



Centurion
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*Shaping Lives...
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Course Structure and Syllabus

of

M. Pharm (Pharmaceutics)

School of Pharmacy and Life Sciences

2024

centurion university of technology and management

Shaping Lives... Empowering Communities...

COURSE STRUCTURE AND SYLLABI

M. Pharm (Pharmaceutics)

2024-25 Batch



Centurion
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Shaping Lives...
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School of Pharmacy and Life Sciences
CENTURION UNIVERSITY OF TECHNOLOGY & MANAGEMENT
Odisha-752050, India

Web Site: - www.cutm.ac.in

**CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT,
ODISHA**

CERTIFICATE



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This is to certify that the syllabus of the M. Pharm (Pharmaceutics) Programme of the School of Pharmacy and Life sciences is approved in the 14th Academic Council Meeting held on 22nd November 2024.

**Dean
School of Pharmacy and Life Sciences
CUTM, Odisha**





SCHOOL OF PHARMACY AND LIFE SCIENCES

SCHEME & SYLLABUS

M.PHARM (PHARMACEUTICS)

FOR

**THE MASTER OF PHARMACY (M. PHARM.)
COURSE REGULATION 2014**

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA No. 362, DATED DECEMBER 11, 2014)



Centurion
UNIVERSITY

Shaping Lives...
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CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT

BHUBANESWAR, ODISHA

2024

VISION:

To be a globally recognized centre for Teaching, Research and Entrepreneurial Training in Pharmaceutical Sciences and to provide Healthcare services for Societal needs.

MISSION:

- To nurture young minds into knowledgeable, skillful and ethical professionals to serve for the society.
- To support research in diverse ways by launching partnerships and collaborations.
- To ensure affordable health care by developing pharmaceutical formulations using in house resources.
- To inculcate the mindset for entrepreneurship and innovativeness to enrich the healthcare system.

Programme Objectives:

1. To develop advanced knowledge and technical expertise in Pharmacy.
2. To cultivate research skills, innovations and professional practice in the Pharmaceutical industry.
3. To Nurture and support an inclination for higher education and entrepreneurship.

PROGRAMME OUTCOMES (POs):

At successfully completing the M. Pharm program, student should have achieved the following program outcomes mentioned below

| SI No. | Programme Outcomes |
|--------|---|
| PO 1 | Pharmacy Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioural, social, and administrative pharmacy sciences; and manufacturing practices. |
| PO 2 | Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines. |
| PO 3 | Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions. |
| PO 4 | Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations. |
| PO 5 | Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being. |
| PO 6 | Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees). |
| PO 7 | Pharmaceutical Ethics: Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions. |
| PO 8 | Communication: Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions. |
| PO 9 | The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice. |
| PO 10 | Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development. |
| PO11 | Entrepreneurship: Develop entrepreneurship skills that support the growth of Pharmaceutical Industry / Pharmaceutical Services leading to economic development. |

| | |
|--------------|--|
| PO 12 | Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis. |
|--------------|--|

PSO (Program Specific Outcomes)

| SI No. | Program Specific Outcomes |
|---------------|---|
| PSO1 | Formulation Development and Optimization: Graduates of Masters in Pharmacy in Pharmaceutics will be able to develop and optimize various pharmaceutical formulations, such as tablets, capsules, creams, and ointments, using appropriate excipients and techniques. They will demonstrate expertise in selecting suitable drug delivery systems based on the physicochemical properties of drugs and the desired therapeutic outcomes. |
| PSO2 | Drug Delivery Systems: Design Students will be equipped with the knowledge and skills to design novel drug delivery systems that improve drug efficacy, patient compliance, and safety. They will be able to explore various routes of drug administration and incorporate advanced technologies, such as nanoparticles, liposomes, and microspheres, to achieve targeted and sustained drug release. |
| PSO3 | Research and Development: Graduates will be capable of conducting scientific research in pharmaceutics, contributing to the development of new drug delivery technologies, dosage forms, and innovative formulations. They will apply research methodologies, data analysis, and interpretation to address pharmaceutical challenges. |

CHAPTER – I: REGULATIONS

Short Title and Commencement

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

2. Minimum qualification for admission

A Pass in the following examinations

- a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)
- b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course.

Similarly, the credit associated with any of the other academic, co/extra- curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits 23 are distributed semester-wise as shown in Table 5. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

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

9. Course of study

The course of study for M. Pharm specializations shall include Semester wise Theory & Practical as given in Table – 1. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 1.

