Regulations and Curriculum for
Master of Pharmacy
M.Pharm

(Semester Scheme)

Amended up to 2021-22

(under Section 3 of UGC Act, 1956)
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VISION

To build a humane society through excellence in education and healthcare

MISSION

To develop
Nitte (Deemed to be University)
As a centre of excellence imparting quality education,
generating competent, skilled manpower to face the scientific and social challenges with a high degree of credibility, integrity,
ethical standards and social concern

Contents

No. F.9-13/2007-U.3 (A)
Government of India
Ministry of Human Resource Development
(Department of Higher Education)
U.3(A) Section

Shastri Bhavan, New Delhi
Dated: 4th June 2008

NOTIFICATION

1. Whereas the Central Government is empowered under Section 3 of the University Grants Commission (UGC) Act, 1956 to declare, on the advice of the UGC, an institution of higher learning as a deemed-to-be-university;
2. And whereas, a proposal was received in February, 2007 from Nitte Education Trust, Mangaluru, Karnataka seeking grant of status of deemed-to-be university in the name of Nitte (Deemed to be University) under section 3 of the UGC Act, 1956;
3. And whereas, the University Grants Commission has examined the said proposal and vide its communication bearing No. F.26-10/2007(CPP-I/DU), dated the 10th March, 2008 has recommended conferment of status of 'deemed-to-be-university' in the name and style of Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Mangaluru.
4. Now, therefore, in exercise of the powers conferred by section 3 of the UGC Act, 1956, the central Government, on the advice of the University Grants Commission (UGC), hereby declare that Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru, shall be deemed to be a University for the Purposes of the aforesaid Act.

Sd/
(Sunil Kumar)
Joint Secretary to the Government of India

(True Extract of the Notification)

University Grants Commission
Bahadurshah Zafar Marg
New Delhi – 110002

No. F.26-5/2008(CPP-1) Dated: 24th March, 2009

OFFICE MEMORANDUM

1. Whereas the Government of India, Ministry of Human Resource Development, Department of Higher Education vide Notification No. F.9-13/2007-U3(A) dated 4th June, 2008 declared Nitte (Deemed to be University), Mangaluru, Karnataka comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru as Deemed to be University under Section 3 of UGC Act, 1956.
2. And whereas now, the University Grants Commission, on the recommendation of an Expert Committee constituted by the Chairman, UGC has agreed for bringing (i)K. S. Hegde Medical Academy, Deralakatte, Mangaluru (ii) Nitte Usha Institute of Nursing Sciences, Deralakatte, Mangaluru (iii) Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Deralakatte, Mangaluru, (iv) Nitte Institute of Physiotherapy, Deralakatte, Mangaluru under the ambit of Nitte (Deemed to be University), Deralakatte, Mangaluru.

Sd/
(K. P. Singh)
Joint Secretary, University Grants Commission

(True Extract of the Office Memorandum)

NITTE
(Deemed to be University)

(Established under Section 3 of UGC Act, 1956)
Placed under Category 'A' by MHRD, Govt. of India
Accredited with 'A' Grade by NAAC

Ref. No. NU/REG/AC/2016-17/655 Date: 20.03.2017

NOTIFICATION

Subject: Regulations and Curriculum pertaining to Master of Pharmacy

Reference: Minutes of the 31st Academic Council meeting held on 14.03.2017

In exercise of the Powers conferred under Rule R-08 (g) of the Memorandum of Association, the Academic Council has been pleased to approve the Regulations and Course Curriculum for the M.Pharm Course as per the All India Council for Technical Education (AICTE) and Pharmacy Council of India (PCI) norms in the Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences.

The Regulations and course curriculum shall come into force from the academic year 2017- 18.

By Order,

Registrar

NITTE
(Deemed to be University)

(Established under Section 3 of UGC Act, 1956)
Placed under Category 'A' by MHRD, Govt. of India
Accredited with 'A' Grade by NAAC

Ref: NU/REG/AC-NGSMIPS/2018-19/371 **Date: 01.12.2018**

NOTIFICATION

Sub: Guidelines for the change of pharmacy PG specialization.

In exercise of the powers conferred under Rule No. R.9 of the MOA, the Academic Council in its 37th meeting held on 20.11.2018 under the agenda item no. AC/4-37/18 is pleased to approve the guidelines for change of pharmacy PG specialization from the Academic Year 2019-20.

By Order,
REGISTRAR

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(Placed under Category 'A' by MHRD, Govt. of India, Accredited with 'A' Grade by NAAC)
Mangalore, Karnataka, India

Regulations and Curriculum for Master of Pharmacy (M.Pharm)

(Amended up to 2019-20)

Preamble:

Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, imparting education and training in pharmaceutical sciences since 1983, started B. Pharm program in 1984. M.Pharm programs were introduced in 1991. From the year 2009-10 the Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences became a constitute college of Nitte (Deemed to be University). The Pharm.D program was started in the year 2012-13. Consequent to introducing semester system for M.Pharm program as per PCI course regulations 2014, the new regulations are formulated as under:

1. Introduction

1.1. These regulations shall be called as revised regulations for the M.Pharm degree program of Nitte (Deemed to be University). The Regulations for M.Pharm program shall govern the policies and procedures including selection, admission, imparting of instructions, conduct of examinations, evaluation and certification of candidate's performance and all amendments there to, leading to the award of M.Pharm degree. The regulations are in conformance with "The Revised Regulations for M.Pharm. degree program of Pharmacy Council of India" and All India Council for Technical Education (AICTE) regulations of Master of Pharmacy (M.Pharm) degree program.

1.2. This set of regulations shall be binding on all the candidates undergoing the said degree programme. The regulations shall come into effect from the academic year 2019-20.

1.3. These regulations may be modified from time to time as mandated by the statutes of the University, the AICTE and the PCI.

1.4. This set of regulations may evolve and get refined or updated or amended or modified or changed through appropriate approvals from the Academic

Council or the Board of Management from time to time and shall be binding on all parties concerned including the candidates, faculty, staff, departments and institute authorities.

1.5. All disputes arising from this set of regulations shall be addressed to the Board of Management. The decision of the Board of Management is final and binding on all parties concerned. Further, any legal disputes arising out of this set of regulations shall be limited to the jurisdiction of Courts of Mangaluru only.

2. Definitions:

Unless the context otherwise requires

- *Academic Year* means two consecutive (one odd + one even) semesters
- *BOM* means Board of Management of Nitte (Deemed to be University)
- *BOS* means Board of Studies in Pharmaceutical Sciences
- *College/Institution* means Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences
- He includes both genders He and She; similarly his and / or him, himself includes her, as well in all cases
- *Head of the Institution means the Principal of the College (Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences)*
- *Regulations means this set of academic regulations*
- *Regulatory Authority – Authority appointed / constituted by the central / state government/s to regulate Pharmaceutical Sciences Education*
- *University means Nitte (Deemed to be University)*
- *Program means a set of courses which the student has to complete for the award of M.Pharm. degree*
- *Course means a subject or a paper. A course may comprise either theory or practical listed under the program*
- *Credit means a unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture)/journal club/research work presentation/discussion with supervisor or two hours of research work/practical/seminar/assignment/ project work per week.*
- *Semester Grade Point Average (SGPA) means a measure of performance of work done in a semester. It is ratio of total credit points secured by a student in various courses registered in a semester and the total course*

credits taken during that semester. It shall be expressed up to two decimal places

- *Cumulative Grade Point Average (CGPA) means a measure of overall cumulative performance of a student over all semesters. The CGPA is the ratio of total credit points secured by a student in various courses in all semesters and the sum of the total credits of all courses in all the semesters. It is expressed up to two decimal places.*
- *Letter Grade is an index of the performance of a candidate in a said course. Grades are denoted by letters O, A, B, C, D, F and AB.*
- *Grade Point means a numerical weight allotted to each letter grade on a 10-point scale.*
- *IA means Internal Assessment comprising of continuous mode and sessional exams*
- *ESE means End Semester Examination*

3. Minimum qualification for admission

A Pass in the following examination

A candidate seeking admission to M. Pharm course must have a bachelor's degree / B.Pharm degree awarded by an Indian University recognized by PCI/ AICTE and who has secured not less than 55% of the maximum marks (aggregate of four years) prescribed for the qualifying examination shall be eligible for the admission to the M. Pharm course.

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

Foreign nationals who have qualified from a foreign university should obtain permission from the Nitte (Deemed to be University) prior to the admission for equivalence of the degree.

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

4. 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.

5. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

6. Maximum Period for completion of the course:

The maximum period for completion of the M.Pharm course is four years.

7. Selection of eligible candidates:

Selection to the M.Pharm course shall be based on the basis of merit obtained in the qualifying examination.

8. Withdrawal – Temporary and Permanent:

8.1. Temporary withdrawal:

8.1.1. A candidate who has been admitted to the course may be permitted to withdraw temporarily for a period of six months or more upto one year on the grounds of prolonged illness, grave calamity in the family etc., provided:

a) He applied stating the reason of withdrawal with supporting documents and endorsement by parent / guardian.

b) The Institute is satisfied that without counting the period of withdrawal candidate is likely to complete his requirement of the degree within maximum time specified.

c) There are no outstanding dues or demands with the department, library, hostel, Institute etc.

8.1.2. The tuition fee for the subsequent year may be collected in advance based on the severity of the case before giving approval for any such temporary withdrawal.

8.1.3. Scholarship holders are bound by the appropriate rules applicable.

8.1.4. The decision of the Institute / University regarding withdrawal of a candidate is final and binding.

8.2. Permanent withdrawal:

8.2.1. A candidate who withdraws admission before closing date of admission for the academic session is eligible for the refund of the deposit only. The fees once paid will not be refunded on any account.

8.2.2. Once the admission for the year is closed, and if a candidate wantsto leave the Institution, he will be permitted to do so and take the Transfer Certificate from the institute, if required, only after remitting all the tuition fees for the remaining years.

8.2.3. Those candidates who have received any scholarship / stipend / other forms of assistance from the institute shall repay all such amounts in addition to those mentioned in the clause above.

8.2.4. The decision of the institute / university regarding withdrawal of a candidate is final and binding.

9. Conduct and discipline:

9.1. Candidates shall conduct themselves within and outside the premises of the Institute in a manner befitting the student of professional Institution.

9.2. As per the order of Honorable Supreme Court of India, ragging in any form is considered as a criminal offence and is banned. Any form of ragging will be severely dealt with.

9.3. The following act of omission and/or commission shall constitute gross violation of the code of conduct and are liable to invoke disciplinary measures:

9.3.1. Ragging as defined and described by the Supreme Court/Government.

9.3.2. Lack of courtesy and decorum; indecent behaviour anywherewithin or outside the campus.

9.3.3. Willful damage or stealthy removal of any property/belongings ofthe College/Hostel or of fellow candidates/citizens.

9.3.4. Possession, consumption or distribution of alcoholic drinks or anykind of hallucinogenic drugs.

9.3.5. Mutilation or unauthorized possession of library books.

9.3.6. Noisy or unseemly behavior, disturbing studies of fellowcandidates.

9.3.7. Hacking in computer systems (such as entering into other person's domain without prior permission, manipulation and/or damage to the computer hardware and software or any other cyber crime etc.)

9.3.8. Plagiarism of any nature.

9.3.9. Any other act of gross indiscipline as decided by the Board of management from time to time.

9.4. Commensurate with the gravity of offense, the punishment may be: reprimand, fine, expulsion from the hostel, debarment from an examination, disallowing the use of certain facilities of the Institute, rustication for a specific period or even outright expulsion from the Institute, or even handing over the case to appropriate law enforcement authorities or the judiciary, as required by the circumstances.

