SVU COLLEGE OF PHARMACEUTICAL SCIENCES

SRI VENKATESWARA UNIVERSITY: TIRUPATI

MASTER OF PHARMACY SYLLABUS AND REGULATIONS

2021 - 2022

RULES, REGULATIONS AND SYLLABI FOR

MASTER OF PHARMACY COURSE

CHOICE BASED CREDIT SYSTEM (CBCS)

1. SHORT TITLE AND COMMENCEMENT

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Choice Based credit System (CBCS). They shall come into effect from the Academic Year 2021-2022. 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 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 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 Pharmacy 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 semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of Aug/Sep to Jan/Feb and the even semesters shall be conducted from the month of Feb/March to July/Aug 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.

Core, elective and self-study courses

- The various courses offered to students are of three types.

CORE COURSE:

- Core courses are those, knowledge of which is essential for students registered. These courses are mandatory.

ELECTIVE:

- An elective allows students to gain knowledge in areas where the concerned subject has applications.
- A department declares electives for its own students, out of which the desired electives are chosen by the students of parent department. These are called Internal Electives (IE).
- A department declares electives for the students of other departments (External elective (EE)).
- The credits obtained are mandatory.
- By choosing an elective from outside the department, a candidate may have to sacrifice an elective of her own department.

SELF STUDY COURSE :

- The concerned department allows students to choose an additional one or more course, to acquire more knowledge and extra credits. But these credits are not to be taken into account for awarding grades or class. Such courses should be in advanced areas of the subject. A teacher shall supervise the student. For self-study courses question paper setting and evaluation are internal only.

Course registration

The students have to register for courses at the beginning of a semester. Late registration may be allowed by the Head of the Department. Time of withdrawal: one week from the date of registration. An elective may be dropped and another elective course may be substituted with valid reasons. The Head of the Department is empowered to allow the student to do so.

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 contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact 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 9**. 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, and Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses. Self-study courses, question paper setting and evaluation are done by respective departments.

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.	Pharmacology	MPL
2.	Pharmaceutics	MPH

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in **Tables – 2 to 5**. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in **Tables – 2 to 5**.

STRUCTURE OF COURSES
MASTER OF PHARMACY
FROM 2021-2022

TABLE –2: COURSE OF STUDY FOR M. PHARM - PHARMACOLOGY

I SEMESTER

Course code	Course	Credit hours	Credit points	Hrs/wk	Marks	Core/Elective
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100	Core
MPL102T	Advanced Pharmacology-I	4	4	4	100	Core
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100	Core
MPL104T	Cellular and Molecular Biology	4	4	4	100	Core
MPL105P	Pharmacology Practical I	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	

II SEMESTER

Course code	Course	Credit Hours	Credit points	Hrs/wk	Marks	Core/Elective
MPL201T	Advanced Pharmacology II	4	4	4	100	Core
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100	Core
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100	Core
-	**Elective**	4	4	4	100	
MPL205P	Pharmacology Practical II	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	

ELECTIVES OFFERED

Course code	Course	Credit Hours	Credit points	Hrs/wk	Marks	Core/Elective
MPH 203T	Computer Aided Drug Delivery System	4	4	4	**100**	Elective
MPC 203T	Computer Aided Drug Design	4	4	4	**100**	Elective
MPA 203T	Quality Control & Quality Assurance	4	4	4	**100**	Elective
MPH 204T	Cosmetic & Cosmeceuticals	4	4	4	**100**	Elective
MPL 203T	Principles of Drug Discovery	4	4	4	**100**	Elective

TABLE 3: COURSE OF STUDY FOR M. PHARM - PHARMACEUTICS

I SEMESTER						
Course code	**Course**	**Credit hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100	Core
MPH102T	Drug Delivery System	4	4	4	100	Core
MPH103T	Modern Pharmaceutics	4	4	4	100	Core
MPH104T	Regulatory Affairs	4	4	4	100	Core
MPH105P	Pharmaceutics Practical I	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
	Total	**35**	**26**	**35**	**650**	
II SEMESTER						
Course code	**Course**	**Credit Hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100	Core
MPH202T	Advance Bio Pharmaceutics and Pharmacokinetics	4	4	4	100	Core
MPH 204T	Cosmetic & Cosmeceuticals	4	4	4	100	Core
-	**Elective**	4	4	4	100	

