



KOMMAREDDY VENKATA SADASIVA RAO

SIDDHARTHA COLLEGE OF PHARMACEUTICAL SCIENCES

(AUTONOMOUS)

Siddhartha Nagar, Vijayawada - 520010, AP, INDIA

(Sponsors: Siddhartha Academy of General & Technical Education)

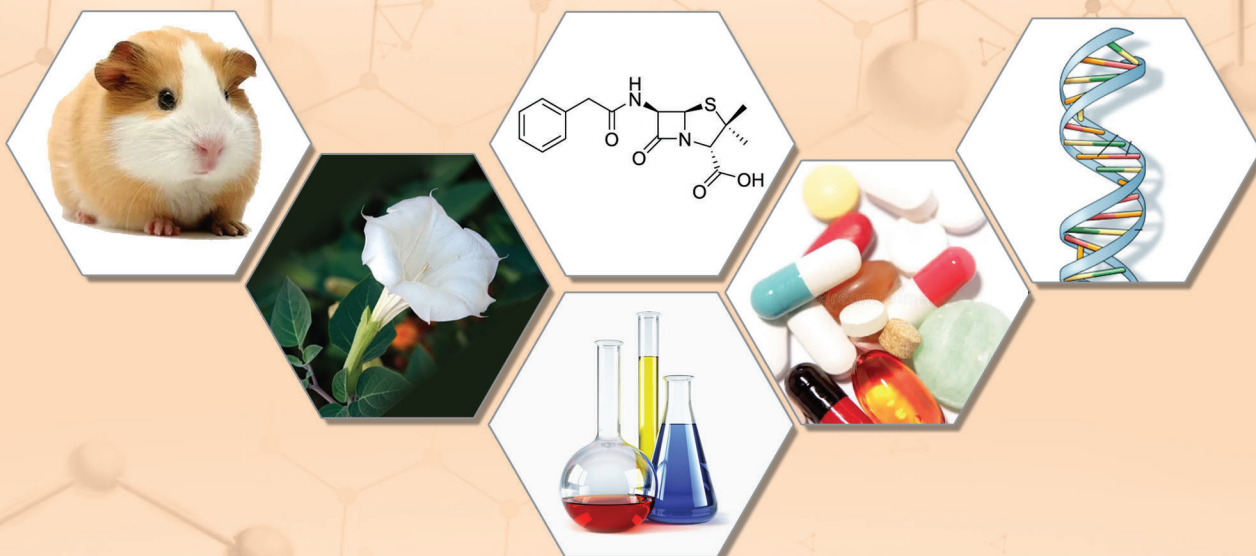
ISO 9001:2015, ISO14001:2015 & ISO50001:2011 CERTIFIED INSTITUTION

Affiliated to Krishna University, Machilipatnam

Approved by AICTE, PCI, New Delhi and Govt. of Andhra Pradesh

E-mail: kvsrsiddharthapharma@gmail.com

PHARMACY COUNCIL OF INDIA
NEW DELHI



MASTER OF PHARMACY COURSE **ACADEMIC REGULATIONS AND SYLLABUS**



Web: www.kvsrsiddharthapharma.edu.in



Kommareddy Venkata Sadasiva Rao Siddhartha College of Pharmaceutical Sciences

Tel: 0866- 2479775
0866- 2493347

(AUTONOMOUS)

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PHARMACIST'S OATH

- ❖ I swear by the Code of Ethics of Pharmacy Council of India, in relation to the community and shall act as an Integral part of health care team.
- ❖ I shall uphold the laws and standards governing my profession.
- ❖ I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
- ❖ I shall follow the system which I consider best for pharmaceutical care and counselling of patients.
- ❖ I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.
- ❖ I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.
- ❖ I shall associate with organizations having their objectives for betterment of the profession of pharmacy and make contribution to carry out the work of those organizations.
- ❖ While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times !
- ❖ Should I trespass and violate this oath, may the reverse be my lot !



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KVSR Siddhartha College of Pharmaceutical Sciences (KVSR SCOPS), a NAAC "A" accredited institution and an autonomous college with 30 years of academic excellence, was established with the vision of delivering quality pharmaceutical education. Approved by the Pharmacy Council of India (PCI), New Delhi, and affiliated with Krishna University, Machilipatnam, it is recognized under Section 2(f) of the UGC Act and as a research center by Krishna University.

The college offers diverse programs, supported by a legacy of dedicated and experienced faculty members. KVSR SCOPS features state-of-the-art infrastructure, including digital classrooms, a modern opaque laboratory with advanced instruments, a well-stocked library, an air-conditioned seminar hall, and CCSEA-approved animal facilities. Unique highlights include a NABL-accredited laboratory, a primary healthcare center, two air-conditioned computer labs, and indoor and outdoor sports facilities.