9.5. For any offence committed in (i) a hostel (ii) a department or in a classroom and (iii) elsewhere, the Chief Warden, the Head of the Department and the Head of the Institution, respectively, shall have the authority to reprimand or impose fine.

9.6. All cases involving punishment other than reprimand shall be reported to the Vice- chancellor.

9.7. Cases of adoption of unfair means and/or any malpractice in an examination shall be reported to the Controller of Examinations for taking appropriate action.

10. 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 July/August to December/January and the even semesters shall be conducted from the month of January/February to June/July in every calendar year.

11. Attendance and Monitoring Progress of Students:

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.

11.1. Attendance

11.1.1. A candidate pursuing M.Pharm course shall study in the concerned Department of the Institution for the entire period as a full time candidate. No candidate is permitted to work in any laboratory / Institution / industry / pharmacy, etc., during the period of study. No candidate should join any other course of study or appear for any other degree examination conducted by this university or any other university in India or abroad during

the period of registration.

11.1.2. Each semester shall be taken as a unit for the purpose of calculating attendance.

11.1.3. A student shall attend symposia, seminars, conferences, journal review meetings, journal club and lectures during each semester as prescribed by the department / college / university and not absent himself / herself without valid reason.

11.1.4. A candidate who has put in a minimum of 80% of attendance in the theory and practical assignments separately and who has fulfilled all other requirements of the course shall be permitted to appear for the semester end examination.

11.1.5. Only the candidate who has put in a minimum of 80% of attendance in II year shall be eligible to submit the dissertation.

11.2. Monitoring Progress of Studies:

11.2.1. A student shall maintain a work diary and record of his participation in the training programmes such as review of journal, seminars etc. conducted by the department / institution.

11.2.2. The work diary shall be scrutinized and certified by the Head of the Department and Head of the Institution, and presented in the University practical examination.

11.2.3. Special mention may be made of the presentations by the student as well as details of experiments or laboratory procedures, conducted by the student.

12. 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.

12.1. Credit assignment

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 (½) 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.

12.2. Minimum credit requirements

The minimum credit points required for the award of M.Pharm degree is 93. A student may earn upto a maximum of 98 credit points including the 5 credit points assigned to co-curricular and extra-curricular activities. 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 10. 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.

13. Academic work:

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

14. Course of study:

14.1. The specializations offered in M.Pharm program are listed in Table 1. Students have to opt for one of the specializations at the time of admission.

14.2. Change of Specialization after admission:

1. Request for change of departments should be made within 15 daysof the commencement of PG programmes which should be endorsed by the parents.
2. The reason for change should be clearly explained by the student.
3. The NOC from both the department heads should be obtained.
4. There should be vacancy in the department where the student wishes to join.
5. To avoid such requests, the department heads should conduct induction/orientation programme for atleast a week to the studentswho join the programme explaining the methods, objectives, skillsrequired etc.. for the program.
6. In case the transfer is approved, the department to which the student migrates should conduct classes which the student has missed and maintain relevant records.
7. The last date for withdrawal should be at least 15 days earlier than the last date of admission with fine, so that the vacancy created canbe filled.

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

S. No.	Specialization	Code
1.	Pharmaceutics	MPS
2.	Pharmaceutical Chemistry	MPC
3.	Pharmaceutical Quality Assurance	MQA
4.	Pharmaceutical Regulatory Affairs	MRA
5.	Pharmacy Practice	MPP
6.	Pharmacology	MPY

14.3 The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Tables 2 to 7. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in the tables.

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

Course Code	Course	Credit Hours	Credit Points	Hrs. / wk	Marks
Semester I					
17MPS11	Modern Pharmaceutical Analytical Techniques	4	4	4	100
17MPS12	Drug Delivery Systems	4	4	4	100
17MPS13	Modern Pharmaceutics	4	4	4	100
17MPS14	Regulatory Affair	4	4	4	100
17MPS15P	Pharmaceutics Practicals I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
17MPS21	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
17MPS22	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
17MPS23	Computer Aided Drug Development	4	4	4	100
17MPS24	Cosmetics and Cosmeceuticals	4	4	4	100
17MPS25P	Pharmaceutics Practical - II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 3: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
17MPC11	Modern Pharmaceutical Analytical Techniques	4	4	4	100
17MPC12	Advanced Organic Chemistry -I	4	4	4	100
17MPC13	Advanced Medicinal chemistry	4	4	4	100
17MPC14	Chemistry of Natural Products	4	4	4	100
17MPC15P	Pharmaceutical Chemistry Practical -I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
17MPC21	Advanced Spectral Analysis	4	4	4	100
17MPC22	Advanced Organic Chemistry -II	4	4	4	100
17MPC23	Computer Aided Drug Design	4	4	4	100
17MPC24	Pharmaceutical Process Chemistry	4	4	4	100
17MPC25P	Pharmaceutical Chemistry Practical - II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 4: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
17MQA11	Modern Pharmaceutical Analytical Techniques	4	4	4	100
17MQA12	Quality Management System	4	4	4	100
17MQA13	Quality Control and Quality Assurance	4	4	4	100
17MQA14	Product Development and Technology Transfer	4	4	4	100
17MQA15P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Semester II					
Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./ wk**	**Marks**
17MQA21	Hazards and Safety Management	4	4	4	100
17MQA22	Pharmaceutical Validation	4	4	4	100
17MQA23	Audits and Regulatory Compliance	4	4	4	100
17MQA24	Pharmaceutical Manufacturing Technology	4	4	4	100
17MQA25P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 5: Course of study for M. Pharm. (Pharmaceutical Regulatory Affairs)

Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./ wk**	**Marks**
Semester I					
17MRA11	Good Regulatory Practices	4	4	4	100
17MRA12	Documentation and Regulatory Writing	4	4	4	100
17MRA13	Clinical Research Regulations	4	4	4	100
17MRA14	Drugs Regulations and other Legislation in India and Intellectual Property Rights	4	4	4	100
17MRA15P	Regulatory Affairs Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
17MRA21	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
17MRA22	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
17MRA23	Regulatory Aspects of Medical Devices	4	4	4	100
17MRA24	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
17MRA25P	Regulatory Affairs Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 6: Course of study for M. Pharm. (Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
17MPP11	Clinical Pharmacy Practice	4	4	4	100
17MPP12	Pharmacotherapeutics-I	4	4	4	100
17MPP13	Hospital & Community Pharmacy	4	4	4	100
17MPP14	Clinical Research	4	4	4	100
17MPP15P	Pharmacy Practice Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
17MPP21	Principles of Quality Use of Medicines	4	4	4	100
17MPP22	Pharmacotherapeutics II	4	4	4	100
17MPP23	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
17MPP24	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
17MPP25P	Pharmacy Practice Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 7: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
17MPY11	Modern Pharmaceutical Analytical Techniques	4	4	4	100
17MPY12	Advanced Pharmacology-I	4	4	4	100
17MPY13	Pharmacological and Toxicological Screening Methods – I	4	4	4	100
17MPY14	Cellular and Molecular Pharmacology	4	4	4	100
17MPY15P	Pharmacology Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Semester II					
Course Code	**Course**	**Credit Hours**	**Credit Points**	**Hrs./ wk**	**Marks**
17MPY21	Advanced Pharmacology-II	4	4	4	100
17MPY22	Pharmacological and Toxicological Screening Methods – II	4	4	4	100
17MPY23	Principles of Drug Discovery	4	4	4	100
17MPY24	Clinical Research and Pharmacovigilance	4	4	4	100
17MPY25P	Pharmacology Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table 8: Course of Study for M.Pharm III Semester (Common for all Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Discussion / Presentation (proposal Presentation)	2	2
-	Research Work	28	14
Total		**35**	**21**

***Non University Examination**

Table 9: Course of Study for M.Pharm IV Semester (Common for all Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion / Final Presentation	3	3
	Total	35	20
-	Co-curricular and extra-curricular activities	5	5
Grand total		**40**	**25**

Table 10: Semester Wise Credit Distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular and extra-curricular activities	5
Grand total	**98**

Table 11: Guidelines for awarding credit points for co-curricular and extracurricular activities

Sl.No.	Name of the Activity	Marks	Evidence
1.	Participation in National Level seminar/ Conference/ Workshop / Symposium /Training Programs (related to the specialization of the student)	10	Participation certificate issued bythe organizers
2.	Participation in international Level Seminar/ Conference /Workshop /Symposium /Training Programs (related to the specialization of the student)	20	Participation certificate issued bythe organizers
3.	Academic Award /Research Award from State Level /National Agencies	10	Award certificate
4.	Academic Award /Research Award from International Agencies	20	Award certificate
5.	Research / Review Publication as first author in National /international Journals (Indexed in Scopus / Web of Science)	20	Publication re print
6.	Research / Review papers as first author communicated to national /International Journals (Indexed in Scopus / Web of Science)	10	Proof of communication
7.	Active involvement in organizing seminars /guest lectures etc. of the department	05/event	Certification by event coordinator & guide
8.	Contribution to institutional publication such as NGSM Herald, Pharmacy practice communicator	05/ contribution	Proof of contribution
9.	Active participation in sports	05	Certification by Physical Director and Guide
10.	Participation in annual day, cultural day, national festivals such as independence day, republic day etc.	2 marks/ event	Certification by event coordinator &guide
11.	Participation in NSS activities of the college	02 marks/ program	Certification by NSS coordinator & guide
12.	Participation in the campus placement activities/interviews	05/partici pation	Certification by Placement officer & guide
13.	Involvement in guiding the junior students by delivering special talks to UG and diploma students	05	Certification by the guide with proof
14.	General skills, attitude and contribution to the vision and mission of the college	05	Certification by Guide
15.	Industrial visit/tour	05	Report on the industrial visit
16.	Any other significant curricular / extra-curricular activity as certified by Heads of the department	05	Certification by the HoDs

The credit points assigned for extra-curricular and co-curricular activities shall be earned by the students on the basis of their performance in defined activities. The assessment of the extra-curricular and co-curricular attainment shall be made by the activity coordinators, guides and the heads of the departments. The marks obtained by the students shall be sent to the University by the Head of the Institution. However, the maximum marks for these activities shall not exceed 50. The marks obtained by the students shall be converted into letter grades and grade points as indicated in Table 22, which shall be taken into account while calculating CGPA. The criteria to acquire this credit point shall be defined by the college from time to time.