MPH205P	Pharmaceutics Practical II	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	

ELECTIVES OFFERED

Course code	Course	Credit Hours	Credit points	Hrs/wk	Marks	Core/Elective
MPH 203T	Computer Aided Drug Delivery System	4	4	4	**100**	Elective
MPC 203T	Computer Aided Drug Design	4	4	4	**100**	Elective
MPA 203T	Quality Control & Quality Assurance	4	4	4	**100**	Elective
MPL 204T	Clinical Research & Pharmacovigilance	4	4	4	**100**	Elective
MPL 203T	Principles of Drug Discovery	4	4	4	**100**	Elective

TABLE –4: COURSE OF STUDY FOR M. PHARM III SEMESTER (COMMON FOR ALL SPECIALIZATIONS)

Course code	Course	Credit Hours	Credit Points	Marks
MRM 301T	Research Methodology and Biostatistics*	4	4	100
-	Journal Club*	2	2	50
-	Research Proposal Presentation*	8	4	100
-	Viva-voce*	1	1	25
	Total	15	11	275

*** Non- University Examinations**

TABLE – 5: COURSE OF STUDY FOR M. PHARM. IV SEMESTER (COMMON FOR ALL SPECIALIZATIONS)

Course code	Course	Credit Hours	Credit Points	**Marks**
-	Thesis Evaluation	40	20	500
-	Research Work and Colloquium	10	10	250
	Total	50	30	750

TABLE – 6: SEMESTER WISE CREDITS DISTRIBUTION

Semester	Credit Points
I	26
II	26
III	11
IV	30
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

TABLE – 7: 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 **(or)** Presentation in National Level Seminar/Conference/Symposium (related to Specialization)	02 (One for each Participation) (or) 02
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs	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

Note: Internal Conference: Held outside India
Note: International Journal: The Editorial Board Outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Departmental Research Committee (DRC) of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the DRC 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 each M.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. Communicating its recommendation to the Head of the institution on academic matters.

The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. EXAMINATIONS/ASSESSMENTS

The schemes for internal assessment and end semester examinations are given in Table – 10-14.

TABLE – 8: SCHEMES FOR INTERNAL ASSESSMENTS AND END SEMESTER EXAMINATIONS (PHARMACOLOGY-MPL)

Course code	Course	Internal assessment				End semester examinations		Total marks
		Continuous mode	Sessional exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER I								
MPL101T	Modern Pharmaceutical Analytical Techniques	5	20	2Hr	25	75	3Hr	100
MPL102T	Advanced Pharmacology-I	5	20	2Hr	25	75	3 Hr	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	5	20	2Hr	25	75	3 Hr	100
MPL104T	Cellular and Molecular Bology	5	20	2Hr	25	75	3 Hr	100
MPL105P	Pharmacology Practical I	20	30	6 Hr	50	150	12Hr	200
-	Seminar/Assignment	-	-	-	-	-	-	50
Total								650
SEMESTER II								

MPL201T	Advanced Pharmacology II	5	20	2Hr	25	75	3 Hr	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	5	20	2Hr	25	75	3 Hr	100
	Elective	5	20	2Hr	25	75	3 Hr	100
MPL204T	Clinical Research and Pharmacovigilance	5	20	2Hr	25	75	3 Hr	100
MPL205P	Pharmacology Practical II	20	30	6 Hr	50	150	12Hr	200
-	Seminar/Assignment	-	-	-	-	-	-	50
Total								650

TABLE – 9: SCHEMES FOR INTERNAL ASSESSMENTS AND END SEMESTER EXAMINATIONS (PHARMACEUTICS-MPH)

Course code	Course	Internal assessment				End semester examinations		Total marks
		Continuous mode	Sessional exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER I								
MPH101T	Modern Pharmaceutical Analytical Techniques	5	20	2Hr	25	75	3Hr	100
MPH102T	Drug Delivery System	5	20	2Hr	25	75	3 Hr	100
MPH103T	Modern Pharmaceutics	5	20	2Hr	25	75	3 Hr	100
MPH104T	Regulatory Affairs	5	20	2Hr	25	75	3 Hr	100
MPH105P	Pharmaceutics Practical I	20	30	6 Hr	50	150	12 Hr	200
-	Seminar/Assignment	-	-	-	-	-	-	50
Total								650
SEMESTER II								
MPH201T	Molecular Pharmaceutics (NanoTech and Targeted DDS)	5	20	2Hr	25	75	3 Hr	100