The college's strong collaborations are reflected in MOUs with Dr. Pinnamaneni Siddhartha Institute of Medical Sciences and leading pharmaceutical industries, including multinational corporations, to enhance research, training, and placement opportunities. This vibrant institution remains committed to fostering innovation, academic excellence, and holistic development.



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VISION

- To create competent Pharmacy Professionals in demonstrating health care delivery and research in promoting academic and professional excellence.

MISSION

- To Provide transformative learning experience that prepares students for successful careers in research education and pharmacy practice
- To promote values of professionalism, life -long learning and leadership skills among students

OBJECTIVES

- Foster graduates dedicated to continuous learning through advanced studies, empowering them to navigate a dynamic global landscape of emerging trends.
- To equip pharmacy professionals with the skills for innovative and problem-based research, enabling successful careers in diverse pharmaceutical and healthcare systems.
- To inculcate robust ethical values and exemplary professional behaviour to embrace and assimilate emerging changes in the pharmacy profession effectively.



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Principal's Message



Greetings!

It gives me immense pride and joy to address you as the Principal of KVSR Siddhartha College of Pharmaceutical Sciences, an institution that has consistently upheld excellence in pharmaceutical education and research. Over the years, KVSR SCOPS has emerged as a beacon of knowledge and innovation, shaping the future of countless students and contributing meaningfully to the advancement of the pharmaceutical sciences.

With the recent conferment of autonomous status by UGC and achieving NAAC 'A' grade accreditation, our institution stands at the forefront of academic excellence. These milestones are a testament to the collective efforts of our dedicated faculty, talented students, and supportive management.

At KVSR SCOPS, we strive to create a nurturing environment that fosters creativity, critical thinking, and lifelong learning. Our robust PhD and research programs reflect our commitment to pushing the boundaries of knowledge and addressing contemporary challenges in healthcare and allied fields.

As we embark on a new chapter, I invite you to join hands with us in our journey towards shaping a healthier, better tomorrow. Together, let us continue to inspire and achieve greater heights.

With Best Regards

Prof. A.SUNEETHA
Principal



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Web: www.kvrsiddharthapharma.edu.in

GOVERNING BODY

S.No.	Name of the Member	Category	Nature
1.	Dr. C.Nageswara Rao	Management	Chairman
2.	Sri. P. LakshmanaRao	Management	Member
3.	Sri. S. VenkateswaraRao	Management	Member
4.	Sri N. Lalitha Prasad	Management	Member
5.	Sri. Ch. Arun Kumar	Management	Member
6.	Dr.A. Suneetha	Principal of the College	Principal & Professor
7.	Dr. M. BasaveswaraRao	University Nominee	External Member
8.	Prof. N. Usha	State Government Nominee	External Member
9.	Dr.K.R.S.SambasivaRao	Educationist	External Member
10.	Dr.G.Vijaya Kumar	Teachers of the college	Internal Member
11.	Dr.G. Ramana	Teachers of the college	Internal Member
12.	Dr. M. Vijaya Lakshmi	Administrative staff of the College	Internal Member