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

15. 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.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

16. Examinations / Assessments:

The schemes for internal assessment and end semester examinations are given in Table 12-18

16.1. End Semester Examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the university except for the subject with asterisk symbol (*) in table 8 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Table 12: Schemes for internal assessments and end semester examinations (Pharmaceutics – MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MPS11	Modern Pharmaceutical Analytical Techniques	10	15	1½ Hr	25	75	3 Hrs	100
17MPS12	Drug Delivery System	10	15	1½ Hr	25	75	3 Hrs	100
17MPS13	Modern Pharmaceutics	10	15	1½ Hr	25	75	3 Hrs	100
17MPS14	Regulatory Affairs	10	15	1½ Hr	25	75	3 Hrs	100
17MPS15P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MPS21	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1½ Hr	25	75	3 Hrs	100
17MPS22	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1½ Hr	25	75	3 Hrs	100
17MPS23	Computer Aided Drug Development	10	15	1½ Hr	25	75	3 Hrs	100
17MPS24	Cosmetic and Cosmeceuticals	10	15	1½ Hr	25	75	3 Hrs	100
17MPS25P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table 13: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry - MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MPC11	Modern Pharmaceutical Analytical Techniques	10	15	1½ Hr	25	75	3 Hrs	100
17MPC12	Advanced Organic Chemistry -I	10	15	1½ Hr	25	75	3 Hrs	100
17MPC13	Advanced Medicinal chemistry	10	15	1½ Hr	25	75	3 Hrs	100
17MPC14	Chemistry of Natural Products	10	15	1½ Hr	25	75	3 Hrs	100
17MPC15P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MPC21	Advanced Spectral Analysis	10	15	1½ Hr	25	75	3 Hrs	100
17MPC22	Advanced Organic Chemistry -II	10	15	1½ Hr	25	75	3 Hrs	100
17MPC23	Computer Aided Drug Design	10	15	1½ Hr	25	75	3 Hrs	100
17MPC24	Pharmaceutical Process Chemistry	10	15	1½ Hr	25	75	3 Hrs	100
17MPC25P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment		-	-	-	-	-	100
Total								**650**

Table 14: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance - MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MQA11	Modern Pharmaceutical Analytical Techniques	10	15	1½ Hr	25	75	3 Hrs	100
17MQA12	Quality Management System	10	15	1½ Hr	25	75	3 Hrs	100
17MQA13	Quality Control and Quality Assurance	10	15	1½ Hr	25	75	3 Hrs	100
17MQA14	Product Development and Technology Transfer	10	15	1½ Hr	25	75	3 Hrs	100
17MQA15P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MQA21	Hazards and Safety Management	10	15	1½ Hr	25	75	3 Hrs	100
17MQA22	Pharmaceutical Validation	10	15	1½ Hr	25	75	3 Hrs	100
17MQA23	Audits and Regulatory Compliance	10	15	1½ Hr	25	75	3 Hrs	100
17MQA24	Pharmaceutical Manufacturing Technology	10	15	1½ Hr	25	75	3 Hrs	100
17MQA25P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table 15: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs - MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MRA11	Good Regulatory Practices	10	15	1½ Hr	25	75	3 Hrs	100
17MRA12	Documentation and Regulatory Writing	10	15	1½ Hr	25	75	3 Hrs	100
17MRA13	Clinical Research Regulations	10	15	1½ Hr	25	75	3 Hrs	100
17MRA14	Drugs Regulations and other Legislation in India and Intellectual Property Rights	10	15	1½ Hr	25	75	3 Hrs	100
17MRA15P	Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MRA21	Regulatory Aspects of Drugs & Cosmetics	10	15	1½ Hr	25	75	3 Hrs	100
17MRA22	Regulatory Aspects of Herbal & Biologicals	10	15	1½ Hr	25	75	3 Hrs	100
17MRA23	Regulatory Aspects of Medical Devices	10	15	1½ Hr	25	75	3 Hrs	100
17MRA24	Regulatory Aspects of Food & Nutraceuticals	10	15	1½ Hr	25	75	3 Hrs	100
17MRA25P	Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**

Table 16: Schemes for internal assessments and end semester examinations (Pharmacy Practice - MPP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MPP11	Clinical Pharmacy Practice	10	15	1½ Hr	25	75	3 Hrs	100
17MPP12	Pharmacotherapeutics-I	10	15	1½ Hr	25	75	3 Hrs	100
17MPP13	Hospital & Community Pharmacy	10	15	1½ Hr	25	75	3 Hrs	100
17MPP14	Clinical Research	10	15	1½ Hr	25	75	3 Hrs	100
17MPP15P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MPP21	Principles of Quality Use of Medicines	10	15	1½ Hr	25	75	3 Hrs	100
17MPP22	Pharmacotherapeutics II	10	15	1½ Hr	25	75	3 Hrs	100
17MPP23	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1½ Hr	25	75	3 Hrs	100
17MPP24	Pharmacoepidemiology & Pharmacoeconomics	10	15	1½ Hr	25	75	3 Hrs	100
17MPP25P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table 17: Schemes for internal assessments and end semester examinations (Pharmacology - MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
17MPY11	Modern Pharmaceutical Analytical Techniques	10	15	1½ Hr	25	75	3 Hrs	100
17MPY12	Advanced Pharmacology-I	10	15	1½ Hr	25	75	3 Hrs	100
17MPY13	Pharmacological and Toxicological Screening Methods - I	10	15	1½ Hr	25	75	3 Hrs	100
17MPY14	Cellular and Molecular Pharmacology	10	15	1½ Hr	25	75	3 Hrs	100
17MPY15P	Pharmacology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar /Assignment	-	-	-	-	-	-	100
Total								**650**
Semester II								
17MPY21	Advanced Pharmacology-II	10	15	1½ Hr	25	75	3 Hrs	100
17MPY22	Pharmacological and Toxicological Screening Methods – II	10	15	1½ Hr	25	75	3 Hrs	100
17MPY23	Principles of Drug Discovery	10	15	1½ Hr	25	75	3 Hrs	100
17MPY24	Clinical Research and Pharmacovigilance	10	15	1½ Hr	25	75	3 Hrs	100
17MPY25P	Pharmacology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
	Seminar/Assignment	-	-	-	-	-	-	100
Total								**650**

Table 18: Schemes for internal assessments and end semester examinations (Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1½ Hr	25	75	3 Hrs	100
-	Journal Club	-	-	-	25	-	-	25
-	Discussion / Presentation (proposal Presentation)	-	-	-	50	-	-	50
-	Research Work*	-	-	-	-	350	1 Hr	350
Total								**525**
Semester IV								
-	Journal Club				25	-	-	25
-	Discussion / Final Presentation				75	-	-	75
-	Research Work and Colloquium				-	400	1 Hr	400
Total								**500**

*Non University Examination

16.2. Internal Assessment: Continuous Mode

The marks allocated for Continuous mode of Internal Assessment shallbe awarded as per the scheme given below:

Table 19: Scheme for awarding internal assessment: Continuous Mode

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

Table 20: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95–100	8	10
90-94	6	7.5
85-89	4	5.0
80-84	2	2.5
Less than 80	0	0

16.2.1. Sessional Exams

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

Question paper pattern for sessional theory examinations

1. Long Answers (Answer 1 out of 2) - 1 x 10 = 10
2. Short Answers (Answer 4 out of 5) - 4 x 5 = 20

=========

Total = 30 Marks

=========

Question paper pattern for sessional Practical examinations

1. Synopsis - 10
2. Experiment – I (Core Subject) - 25
3. Experiment – II (MPAT) - 15
4. Viva voce - 10

==========

Total = 60 Marks

==========

Question Paper pattern - Modern Pharmaceutical Analytical Techniques (MPAT)

Sessional Practical examinations

	Core subject	MPAT	Total
Synopsis	07	03	10
Experiment-I	25	-	25
Experiment-II	-	15	15
Viva-voce	08	02	10
Total	**40**	**20**	**60**

Scheme for awarding internal assessment in continuous mode

	Core subject	MPAT	Total
Attendance	07	03	10
Practical records and viva voce	07	03	10
Total	**14**	**06**	**20**

17. Promotion and award of grades:

A candidate shall be declared as pass if he secures 50% of marks (including internal assessment) in each subject in theory and practical examination separately in each semester provided he/she secures a minimum of 40% marks in internal assessment and end semester university examinations.

Theory and practical subjects are considered as independent subjects. The candidate who fails either in theory or practical subject has to appear only in theory or practical as the case may be in the subsequent examinations.

18. Carry forward of marks:

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

19. Improvement of internal assessment:

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

20. Re-examination of end semester examinations:

Re-examination of end semester examination shall be conducted as per the schedule given in table 21. The exact dates of examinations shall be notified from time to time.

Table – 21: Tentative schedule of end semester examinations

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

Question paper pattern for end semester theory examinations

1. Long Answers (Answer 3 out of 4) - 3 x 10 = 30
2. Short Answers (Answer 9 out of 11) - 9 x 5 = 45

Total =75 Marks

Question paper pattern for end semester Practical examinations

1. Synopsis - 15
2. Experiment – I - 40
3. Experiment – II - 30
4. Viva voce - 15

Total = 100 Marks

Question Paper pattern for **end semester Practical examinations** -
Modern Pharmaceutical Analytical Techniques (MPAT)

	Core subject	MPAT	Total
Synopsis	10	05	15
Experiment 1	30	10	40
Experiment 2	20	10	30
Viva-voce	10	5	15
Total	**70**	**30**	**100**

Question paper pattern for sessional Practical examinations

	Core subject	MPAT	Total
Synopsis	04	02	06
Experiment 1	12	06	18
Viva-voce	04	02	06
Total	**20**	**10**	**30**

Scheme for awarding internal assessment in continuous mode

	Core subject	MPAT	Total
Attendance	07	03	10
Practical records& Viva Voce	07	03	10
Total	14	06	20

21. Allowed To Keep Terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 11. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters to III semester. However, the student will be permitted to appear for the viva voce examination only after clearing all the courses of I, II and III Semesters.

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

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

22. 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 – 22.

Table – 22: Letter grades and grade points equivalent to Percentage of marks and performances

Marks Range (%)	Grade Point	Letter Grade	Description	
90 & Above	10	O	Outstanding	First Class with Distinction
80-89.9	09	A	Excellent	
75-79.9	08	B	Very Good	
60-74.9	07	C	Good	First Class
55-59.9	06	D	Fair	Second Class
50-54.9	05	E	Average	Pass
Less than 50	0	F	Fail	Fail
Absent	0	AB	Fail	Fail

A student who remains absent for any semester end 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.

23. 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:

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

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, the SGPA shall then be computed as:

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

24. Cumulative Grade Point Average (CGPA):

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

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

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,…. .

25. Declaration of Results and Classification:

The class shall be awarded to those who pass the examination in first attempt

on the basis of CGPA as follows:

First Class with Distinction : CGPA 7.50 and above
First Class : CGPA 6.00 to 7.49
Second Class : CGPA 5.00 to 5.99

Candidates who pass the examination in more than one attempt shall be declared as passed in "pass" class irrespective of the percentage of marks secured.

An attempt means the appearance of a candidate for one or more courses either in part or full in a particular examination.

A candidate who fails in main examination and passes one or more subjects or all subjects in the supplementary examination is not eligible for award of class or distinction. Passing in supplementary examination by such candidates shall be considered as attempt.

If a candidate submits application for appearing for the regular examination but does not appear for any of the courses/subjects in the regular University examination, he can appear for supplementary examination provided other conditions such as attendance requirement, internal assessment marks, etc. are fulfilled and his appearing in the supplementary examination shall be considered as the first attempt.

Candidates who pass the subjects in the supplementary examinations are not eligible for the award of Gold Medal or Merit Certificate.

26. Project work (Dissertation):

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

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

Evaluation of Dissertation Book:	
Objective(s) of the work done	25 Marks
Methodology adopted	75 Marks
Results and Discussions	100 Marks
Conclusions and Outcomes	50 Marks
Total	**250 Marks**

Evaluation of Presentation:	
Presentation of work	75 Marks
Communication skills	50 Marks

Question and answer skills	25 Marks
Total	**150 Marks**

The minimum Marks for Pass in the dissertation is 50% of marks of the aggregate marks for University Evaluation.

27. Dissertation

As a partial requirement of the course, a candidate is required to carry out a study in a select area of his specialty, under the supervision of a faculty Guide. The results of such a study shall be submitted to the University in the form of a dissertation as per the prescribed format and within the date stipulated by the University. Only a candidate who has put in a minimum of 80% attendance in the second year be eligible to submit the dissertation. The dissertation is aimed at training a postgraduate candidate in research methodology and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis and comparison of results and drawing conclusions.