MPH202T	Advance bio Pharmaceutics and Pharmacokinetics	5	20	2Hr	25	75	3 Hr	100
	Elective	5	20	2Hr	25	75	3 Hr	100
MPH204T	Cosmetic & Cosmeceuticals	5	20	2Hr	25	75	3 Hr	100
MPH205P	Pharmaceutics Practical II	20	30	6 Hr	50	150	12Hr	200
-	Seminar/Assignment	-	-	-	-	-	-	50
Total								650

TABLE – 10: SCHEMES FOR INTERNAL ASSESSMENTS AND END SEMESTER EXAMINATIONS (Semester III & IV)

SEMESTER III

Course code	Course	Internal assessment				End semester examinations		Total marks
		Continuous mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
MRM30 IT	Research Methodology & Biostatistics*	05	20	2Hr	25	75	3Hr	100
-	Journal club*	-	-	-	50	-	-	50
-	Research Proposal Presentation *	-	-	-		100	1 Hr	100
-	Viva Voce*					25		25
Total								275

- *Non University Examination
- ***Note:** There shall be 2 Presentations in Journal Club, carrying 25 Marks each
- Journal club and Research proposal presentation including viva voce shall be evaluated by three internal examiners, two from the same specialization and one from other specialization.

SEMESTER IV

Course code	Course	Internal assessment				End semester examinations		Total marks
		Continuous mode	Sessional exams		Total			
			Marks	Duration		Marks	Duration	
-	Thesis Evaluation	-	-	-	-	500	1 Hr	500
-	Research Work and Colloquium	-	-	-	250	-	-	250
Total								750

- The project work is spread over two semesters (III & IV) At the end of the III Semester progress of project work shall be evaluated. At the end of the IV Semester the total project work shall be evaluated.

- Marks for Research Work and colloquium shall be evaluated by both Internal and External.

- The Internal and External Examiner appointed by University shall Evaluate the Thesis for 250 Marks each.

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university except for the subject with asterix symbol (*) in table 16 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Internal assessment: Continuous mode

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

TABLE – 11: SCHEME FOR AWARDING INTERNAL ASSESSMENT: CONTINUOUS MODE

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 18)	4
Student – Teacher interaction	1
Total	5
Practical	
Attendance (Refer Table – 18)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

TABLE – 12: GUIDELINES FOR THE ALLOTMENT OF MARKS FOR ATTENDANCE

Percentage of Attendance	Theory	Practical
95-100	4	10
90-94	3	7.5
85-89	2	5
80-84	1	2.5
Less than 80	0	0

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 sessional examinations is given below.

Question paper pattern for theory sessional examinations

Answer any **Four** questions out of **Five** questions. Marks 4 X 10 = 40M

The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Sessional exams shall be conducted for 40 Marks for theory and shall be computed for 20 Marks. Similarly sessional exam for practicals shall be conducted for 30 Marks

Seminars

There shall be two seminars in each semester which will be evaluated for 25 marks each.

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 she secures at least 50% marks in that particular course including 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 she shall reappear for the end semester examination of that course. However her marks of the Internal Assessment shall be carried over and she shall be entitled for grade obtained by her on passing.

14. QUESTION PAPER PATTERN FOR END SEMESTER THEORY EXAMINATIONS

Answer any five questions out of seven questions 15 X 5 = 75M

15. PANEL OF EXAMINERS FOR M. PHARM I & II SEMESTER EXAMINATIONS

For Theory & Practical Examinations, there will be one internal and one external Examiner for each subject

16. ALLOWED TO KEEP TERMS (ATKT):

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

A student shall be eligible to get 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

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 – 19.

TABLE –13: LETTER GRADES AND GRADE POINTS EQUIVALENT TO PERCENTAGE OF MARKS AND PERFORMANCES

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
85-100	O	10	Outstanding
75-84.99	A^+	9	Excellent
65-74.99	A	8	Very Good
60-64.99	B	7	Good
55-59.99	C	6	Fair
50-54.99	D	0	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:

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

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, theSGPA shall then be computed as:

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

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 statusin 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:

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

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 Thesis book:

Objective(s) of the work done	25 Marks
Methodology adopted	75 Marks
Results and Discussions	125Marks
Conclusions and Outcomes	25 Marks
Total	250Marks

Evaluation of Presentation:

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

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. 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.