Table – 1: Course of study for M. Pharm. (Pharmaceutics)

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|--------------------|--|--------------|---------------|---------|-------|
| Semester I | | | | | |
| MPH101T | Modern Pharmaceutical Analytical Technique | 4 | 4 | 4 | 100 |
| MPH102T | Drug Delivery System | 4 | 4 | 4 | 100 |
| MPH103T | Modern Pharmaceutics | 4 | 4 | 4 | 100 |
| MPH104T | Regulatory Affairs | 4 | 4 | 4 | 100 |
| MPH105P | Pharmaceutics Practical I | 12 | 6 | 12 | 150 |
| MPH106P | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |
| Semester II | | | | | |
| MPH201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 4 | 4 | 4 | 100 |
| MPH202T | Advanced Biopharmaceutics & Pharmacokinetics | 4 | 4 | 4 | 100 |
| MPH203T | Computer Aided Drug Delivery System | 4 | 4 | 4 | 100 |
| MPH204T | Cosmetic and Cosmeceuticals | 4 | 4 | 4 | 100 |
| MPH205P | Pharmaceutics Practical II | 12 | 6 | 12 | 150 |
| MPH206P | Seminar/Assignment | 7 | 4 | 7 | 100 |
| Total | | 35 | 26 | 35 | 650 |

**Table – 2: Course of study for M. Pharm. III Semester
(Common for All Specializations)**

| Course Code | Course | Credit Hours | Credit Points |
|-------------|--|--------------|---------------|
| MRM 301T | Research Methodology Biostatistics* | 4 | 4 |
| MPH302P | Journal Club | 1 | 1 |
| MPH303P | Discussion / Presentation(Proposal Presentation) | 2 | 2 |
| MPH304P | Research Work | 28 | 14 |
| Total | | 35 | 21 |

* Non-University Exam

**Table – 3: Course of study for M. Pharm. IV Semester
(Common for All Specializations)**

| Course Code | Course | Credit Hours | Credit Points |
|-------------|---------------------------------|--------------|---------------|
| MPH401P | Journal Club | 1 | 1 |
| MPH402P | Research Work | 31 | 16 |
| MPH403P | Discussion / Final Presentation | 3 | 3 |
| Total | | 35 | 20 |

Table – 4: Semester wise credits distribution

| Semester | Credit Points |
|--|----------------------------|
| I | 26 |
| II | 26 |
| III | 21 |
| IV | 20 |
| Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities) | Minimum=02 Maximum=07* |
| Total Credit Points | Minimum=95 Maximum=100* |

Table – 5: Guidelines for Awarding Credit Points for Co-Curricular Activities

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

Note: International Conference: Held Outside India

International Journal: The Editorial Board outside India

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

10. Program Committee

1. The M. Pharm. Programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows: A teacher at the cadre of Professor shall be the Chairperson; One Teacher from 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.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in **Table – 6**.

11.1. End semester examinations

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

Tables – 6: Schemes for internal assessments and end semester (Pharmaceutics)

| Course Code | Course | Internal Assessment | | | End Semester Exams | | Total Marks | |
|-------------------|---|---------------------|-----------------|-------|--------------------|-------|-------------|------------|
| | | Continuous Mode | Sessional Exams | | Total | Marks | | Duration |
| Marks | Duration | | | | | | | |
| Semester I | | | | | | | | |
| MPH101T | Modern Pharmaceu- tical Analytical Techniques | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH102T | Drug Delivery System | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH103T | Modern Pharmaceuti Cs | 10 | 15 | 1 Hr | 25 | 75 | 3Hrs | 100 |
| MPH104T | Regulatory Affair | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH105P | Pharmaceuti cs Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| MPH106P | Seminar /Assignment | - | - | - | - | - | - | - |
| Total | | | | | | | | 650 |

| Semester II | | | | | | | | |
|-------------|--|----|----|-------|----|-----|-------|-----|
| MPH201T | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH202T | Advanced Biopharmaceutics & Pharmacokinetics | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH203T | Computer Aided Drug Delivery System | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH204T | Cosmetic and Cosmeceuticals | 10 | 15 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH205P | Pharmaceutics Practical I | 20 | 30 | 6 Hrs | 50 | 100 | 6 Hrs | 150 |
| MPH206P | Seminar /Assignment | - | - | - | - | - | - | 100 |
| Total | | | | | | | | 650 |