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LIST OF TEACHING STAFF

S.No.	Name of the staff	Designation
1.	Dr.A.Suneetha	Principal & Professor Head
2.	Dr.M.Vijaya Lakshmi	Associate Professor
3.	Ms.T.S.Mrinalini	Assistant Professor
4.	Ms. S. L.S.Mounica Pratyusha	Assistant Professor
5.	Smt.K.Jyothi	Assistant Professor
6.	Dr.G.Ramanaiah	Professor & HOD
7.	Dr A. Bharathi	Professor
8.	Dr. T. P. Rao	Associate Professor
9.	Dr N. Kanaka Durga Devi	Associate Professor
10.	Dr.D. Jyothirmayee	Associate Professor
11.	Dr.K.Ravi Shankar	Assistant Professor
12.	Dr. Sk.Arifa Begum	Assistant Professor
13.	Sri. K. Anil Kumar	Assistant Professor
14.	Smt.K.Haritha	Assistant Professor
15.	Smt.R.Anusha	Assistant Professor
16.	Mr.P.Srinivasu	Assistant Professor
17.	Dr.B.Anupama	Associate Professor & HOD
18.	Dr. T. Sarala Devi	Assistant Professor
19.	Dr. V.Narendra	Assistant Professor
20.	Ms.Sk.Jareena	Assistant Professor
21.	Sri.K.Durga Prasad	Assistant Professor
22.	Dr. Ch.Supriya	Associate Professor & HOD
23.	Dr. Ch.Siva Reddy	Professor & HOD
24.	Dr. Ch. Nagabhushanam	Assistant Professor
25.	Sri.A.V.S.Ravi Sai Nadh	Assistant Professor
26.	Smt.O.Iswarya	Assistant Professor
27.	Smt.J.Jyothirmayi	Assistant Professor
28.	Dr.V.Karuna Sree	Associate Professor & HOD
29.	Dr. P. Swetha	Assistant Professor
30.	Mr.J.Susanth	Assistant Professor
31.	Dr. G. Vijaya Kumar	Professor & HOD
32.	Smt.A Lakshmi Pavani	Assistant Professor
33.	Smt.K.Harshavardhini	Assistant Professor
34.	Ms.R.Triveni	Assistant Professor
35.	Smt. K. Sirisha	Assistant Professor
36.	Smt. K.Pradeepthi	Assistant Professor
37.	Smt.S.Pranathi	Assistant Professor
38.	Ms.A.Soujanya	Assistant Professor
39.	Dr.P. Lakshmi prasanna	Assistant Professor
40.	Smt. Patibandla Jahnavi	Assistant Professor
41.	Smt.Viswa Srujani	Assistant Professor
42.	Sri. L.Vinay Sekhar	Physical Director



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NON-TEACHING STAFF

S.No.	Name of the staff	Designation
1.	Sri.S.Veerabhadra Rao	Student Counsellor
2.	Sri.K.Venkata Rao	Senior Asst.
3.	Sri.K.Nagamalliswara Rao	Accountant
4.	Smt.A.Saileela	Asst. Librarian
5.	Smt. S.Srilakshmi	Data Entry Operator
6.	Smt.P.Venkata Krishnaveni	Data Entry Operator
7.	Smt.M.Anupama	Office Assistant -cum-Data Entry Operator
8.	Sri.T.Venkat Rao	Office Assistant -cum-Data Entry Operator
9.	Smt.B.Padma Priya Choudary	Office Assistant -cum-DEO
10.	Smt.V.Indumathi	Lab Assistant
11.	Smt.S.Hari Kumari	Lab Assistant
12.	Smt.M.Sailaja	Lab Assistant
13.	Smt.V.Sridevi	Lab Assistant
14.	Smt.A.Pavani Kumari	Technician
15.	Smt.M.Visala Gowthami	Lab Assistant
16.	Smt.J.Nagalakshmi	Lab Assistant
17.	Smt.G.Nagalakshmi	Lab Assistant
18.	Ms. D.Beulah	Lab Assistant
19.	Sri.B.Nagababu	Attender
20.	Smt.M.Suryam	Sweeper
21.	Sri.T.Arjun	Sweeper
22.	Sri.T.Seshubabu	Lib. Attender
23.	Sri.Y.Appa Rao	Gardener
24.	Smt.S.Rani	Sweeper
25.	Smt.K.Pravallika	Lib. Attender
26.	Smt. B.Savitri	Sweeper
27.	Smt. G.Rutamma	Sweeper
28.	Smt. Anitha	Sweeper
29.	Smt.Y.Philomin Rani	Sweeper



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CODE OF CONDUCT

KVSR Siddhartha College of Pharmaceutical Sciences is committed to upholding the highest standards of ethics, integrity, and accountability in all aspects of its operations. The college has a prescribed code of conduct for students, staff and administrators and organizes periodic programmes in this regard.

- 1) Integrity and Honesty:** All members of the KVSRSOCPS community are expected to act with honesty, transparency, and truthfulness in all interactions, both within the college and with external stakeholders.
- 2) Respect and Dignity:** KVSRSOCPS values diversity and inclusivity. All individuals are expected to treat one another with respect, fairness, and dignity, regardless of gender, religion, nationality, or other characteristics.
- 3) Academic Integrity:** KVSRSOCPS is committed to promoting a culture of academic honesty. Plagiarism, cheating, and other forms of academic dishonesty will not be tolerated.
- 4) Conflicts of Interest:** Any situation that may compromise or appear to compromise the objectivity or fairness of a decision or action should be disclosed promptly. If any member of the KVSRSOCPS community believes that an ethical violation has occurred, they are encouraged to report it through the appropriate channels. The college will take all reports seriously and will conduct a thorough investigation.
- 5) Code of Conduct for students:** Students must follow the General Rules. Violation of any of the following rules and regulations specified will lead to disciplinary action taken by the authorities against the concerned student.
 - Students must reach the college every day at 9:20 am and on Saturday 8:20 am i.e., the time for stroke of the first bell and sit only in the respective classroom.