SYLLABUS

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

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

THEORY **60 Hrs**

1. **UV-Visible spectroscopy: Theory, Laws, Instrumentation associated with UV- Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.**

   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, Data Interpretation.

   b. **Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   c. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **14Hrs**

2. **^{1}HNMR spectroscopy**

   Principle, Instrumentation, Solvent requirement in ^{1}HNMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Applications of ^{1}HNMR spectroscopy. Brief outline of principles of ^{13}C NMR. **8Hrs**

3. **Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **8Hrs**

4. **Chromatography**: Principle, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

   a. High Performance Thin Layer Chromatography.
   b. Gas chromatography
   c. High Performance Liquid chromatography
   d. Ultra High Performance Liquid chromatography
   e. LC-MS
   f. Affinity chromatography **14Hrs**

5. **a. Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 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. **10Hrs**

6. **a. Immunoassays**: Principles, procedures and types of RIA, ELISA

   b. Thermal techniques: Principle, instrumentation and pharmaceutical applications of DTA,DSC, TGA. **6Hrs**

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ADVANCED PHARMACOLOGY – I (MPL 102T)

SCOPE

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

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

THEORY **60Hrs**

1. Neurotransmission

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters - Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitter pathways - Serotonergic, dopaminergic, GABA, glutamate and glycine pathways).

d. Non adrenergic non cholinergic transmission (NANC). Cotransmission

e. Peptidenergic neurotransmission: Neuropeptides and Neuromodulators **12Hrs**

2. Systemic Pharmacology

A detailed study on pathophysiology of diseases wherever applicable, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and Parasympatholytics,

Sympathomimetics and Sympatholytics

Agents affecting neuromuscular junction. **12Hrs**

3. Central nervous system Pharmacology

General and local anesthetics. Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-

narcotic analgesics. **12Hrs**

4. Cardiovascular Pharmacology

Diuretics, anti-hypertensives, anti-ischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet drugs.

12Hrs

5. Autocoid Pharmacology

The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists. **12 Hrs**

REFERENCES

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. Robbins & Cortan Pathologic Basis of Disease,9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published byAPC Avichal Publishing Company
11. KD.Tripathi. Essentials of Medical Pharmacology.
12. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E.,Lippincott Publishers.
13. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.

14. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
15. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(MPL 103T)

SCOPE

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

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 laboratorypractices 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

THEORY **60 Hrs**

1. Laboratory Animals

Common laboratory animals: Description, handling and applications of different species andstrains of animals.

Transgenic animals: Production, maintenance and applications.

Anaesthesia and euthanasia of experimental animals.

Maintenance and breeding of laboratoryanimals.

CPCSEA guidelines to conduct experiments on animals.

Bioassay-Principle, scope, Types and limitations and methods. **12Hrs**

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

General principles of preclinical screening.

CNS Pharmacology, CNS stimulants and depressants, anxiolytics, anti-psychotics and anti-epileptics

Drugs for neurodegenerative diseases like Parkinsonism and Alzheimers.

Drugs acting on Autonomic Nervous System. **12 Hrs**

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

   Respiratory Pharmacology: anti-asthmatics and anti-allergics.

   Reproductive Pharmacology: Aphrodisiacs and anti-fertility agents.

   Analgesics, anti-inflammatory and anti-pyretic agents.

   Gastrointestinal drugs: anti-ulcer, anti -emetic, anti-diarrheal and laxatives. **12Hrs**

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

   Cardiovascular Pharmacology: anti-hypertensives, anti-arrythmics, anti-ischemics,anti-atherosclerotic agents and diuretics.

   Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic agents.

   Anti-cancer agents.

   Hepatoprotective screening methods. **12Hrs**

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

   Immunomodulators, Immunosuppressants and immunostimulants

   Limitations of animal experimentation

   Alternate animal experiments- *In silico* and *in vitro* approaches

   Extrapolation of *in vitro* data to preclinical and preclinical to humans **12Hrs**

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)

SCOPE

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

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 drugdiscovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY **60Hrs**

1. Cell biology

Structure and functions of cell and its organelles. Introduction to Cell Biology

Protein Structure and Function. Membranes and Cell Architecture. MembraneTransport.

Genes, Genomics and Chromosomes.