27.1. Schedule

Submission of the synopsis to the University	Within one month of the commencement of II semester
Ethical clearance	Fifteen days before the end of second semester
Final submission of the dissertation	1 month before the IV semester University examination or as per dates specified by the University

27.2. Guide

A guide shall be a full time post graduate teacher of the Institution and recognized by the University as a Guide for supervision of dissertation work. However, a co- guide can be opted wherever required with prior permission of the Institution and University. The co-guide shall also be a postgraduate teacher recognized by the University as Guide. In the event of registered guide leaving the Institution or in the event of death of the guide, a change of guide shall be permitted by the University, on the specific recommendation of the Institution.

27.3. Ethical Clearance:

Ethical clearance should be obtained for a study involving any procedure

on human subject. A candidate should apply for the certificate to the Ethics Committee of the Institute, through the Guide and present the study before the Committee for clearance. A copy of the certificate should be attached along with the synopsis forwarded at the time of approval of synopsis. All such clearance should be sought within six months of the commencement of the course.

27.4. Submission of Synopsis

A candidate shall submit a synopsis to the University through the Guide and Head of the Institution, not later than nine months from the commencement of the I year OR within the date notified by the University, whichever is earlier. Once the synopsis is approved and registered by the University no change in the topic or Guide shall be made without the prior approval of the University.

27.5. Preparation of Dissertation:

a. The dissertation should be written under the following headings and order:
   i. Introduction
   ii. Aims or Objectives of the study
   iii. Review of literature
   iv. Material and methods
   v. Results
   vi. Discussion
   vii. Summary and Conclusions
   viii. References
   ix. Tables
   x. Annexure
b. The written text of dissertation shall be not less than 75 pages and shall not exceed 200 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed with double line spacing on one side of the bond paper (A4 size, 8.27" x 11.69") and bound properly. Spiral binding should be avoided.

27.6. Submission of Dissertation:

The final dissertation in the prescribed format and certified by the Guide and co-guide if any, Head of the Department and Head of the Institution should be submitted to the University one month before the final examination or as notified by the University.

27.7. Viva-Voce Examination:

The Viva-Voce examination shall aim at assessing the depth of knowledge, logical reasoning, confidence and oral communication skills.

The Viva-Voce examination shall be held after the submission of dissertation. If any candidate fails to submit the dissertation on or before the date prescribed, his Viva-Voce shall be conducted during the subsequent examination.

28 Graduation Requirements:

A candidate shall be declared eligible for the award of the degree if he has:

- Fulfilled Degree Requirement
- No dues to the University, Institute, Departments, Hostels, Library etc.
- No disciplinary action pending against him.

The award of the degree must be recommended by the Board of Management.

29 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.

30 Award of degree:

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

31 Revaluation / Re-totaling of answer papers:

There is no provision for revaluation of the answer papers in any examination. The candidates can apply for retotaling/photocopy of the answer scripts by paying prescribed fee.

32 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.

33 Convocation:

Degrees will be awarded in person for the candidates who have graduated during the preceding academic year. Degrees will be awarded in absentia to such candidates who are unable to attend the convocation. Candidates are required to apply for the convocation along with prescribed fee within the specified date, after having satisfactorily completed all degree requirements of the course.

Provisional pass certificate will be issued by the University provided the candidate fulfills requirements mentioned in clause (11) above. The provisional certificate will be issued on submission of an application through the college and will be valid until the convocation.

GUIDELINES FOR PHARMACY STUDENTS FOR CARRYING OUT INDUSTRIAL PROJECTS IN PARTIAL FULFILLMENT OF M.PHARM DEGREE

Preamble:

In an attempt to increase industry-academic collaboration, it was proposed to permit certain percentage of M.Pharm students to pursue the research work leading to the dissertation work of II year M.Pharm course at pharmaceutical industry/research laboratories of public or private section. The long term benefits of such initiatives are:

1. Possible better placement opportunities
2. Exposure to industrial environment while being a student
3. Institution-industry collaboration may result in funded projects from the industry
4. Relevance of curriculum up gradation.

In the past, some colleges have practiced this.

Care to be taken by the sponsoring institution to see that students pursue the projects seriously, serious monitoring of the work being done and work taken up is of high standard.

Guidelines:

1. The candidates desire of doing the projects in industry, after preliminary home work of selection of industry, co guide and project title, shall apply to the principal at least one month prior to the start of II Sem. M.Pharm University Examinations.
2. The Principal along with the Committee appointed for the purpose of scrutinizing the applications shall select and approve the projects with the following conditions:
    i. Not more than 30% of students from each branch will be permitted.
    ii. Not more than one student from the institutional guide will be permitted
    iii. The industry/research lab should be approved by the College/University. (The candidate has to supply the particulars regarding the organization and co-guide).
    iv. The name of the co-guide should be approved by the University BOS in the faculty.

v. The candidates will be selected on the basis of merit (B.Pharm marks and M.Pharm internal assessment marks)
vi. Only those students who have put minimum of 80% attendance and have passed all the subjects in I year M.Pharm will be eligible.

3. The candidates shall submit the project protocol along with the application to the college duly endorsed by the guide and co-guide.
4. The student shall do the project work at the selected centre for a minimum of 180 days and maximum of 220 days
5. Letter of consent from the co-guide and No Objection from the Project Centre Headshould be produced along with the application.
6. The first, second and third presentation of the Protocol by the student will be at the institution.

Minimum qualification for Co- guideship for M.Pharm.

- Industrial Pharmacy: M. Pharm or Ph.D. with 3 years of experience in manufacturing or in R & D / Quality Control in a reputed pharmaceutical industry.
- Pharmacy Practice: A recognized PG teacher of Nitte (Deemed to be University) belonging to any faculty of health sciences from any affiliated colleges having approved post graduate courses.
- A co-guide can guide a maximum of two students at a time.

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PHARMACEUTICS (MPS)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (17MPS11)

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

Course Outcome

At the end of the course students will be able to...

CO1	Explain general principles and theory of spectroscopy
CO2	Understand the basic instrumentation of HPTLC, HPLC, GC for identification, and characterization of compounds
CO3	Understand the basic concept and instrumentation of Chromatographic techniques
CO4	Learn various separation techniques by employing chromatographic methods
CO5	Understand the basic principles and instrumentation of fluorimeter and atomic absorption spectrometer
CO6	Learn general principles and instrumentation of ion selective electrodes.
CO7	Identify organic compounds by –X-ray crystallography
CO8	Explain Instrumentation, separation and identification of compounds by electrophoresis technique.

Units	Contents	Hours
1	a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice Hrs 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	10

	fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	10
5	a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the Hrs 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.	10
6	a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. b. **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	10

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 (17MPS12)

Scope

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

Course Outcome

At the end of the course students will be able to...

CO1	Select drugs as suitable candidates for various novel drug delivery systems based on their physic-chemical properties
CO2	Select polymers, retardants and other additives based on the requirements and desired characteristics of the drug delivery system
CO3	Formulate and design controlled release and sustained release drug delivery systems.
CO4	Evaluate drug delivery systems for physic-chemical characteristics, in vitro and in vivo drug release
CO5	Conduct stability studies for dosage forms as per prescribed guidelines
CO6	Describe the importance of personalized medicine in the optimization of therapy in patients
CO7	Develop the concept of Telepharmacy to benefit hospitals and clinics without direct access to a pharmacist
CO8	Apply knowledge of protein drugs and biological products such as vaccines in their development and evaluation

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

2	**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10
3	**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10
4	**Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.	06
5	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10
6	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08
7	**Vaccine delivery systems**: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06

References

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

Journals

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

MODERN PHARMACEUTICS (17MPS13)

Scope

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

Course Outcome

At the end of the course students will be able to...

CO1	Understand the concept and importance of preformulation parameters
CO2	Know the compression and consolidation parameters for powders and granules in tablet development.
CO3	Apply the statistical design in the development of different formulations.
CO4	Have knowledge of optimization techniques and their applications in pharmaceutical industries.
CO5	Know the scope and merits of validation and different types of validation
CO6	Understand the importance of industrial management principles and GMP Considerations.
CO7	Understand the importance of materials management and production management in pharmaceutical industries
CO8	Know the ICH and WHO guidelines for calibration and validation of equipments

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

2	**Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10
3	**cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, Hrs services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10
4	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10
5	**Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10

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 (17MPS14)

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

Course Outcome

At the end of the course students will be able to...

CO1	Discuss the concept of innovator and generic drugs, drug development process
CO2	Discuss the regulatory guidance's and guidelines for filing and approval process
CO3	Categorize the preparation of dossiers and their submission to regulatory agencies in different countries
CO4	Assess the post approval requirements for actives and drug products
CO5	Enumerate the documents required for submission in CTD/eCTD
CO6	Describe the clinical trials requirements for approvals for conducting clinical trials
CO7	Discuss the concept of non-clinical drug development
CO8	Discuss the role of pharmacovigilance and the process of monitoring in clinical trials

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

2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12
3	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12
4	**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12

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 (17MPS15P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. 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) (17MPS21)

Scope

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

Course Outcome

At the end of the course students will be able to...

CO1	Design drug delivery systems for targeting drugs to tumours and to the brain
CO2	Prepare and evaluate nanoparticles and liposomes as carriers for drug targeting
CO3	Select drugs and polymers in the design of microspheres and microcapsules for various applications.
CO4	Formulate aquasomes, niosomes, phytosomes and electrosomes for various applications in drug targeting
CO5	Develop strategies for improving nasal absorption in the design of nasal drug delivery systems
CO6	Optimize pulmonary delivery by the design of suitable aerosols, nebulizers and dry powder inhalers
CO7	Apply knowledge of antisense molecules and aptamers in the design of novel drug delivery systems
CO8	Apply gene therapy in the treatment of cancer and inherited diseases

Units	Contents	Hours
1	**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Hrs Brain specific delivery.	12
2	**Targeting Methods:** introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12
3	**Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies: preparation and application, Hrs preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12
4	**Pulmonary Drug Delivery Systems:** Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12

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

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 (17MPS22)

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.

Course Outcome

At the end of the course students will be able to...

CO1	Explain mechanism of drug absorption &various factors affecting drug absorption
CO2	Learn various biopharmaceutic factors affecting drug bioavailability
CO3	Learn various method of dissolution testing. *In vitro–in vivo* correlation dissolution data.
CO4	Understand basic considerations of pharmacokinetic models. Understand different compartment model and non-compartment model
CO5	Explain the design and evaluation of dosage regimens of the drugs using pharmacokinetic and `biopharmaceutic parameters.
CO6	Learn different types of drug interactions which alter the pharmacokinetics of such as drug-protein /drug-tissue binding interactions
CO7	Elaborate design Bioavailability and Bioequivalence studies of new drugs or dosage forms
CO8	Study the application of pharmacokinetics and pharmacodynamics of biotechnology drugs.

Units	Contents	Hours
1	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH– partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods ,Formulation and processing factors	12

	Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	
2	**Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	12
3	**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue- binding interactions,cytochrome p450-based drug interactions, drug interactions linked to transporters.	12
4	**Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In- vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12

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

References

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded 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, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT (17MPS23)

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.

Course Outcome

At the end of the course students will be able to...