- They must stay in the campus all through the working hours. Students should not gather or loiter unnecessarily in the corridors.
- The college campus is to be kept clean and the garbage bins have to be used for waste disposal.
- Students should attend the college only in the uniform on all working days except on Friday. They has to wear the ID card always, while in the campus.
- Student's behaviour towards the teachers, non-teaching staff and other students should be decent and humble. Arrogant attitude or rude behaviour shown towards any would be considered condemnable and punishable as well.
- They must use of all resources optimally on the campus, be regular in attending the classes and attentive in the classroom.
- In case of any problem they must contact the respective HOD or student counselor.
- Use of mobile phone/tablet/similar electronic gadget is strictly restricted inside the classroom/examination hall, library, laboratories and corridors. Violation of this rule may be followed by a penalty.
- Ragging, in any of its forms, is strictly prohibited inside and outside the college premises. Strict action (even rustication) would be taken against anyone found guilty in this matter (UGC Regulation 2009).
- They should not tease the girl students. They should not misbehave with anyone in the campus. Non-compliance invites strict legal action.
- They should not utter any unparliamentarily word in the campus.



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Y24 M.PHARM. ACADEMIC CALENDAR-2024-2025

Specialisations: Pharmaceutics & Bio-technology and Pharmaceutical Analysis (Tentative)

Particulars/ Details	I SEM	II SEM
Induction Programme	14.10.2024 to 16.10.2024	NA
Class work Commencement	17-10-2024	17.03.2025
Closure of Instructions	23.02.2025	09.08.2025
Total number of workingdays	101	101
I Internal Examinations	10.12.2024	04.06.2025
II Internal Examinations	24.02.2025	11.08.2025
Submission of Application Forms & Attendance particulars to the controller of Examinations	20.02.2025	06.08.2025
Payment of Examination fee	24.02.2025 to 26.02.2025	11.08.2025 to 13.08.2025
University Theory Examinations	05.03.2025	18.08.2025
University Practical Examinations	Immediately after theory Examinations	Immediately after theory Examinations
Commencement of next semester	17.03.2025	25.08.2025



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Academic Rules & Regulations for M.Pharmacy Programme

(As Approved by the Academic Council of

KVSR Siddhartha College of Pharmaceutical Sciences)

(Applicable to the students admitted into the First year M.Pharmacy from
the
Academic year 2024-2025 onwards)

Preamble:

Kommareddy Venkata Sadasiva Rao Siddhartha College of Pharmaceutical Sciences (KVSR SCOPS) has consistently pursued initiatives to achieve academic excellence, enhance quality, and implement administrative reforms. In alignment with the institution's vision and mission, significant milestones have already been accomplished, ensuring progressive growth and innovation.

The institution is recognized and approved by the **Pharmacy Council of India (PCI)** and the **Andhra Pradesh State Council for Higher Education (APSCHE)**. It has been accredited by the **National Assessment and Accreditation Council (NAAC)** and holds recognition from the **University Grants Commission (UGC)** and the **Department of Scientific & Industrial Research (DSIR)** for its contributions to education and research.

As a forward-looking institution, KVSR SCOPS is proud to announce the implementation of the **Choice Based Credit System (CBCS)** for the **M.Pharmacy Programme**, starting from the academic year 2024-2025. This step reflects the college's commitment to providing a flexible, student-centric learning environment that fosters skill development, industry readiness, and academic excellence.

Title:

The academic rules and regulations shall be referred to as the "**Credit Based Semester System (CBSS)**", applicable to the **M.Pharmacy Programme** of **Kommareddy Venkata Sadasiva Rao Siddhartha College of Pharmaceutical Sciences (KVSR SCOPS)**, located in **Vijayawada-520010, Andhra Pradesh, India**.

This system is designed to align with the latest academic frameworks, ensuring a structured, flexible, and learner-centric approach to postgraduate education in pharmaceutical sciences.

Scope, Application, and Commencement:

The academic regulations outlined herein are applicable to the **M.Pharmacy Programme** (including regular and lateral entry pathways) offered by **Kommareddy Venkata Sadasiva Rao Siddhartha College of Pharmaceutical Sciences (KVSR SCOPS)**. These regulations encompass:

1. **Definitions:** Key terms and critical concepts related to the programme.
2. **Methodologies:** Guidelines for calculations, assessments, and performance evaluations.
3. **Committees:** Details of committees established for academic and administrative purposes.
4. **Evaluation System:** Comprehensive framework for evaluating academic performance, including continuous assessment and semester-end evaluations.