Applications of siRNA and micro RNA, gene mapping and gene sequencing. **10 Hrs**

2. Cell signaling

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure of ligand gated ion channels;

G-proteincoupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

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. **12Hrs**

3. Molecular pharmacology

Pharmacology of sodium, calcium, potassium and chloride channels and their modulators. NMDA, GABA, Glycine, Serotonin, Dopamine, Histamine and Endothelin (ET) receptors,

their classification, signal transduction mechanism, agonists and antagonists.

Role of Cytokines, Prostaglandins, TNF-α, Bradykinins, Leucotrienes, PAF, Interferons and Adhesion molecules in Inflammation. **12Hrs**

4. Cell Cycle

Introduction to the Cell Cycle, Phase and Regulation of Cell cycle and Cell Proliferation, Mitosis, Meiosis and Cytokinesis.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy. **12Hrs**

5. Cell culture techniques and Biosimilars

Basic equipment's 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.

Biosimilars: Definitions, Generics and Branded drugs, biosimilars, introduction to biologics, differences between biosimilars and generics, manufacturing process and technical challengesassociated with production of biosimilar molecules, current status of biosimilars.

14 Hrs

REFERENCES

1. Molecular Biology of The Cell - Bruce Alberts and et al. 5th ed. Garland Science.
2. Cell and Molecular Biology - E.D.P. De Robertis & E.M.F. De Robertis Jr. 8th ed. Wolter Publications.
3. Molecular Cell Biology - Harvey Lodish et al. 6th ed. W.H. Freeman & Company.
4. Molecular Biology and Biotechnology - John M Walker & Ralph Raple. 5th ed. RSC Publications.
5. A Concise Reference Advanced Molecular Biology - R.M. Twyman, Viva Books Pvt. Ltd.
6. Principles of Gene Manipulation and Genomics - S.B. Primrose & R.M. Twyman. 7th edn.
7. The Cell, A Molecular Approach - Geoffrey M Cooper.

8. Pharmacogenomics - J. Licinio & M.L. Wong
9. Handbook of Cell Signaling – A. Ralph et al. 2nd ed.
10. Molecular Pharmacology: From DNA to Drug Discovery - John Dickenson et al.
11. Basic Cell Culture Protocols - Cheril D Helgason & Cindy L Miller
12. Basic Cell Culture (Practical Approach) - J. M. Davis.
13. Animal Cell Culture: A Practical Approach - John R Masters.
14. Current Protocols in Molecular Biology - Frederick M. Ausuvel et al. Vol 1 to 6.

PHARMACOLOGICAL PRACTICAL - I(MPL 105P)

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, PC, TLC & HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry.

1. Handling of laboratory animals.
2. Various routes of drug administration.
3. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
4. Functional observation battery tests (modified Irwin test)
5. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
6. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
7. Evaluation of diuretic activity.
8. Evaluation of antiulcer activity by pylorus ligation method.
9. Oral glucose tolerance test.
10. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
11. Isolation of RNA from yeast
12. Estimation of proteins by Braford/Lowry's in biological samples.
13. Estimation of RNA/DNA by UV Spectroscopy
14. Gene amplification by PCR.
15. Protein quantification Western Blotting.
16. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
17. Cell viability assays (MTT/Trypan blue/SRB).
18. DNA fragmentation assay by agarose gel electrophoresis.

19. DNA damage study by Comet assay.
20. Apoptosis determination by fluorescent imaging studies.
21. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
22. Enzyme inhibition and induction activity
23. Extraction of drug from various biological samples and estimation of drugsin biological fluids using different analytical techniques (UV)
24. Extraction of drug from various biological samples and estimation of drugsin 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)

SCOPE

The subject is designed to strengthen the basic knowledge in the field of pharmacology and toimpart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

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 intreatment of diseases

THEORY **60Hrs**

1. **Endocrine Pharmacology**

   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. **12 Hrs**

2. **Chemotherapy**

   a. 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.

   b. Drugs used in Protozoal Infections

   Drugs used in the treatment of Helminthiasis

   Chemotherapy of cancer. **14 Hrs**

3. **Immunopharmacology** :

   Cellular and biochemical mediators of inflammation and immune response.

   Allergic or hypersensitivity reactions.

   Pharmacotherapy of asthma and COPD.

   Immunosuppressants and Immunostimulants **12Hrs**

4. GIT Pharmacology

Antiulcer drugs, Prokinetics, anti-emetics, anti-diarrheals and drugs for constipation andirritable bowel syndrome.

