANTS ADMINISTRATION

(Theory) (4 Hrs/Week)

CREDITS :04

APPLICATION OF ADMINISTRATION PRINCIPLE TO PHARMA PLANTS

UNIT ONE

I. Introduction to administration

1. Concept of management and administration
2. Management social responsibility and ethics
3. Function of management

II. Planning and decision making

1. Types of plans and steps in planning
2. Planning process

3. Concept of objectives & MBO
4. Strategic planning process
5. Effective implementation and strategies
6. Process of decision making

UNIT TWO

I. Organising

1. Formal and informal organizations
2. Concept of span of control
3. Structure and process of organizing
4. Departmentalisation
5. Line and staff concept
6. Making organizations effective and developing positive organization culture

II. Staffing

1. Definition of staffing
2. Systems approach to human resource management and an overview of staffing function
3. Performance appraisal of staffing function
4. Manager development process and training

UNIT THREE

I. Leading

1. Human factors in managing
2. Human motivation theories of:-

- Abraham Maslow
- McClelland's needs theory

3. Communication process in organizations

II. Controlling

1. Basic control process
2. Critical control points and standards
3. Feedback and feed forward controls
4. Requirements for effective control

UNIT FOUR

I. Productivity and operations management

1. Productivity problems and measurement
2. Production and operations management
3. Controlling and improving productivity

II. Overall and preventive control

1. Control of overall performance
2. Direct control
3. Preventive control

Recommended Books

(1) Essentials of management by Dr.Herold Koontz and Heinz Weitnrich

(2) Managing productivity in organizations by Kopelman

(3) Effective supervision : A practical approach by Hodgetts

All the above books are published by McGraw Hill publishing company.

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19.BULK DRUG TECHNOLOGY

(Theory) (4 Hrs/Week)

UNIT I

1) a) Stoichiometry and its importance in the manufacture of drugs

b) Discussion on the following processes (reaction types in relation to manufacturing of drugs.

Acetylation, Nitration, Sulphonation, chlorosulphonation,Oxidation, Reduction, alkylation, Halogenation, Carboxylation, Decarboxylation, Esterification, Addition, epoxidation and important rearrangements.

UNIT II

2) Unit processes: Study of the following chemical processes (with reference to reagents, mechanisms, equipments, and manufacture of drugs given below): Acylation, esterification, alkylation, amination, halogenation, hydrolysis, nitration, oxidation, reduction.

3) Further discussion on unit operations important to drug synthesis e.g. mixing, distillation, drying, filteration and centrifugation, evaporation, crystallization, counter current extraction Effluent treatment and Pollution Control.

UNIT III

4) Principles and design of the reactors - Factors to be considered (including material selection) construction of flow diagrams- selection of Equipment.

5) Detailed manufacturing aspects, inclusive of processes and operations involved for : Aspirin, Adrenaline, Aneurine, Barbitones, Benzocaine, Chloramphenicol, Sulphathiazole.

UNIT IV

6) Safety and Hazards concepts.

Recommended Books :

1) M.G.Larians : Fundamentals of Chemicals Engineering Operations

2) W.L.Badger and Banchero : Introduction to chemical engineering (McGraw Hill Servies)

3) L.Lachman- the theory and practice of Industrial Pharmacy (Vergaese Publishing)

4) Ganderton G ; Unit processes in Pharmacy

5) Groggin P.K.:Unit processes in Organic synthesis (McGraw Hill Publication London)

6) Marshall Sitting : Organic Chemical Processes

7) Dryden C.L.:Outlines of chemical Technology (Affiliated East-West Press Pvt. Ltd.)

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20. FERMENTATION TECHNOLOGY

(Theory) (4 Hrs/Week)

Credits 4

Unit 1 Basic principle of Bioprocess engineering

Isolation, screening and maintenance of industrially important microbes; Strain improvement for increased yield and other desirable characteristics. Isolation and screening of industrially important microbes; Large scale cultivation of industrial microbes; Strain improvement to improve yield of selected compounds e.g. antibiotics, enzymes or recombinant proteins (Cellular control regulating production of microbial metabolites – Primary and Secondary metabolite – Induced mutation technique – Analogue resistant mutant – Catabolic derepressed mutants – Genetically engineered strain – Protoplast fusion technique). Industrial microbes as cloning hosts (Streptomyces/Yeast). Recombinant protein production in microbes; Commercial issues pertaining to the production recombinant products from microbes.