Tables – 7: 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 | 1 Hr | 25 | 75 | 3 Hrs | 100 |
| MPH302P | Journal Club | - | - | - | 25 | - | - | 25 |
| MPH303P | Discussion / Presentation (Proposal Presentation) | - | - | - | 50 | - | - | 50 |
| MPH304P | Research work | - | - | - | - | 350 | - | 350 |
| Total | | | | | | | | 525 |
| Semester IV | | | | | | | | |
| MPH401P | Journal club | - | - | - | 25 | - | - | 25 |
| MPH402P | Discussion / Presentation (Proposal Presentation) | - | - | - | 75 | - | - | 75 |
| MPH403P | Research work and Colloquium | - | - | - | - | 400 | 1 Hr | 400 |
| Total | | | | | | | | 500 |

*Non University Examination

11.2. Internal assessment: Continuous mode

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

Table – 8: Scheme for awarding internal assessment: Continuous mode

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

Table – 9: Guidelines for the allotment of marks for attendance

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

11.2.1. Sessional Exams

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

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

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

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 11. The exact dates of examinations shall be notified from time to time.

Table – 10: 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 |

16. Allowed to keep terms (ATKT):

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

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

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

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

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table –11.

Table – 11: Letter grades and grade points equivalent to Percentage of marks and performances

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

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

18. The Semester grade point average (SGPA)

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

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

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

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

19. Cumulative Grade Point Average (CGPA)

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

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

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

20. Declaration of class

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

First Class with Distinction = CGPA of 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

21. Project work

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

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

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

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

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation I Retotaling of answer papers

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

26. Re-admission after break of study

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

CHAPTER - II: SYLLABUS

SEMESTER-I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH101T)

Course Objective:

- To get fundamental knowledge of advanced analytical instrumental techniques for identification, characterization and quantification of drugs
- To handle instruments like NMR, Mass spectrometer, IR, HPLC, GC, etc.
- To perform analysis of elemental impurities

Course Outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|---|--------------------------------|
| CO-1 | <i>Analyze</i> of various drugs in single and combination dosage forms. | PO1, PO2, PO3, PO11, PO12 |
| CO-2 | <i>Analyze</i> Chemicals and Excipients | PO1, PO2, PO3, PO11, PO12 |
| CO-3 | <i>Explain</i> general principles and theory of spectroscopy | PO1, PO2, PO3, PO4, PO11, PO12 |
| CO-4 | <i>Describe</i> various separation techniques by employing chromatographic methods. | PO1, PO2, PO3, PO4, PO11, PO12 |
| CO-5 | <i>Understand</i> basic principles of biological tests and immunoassay. | PO1, PO2, PO3, PO11, PO12 |

THEORY

60 Hours

11 Hrs

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

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

c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

11 Hrs

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

11 Hrs

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

11 Hrs

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

a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

11 Hrs

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 diffraction 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 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.

c. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

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

REFERENCES

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

DRUG DELIVERY SYSTEMS (MPH102T)

Course Objective:

- To equip students with the knowledge and skills required to design, develop drug delivery system.
- To develop, and evaluate drug delivery systems for enhancing drug efficacy,
- To get knowledge on drug delivery system of vaccine

Course Outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|---|--------------------------|
| CO-1 | <i>Describe</i> Drug Delivery Principles a clear understanding of drug delivery, including drug absorption, distribution, metabolism, and excretion. | PO1, PO2, PO3, PO12 |
| CO-2 | <i>Identify</i> different routes of drug administration and understand the factors influencing drug delivery through each route. | PO1, PO2, PO3, PO12 |
| CO-3 | <i>Evaluate and compare</i> various drug delivery technologies, such as liposomes, nanoparticles, microspheres, and implants, in terms of drug release kinetics, targeting, and biocompatibility. | PO1, PO2, PO3, PO4, PO12 |
| CO-4 | <i>Discuss</i> the concept of targeted drug delivery and its potential applications in delivering drugs to specific sites in the body, enhancing treatment efficacy, and reducing side effects. | PO1, PO2, PO3, PO12 |
| CO-5 | <i>Assess</i> biocompatibility and Safety: Assess the biocompatibility and safety aspects of various drug delivery technologies, considering their potential impact on patient health. | PO1, PO2, PO3, PO12 |

THEORY

60 Hours

10 Hrs

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

10 Hrs

2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and

Osmotic Activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

10 Hrs

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

6 Hrs

4. Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

10 Hrs

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

8 Hrs

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

6 Hrs

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

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 (MPH103T)

Course Objective:

- To equip students with the knowledge and skills required to work in the forefront of pharmaceutical research and development
- To apply cutting-edge technologies
- To improve strategies on drug delivery, formulation, and patient care.