These academic regulations are effective starting with the admissions for the **2024-2025 academic year** and are designed to provide a structured, transparent, and efficient framework for academic governance and evaluation.

Rationale for Introducing the Credit-Based Semester System (CBSS):

1. **Alignment with Educational Policies:**
The Ministry of Human Resource Development (MHRD) has emphasized adopting transformative measures to improve the quality of education in higher learning institutions across India. Implementing CBSS ensures compliance with these recommendations.
2. **Enhanced Learning Opportunities:**
CBSS enables the provision of diverse and advanced learning opportunities tailored to meet the scholastic needs and aspirations of students. This system enhances educational quality and excellence by fostering a student-centric approach.
3. **Flexibility for Learners:**
The system allows students to complete their academic programmes within a specified timeframe while offering flexibility to learn at their own pace. It accommodates varied learning preferences and helps students explore multidisciplinary interests.
4. **Global Trends and Standardization:**
CBSS aligns with global educational trends by adopting an internationally recognized framework. This includes a robust grading system that accurately reflects learner performance, ensuring standardization and comparability of educational programmes.
5. **Skill Enhancement and Employability:**
By integrating electives and interdisciplinary subjects, CBSS prepares students for a dynamic professional landscape, enhancing both skill development and employability.

Advantages of the Choice-Based Credit System (CBCS):

1. **Student-Centric Approach:**
The CBCS shifts the focus from traditional teacher-centered education to a student-centered framework, empowering learners to take charge of their academic journey.
2. **Flexibility in Course Selection:**
Students have the freedom to choose courses across disciplines, including interdisciplinary, intra-disciplinary, and skill-oriented subjects, catering to their interests and career aspirations.
3. **Global Compatibility:**
CBCS aligns educational systems with global standards, enhancing the institution's

reputation and increasing student opportunities for international education and employment.

4. **Learner Autonomy:**

This system respects the individuality of learners by allowing them to tailor their education based on their needs, aptitudes, and interests.

5. **Transparency and Compatibility:**

CBCS promotes clear and transparent evaluation methods, ensuring uniformity and comparability between different institutions and educational structures.

6. **Enhanced Co-Curricular Participation:**

Students are encouraged to engage in co-curricular and extracurricular activities to earn additional credits, fostering holistic development outside the traditional classroom setup.

7. **Optimal Faculty Utilization:**

The system ensures that faculty expertise is leveraged across diverse courses, enriching the teaching-learning process.

DEFINITIONS:

Academic Year: Two consecutive (one odd + one even) semesters constitute one academic year.

Credit Based Credit System (CBCS): Credit based semester system is a flexible system of learning that permits students to select from the prescribed elective courses.

Programme: 'Programme' means a set of the required number of semesters leading to the award of M.Pharmacy degree.

Course: Usually referred to, as "papers" is a component of a programme. All courses need not carry the same weightage. The courses should define learning objectives and learning outcomes. A course may be designed to comprise lectures/ tutorials/laboratory work/ field work/ outreach activities/ project work/ industrial training/viva-voce/ seminars/ group discussion/ soft skills/ technical skills/ entrepreneurship /assignments/ presentations etc., or a combination of some of these to meet the objectives/outcomes.

Semester: 'Semester' means a term consisting of a minimum of 630 contact periods distributed over 90 working days spread over 15 weeks of six-day duration each and seven contact periods with 50 minutes duration. Depending upon its duration, each academic year will be divided into two semesters. Semesters will be known as either odd Semester or even semester. The Semester from July to November will be semesters I or III similarly the semester from December to April will be semesters II or IV.

Credit Based Semester System (CBSS): Under the CBSS, the requirement for awarding a degree is prescribed in terms of number of credits to be completed by the students.

Credits:

Credit is a kind of weightage given to the contact hours to teach the prescribed syllabus, which is in a unit form. One credit is equivalent one hour of teaching (lecture) and for practical one credit is equivalent to two hours.

Credit point (p):

Credit point is the value obtained by multiplying the grade point (G) by the credit (C): $P = G \times C$.

Grade point (G):

Grade point is an integer indicating the numerical equivalent of the letter grade.

Semester Grade Point Average (SGPA):

Semester Grade Point Average (SGPA) is the value obtained by dividing the sum of credit points earned by a student in various courses taken together in a semester by the total number of credits earned by the student in that semester. SGPA shall be rounded off to two decimal places. SGPA indicates the comprehensive academic performance of a student in a semester.

Cumulative Grade Point Average (CGPA):

Cumulative Grade Point Average (CGPA) is the value obtained by dividing the sum of credit points in all the courses earned by a student for the entire programme, by the total number of credits. CGPA shall be rounded off to two decimal places. CGPA indicates the comprehensive academic performance of a student in a programme.