Unit 2 Bioreactors and Fermenter Design

Introduction to bioreactors; Batch and Fed-batch bioreactors, Continuous bioreactors; immobilized cells; Bioreactor operation; Sterilization; Aeration; Instrumentation & control, Culture-specific design aspects: plant/mammalian cell culture reactors. Description of industrial processes. Solid substrate, surface and

submerged fermentation; Fermentation media; Fermenter design, Mechanically agitated; Pneumatic and hydrodynamic fermenters; Large scale animal and plant cell cultivation and air sterilization; Upstream processing: Media formulation; Sterilization; Aeration and agitation in bioprocess; Measurement and control of bioprocess parameters; Scale up and scale down process.

Unit 3 Principles of enzyme catalysis and microbial growth

Proteins as enzymes; Michaelis-Menten kinetics; Kinetics and Statistics; Inhibition; Effect of pH and temperature; Enzymology; Immobilized enzymes: methods, mass transfer considerations; Industrial enzymes: Factors affecting microbial growth; Stoichiometry: mass balances; energy balances; Growth kinetics; Measurement of growth (an example from each group, particularly with reference to industrially useful microorganisms).

Unit 4 Applications of enzymes in food processing

Enzymic bioconversions e.g. starch and sugar conversion processes; High-Fructose Corn Syrup; Inter-esterified fat; Hydrolyzed protein etc. and their downstream processing; baking by amylases, deoxygenation and desugaring by glucosesoxidase, beer mashing and chill proofing; cheese making by proteases and various other enzyme catalytic actions in food processing. Applications of Microbes in food process operations and production: Fermented foods and beverages; Food ingredients and additives prepared by fermentation and their purification; fermentation as a method of preparing and preserving foods; producing colours and flavours, alcoholic beverages and other products; Production of Bioethanol, Biohydrogen and biopesticides.

Text/References :

1. Michael Shuler and Fikret Kargi, Bioprocess Engineering: Basic Concepts, 2nd Edition, Prentice Hall, Englewood Cliffs, NJ, 2002.
2. Stanbury RF and Whitaker A., Principles of Fermentation Technology, Pergamon press, Oxford, 1997.
3. Baily JE and Ollis DF., Biochemical Engineering fundamentals, 2nd Edition, McGraw-Hill Book Co., New York, 1986.
4. Pauline Doran, Bioprocess engineering principles, 1 Edition, Academic Press, 1995.
5. Colin Ratledge, Bjorn Kristiansen, Basic Biotechnology, 2nd Edition, Cambridge University Press, 2001.
6. Roger Harrison et al., Bioseparations Science and Engineering, Oxford University Press, 2003.
7. Jackson AT., Bioprocess Engineering in Biotechnology, Prentice Hall, Engelwood Cliffs, 1991.
8. Aiba S, Humphrey AE and Millis NF, Biochemical Engineering, 2nd Edition, University of Tokyo press, Tokyo, 1973.

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21.ANIMAL CELL CULTURE AND APPLICATIONS

(Theory) (4 Hrs/Week)

Credits 4

Unit 1: Cell culture Laboratory design & Equipments,

History of animal cell culture; Different tissue culture techniques; Equipments and materials for animal cell, Types of primary culture; Chicken embryo fibroblast culture; Secondary culture; Trypsinization; Cell separation; Continuous cell lines; Suspension culture; Organ culture etc.; Behavior of cells in culture conditions: division, growth pattern, estimation of cell number; Development of cell lines; Characterization and maintenance of cell lines, stem cells; Cryopreservation; Common cell culture contaminants.

Unit 2: Media and reagents, Different types of cell cultures, scale up

Types of cell culture media; Ingredients of media; Introduction to the balanced salt solutions and simple growth medium, Physiochemical properties; CO_2 and bicarbonates; Buffering; Oxygen; Osmolarity; Temperature; Surface tension and foaming; Antibiotics, growth supplements; Foetal bovine serum; Serum free media; Trypsin solution; Selection of medium and serum; Conditioned media; Other cell culture reagents; Preparation and sterilization of cell culture media, serum and other reagents.

Unit 3: Application of animal cell culture

Toxicological study, Measurement of viability and cytotoxicity; Biology and characterization of the cultured cells, measuring parameters of growth; cell cycle regulation study, apoptosis, drug testing, bioactivity assays. Cell cloning and micromanipulation; Cell transformation;

Unit 4: Stem cells and applications

Stem cell cultures, embryonic stem cells and their applications; Cell culture based vaccines, Somatic cell genetics. Organ and histotypic cultures; Measurement of cell death; Apoptosis, three dimensional culture and tissue engineering.