Course Outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|---|--------------------------|
| CO-1 | <i>Demonstrate</i> a comprehensive understanding of modern drug development processes. | PO1, PO2, PO3, PO9, PO12 |
| CO-2 | <i>Apply</i> the principles of biopharmaceutics and pharmacokinetics to analyze drug absorption, distribution, metabolism, and excretion | PO1, PO2, PO3, PO12 |
| CO-3 | <i>Design and optimize</i> advanced drug delivery systems, such as nanoparticles, liposomes, microspheres, and implants, to achieve targeted and controlled drug release. | PO1, PO2, PO3, PO4, PO12 |
| CO-4 | <i>Evaluate</i> the concept of personalized medicine and its applications in pharmaceuticals, considering individualized drug dosing and tailored therapies. | PO1, PO2, PO3,, PO12 |
| CO-5 | <i>Implement</i> Quality by Design (QbD) principles in pharmaceutical product development | PO1, PO2, PO3, PO4, PO12 |

THEORY

60 Hours

10 Hrs

1. a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental –physiological and formulation consideration, Manufacturing and evaluation.

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 Hrs

2. Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation,

Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

10 Hrs

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

10 Hrs

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

10 Hrs

5. Study of consolidation parameters: Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f_2 and f_1 , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

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 (MPH104T)

Course Objective:

- To knowledge and skills necessary to navigate the complex and evolving regulatory landscape in the pharmaceutical industry
- To ensure compliance, facilitate efficient drug development
- To contribute towards the successful registration and commercialization of pharmaceutical products

Course outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|---|--|
| CO-1 | Demonstrate a comprehensive understanding of the national and international regulatory frameworks governing the pharmaceutical industry | PO1, PO2, PO3, PO5, PO6, PO7, PO11, PO12 |
| CO-2 | Interpret and apply regulatory guidelines, including Good Manufacturing Practices (GMP), Good Clinical Practice (GCP), and Good Laboratory Practice (GLP) | PO1, PO2, PO3, PO5, PO6, PO7, PO11, PO12 |
| CO-3 | Develop the ability to prepare and submit regulatory documents, such as Investigational New Drug (IND) applications, New Drug Applications (NDAs), and Marketing Authorization Applications (MAAs) | PO1, PO2, PO3, PO5, PO6, PO7, PO11, PO12 |
| CO-4 | Manage regulatory timelines effectively to ensure timely submissions, approvals, and compliance | PO1, PO2, PO3, PO5, PO6, PO7, PO11, PO12 |
| CO-5 | Develop problem-solving skills to address regulatory challenges and navigate potential hurdles during drug development and marketing. | PO1, PO2, PO3, PO5, PO6, PO7, PO11, PO12 |

THEORY

60 Hours
12 Hrs

1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in – vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

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 Hrs

2.CMC, post approval regulatory affairs: Regulation for combination products and medical devices' 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 Hrs

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

12 Hrs

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.

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 (MPH105P)

Course Objective:

- To verify different processes/methods discussed in theory classes through experiments
- To gain practical skills on the formulation and evaluation of various types of tablets and novel drug delivery systems
- To estimate pharmaceutical active ingredients and their formulations through preformulation and analytical techniques

Course outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|--|-----------------------------|
| CO-1 | <i>Understand</i> the formulation techniques for various types of drug delivery systems and to evaluate them. | PO1,PO2,PO3,PO4, PO11, PO12 |
| CO-2 | <i>Impart</i> knowledge on analytical techniques for estimation of pharmaceutical active ingredients and their formulations. | PO1,PO2,PO3,PO4, PO11, PO12 |
| CO-3 | <i>Assess</i> the drug release from sustained and controlled drug delivery systems | PO1,PO2,PO3,PO4, PO11, PO12 |
| CO-4 | <i>Evaluate</i> the dosage forms, construct kinetic plots and determine similarity factor | PO1,PO2,PO3,PO4, PO11, PO12 |
| CO-5 | <i>Simplify</i> the formulation techniques and prepare matrix tablets, floating tablets and cosmetics. | PO1,PO2,PO3,PO4, PO11, PO12 |

1. Analysis of pharmacopoeial compounds and their formulations by UV Visible 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.