Letter Grade:

It is an index of the performance of students in a said course. Grades are denoted by letters O, A, B, C, D, E, F and AB.

Transcript or Grade Card or Certificate:

Based on the grades earned, a grade certificate shall be issued to all the registered students after every semester. The grade certificate will display the course details (code, title, number of credits, grade secured) along with GPA of that semester and CGPA earned till that semester.

CHAPTER –I

REGULATIONS

1. Short Title and Commencement

These regulations shall be called as “The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2024-25. The regulations framed are subject to modifications from time to time by the authorities of the college.

2. Minimum qualification for admission

A Pass in the following examinations

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

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

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by 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/extracurricular 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 are distributed semester-wise as shown in Table 6. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

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

9. Course of study

The specializations in M.Pharm program is given in Table 1.(As per PCI)

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

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table No. 2 to 5. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table No. 2 to 5.

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

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis 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. 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 Exam**

**Table – 5: Course of study for M. Pharm. IV Semester
(Common for All Specializations)**

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

Table – 6: 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

***Credit Points for Co-curricular Activities**

Table – 7: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (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 – 8 & 9.

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 – 8 : Schemes for internal assessments and end semester

(Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester-I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPH102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hr	100
MPH103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hr	100
MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hr	100
MPH105P	Pharmaceutics Practical I	20	30	6 Hr	50	100	6 Hr	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
Semester-II								
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hr	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hr	100
MPH203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hr	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hr	100
MPH205P	Pharmaceutics Practical II	20	30	6 Hr	50	100	6 Hr	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

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**Tables – 9: Schemes for internal assessments and end semester examinations
(Pharmaceutical Analysis-MPA)**

Course Code	Course	Internal Assessment				End Semester		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester-I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hr	100
MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA105P	Pharmaceutical Analysis Practical I	20	30	6 Hr	50	100	6 Hr	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650
Semester-II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPA203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hr	100
MPA204T	Herbal and Cosmetic Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA205P	Pharmaceutical Analysis Practical II	20	30	6 Hr	50	100	6 Hr	150
-	Seminar/Assignment	-	-	-	-	-	-	100
Total								650

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 – 10: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 11)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 11)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 11: 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 12. The exact dates of examinations shall be notified from time to time.

Table – 12: 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

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 -13.

Table – 13: 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 valuation/ 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:

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

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed 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

Presentation of work 100 Marks Communication skills 50 Marks Question and answer skills 100 Marks Total 250 Marks shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

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

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

20. Declaration of class

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

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

21. Project work

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

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

Evaluation of 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 of answer papers

There is provision for revaluation of the answer papers in any examination. However, the candidates can apply for revaluation by paying prescribed fee.

26. Re-admission after break of study

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

PHARMACEUTICS(MPH)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPH 101T)

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,

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

THEORY

60 HOURS

11Hrs

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. Spectro fluorimetric: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy:

11Hrs

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. Application of NMR spectroscopy.

3. Mass Spectroscopy:

11Hrs

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.

4. Chromatography:

11Hrs

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.

11Hrs

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 Xray diffraction.

11Hrs

6 Immunological assays : RIA (Radio immune assay), ELISA, Bioluminescence assays

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

(MPH 102T)

cope:

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

OBJECTIVES

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

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

THEORY

60 Hrs

10Hrs

UNIT-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, Bioelectronics Medicines, 3D printing of pharmaceuticals, Telepharmacy.

10Hrs

UNIT- 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.

10Hrs

UNIT- 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.

16Hrs

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

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

14Hrs

UNIT-5. Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

REFERENCES:

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

JOURNALS

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

MODERN PHARMACEUTICS

(MPH 103T)

Scope:

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

Objectives:

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

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

THEORY

60 HRS

10Hrs

UNIT-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.

10Hrs

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.

10Hrs

UNIT-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.

10Hrs

UNIT-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.

10Hrs

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

10Hrs

UNIT-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.

REFERENCES

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

REGULATORY AFFAIRS

(MPH 104T)

Scope:

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

- To know the approval process and filing process of IND, NDA and ANDA
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for regulatory submissions

Objectives:

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

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

THEORY

60Hrs

Unit 1: Documentation In Pharmaceutical Industry:

12 Hours

Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL, REGULATION), **The Patents Act 1970-Drug related case studies**, 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.

Unit 2: Regulatory requirement for product approval:

12 Hours

API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.