CO1	Understand the applications of computers in pharmaceutical product development
CO2	Learn statistical modeling principles & optimization using computer applications
CO3	Understand the basics of Quality by design in formulation development
CO4	Know the basic computational modeling principles for drug disposition
CO5	Learn computer aided biopharmaceutical characterization of drugs
CO6	Learn computer simulation in pharmacokinetics and pharmacodynamics
CO7	Study the use of computers in clinical development of drugs
CO8	Undertand the need of industrial automation by application of artificial intellingence, robotics and computational fluid dynamics

Units	Contents	Hours
1	a. **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Hrs Pharmaceutical Research and Development. Statistical modelingin Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling	12

	b. **Quality-by-Design in Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	
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.	12
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	12
4	a. **Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations b. **Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. **Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems	12
5	**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12

References

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

COSMETICS AND COSMECEUTICALS (17MPS24)

Scope

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

Course Outcome

At the end of the course students will be able to...

CO1	Describe the regulatory provisions related to the import and manufacture of cosmetics as per the Drugs and Cosmetics Act 1940 and the Rules 1945
CO2	Select key ingredients suitable in the formulation of various cosmetics
CO3	Explain the various problems related to the skin and hair
CO4	Design cosmetics that take care of cleansing needs ofthe face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm
CO5	Design cosmetics and cosmeceuticals with desired safety, stability and efficacy with a knowledge of the various technologies involved in their manufacture
CO6	Design cosmeceuticals for sun protection, dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth
CO7	Select herbal ingredients in the formulation of cosmetics for hair care, skin care and oral care
CO8	Describe the guidelines for the regulation of herbal cosmetics by private bodies

Units	Contents	Hours
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.	12
2	**Cosmetics - Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly hat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12

3	**Formulation Building blocks:** Building blocks for different 12 product formulations of cosmetics/cosmeceuticals. Surfactants – Hrs Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. **Perfumes:** Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. **Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.	12
4	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun- protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	12
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.	12

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 (17MPS25P)

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® 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

PHARMACEUTICAL CHEMISTRY (MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (17MPC11)

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.

Course Outcome

At the end of the course students will be able to...

CO1	Explain general principles and theory of spectroscopy
CO2	Understand the basic instrumentation of HPTLC, HPLC, GC for identification, and characterization of compounds
CO3	Understand the basic concept and instrumentation of Chromatographic techniques
CO4	Learn various separation techniques by employing chromatographic methods
CO5	Understand the basic principles and instrumentation of fluorimeter and atomic absorption spectrometer
CO6	Learn general principles and instrumentation of ion selective electrodes.
CO7	Identify organic compounds by –X-ray crystallography
CO8	Explain Instrumentation, separation and identification of compounds by electrophoresis technique.

Units	Contents	Hours
1	a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 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.	10

	c. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	10
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	10

	b. **X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	
6	a. **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. b. **Thermal Techniques:** Principle, thermal transitions andInstrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. c. **Immunological assays:** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	10

References

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

ADVANCED ORGANIC CHEMISTRY - I (17MPC12)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Course Outcome

At the end of the course students will be able to...

CO1	Explain the different organic intermediates involved in determining the reaction mechanism
CO2	Explain SN_1, SN_2 and E_1, E_2 mechanism
CO3	Discuss the mechanism and applications of various named reactions
CO4	Explain the applications of various synthetic reagents
CO5	Explain the various protecting and de-protecting groups
CO6	Explain the chemistry, synthesis and mechanism of reactions in heterocyclic compounds
CO7	Explain the principle and applications of retrosynthesis
CO8	Discuss the disconnection approach to develop synthetic routes for small target molecule

Units	Contents	Hours
1	**Basic Aspects of Organic Chemistry:** 1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications. 2. Types of reaction mechanisms and methods of determining them, 3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. **Addition reactions** a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2) b)Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) c) Rearrangement reaction	12

2	**Study of mechanism and synthetic applications of following named Reactions:** Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction	12
3	**Synthetic Reagents & Applications:** Aluminiumisopropoxide, N- bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP). Protecting groups a. Role of protection in organic synthesis b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals c. Protection for the Carbonyl Group: Acetals and Ketals d. Protection for the Carboxyl Group: amides and hydrazides, esters e. Protection for the Amino Group and Amino acids: carbamates and amides	12
4	**Heterocyclic Chemistry:** Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis. Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizolesodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.	12

5	**Synthon approach and retrosynthesis applications** i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA) ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds iii. Strategies for synthesis of three, four, five and six-membered ring.	12

References

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

ADVANCED MEDICINAL CHEMISTRY (17MPC13)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Course Outcome

At the end of the course students will be able to...

CO1	Learn the different stages of drug discovery & Role of medicinal chemistry in drug research
CO2	Learn different techniques for drug discovery
CO3	Understand various strategies to design and develop a new drug like molecules for biological targets
CO4	Explain drug receptor concept
CO5	Elaborate prodrug development and applications
CO6	Learn the structural activity relationship of the important class of drugs
CO7	Explain types of Enzyme inhibition and its application in medicine
CO8	Discuss peptidomimetics approach and applications

Units	Contents	Hours
1	**Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. **Biological drug targets:** Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.	12
2	**Prodrug Design and Analog design:** a. **Prodrug design:** Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design. b. **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance. c. **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching,	12

	changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.	
3	a) Medicinal chemistry aspects of the following class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: a. Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents. b. Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.	12
4	**Rational Design of Enzyme Inhibitors**: Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.	12
5	**Peptidomimetics**: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.	12

References

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.

8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (17MPC14)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Course Outcome

At the end of the course students will be able to...

CO1	Learn the different types of alkaloids, glycosides & terpenes etc and their chemistry and medicinal importance.
CO2	Explain the importance of natural compounds as lead molecules for new drug discovery.
CO3	Learn the constituent present in crude drugs responsible for anti-diabetic activity
CO4	Discuss rDNA technology tool for new drug discovery.
CO5	Explain vitamins Chemistry and Physiological significance of Vitamin
CO6	Elaborate general methods of structural elucidation of compounds of natural origin.
CO7	Learn advanced methods of structural elucidation of compounds of natural origin.
CO8	Understand isolation, purification and characterization of simple chemical constituents from the natural source

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

2	a) **Alkaloids:** General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine. b) **Flavonoids:** Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin. c) **Steroids:** General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocor-ticoids (Cortisone), contraceptive agents and steroids (Vit – D).	12
3	a) **Terpenoids:** Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene). b) **Vitamins:** Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	12
4	a) **Recombinant DNA technology and drug discovery:** rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation b) **Active constituent of certain crude drugs used in Indigenous system Diabetic therapy –** Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.	12
5	**Structural Characterization of natural compounds**: Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.	12

References

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I (17MPC15P)

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

To perform the following reactions of synthetic importance

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

ADVANCED SPECTRAL ANALYSIS (17MPC21)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Course Outcome

At the end of the course students will be able to...

CO1	Explain the theoretical principles of UV, IR ,MASS and NMR spectroscopy
CO2	Discuss structural elucidation of organic and natural compounds by IR, NMR and MASS spectral data
CO3	Understand the theoretical principles of Woodward-Fieser rule
CO4	Learn instrumentation and Interpretation of organic compounds by Raman spectroscopy
CO5	Learn the general theory and principles of thermal analysis
CO6	Learn the general theory and principles of Hyphenated Techniques
CO7	Explain the general theory and principles of bioassay and ELISA
CO8	Understand principles and techniques involved in radioimmuno assay

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

5	a) **Thermal methods of analysis:** Introduction, principle, instrumentation and application of DSC, DTA and TGA. b) **Raman Spectroscopy:** Introduction, Principle, Instrumentation and Applications. c) **Radio immuno assay:** Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.	12

References

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

ADVANCED ORGANIC CHEMISTRY - II (17MPC22)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Course Outcome

At the end of the course students will be able to...

CO1	Discuss the principles and applications of green chemistry
CO2	Explain the chemistry, synthesis and side reactions of peptides
CO3	Explain the principles of different types of photochemical reactions
CO4	Discuss the principles of different types of pericyclic reactions
CO5	Explain the applications of homogeneous and heterogeneous catalysis in the synthesis of drugs
CO6	Discuss the applications of biocatalysis and phase transfer catalysis in organic reaction
CO7	Explain the basic concept of stereochemistry
CO8	Discuss the principle of asymmetric synthesis

Units	Contents	Hours
1	**Green Chemistry:** a. Introduction, principles of green chemistry b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, itsapplications in various organic reactions and heterocycles synthesis c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications d. Continuous flow reactors: Working principle, advantages and synthetic applications.	12

2	**Chemistry of peptides** a. Coupling reactions in peptide synthesis b. Principles of solid phase peptide synthesis, t-BOC and FMOCprotocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.	12
3	**Photochemical Reactions**: Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. **Pericyclic reactions:** Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples	12
4	**Catalysis:** a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. f. Phase transfer catalysis - theory and applications	12

5	**Stereochemistry & Asymmetric Synthesis** a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. b. Methods of asymmetric Synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.	12

References

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

COMPUTER AIDED DRUG DESIGN (17MPC23)

Scope

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

Course Outcome

At the end of the course students will be able to...

CO1	Explain the Role of CADD in drug discovery
CO2	Understand the physicochemical Properties and the techniques involved in QSAR
CO3	Learn the concept of molecular and quantum mechanics
CO4	Learn the working with molecular modelling softwares to design new drug molecules
CO5	Understand in silico virtual screening protocols
CO6	Explain pharmacophore concept and the techniques involved in modeling
CO7	Learn various structure based drug design methods (Denovo drug design, fragment based drug design)
CO8	Elaborate homology modelling and its experimental procedures

Units	Contents	Hours
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 effects and parameters (log P, pi- substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.	12
2	**Quantitative Structure Activity Relationships:** Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.	12

3	**Molecular Modeling and Docking** a) Molecular and Quantum Mechanics in drug design. b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)	12
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. c) Homology modeling and generation of 3D-structure of protein.	12
5	**Pharmacophore Mapping and Virtual Screening:** Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.	12

References

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

PHARMACEUTICAL PROCESS CHEMISTRY (17MPC24)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Course Outcome

At the end of the course students will be able to…

CO1	Learn the strategies of scale up process of APIs and intermediates
CO2	Discuss the different types of unit operations in process chemistry
CO3	Carry out case study based on unit operations and unit process, scaled up the product
CO4	Explain the various unit process in process chemistry
CO5	Learn the reaction progress kinetic analysis
CO6	Explain fermentation: Aerobic and Anaerobic
CO7	Discuss kinetics and mechanism of Nitration, Halogenation & Oxidation
CO8	Understand the industrial safety process chemistry

Units	Contents	Hours
1	**Process chemistry:** Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities	12
2	**Unit operations** a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction. b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,	12

	c) Distillation: azeotropic and steam distillation d) Evaporation: Types of evaporators, factors affecting evaporation. e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and f) amorphous APIs.	
3	**Unit Processes - I** a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process. c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.	12
4	**Unit Processes – II** a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) Fermentation: Aerobic and anaerobic fermentation. Production of Antibiotics; Penicillin and Streptomycin, Vitamins: B2 and B12 c) Statins: Lovastatin, Simvastatin Reaction progress kinetic analysis Streamlining reaction steps, route selection, Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.	12
5	**Industrial Safety** a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) b) Fire hazards, types of fire & fire extinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management	12

References

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

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

PHARMACEUTICAL CHEMISTRY PRACTICALS – II (17MPC25P)

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

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (17MQA11)

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.

Course Outcome

At the end of the course students will be able to…

CO1	Explain general principles and theory of spectroscopy
CO2	Understand the basic instrumentation of HPTLC, HPLC, GC for identification, and characterization of compounds
CO3	Understand the basic concept and instrumentation of Chromatographic techniques
CO4	Learn various separation techniques by employing chromatographic methods
CO5	Understand the basic principles and instrumentation of fluorimeter and atomic absorption spectrometer
CO6	Learn general principles and instrumentation of ion selective electrodes.
CO7	Identify organic compounds by –X-ray crystallography
CO8	Explain Instrumentation, separation and identification of compounds by electrophoresis technique.