SEMESTER-II

**MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS)
(NTDS) (MPH201T)**

Course Objective:

- To impart knowledge in the area of advances in novel drug delivery systems.
- To recall the concepts of preformulation and relate them to formulation development.
- To illustrate the parameters of optimization and its applications in formulation development

Course outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|-------------|---|------------------------------|
| CO-1 | <i>Demonstrate</i> a comprehensive understanding of the principles and applications of nanotechnology in pharmaceutical sciences | PO1,PO2,PO3,PO4, PO12 |
| CO-2 | <i>Assess</i> the potential toxicity of nanomaterials and nanoparticles and consider safety aspects in developing nanotechnology-based drug delivery systems. | PO1,PO2,PO3,PO4, PO12 |
| CO-3 | <i>Analyse</i> the formulation of pulmonary drug delivery systems and their evaluation | PO1,PO2,PO3,PO4, PO12 |
| CO-4 | <i>Describe</i> criteria for selection of drugs and polymers for the development of NTDS | PO1,PO2,PO3,PO4, PO12 |
| CO-5 | <i>Perceive</i> the concepts of gene therapy and liposomal gene delivery. | PO1,PO2,PO3,PO4, PO12 |

THEORY

60 Hours

12 Hrs

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

12 Hrs

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

12 Hrs

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

12 Hrs

4.Pulmonary Drug Delivery Systems: Aerosols, propellants, Containers Types, preparation and

evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

12Hrs

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

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 (MPH202T)

Course Objective:

- To impart knowledge and skills necessary for dose calculations and dose adjustments and to apply biopharmaceutics theories to practical problems.
- To discuss the principles of biopharmaceutics and pharmacokinetics
- To predict pharmacokinetic and pharmacodynamic drug interactions

Course outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|---|-----------------------|
| CO-1 | <i>Understand</i> the mechanisms, interpret various factors affecting drug absorption, distribution, metabolism and excretion of drugs. | PO1,PO2,PO3,PO4, PO12 |
| CO-2 | <i>Predict</i> pharmacokinetic and pharmacodynamic drug interactions. | PO1,PO2,PO3,PO4, PO12 |
| CO-3 | <i>Apply</i> the pharmacokinetic models for the determination of pharmacokinetic parameters | PO1,PO2,PO3,PO4, PO12 |
| CO-4 | <i>Analyse</i> the drug product performance by in-vitro, in-vivo and in-situ models | PO1,PO2,PO3,PO4, PO12 |
| CO-5 | <i>Determine</i> the bioavailability testing protocol of a drug and compare the bioequivalence among marketed products. | PO1,PO2,PO3,PO4, PO12 |

THEORY

60 Hours

12 Hrs

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, 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.

12 Hrs

2. Biopharmaceutic considerations in drug product design and In-Vitro Drug Product

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

12 Hrs

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

12 Hrs

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. 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 Hrs

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.

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, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 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. 49Scope

COMPUTER AIDED DRUG DEVELOPMENT (MPH203T)

Course Objective:

- To assess the applications of computers in clinical data management
- To discuss the principles of integrated and coherent use of computerized information (informatics) in the drug development process
- To discuss the impact of artificial intelligence, robotics and computational fluid dynamics.

Course outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|--|-----------------------|
| CO-1 | <i>Apply</i> computational tools and software for molecular modelling, virtual screening, and structure-based drug design to identify potential drug candidates. | PO1,PO2,PO3,PO4, PO12 |
| CO-2 | <i>Describe</i> the concepts for computer-aided formulation development | PO1,PO2,PO3,PO4, PO12 |
| CO-3 | <i>Simplify</i> the pharmacokinetic and pharmacodynamics characteristics of drugs by simulations. | PO1,PO2,PO3,PO4, PO12 |
| CO-4 | <i>Utilize</i> molecular docking and molecular dynamics simulations to predict ligand-receptor interactions and binding affinities. | PO1,PO2,PO3,PO4, PO12 |
| CO-5 | <i>Explain</i> the impact of artificial intelligence, robotics and computational fluid dynamics. | PO1,PO2,PO3,PO4, PO12 |

THEORY

60 Hours

12 Hrs

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

b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

12Hrs

2. Computational Modeling Of Drug Disposition: Introduction, Modelling 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 Hrs

3. Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

12Hrs

4 a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12Hrs

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

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1 st 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 (MPH204T)

Course Objective:

- To impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.
- To develop effective cosmetic and cosmeceutical formulations
- To maintain desired Safety, stability, and efficacy of developed cosmetic and cosmeceutical