10 Hrs

5. Pharmacology of Free radicals

Generation of free radicals, role of free radicals in etiopathology of various diseases such asdiabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidants.

Recent Advances in antioxidant treatment of Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus **12Hrs**

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)

SCOPE

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug& new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

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.

THEORY **60Hrs**

1. **Basic definition and types of toxicology** (general, mechanistic, regulatory and descriptive)

   Regulatory guidelines for conducting toxicity studies OECD, ICH and EPA.

   OECD principles of Good laboratory practice (GLP).

   History, concept and its importance in drug development **12Hrs**

2. **Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.**

   Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

   Test item characterization- importance and methods in regulatory toxicology studies.

   12 Hrs

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)

   In vivo carcinogenicity studies . **12Hrs**

4. IND enabling studies (IND studies)

Definition of IND, importance of IND, industry perspective, list of studies needed for INDsubmission.

Safety pharmacology studies- origin, concepts and importance of safety pharmacology. HERG assay.

12Hrs

5. Toxicokinetics

Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies**.**

Alternative methods to animal toxicity testing- US FDA, ECVAM, CAAT and OECD approved methods. **12Hrs**

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphand book. 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)

CLINICAL RESEARCH AND PHARMACOVIGILANCE

(MPL 204T)

SCOPE

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

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 systems and communication in Pharmacovigilance

THEORY **60Hrs**

1. Regulatory Perspectives of Clinical Trials:

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 content of an Informed Consent Process Ethical principles governing informed consent process. **9Hrs**

2 . Clinical Trials: Types and Design

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. **12 Hrs**

3. **Clinical Trial Documentation**

Guidelines to the preparation of documents, 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. **12Hrs**

4. **Basic aspects, terminologies and establishment of pharmacovigilance**

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. **12Hrs**

5. **Methods, ADR reporting and tools used in Pharmacovigilance**

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, Vigi Flow,Statistical methods for evaluating medication safety data. **12Hrs**

6. **Pharmaco epidemiology**.

Study methodology, measurement of treatments and outcomes, sources of bias and control ofconfounding, techniques to reduce bias and confounding.

3Hrs

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 - David Machin, Simon Day & Sylvan Green. John Wiley and Sons, March 2005.
5. Clinical Data Management – R.K. Rondels, S.A. Varley & C.F. Webbs. 2nd ed. Wiley Publications, Jan 2000.
6. Handbook of Clinical Research - Julia Lloyd & Ann Raven. Churchill Livingstone.
7. Principles of Clinical Research - Giovanna di Ignazio & Di Giovanna and Haynes.
8. Relevant Research and Review articles and guidelines

PHARMACOLOGY PRACTICAL – II (MPL 205P)

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 suitableisolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitabletissue 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 suitabletissue 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 andAndrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES(MPH 101T)

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

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

THEORY **60Hrs**

1. a. UV-Visible spectroscopy: 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. **14Hrs**

2. ^{1}HNMR spectroscopy: Principle, Instrumentation, Solvent requirement in ^{1}HNMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Applications of ^{1}HNMR spectroscopy. Brief outline of principles of ^{13}C NMR **8Hrs**

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **8Hrs**

4. Chromatography: Principle, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a. High Performance Thin Layer Chromatography.

b. Gas chromatography

c. High Performance Liquid chromatography

d. Ultra High Performance Liquid chromatography

e. LC-MS

f. Affinity chromatography **14Hrs**

5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis **b)** 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. **10Hrs**

6. a. Immunoassays: Principles, Procedures and type of RIA & ELISA

b. Thermal techniques: Principle, instrumentation and pharmaceutical applications of DTA, DSC, TGA. **6Hrs**

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.

DRUG DELIVERY SYSTEMS

(MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

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.