Units	Contents	Hours
1	a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 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.	10

	d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	10
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.	10

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

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, K A.Connors, 3rd Edition, John Wiley Sons, 1982.

QUALITY MANAGEMENT SYSTEMS (17MQA12)

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Course Outcome

At the end of the course students will be able to…

CO1	Understand and define quality and its concept and cost involved
CO2	Learn strategic planning and implementation of quality systems
CO3	Understand the keys to customer satisfaction
CO4	Learn the various guidelines and certifications for quality management in pharmaceuticals
CO5	Describe various tools and systems for quality management
CO6	Learn important ICH guidelines on pharmaceutical product development and testing
CO7	Understand the concept of statistical process control in pharmaceutical manufacturing
CO8	Learn the concept of benchmarking in quality aspect

Units	Contents	Hours
1	**Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality **Quality as a Strategic Decision:** Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality Objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality **Customer Focus:** Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. **Cost of Quality:** Cost of quality, Categories of cost of Quality, Models of	12

	cost of quality, Optimising costs, Preventing cost of quality.	
2	**Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	12
3	**Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. **Quality systems:** Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	12
4	**Drug Stability:** ICH guidelines for stability testing of drug substances and drug products. **Study of ICH Q8, Quality by Design and Process development report** **Quality risk management:** Introduction, risk ssessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12
5	**Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	8
6	Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	4

References

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (17MQA13)

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.

Course Outcome

At the end of the course students will be able to…

CO1	Understand and differentiate quality control and quality assurance
CO2	Learn good laboratory practices for non clinical laboratory
CO3	Discuss GMP guidelines by various regulated countries
CO4	Learn pharmacopoeal guidelines about in process quality control testing
CO5	Appreciate the need of documentation in pharmaceutical industry
CO6	Overview of CTDs and their requirements in regulated markets
CO7	Learn the quality assurance aspects of manufacturing and process control
CO8	Discuss about intellectual property rights and their scope in pharmaceutical industry

Units	Contents	Hours
1	**Introduction:** Concept and evolution and Scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. **Good Laboratory Practices:** Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	12
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12

3	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12
4	**Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	12
5	**Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, Scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	12

References

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.

5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (17MQA14)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Course Outcome

At the end of the course students will be able to…

CO1	Learn the regulatory principles and requirements of drug discovery and developments
CO2	Understand the concept of preformulation studies for various formulations
CO3	Concept and designing of pilot plants and product scale up
CO4	Leant various pharmaceutical packaging systems and their quality testing
CO5	Learn the concept of technology transfer from R&D to production plant
CO6	Discuss on the new era opportunities and challenges in the pharmaceutical market
CO7	Know the basics of stability studies during formulation development
CO8	Learnt the product registration guidelines in India and USA

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

2	**Pre-formulation studies:** Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	12
3	**Pilot plant scale up:** Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	12
4	**Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	12
5	**Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12

References

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza.

Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL - I (17MQA15P)

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

HAZARDS AND SAFETY MANAGEMENT (17MQA21)

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Course Outcome

At the end of the course students will be able to…

CO1	Learn the multidisciplinary nature of environmental studies and various natural resources
CO2	Understand the concept of an ecosystem and structure and function of an ecosystem
CO3	Learn about sources and types of air based hazards
CO4	Understand the prevention of fire hazards and critical hazard management systems
CO5	Learn the types of chemical based hazards and their prevention
CO6	Discuss the management and prevention of fire and explosion
CO7	Learn the hazard risk management in workplace
CO8	Learn the rules and guidelines on risk assessment and management

Units	Contents	Hours
1	**Multidisciplinary nature of environmental studies:** Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources **Ecosystems:** Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	12
2	**Air based hazards:** Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.	12

3	**Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.	12
4	**Fire and Explosion:** Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.	12
5	**Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.	12

References

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

PHARMACEUTICAL VALIDATION (17MQA22)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Course Outcome

At the end of the course students will be able to…

CO1	Understand the concepts of calibration, qualification and validation
CO2	Know about the qualification of various pharmaceutical equipments and instruments
CO3	Study the Process validation of different dosage forms
CO4	Understand Validation of analytical method for estimation of drugs
CO5	Understand Cleaning validation of equipments employed in the manufacture of pharmaceuticals
CO6	Understand Intellectual property rights and patent filing
CO7	Know about the concept of Qualification of laboratory instruments
CO8	Understand validation of sterile and non sterile plant and computerized system validation

Units	Contents	Hours
1	**Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, Scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. **Qualification:** User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management).	10

2	**Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. **Qualification of analytical instruments**: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.	10
3	**Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus **Validation of Utility systems:** Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	10
4	**Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. **Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines and USP.	10
5	**Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). **Validation of facilities in sterile and non-sterile plant. Computerized system validation:** Electronic records and digital signature - 21 CFR Part 11 and GAMP	10
6	**General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications- provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and Scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	10

References

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

AUDITS AND REGULATORY COMPLIANCE (17MQA23)

Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcome

At the end of the course students will be able to…

CO1	Discuss briefly about audit objectives and their management
CO2	Understand the role of quality systems and audits in pharmaceutical manufacturing environment
CO3	Frame a checklist for auditing pharmaceutical industries
CO4	Lean the requirements for auditing vendors supplying various materials and equipments
CO5	Understand the audition of a microbiological laboratory
CO6	Learn the auditing of quality assurance systems
CO7	Understand the basics of auditing various engineering systems in a manufacturing plant
CO8	Learn about audit report and classification of deficiencies

Units	Contents	Hours
1	**Introduction:** Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	**Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries	12
3	**Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12
4	**Auditing of Microbiological laboratory:** Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials	12

5	**Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12

References

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

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (17MQA24)

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Course Outcome

At the end of the course students will be able to…

CO1	Understand the basics of developing a pharmaceutical industry
CO2	Learn the basics of plant layout and production planning
CO3	Learn the basics of aseptic process technology in pharmaceutical manufacturing
CO4	Discussion of advance sterile manufacturing technologies
CO5	Learn the process automation and lyophilization in sterile manufacturing
CO6	Discuss the basic and advanced technologies for non sterile product manufacturing and coating
CO7	Learn the quality aspects of pharmaceutical containers and closures
CO8	Detailed discussion on Quality by design (QbD) and process analytical technology

Units	Contents	Hours
1	**Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. **Plant layout:** Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. **Production planning:** General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	12
2	**Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). **Advanced sterile product manufacturing technology :** Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment	12

	location, engineering and maintenance. **Process Automation in Pharmaceutical Industry:** With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). **Lyophilization technology:** Principles, process, equipment.	
3	**Non sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-qualitycontrol tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). **Advance non-sterile solid product manufacturingtechnology:** Process Automation in Pharmaceutical Industry withspecific reference to manufacturing of tablets and coatedproducts, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batchmixing, rapid mixing granulators, rota granulators, spheronizersand marumerisers, and other specialized granulation and drying equipments. Problems encountered. **Coating technology:** Process, equipments, particle coating, Fluidized bed coating, application techniques. Problems encountered	12
4	**Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.	12
5	**Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD. Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design	12

	(QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.	

References

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

QUALITY ASSURANCE PRACTICAL – II PRACTICALS

(17MQA25P)

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

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (17MRA11)

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Course Outcome

At the end of the course students will be able to…

CO1	Prepare checklists and SOPs for various good regulatory practices.
CO2	Develop good regulatory practices in the healthcare and related industries
CO3	Demonstrate a plan for the readiness and conduct of audits and inspections.
CO4	Categorize the key regulatory and compliance elements with respect to GMP.
CO5	Categorize the key regulatory and compliance elements with respect to GLP.
CO6	Categorize the key regulatory and compliance elements with respect to GALP.
CO7	Categorize the key regulatory and compliance elements with respect to GDP.
CO8	Describe the quality management system in the Pharmaceutical Industry.

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

2	**Good Laboratory Practices:** Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards	12
3	**Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.	12
4	**Good Distribution Practices:** Introduction to GDP, Legal GDPRequirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12
5	**Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	12

References

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

DOCUMENTATION AND REGULATORY WRITING (17MRA12)

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Course Outcome

At the end of the course students will be able to…

CO1	Discuss the basic Documentation in pharmaceutical industry
CO2	Discuss on dossier preparation and CTD submission
CO3	Learn about eCTD and technologies available
CO4	Understand the basics of CTD submission in India through Sugam system
CO5	Learn the basics of internal and external audits
CO6	Learn ISO standards and guidelines on audits
CO7	Understand inspection systems in pharmaceutical companies and follow up actions
CO8	Learn the regulatory aspects of product lifecycle management and product recalls

Units	Contents	Hours
1	**Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).	12
2	**Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission.	12

	Submission in Sugam system of CDSCO.	
3	**Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.	12
4	**Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).	12
5	**Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard	12

References

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca- loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications.
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (17MRA13)

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Course Outcome

At the end of the course students will be able to…

CO1	Understand the History, origin and ethics of clinical and biomedical research and evaluation
CO2	Know Clinical drug, medical device development process, different types and phases of clinical trials
CO3	Know the regulatory requirements and guidance for conduct of clinical trials and research.
CO4	Understand the European union guidance for clinical evaluation and safety for medicinal products and medical devices.
CO5	Understand the clinical, ethical principles, informed consent form, process and documentation.
CO6	Know the General biostatic principles applied in clinical research.
CO7	Understand FDA guidance for bioavailability and bioequivalence requirements for medicinal products
CO8	Understand Indian GCP, CDSCO and ICMR guidelines for biomedical research.

Units	Contents	Hours
1	**Clinical Drug Development Process** • Different types of Clinical Studies • Phases of clinical trials, Clinical Trial protocol • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish	12

	efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR) **Clinical Investigation and Evaluation of Medical Devices & IVDs** Different Types of Studies, Key Concepts of Medical Device Clinical Evaluation, Key concepts of Clinical Investigation	
2	**Ethics in Clinical Research:** • Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki • Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board/Independent Ethics Committee/ Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data • Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation	12
3	**Regulations governing Clinical Trials** **India:** Clinical Research regulations in India – Schedule Y & Medical Device Guidance **USA:** Regulations to conduct drug studies in USA (FDA) • NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) • FDA Guidance for Industry – Acceptance of Foreign Clinical	12

	Studies • FDA Clinical Trails Guidance Document: Good Clinical Practice EU: Clinical Research regulations in European Union (EMA)	
4	**Clinical Research Related Guidelines** • Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines GHTF study group 5 guidance documents **Regulatory Guidance on Efficacy and Safety ICH Guidance's** • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population: Geriatrics • E8 – General Considerations of Clinical Trials • E10 – Choice of Control Groups and Related Issues in Clinical Trials, • E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population • General biostatics principle applied in clinical researc	12
5	**USA & EU Guidance** **USA: FDA Guidance** • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post-market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA Med Watch • Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment **European Union: EMA Guidance** • EU Directives 2001 • EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use • EU Annual Safety Report (ASR)	12

	• Volume 9A – Pharmacovigilance for Medicinal Products for Human Use • EU MDD with respect to clinical research • ISO 14155	

References

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

Recommended websites:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical- eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts /cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.html
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation /legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterV Drugs andDevices/ucm108 125.htm
6. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk

7. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

DRUGS REGULATIONS AND OTHER LEGISLATION IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (17MRA14)

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Course Outcome

At the end of the course students will be able to…

CO1	Assess the approval process and regulatory requirements for drugs & cosmetics, medical devices, biological & herbals, and food & nutraceuticals
CO2	Examine the Indian Pharmacopoeial and BIS standards
CO3	Review and validate the guidelines for drug testing in animals
CO4	Practice the concept of Intellectual Property Rights
CO5	Describe the different acts and guidelines that regulate drugs & cosmetics, medical devices, biological & herbals, and food & nutraceuticals industry in India
CO6	Categorize the guidelines for drug testing in animals
CO7	Assess the regulatory requirements for bioequivalence study
CO8	Describe the role of IPR in regulatory affairs.