Unit 3: Post approval regulatory requirements for actives and drug products:

12 Hours

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 M Regulatory requirements of EU, MHRA, TGA and ROW countries

Unit 4: Non clinical drug development:**12 Hours**

Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Unit 5: Clinical trials:**12 hours**

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

PHARMACEUTICS PRACTICALS - I
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometer
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 osmotic ally controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

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

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

THEORY

60 Hrs

12Hrs

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

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

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

UNIT-4. Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. **12Hrs**

UNIT-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, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

(MPH 202T)

Scope

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

Objectives

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

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

THEORY

60 Hrs

12Hrs

UNIT-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.

12Hrs

UNIT-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.

12Hrs

UNIT-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.

12Hrs

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

12Hrs

UNIT-5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and Pharmacodynamic, drug interactions. Pharmacokinetics and Pharmacodynamic 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. Brahmkar 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.

COMPUTER AIDED DRUG DEVELOPMENT

(MPH 203T)

Scope

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

Objectives

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

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

THEORY

60Hrs

12Hrs

UNIT-1. a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modelling 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

UNIT-2. Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

12Hrs

UNIT-3. Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in

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

12Hrs

- UNIT-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 Pharmacodynamic: 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

UNIT-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, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopaedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS

(MPH 204T)

Scope

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

Objectives

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

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

THEORY

60Hrs

12Hrs

UNIT-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

UNIT-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

UNIT-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 syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as

allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12Hrs

UNIT-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

UNIT-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 theology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

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

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

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

PHARMACEUTICAL ANALYSIS(MPA)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPA 101T)

Scope

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

Objectives

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

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

THEORY

60Hrs

Unit 1: Spectroscopic Techniques - Fundamentals and Applications 12 Hours:
C101T1

- a) UV-Visible Spectroscopy: Introduction, theory, laws, instrumentation, solvent choice and effects, applications, and difference/derivative spectroscopy.
- b) IR Spectroscopy: Theory, molecular vibration modes, sample handling, dispersive and Fourier-Transform IR instrumentation, factors affecting vibrational frequencies, data interpretation, and applications.
- c) Atomic Absorption Spectroscopy and Flame Emission Spectroscopy : Principles, instrumentation, interferences, and applications.
- d) Spectrofluorimetry: Theory of fluorescence, factors influencing fluorescence, quenchers, instrumentation, and applications.

Unit 2: Nuclear Magnetic Resonance (NMR) Spectroscopy 12 Hours
C101T2

- a) Quantum numbers and their role in NMR, principles,
- b) instrumentation, solvent requirements, relaxation processes, chemical shift and factors affecting it, spin-spin coupling, coupling constants
- c) Nuclear magnetic double resonance, FT-NMR, and ¹³C NMR basics.
- d) Applications of NMR Spectroscopy: Practical applications in analyzing compound structures.

Unit 3: Mass Spectrometry 12 Hours
C101T3

- a) Mass Spectroscopy: Principles, theory, and instrumentation.
- b) Ionization Techniques: Electron impact, chemical ionization, field ionization, FAB, MALDI, APCI, ESI, APPI.
- c) Analyzers: Quadrupole and Time of Flight, mass fragmentation rules, metastable ions, isotopic peaks.
- d) Applications of Mass Spectroscopy

Unit 4: Chromatography Techniques & Electrophoresis C101T4, C101T5 12 Hours

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

- a) Thin Layer Chromatography (TLC)
- b) High Performance Thin Layer Chromatography (HPTLC)

- c) Ion Exchange Chromatography
- d) Column Chromatography
- e) Gas Chromatography (GC)
- f) High Performance Liquid Chromatography (HPLC)
- g) Ultra High Performance Liquid Chromatography (UHPLC)
- h) Affinity Chromatography
- i) Gel Chromatography

Electrophoresis: Principle, instrumentation, working conditions, factors affecting separation, and applications of: a. Paper Electrophoresis, b. Gel Electrophoresis, c. Capillary Electrophoresis, d. Zone Electrophoresis, e. Moving Boundary Electrophoresis, f. Isoelectric Focusing

Unit 5: X-Ray Crystallography, Potentiometry and Thermal Analysis Techniques 12 hours C101T6

- a) X-Ray Crystallography: Production of X-rays, Bragg's law, rotating crystal technique, X-ray powder technique, types of crystals, and applications of X-ray diffraction.
- b) Potentiometry: Principles, ion-selective electrodes, and applications.
- c) Thermal Analysis Techniques: Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA), Derivative Differential Thermal Analysis (DDTA), Thermogravimetric Analysis (TGA), Pharmaceutical applications of each thermal technique.