References:

1. Freshney R. Ian, "Culture of animal cells: A manual of Basic Technique", Willey-Liss Publisher, 5th edition (2005).
2. Morgan, Animal Cell Culture-Biotol Series,1993
3. Davis.J.M Basic Cell Culture Second Edition, Oxford University Press. (First Indian Edition, 2005)
4. Jenkins N, ed., "Animal Cell Biotechnology: Methods and Protocol", Humana Press (1999).
5. Minuth W.W., Strehl R., Schumacher K., "Tissue Engineering: Essential for Daily Laboratory Works", Willey Publisher (2005).
6. Butler, M "Mammalian Cell Biotechnology- A Practical Approach," IRL Oxford University Press (1991)

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22.GENOMICS & PROTEOMICS

(Theory) (4 Hrs/Week)

Credits 4

Unit 1 Introduction

Structural organization of genome in Prokaryotes and Eukaryotes; Organelle DNA mitochondrial, chloroplast; DNA sequencing principles and translation to large scale projects; Recognition of coding and non-coding sequences and gene annotation; Tools for genome analysis-RFLP, DNA fingerprinting, RAPD, PCR, Linkage and Pedigree analysis Physical and genetic mapping.

Unit 2 Genome sequencing projects

Microbes, plants and animals; Accessing and retrieving genome project information from web; Comparative genomics, Identification and classification using molecular markers-16S rRNA typing/sequencing, EST's and SNP's.

Unit 3 Proteomics

Protein analysis (includes measurement of concentration, aminoacid composition, N-terminal sequencing); 2-D electrophoresis of proteins; Microscale solution isoelectricfocusing; Peptide fingerprinting; LC/MS-MS for identification of proteins and modified proteins; MALDITOF; SAGE and Differential display proteomics, Protein-protein interactions, Yeast two hybrid system.

Unit 4 Pharmacogenomics

High throughput screening in genome for drug discovery identification of gene targets, Pharmacogenetics and drug development

Texts/References:

1. Voet D, Voet JG & Pratt CW, Fundamentals of Biochemistry, 2nd Edition. Wiley 2006
2. Brown TA, Genomes, 3rd Edition. Garland Science 2006
3. Campbell AM & Heyer LJ, Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition. Benjamin Cummings 2007
4. Primrose S & Twyman R, Principles of Gene Manipulation and Genomics, 7thEdition, Blackwell, 2006.
5. Glick BR & Pasternak JJ, Molecular Biotechnology, 3rd Edition, ASM Press, 1998.

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23. PHARMACEUTICAL PLANT DESIGN AND OPERATION

(Theory) (4 Hrs/Week)

Credits 4

Unit : One (Regulatory requirements and Project management)

1. Regulatory requirements of pharma facilities with ref. to cGMP and Factory Act
2. Introduction of pharmaceutical project management.

Unit : Two (Formulation Facility Design)

3. Designing of non-sterile products facilities for tablets, hard gelatin capsules, dry syrups ointments/ creams and liquid orals.
4. Designing of sterile products facilities for liquid ampoules, liquid vials dry powder vials.
5. Designing of Q.C. Laboratory and Pilot plant
6. Designing of ware houses.

Unit : Three(Utility Design.)

7. Designing of following utility services
   - Water and stream
   - Electricity
   - Compressed air and other gases
   - Engineering workshop
8. Designing of effluent treatment plant
9. Designing of plant support services like security office, vehicle parking, fuel storage, canteen and cooking, garden and horticulture, scrap yards, Administrative block and traning centre, sports and entertainment block, resident managers bunglow, residences for essential service staff.

Unit: Four :(Operation of Plant)

10. Operation of ware housing department
11. Operation of Q.A./QC department
12. Operation of Production department
13. Operation of Personnel and HRD department
14. Operation of factory Administration department
15. Operation of Engineering department
16. Operation and Production planning and control department.

RECOMMENDED BOOKS ;

1) Project Management by Clifford F. Gray and Erik W. Larson Publisher :McGraw Hill company.
2) Pharmaceutical Production facilities : Design and applications by Graham Cole. Publisher : Taylor & Francis
3) Production/Operations Management by : Elwood Bufa Publisher: Wiley Eastern Limited (New Delhi)
4) Production planning and control by: Samuel Eilon Publisher: Universal book corporation, Mumbai.
5) Pharmaceutical Facilities: Design,Layouts,and Validation By: Dr. M.A.Potdar Publisher: PharmaMed Press, Hydrabad

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Published by :
The Registrar, Bharati Vidyapeeth University, Bharati Vidyapeeth Bhavan, L.B.S. Marg, Pune- 30.
Printed by : Manager, Bharati Printing Press, Pune- 38.
350/10/2012