Units	Contents	Hours
1	**Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):** 1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA 2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India **Other relevant Acts:** Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.	12

2	**Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals:** CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals Format and contents of Regulatory dossier filing Clinical trial/ investigations	12
3	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	12
4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study **Stability requirements:** ICH and WHO **Guidelines for Drug testing in animals/**Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research	12
5	**Intellectual Property Rights:** Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	12

References

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)

8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL - I (17MRA15P)

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

REGULATORY ASPECTS OF DRUGS & COSMETICS (17MRA21)

Scope

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Course Outcome

At the end of the course students will be able to…

CO1	Study the regulatory approval process and registration procedures for API and drug products in USA and Canada
CO2	Explain the role of various committees across the globe (APEC, EAC, GCC, PANDRH, SADC)
CO3	Know the legislation and regulations for import, manufacture, distribution and sale of drugs and cosmetics in EU and Australia
CO4	Understand the cosmetics regulations in regulated and semi-regulated countries
CO5	Understand the legislation and regulations for manufacturing, packaging and labelling of pharmaceuticals in Japan
CO6	Describe the requirements for registration of drugs and post approval requirements in ASEAN countries
CO7	Study the regulatory prerequisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries
CO8	Understand the concept of Certificate of Pharmaceutical Product(CoPP) in General and Country Specific

Units	Contents	Hours
1	**USA & CANADA:** Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA);	12

	Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada.	
2	**European Union & Australia:** Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.	12
3	**Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	12
4	**Emerging Market:** Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) **WHO:** WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product(CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)	12

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

References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites. http://www.who.int/ medicines/areas/quality_safety/regulation_legislation/ ListMRAWebsites.pdf

11. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
12. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981- 230-750-7
13. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
14. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
15. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
16. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
17. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
18. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
19. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east asian studies, Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (17MRA22)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe

It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Course Outcome

At the end of course students will be able to…

CO1	Recognize the regulation for newly developed biologics and biosimilars.
CO2	Explain the pre-clinical and clinical development considerations of biologics.
CO3	Discuss the regulatory requirements of blood and/or its components including blood products and label requirements.
CO4	Set up the quality and safety of herbal products.
CO5	Describe the regulatory requirements for biologics and vaccines.
CO6	Describe the regulatory requirements for the herbal products.
CO7	Set up the quality and safety of herbal products.
CO8	Set up the legislation for herbal products.

Units	Contents	Hours
1	**India :** Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.	12
2	**USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics	12

3	**European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU	12
4	**Vaccine regulations in India, US and European Union:** Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)	12
5	**Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union.	12

References

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

REGULATORY ASPECTS OF MEDICAL DEVICES (17MRA23)

Scope

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Course Outcome

At the end of the course students will be able to…

CO1	Know the basics of medical devices and IVDs, process of development, ethical and quality considerations.
CO2	Know the quality system regulations and quality risk management of medical devices.
CO3	Know the medical devices and IVDs directives in European Union and USA.
CO4	Understand organizational structure, regulatory guidelines and functions of IMDRF/GHTF.
CO5	Know Harmonization initiatives for approval and marketing of medical devices and IVDs.
CO6	Understand regulatory approval process for medical devices and IVDs in India, US, and Europe.
CO7	Know clinical evaluation and investigation of medical devices and IVDs.
CO8	Understand regulatory approval process for medical devices and IVDs in China, Japan and ASEAN countries.

Units	Contents	Hours
1	**Medical Devices:** Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.	12

	IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical DeviceNomenclature (GMDN).	
2	**Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) **Quality: Quality System Regulations of Medical Devices:** ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device	12
3	**USA:** Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.	12
4	**European Union:** Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.	12
5	**ASEAN, China & Japan:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.	12

References

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

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (17MRA24)

Scope

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Course Outcome

At the end of the course students will be able to…

CO1	Define and differentiate nutraceuticals, functional foods, dietary supplements, and medical foods
CO2	Discuss the scope and opportunities in nutraceutical market
CO3	Learn the history of nuraceuticals and their regulations
CO4	Learn the global aspects of regulations in food and nutraceutical markets
CO5	Understand the nutraceutical regulations in India
CO6	Learn the nutraceutical regulations in USA
CO7	Study the nutraceutical regulations in European Union
CO8	Understand and compare the Recommended Dietary Allowance in various regulated countries

Units	Contents	Hours
1	**Nutraceuticals:** Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12
2	**Global Aspects**: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	12
3	**India:** Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.	12

4	**USA:** US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	12
5	**European Union:** European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.	12

References

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)5 36324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL - II (17MRA25P)

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

PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE (17MPP11)

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Course Outcome

At the end of the course students will be able to…

CO1	Describe the elements of pharmaceutical care and patient care services
CO2	Interpret the laboratory results to aid the clinical diagnosis of various disorders
CO3	Discuss the organization and functions of drug and poison information centers.
CO4	Formulate, analyze and interpret the drug and poison information
CO5	Develop the practice skills for providing patient care services
CO6	Assess the drug therapy of patient through medication chart review and clinical review
CO7	Describe patient counselling and medication history interview
CO8	Understand the concept of pharmacovigilance, hemovigilance, materiovigilance and adverse event following immunization

Units	Contents	Hours
1	**Introduction to Clinical Pharmacy:** Definition, evolution and Scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care **Clinical Pharmacy Services:** Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)	12

2	**Clinical Pharmacy Services:** Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.	12
3	**Patient Data Analysis:** **Patient Data & Practice Skills:** Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. **Lab Data Interpretation:** Hematological tests, Renal function tests, Liver function tests	12
4	**Lab Data Interpretation:** Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests	12
5	**Medicines & Poison Information Services** **Medicine Information Service:** Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. **Poison Information Service:** Definition, need, organization and functions of poison information centre.	12

References

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (17MPP12)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Course Outcome

At the end of the course students will be able to…

CO1	Describe the Etiopathogenesis of selected disease states
CO2	Discuss the various methods involved in the diagnosis of selected disease state
CO3	Interpret and analyze the selected laboratory results of specific disease states
CO4	Describe the therapeutic approach to manage the selected diseases
CO5	Discuss the rationale for drug therapy of the selected disease
CO6	Identify the controversies in drug therapy
CO7	Develop the individualized therapeutic plans based on diagnosis
CO8	Identify the patient-specific parameters relevant in initiating the drug therapy

Units	Contents	Hours
Etiopathogenesis and pharmacotherapy of diseases associated with following systems		
1	**Cardiovascular system:** Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias	12
2	**Respiratory system:** Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases	12
3	**Gastrointestinal system:** Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis	12
4	**Gastrointestinal system:** Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease **Hematological diseases:** Anemia, Deep vein thrombosis, Drug induced hematological disorders	12

5	**Bone and joint disorders:** Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis **Dermatological Diseases:** Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders **Ophthalmology:** Conjunctivitis, Glaucoma	12

References

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY (17MPP13)

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Course Outcome

At the end of the course students will be able to…

CO1	Describe the organizational structure of hospital & hospital pharmacy
CO2	Explain different drug policies & committees in the hospital
CO3	Operate various drug distribution methods in the hospital
CO4	Explain management of inventory control in the hospital pharmacy
CO5	Describe the management of community pharmacy
CO6	Analyse and manage the prescriptions in the hospital & community pharmacy
CO7	Recognize the minor ailments and develop the health promotions in the community
CO8	Describe health promotions in community

Units	Contents	Hours
1	**Introduction to Hospitals** – Definition, classification, organizational structure **Hospital Pharmacy:** Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management **Hospital Drug Policy:** Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH	12
2	Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management	12

3	**Education and training:** Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. **Community Pharmacy Practice:** Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers. **Community Pharmacy management:** Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.	12
4	**Prescription –** Legal requirements & interpretation, prescription related problems **Responding to symptoms of minor ailments:** Head ache, pyrexia, menstrual pains, food and drug allergy **OTC medication:** Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors ADR monitoring in community pharmacies	12
5	**Health Promotion –** Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care **National Health Programs-** Role of Community Pharmacist in Malaria and TB control programs **Home Medicines review program –** Definition, Objectives, Guidelines, method and outcomes **Research in community pharmacy Practice**	12

References

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (17MPP14)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Course Outcome

At the end of the course students will be able to…

CO1	Describe the concept of new drug development process
CO2	Recognize the regulatory and ethical requirements in clinical trials
CO3	Describe the types of research designs in clinical research
CO4	Recognize the roles and responsibilities of clinical trial study team
CO5	Develop the various clinical trial documents
CO6	Discuss various procedures and activities involved in the conduct of clinical trials
CO7	Explain the quality assurance and quality control activities in clinical research
CO8	Interpret the various aspects of clinical trial data management.

Units	Contents	Hours
1	**Drug development process:** Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.	12

2	**Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) **Clinical Trial Study team:** Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.	12
3	**Clinical trial Documents:** Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards **Clinical Trial Start up activities:** Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission	12
4	**Investigational Product:** Procurement and Storage of investigation product **Filing procedures:** Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up **Clinical Trial Monitoring and Close out:** **Preparation and conduct of monitoring visit:** Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up **Close-Out visit:** Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.	12

5	**Quality Assurance and Quality Control in Clinical Trials:** Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management **Data Management:** **Infrastructure and System Requirement for Data Management:** Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival **Clinical Trial Data Management:** Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.	12

References

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (17MPP15P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES (17MPP21)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Course Outcome

At the end of the course students will be able to…

CO1	Explain the principles of Quality Use of Medicines
CO2	Describe the Rational drug therapy
CO3	Practice Evidence based medicine
CO4	Describe the Quality Use of Medicine in various settings
CO5	Explain Quality Use of Medicines in special population
CO6	Recognize regulatory aspects of Quality Use of Medicines
CO7	Identify and resolve Medication errors
CO8	Evaluate, assess and monitor Adverse Drug Reactions

Units	Contents	Hours
1	**Introduction to Quality use of medicines (QUM):** Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.	12
2	**Concepts in QUM** **Evidence based medicine:** Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings **Essential drugs:** Definition, need, concept of essential drug, National essential drug policy and list **Rational drug use:** Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.	12

3	**QUM in various settings:** Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. **QUM in special population:** Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients	12
4	**Regulatory aspects of QUM in India:** Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development	12
5	**Medication errors:** Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors **Pharmacovigilance:** Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.	12

References:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors Online: http://medicinesaustralia.com.au/ files/2012/05/MA_QUM_External_Reduced.pdf http://curriculum.racgp.org.au/statements/quality-use-of-medicines/ http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
6. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II (17MPP22)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Course Outcome

At the end of the course students will be able to…

CO1	Describe the etiopathogenesis of selected disease states
CO2	Discuss the various methods involved in the diagnosis of selected disease state
CO3	Interpret and analyze the selected laboratory results of specific disease states
CO4	Describe the therapeutic approach to manage the selected diseases
CO5	Discuss the rationale for drug therapy of the selected disease
CO6	Identify the controversies in drug therapy
CO7	Develop the individualized therapeutic plans based on diagnosis
CO8	Identify the patient-specific parameters relevant in initiating the drug therapy

Units	Contents	Hours
1	**Nervous system:** Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.	12
2	**Psychiatric disorders:** Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease	12
3	**Infectious diseases:** General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.	12

4	**Infectious diseases:** Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections **Gynecological disorders:** Dysmenorrhea, Hormone replacement therapy.	12
5	**Oncology:** General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care	12

References

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (17MPP23)

Scope

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Course Outcome

At the end of the course students will be able to…

CO1	Formulate and design a dosage regimen for individual patients
CO2	Interpret and correlate the plasma drug concentration with patient's therapeutic outcomes
CO3	Recommend dosage adjustment in renal and hepatic disease
CO4	Recommend dosage adjustment for paediatrics and geriatrics
CO5	Analyze and resolvepharmacokintetic drug interactions
CO6	Illustrate and apply pharmacokinetic parameters in clinical settings
CO7	Interpret the impact of genetic poylmorphisms of individuals on pharmacokinetics and pharmacodynamics of drugs
CO8	Employ pharmacokinetic modeling for the given data using the principles of pharmacometrics

Units	Contents	Hours
1	**Introduction to Clinical pharmacokinetics:** Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses **Designing of dosage regimens:** Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.	12

2	**Pharmacokinetics of Drug Interaction:** Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion **Pharmacogenetics:** Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations **Introduction to Pharmacometrics:** Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.	12
3	**Non Linier Mixed Effects Modelling:** The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.	12
4	**Altered Pharmacokinetics:** Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.	12
5	**Therapeutic Drug monitoring:** Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.	12

References

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (17MPP24)

Scope

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome

At the end of the course students will be able to….