Course outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|--|----------------------------|
| CO-1 | <i>Formulate</i> cosmetic products, including creams, lotions, gels, serums, and makeup, using appropriate ingredients and formulation techniques. | PO1,PO2,PO3,PO4, PO11,PO12 |
| CO-2 | <i>Describe</i> Indian regulatory requirements for the manufacture, sale, import and labeling of cosmetics | PO1,PO2,PO3,PO7, PO11,PO12 |
| CO-3 | <i>Outline</i> the biological aspects of cosmetics, basic structure, functions, common problems associated with skin, hair and oral cavity. | PO1,PO2,PO3, PO11,PO12 |
| CO-4 | <i>Apply</i> the principles of formulation building blocks for different cosmetic / cosmeceutical products. | PO1,PO2,PO3, PO11,PO12 |
| CO-5 | <i>Elaborate</i> the regulatory guidelines for herbal cosmetics, herbal ingredients used in hair care, skin care and oral car | PO1,PO2,PO3,PO7,PO11,PO12 |

THEORY

60 Hours

12Hrs

1.Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

12Hrs

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

12Hrs

3.Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological

additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12Hrs

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

12Hrs

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

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 (MPH205P)

Course Objective:

- To provide practical skills on formulation of various novel drug delivery systems.
- To apply design of experiment in formulation development
- To design formulations by QbD concept

Course outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|---|----------------------------|
| CO-1 | <i>Recall</i> the basic techniques for preparation of microspheres, liposomes, niosomes and solid dispersions. | PO1,PO2,PO3,PO4, PO11,PO12 |
| CO-2 | <i>Compare</i> the dissolution studies of various marketed products. | PO1,PO2,PO3,PO4, PO11,PO12 |
| CO-3 | <i>Design</i> formulations by QbD concept, use simulations for estimation of pharmacokinetics and pharmacodynamics. | PO1,PO2,PO3,PO4, PO11,PO12 |
| CO-4 | <i>Determine</i> test for drug binding characteristics, cell permeation and bioavailability of the formulations. | PO1,PO2,PO3,PO4, PO11,PO12 |
| CO-5 | <i>Elaborate</i> the regulatory guidelines for herbal cosmetics, herbal ingredients used in hair care, skin care and oral care. | PO1,PO2,PO3,PO7, PO11,PO12 |

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual

18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

SEMESTER-III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM301T)

Course Objective:

- To provide value addition and current requirement in clinical research and pharmacovigilance
- To conceptualizing, designing, conducting, managing and reporting of clinical trials.
- To develop drug safety data in Pre-clinical and clinical phases of Drug development and post-market surveillance.

Course Outcomes: On completion of this course, the successful students should be able to:

| CO | Statements | Cos & POs Mapping |
|------|---|--------------------------|
| CO-1 | <i>Explain</i> the regulatory requirements for conducting clinical trial | PO1, PO2, PO3, PO7, PO12 |
| CO-2 | <i>Demonstrate</i> the types of clinical trial designs | PO1, PO2, PO3, PO7, PO12 |
| CO-3 | <i>Execute</i> safety monitoring, reporting and close-out activities | PO1, PO2, PO3, PO7, PO12 |
| CO-4 | <i>Describe</i> the principles of Pharmacovigilance | PO1, PO2, PO3, PO7, PO12 |
| CO-5 | <i>Perform</i> the adverse drug reaction reporting systems and communication in Pharmacovigilance | PO1, PO2, PO3, PO7, PO12 |

THEORY

60 Hours

12 Hrs

1. 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.

12Hrs

2. 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 (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

12 Hrs

3. 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.

12 Hrs

4. 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.

12 Hrs

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



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Paralakhemundi, Dist.- Gajapati
Odisha, India. PIN– 761211

Bhubaneswar Campus

Ramchandrapur
P.O. – Jatni, Bhubaneswar
Dist.- Khurda, Odisha,
India, PIN– 752050

Balangir Campus

Behind BSNL Office
IDCO land, Rajib Nagar
Dist.- Balangir, Odisha
India, PIN-767001

Rayagada Campus

IDCO Industrial Area
Pitamahal, Rayagada
Dist.-Rayagada, Odisha
India, PIN-765001

Balasore Campus

Gopalpur,
P.O.-Balasore
Dist.-Balasore, Odisha
India, PIN-756044

Chatrapur Campus

Ramchandrapur,
Kaliabali Chhak,
P.O-Chatrapur, Dist.-Ganjam
Odisha, India, PIN-761020