THEORY **60Hrs**

1. a. 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.

b. 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. **12Hrs**

2. a) Gastro-Retentive Drug Delivery Systems: Principle, concepts, advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. **5Hrs**.

b) Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, mechanism of drug permeation, Methods of formulation and its evaluations**.**

5Hrs

c) Polymers: introduction, definition, classification, Molecular weight averages, Molecular weight determination from viscosity, Polymers as thickening agent, Preparation of polymer solution, Polymers in the solid state, Fabrication technology, and applications. **5Hrs**

3. a) Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 5**Hrs**

b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Formulation and evaluation of Transdermal Drug Delivery Systems. **5Hrs**

4. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of Delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. **12Hrs**

5. Chronotherapeutics Drug Delivery Systems: Introduction, classification, physiology of circadian rhythmicity, circadian rhythm changes in cardiac and liver disease conditions. Chronopharmacokinetics of anti hypertensives and anti asthmatics. **6hrs**

6. . Dosage Form for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines, Customized drug delivery systems, A brief note on Bio electronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

5 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 Wiley Interscience 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 rakashan, 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)

SCOPE

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

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.

THEORY 60Hrs

1. a) Preformulation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.

b) Theories of dispersion: Emulsion and Suspension, SMEDDS. Its formulation and evaluation.

c) Preparation and stability of Large and small volume parenterals – physiological and formulation consideration, Manufacturing and evaluation. **12Hrs**

2. 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 development. **12Hrs**

3. Validation: Introduction to Pharmaceutical Validation, Scope &merits of Validation, Types of Validation, Government regulation, Manufacturing process Model, URS,DQ,IQ,OQ& P.Q.of facilities. Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipment, Process Validation of Tablets, Capsules, Parenterals. **12Hrs**

4. a) cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment and their maintenance.

b) Production management: Production organization. Materials management: handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. **12Hrs**

5. a)Compression and compaction: Physics of tablet compression, compression and consolidation, effect of friction, distribution of forces, compaction profiles.

b) Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot. **12Hrs**

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)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA.

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory
- importance
- To learn the documentation requirements for
- To learn the importance and

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.

THEORY 60Hrs

1. 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), in-vitro drug product performance. **12Hrs**

2. Regulatory requirement for product approval: API, biologics, novel therapies, obtaining NDA, ANDA for generic drugs, ways and means of US registration for foreign drugs. **12Hrs**

3. 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**

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

5. 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, pharmaco vigilance ,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)

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 PC, TLC & 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)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

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.

THEORY 60Hrs

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

2. Targeting Methods: Introduction , types, preparation evaluation. Nano Particles & Liposomes, Niosomes. **12Hrs**

3. Micro Capsules / Micro Spheres: Types, preparation and evaluation ,and applications of Monoclonal Antibodies : Aquasomes, Phytosomes, Electrosomes. **12Hrs**

4. a) Pulmonary Drug Delivery Systems : Types , Preparation and Evaluation of Aerosols, propellents, Containers, Types, preparation and evaluation.

b) Intra Nasal Route Delivery systems; Types, preparation and evaluation. **12Hrs**

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 and its Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. **12Hrs**

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)

SCOPE

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

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

THEORY 60Hrs

1. Drug Absorption from the Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, Formulation and Physicochemical factors. pH–partition theory of drug absorption. Dissolution rate, Dissolution process, Noyes–Whitney equation, Factors affecting the dissolution rate, Formulation and processing factors.

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 , Correlation of invivo data with in vitro dissolution data. Transport model: Permeability, Solubility, Charge State, Properties of the Gastrointestinal Tract (GIT), pH Microclimate, Intracellular pH Environment, Tight-Junction Complex, Oral Absorption enhancers. **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 testing, performance of drug products, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. **12Hrs**

3. a) 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 of bioequivalence example,study submission and drug review process. Biopharmaceutics classification system and methods.

b) 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, Bio waivers **12Hrs**

4. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular; two compartment - model in brief, Non-linear pharmacokinetics: causes of non-linearity, Michaelis – Menten equation, estimation of K_m and V_{max}.

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. Drug interactions involving digoxin, warfarin, theophylline. **12Hrs**

5. a) 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. **09Hrs**

b) Chrono Therapeutic Drug Delivery System: Introduction, classification, physiology of circadian rhythmicity, circadian rhythm changes in cardiac and liver diseased conditions. Chronopharmacokinetics of anti hypertensives and anti asthmatics. **03Hrs**

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. aiswal., 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, 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 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.

COSMETICS AND COSMECEUTICALS

(MPH 204T)

SCOPE

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

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.