CO1	Identify the applications of pharmacoepidemiology and pharmacoeconomics in clinical settings
CO2	Discuss the various pharmacoepidemiological outcome measures
CO3	Describe the concept of risk in pharmacoepidemiology and different methods of measuring risk
CO4	Explain the various pharmacoepidemiological methods
CO5	Explain the various systems for studying drug effects in populations.
CO6	Discuss the methods to measure outcomes in pharmacoecnomic studies
CO7	Describe the current pharmacoeconomic evaluation methods
CO8	Explain the pharmacoecnomic decision analysis methods and its application

Units	Contents	Hours
1	**Introduction to Pharmacoepidemiology:** Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. **Concept of risk:** Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio	12

2	**Pharmacoepidemiological Methods:** Qualitative models: DrugUtilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology	12
3	**Introduction to Pharmacoeconomics:** Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. **Cost categorization and resources for cost estimation:** Direct costs. Indirect costs. Intangible costs. **Outcomes and Measurements of Pharmacoeconomics:** Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.	12
4	**Pharmacoeconomic evaluations:** Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).	12
5	**Definition, Steps involved, Applications, Advantages and disadvantages of the following:** **Health related quality of life (HRQOL):** Definition, Need for measurement of HRQOL, Common HRQOL measures. **Definition, Steps involved, Applications of the following:** Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.	12

References

1. Rascati K L. Essentials of Pharmacoeconomics, Kluw Woulters Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II (17MPP25P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

PHARMACOLOGY (MPY)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(17MPY11)

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.

Course Outcome

At the end of the course students will be able to…

CO1	Explain general principles and theory of spectroscopy
CO2	Understand the basic instrumentation of HPTLC, HPLC, GC for identification, and characterization of compounds
CO3	Understand the basic concept and instrumentation of Chromatographic techniques
CO4	Learn various separation techniques by employing chromatographic methods
CO5	Understand the basic principles and instrumentation of fluorimeter and atomic absorption spectrometer
CO6	Learn general principles and instrumentation of ion selective electrodes.
CO7	Identify organic compounds by –X-ray crystallography
CO8	Explain Instrumentation, separation and identification of compounds by electrophoresis technique.

Units	Contents	Hours
1	a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 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	10

	Applications of fluorescence spectrophotometer. d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10
4	**Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography	10

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

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I (17MPY12)

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

Course Outcome

At the end of the course students will be able to…

CO1	Explain general pharmacological concepts such as pharmacodynamics and pharmacokinetics
CO2	Explain the general concept of Neurotransmission, neuritransmitters and drugs affecting it
CO3	Explain the Pharmacology of sympathetic and parasympathetic neurotransmitters including their agonist and antagonist
CO4	Explain the different Classes of drugs used in various CNS disorders like anxiety, depression, mania, psychosis, epilepsy, neurodegenerative diseases,
CO5	Describe the Pharmacology of general and local anesthetics
CO6	Classify & Explain the Pharmacology of narcotic and non narcotic analgesics
CO7	Explain the Pharmacology of cardiovascular drugs such as diuretics, anti hypertensives, anti ischemic, anti hyperlipidemic, drugs used in CCF, hematinics, coagulants, anti coagulants, fibrinolytics and antiplatlet drugs
CO8	Describe the physiological and pathological role of histamine,5-HT,Kinins,prostaglandins, opioid autacoids and Pharmacology of antihistamines and 5-HT antagonist

Units	Contents	Hours
1	**General Pharmacology** a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of c. drug receptors interaction and elicited effects.	12

2	**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 neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. d. Non adrenergic non cholinergic transmission (NANC). Co- transmission **Systemic Pharmacology:** A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems **Autonomic Pharmacology:** Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	12
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.	12
4	**Cardiovascular Pharmacology**: Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs	12
5	**Autocoid Pharmacology:** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12

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.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (17MPY13)

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

Course Outcome

At the end of the course students will be able to…

CO1	Describe the regulations and ethical requirement for the usage of various species and strains of experimental animals and explain CPCSEA guidelines, GLP,
CO2	Classify Bioassay, Explain the principle, scope, limitations and methods of bioassay
CO3	Classify and explain various preclinical invitro , invivo and other possible animal alternative models for the screening of following classes of drugs such as behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.
CO4	Classify and explain various preclinical invitro , invivo and other possible animal alternative models for the screening of following classes of drugs such as Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.
CO5	Classify and explain various preclinical invitro , invivo and other possible animal alternative models for the screening of following classes of drugs such as Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.
CO6	Classify and explain various preclinical invitro , invivo and other possible animal alternative models for the screening of following classes of drugs such as Iimmunomodulators, Immunosuppressants and immunostimulants

CO7	Describe general principles of Immunoassay and explain Immunoassay methods of evaluation
CO8	Describe limitations of animal experimentation , alternate animal experiments and explain Extrapolation of in vitro data to preclinical and preclinical to humans

Units	Contents	Hours
1	**Laboratory Animals**: Common laboratory Description, handling and animals: applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, Scope and limitations and methods	12
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: behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.	12
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, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti-emetic, anti-diarrheal and laxatives.	12
4	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti	12

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

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 (17MPY14)

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.

Course Outcome

At the end of the course students will be able to…

CO1	Explain cellular structure and functions and cell regulation
CO2	Describe molecular and cellular cell signaling pathways
CO3	Describe in detail Principles and applications of genomic and proteomic tools
CO4	Principles ,applications and recent advances in gene therapy
CO5	Describe in detail Principles and applications of Pharmacogenomics
CO6	Explain the Principles and applications of proteomics science
CO7	Describe in detail Principles and applications of Immunotherapeutics
CO8	Describe Cell culture techniques and biosimilars

Units	Contents	Hours
1	**Cell biology**: Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.	12
2	**Cell signaling**: Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase	12

	(JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	
3	**Principles and applications of genomic and proteomic tools:** DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene Basic principles of recombinant DNA technology-Restriction therapy enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12
4	**Pharmacogenomics:** Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics **Immunotherapeutics**: Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	12
5	a. **Cell culture techniques**: Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12

References:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller

6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I (17MPY15P)

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

Handling of laboratory animals

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

21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

References

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

ADVANCED PHARMACOLOGY - II (17MPY21)

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, the subject helps the student to understand the concepts of drug action and mechanism involved

Course Outcome

At the end of the course students will be able to…

CO1	Describe the molecular and cellular mechanism of actions of hormones and drugs affecting it
CO2	Describe the Pharmacological aspects of chemotherapeutic agents
CO3	Explain the concept of immunity and drugs affecting it
CO4	Describe the Pharmacological aspects of drugs affecting GI system
CO5	Explain the concept and applications of chronopharmacology
CO6	Describe the concept of free radicals , anti oxidants and their role in various disordres
CO7	Explain the recent advancement in the treatment of Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus
CO8	Explain the Pharmacotherapy of Asthma and COPD

Units	Contents	Hours
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
2	**Chemotherapy:** 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.	12
3	**Chemotherapy:** Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer **Immunopharmacology:** Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity	12

	reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	
4	**GIT Pharmacology:** Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. **Chronopharmacology:** Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12
5	**Free radicals Pharmacology:** Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant **Recent Advances in Treatment:** Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12

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 (17MPY22)

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.

Course Outcome

At the end of the course students will be able to…

CO1	Explain the basics and the types of toxicology
CO2	Describe the regulatory guidelines for conducting toxicological studies
CO3	Explain various toxicity studies as per OECD guidelines
CO4	Describe special toxicity studies
CO5	Describe in detail about various methods employed in drug discovery and development
CO6	Explain the concept of Safety pharmacology studies
CO7	Explain the Importance and applications of toxicokinetics
CO8	Explain Alternative methods to animal toxicity testing.

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

4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	12
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12

References

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

PRINCIPLES OF DRUG DISCOVERY (17MPY23)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Course Outcome

At the end of the course students will be able to…

CO1	Describe in detail about various stages involved in modern drug discovery process
CO2	Explain the role of genomics, proteomics and bioinformatics in drug discovery
CO3	Explain various targets for drug discovery.
CO4	Explain various lead seeking method and lead optimization
CO5	Describe in detail about the concept of Rational Drug Design
CO6	Explain the concept of molecular docking and its applications
CO7	Explain the concept of QSAR and QSAR statistical methods
CO8	Explain Rationale of prodrug design and practical consideration of prodrug design

Units	Contents	Hours
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.	12
2	**Lead Identification-** combinatorial chemistry & high throughputscreening, in silico lead discovery 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 of NMR and X- raycrystallography in protein structure prediction	12

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 likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	12
4	**Molecular docking:** Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12
5	**QSAR Statistical methods –** regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA **Prodrug design**-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12

References

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE

(17MPY24)

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.

Course Outcome

At the end of the course students will be able to…

CO1	Explain the regulatory requirements for conducting clinical trial
CO2	Describe in detail about various types of clinical trial designs
CO3	Explain the responsibilities of key players involved in clinical trials
CO4	Describe the documentational requirements for Clinical trials
CO5	Explain Adverse drug reaction and its management
CO6	Describe basic concepts, and establishment of Pharmacovigilence
CO7	Explain ADR reporting, methods and tools used in Pharmacovigilence
CO8	Describe Pharmacoepidemiology, pharmacoeconomics and safety pharmacology

Units	Contents	Hours
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	12

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
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.	12
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	12
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, VigiFlow, Statistical methods for evaluating medication safety data.	12
6	**Pharmacoepidemiology, pharmacoeconomics, safety pharmacology**	12

References

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite

Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II (17MPY25P)

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

References

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen

4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

Semester III

MRM 301T - Research Methodology & Biostatistics

Course Outcome

At the end of the course students will be able to…

CO1	Learn general research methodology
CO2	Understand the basic concepts of biostatistics
CO3	Learn different parametric and non-parametric tests
CO4	Understand the functions of ethics committees in medical research
CO5	Learn the guidelines for developing animal facilities
CO6	Explain the guidelines and importance of medical research
CO7	Learn the guidelines for the experimentation on animals
CO8	Understand the genesis of bioethics with special reference to Helsinkl declaration

UNIT – I

General Research Methodology: Research, objective, 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

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non- parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, 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 – IV

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, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.