THEORY 60Hrs

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. Products for Cleansing and care for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm**.** **12Hrs**

3. Building blocks for different product formulations of cosmetics/cosmeceuticals: Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobials, preservatives, their merits and demerits. Factors affecting preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste, Soaps and syndet bars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane. **12Hrs**

4. Design of cosmeceutical products: 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)

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 Winnoline R 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

ELECTIVES

COMPUTER AIDED DRUG DELIVERY SYSTEMS(MPH 203T)

SCOPE

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

OBJECTIVES

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY **60Hrs**

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 guidelines, Regulatory and industry views on QbD, Scientifically based QbD - examples of application. **16Hrs**

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 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. **12Hrs**

4. 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- invivo correlation, Biowaiver considerations. **10Hrs**

5. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems. **10Hrs**

REFERENCES

2. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.

3. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing

4. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COMPUTER AIDED DRUG DESIGN

(MPC 203T)

SCOPE

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

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 modelling softwares to design new drug molecules
- The *in silico* virtual screening protocols

THEORY 60 Hrs

1. **Introduction to Computer Aided Drug Design (CADD)** History, different techniques and applications. 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 effectsand parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters. **12Hrs**

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 like COMFA and COMSIA.

QSAR statistical methods: regression analysis and partial least square analysis. **12Hrs**

3. **Molecular Modelling and Docking**

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

b) Methods to derive three-dimensional structure of protein : X-Ray Crystallography, NMR, homologous modeling.

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking, manual docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-Co A reductase and HIV protease, choline esterase (AchE & BchE) **15Hrs**

4. Molecular Properties and Drug Design

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. **9Hrs**

5 .Pharmacophore Mapping and Virtual Screening

a) Concept of pharmacophore, pharmacophore mapping,identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

b) Virtual Screening Techniques

Drug-likeness screening, Similarity based methods and Pharmacophore based screening, structure based *in-silico* virtual screening protocols. **12Hrs**

REFERENCES

1. Computational and structural approaches to drug discovery, Robert MStroud 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, ElsevierPublishers.

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, OxfordUniversity Press.

8. Wilson and Gisvold's Text book of Organic Medicinal and PharmaceuticalChemistry, Ippincott Williams & Wilkins.

9. Comprehensive Medicinal Chemistry – Corwin and Hansch, PergamonPublishers.

10. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

11. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

12. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.

13. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons,Inc.,NewJersey.

QUALITY CONTROL AND QUALITY ASSURANCE(MPA 203T)

SCOPE :

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

OBJECTIVES

At the completion of this subject it is expected that the student shall be able to know

- 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

THEORY **60Hrs**

1. Concept and Evolution 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. **12Hrs**

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. CPCSEA guidelines. **12Hrs**

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 formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials. **12Hrs**

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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. **12Hrs**

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. **12Hrs**

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, SusmitPublishers, 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.

PRINCIPLES OF DRUG DISCOVERY(MPL 203T)

SCOPE : The subject imparts basic knowledge of drug discovery process. This informationwill makethe student competent in drug discovery process.

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 indrug 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 drugdiscovery

THEORY 60Hrs

1. An overview of modern drug discovery process:

Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. 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. **12Hrs**

2. Lead Identification- combinatorial chemistry & high throughput screening, in silico leaddiscovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application ofNMR and X-ray crystallography in protein structure prediction. **12Hrs**

3. Rational Drug Design

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 likenessscreening, Concept of pharmacophore mapping and pharmacophore based Screening. **12Hrs**

Molecular docking: Rigid docking, flexible docking, manual docking; Docking basedscreening. 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**

4 QSAR Statistical methods – regression analysis, partial least square analysis (PLS) andother 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 2Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification andValidation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer NewYork Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principlesin Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods andPrinciples in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series;

7. American Chemical Society: Washington,DC, 1999.

8. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley &Sons, Inc., New Jersey

SEMESTER III

MRM 301T - Research Methodology & Biostatistics

UNIT-I **10Hrs**

General Research Methodology: Research, objectives, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II **10Hrs**

Biostatistics: Definition, applications, sample size, importance of sample size, factors influencing sample size, drop outs, statistical tests of significance, Spearman correlation, regression analysis, null hypothesis, P values, degrees of freedom, interpretation of P values.

UNIT – III **10Hrs**

Parametric tests -students "t" test, ANOVA non-parametric tests - chi square test, Sign test, Signed rank test, wilcoxon rank-sum test.

UNIT – IV **15Hrs**

Medical and Human Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non- maleficence, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – V **15Hrs**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, record keeping, SOPs, personnel and training, transport of lab animals.