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, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

- c) Photostability and ICH Stability Guidelines: Focus on stability testing for biological products.
- d) Regulatory Requirements and Protocols: Protocols specific to phytopharmaceuticals, HPTLC/HPLC fingerprinting, interactions, and complexities in stability testing.

Unit 4: Biological Testing and assays of the following

12 hours C102T5

- a) Adsorbed Tetanus vaccine,
- b) adsorbed Diphtheria vaccine,
- c) Human anti-haemophilic vaccine,
- d) Rabies vaccine,
- e) tetanus Anti-toxin,
- f) tetanus Anti-serum,
- g) Oxytocin,
- h) Heparin sodium IP,
- i) Antivenom,
- j) PCR studies for gene regulation, instrumentation .(Principles and procedures)

Unit 5: Immuno assays

12 hours C102T6

- a) Basic principles, antibody production, separation of bound/unbound drug, techniques in Radioimmunoassay,
- b) Optical IA
- c) Enzyme IA
- d) Fluoro IA
- e) Luminescence IA
- f) quantification and applications of IA

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION (MPA 103T)

Scope

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

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY

60 Hrs

12Hrs

Unit 1: Introduction to Qualification and Validation 12 Hours C103T1

- a) **Basics of Qualification and Validation:** Definition, advantages, streamlining qualification and validation processes, and understanding the Validation Master Plan.
- b) **Qualification Processes:** User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (including Calibration, Preventive Maintenance, Change Management).
- c) **Qualification of Equipment:** Manufacturing equipment, analytical instruments, and laboratory equipment.

Unit 2: Qualification of Analytical Instruments and Glassware C103T2

12 Hours

- a) **Analytical Instruments:** Qualification procedures for electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, and HPTLC.
- b) **Glassware Qualification:** Qualification standards for volumetric flasks, pipettes, measuring cylinders, beakers, and burettes.

Unit 3: Validation of Utility Systems and Cleaning Processes C103T3 12 Hours

- a) **Utility System Validation:** Pharmaceutical water systems, pure steam, HVAC systems, compressed air, and nitrogen.
- b) **Cleaning Validation:** Development of cleaning methods, validation of analytical methods used in cleaning, equipment and facility cleaning, and Cleaning in Place (CIP).

Unit 4: Analytical Method Validation and Computerized System Validation 12 Hours C103T4

- a) **Analytical Method Validation:** General principles and validation as per ICH guidelines and USP standards.
- b) **Computerized System Validation:** Validation of electronic records, digital significance (21 CFR Part 11), and understanding GAMP 5 guidelines.

Unit 5: Intellectual Property in the Pharmaceutical Industry C103T5, C103T6
12 Hours

- a) **Introduction to Intellectual Property (IP):** Concepts of IP, IP Protection (IPP), Intellectual Property Rights (IPR), economic importance, and protection mechanisms (patents, copyright, trademarks).
- b) **Patent Applications and Procedures:** Filing processes, types of patents (provisional, non-provisional, PCT, convention), international patenting requirements, costs, rights, and responsibilities of a patentee.
- c) **Intellectual Property Ethics and Technology Transfer:** Impact of IP on society, ethical considerations, avoiding unethical practices, and significance of technology transfer (TOT) in the pharmaceutical industry.

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, (Marcel Dekker).
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, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

OOD ANALYSIS (MPA 104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and
- legislations

THEORY

60 Hrs

12Hrs

Unit 1: Carbohydrates and Proteins in Food 12 Hours C104T1

- a) Carbohydrates: Classification and properties of food carbohydrates, general methods of carbohydrate analysis, changes during food processing, digestion, absorption, metabolism, dietary fiber, crude fiber, and applications of food carbohydrates.
- b) Proteins: Chemistry and classification of amino acids and proteins, physico-chemical properties and structure, general methods of analysis, digestion, absorption, and metabolism of proteins.

Unit 2: Lipids and Vitamins 12 Hours C104T2

- a) Lipids: Classification, general methods of analysis, refining of fats and oils, hydrogenation of vegetable oils, detection of adulteration, and methods for measuring spoilage in fats and fatty foods.
- b) Vitamins: Classification, methods of vitamin analysis, and principles of microbial assays for B-series vitamins.

Unit 3: Food Additives and Pigments 12 Hours C104T3

- a) Food Additives: Introduction to preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening agents, and gelling agents, with analysis methods.
- b) Pigments and Synthetic Dyes: Characteristics of natural pigments, permitted synthetic dyes, non-permitted synthetic dyes used in industry, and detection methods for natural, permitted, and non-permitted dyes.

Unit 4: Analysis of Dairy and Fermentation Products 12 Hours C104T4

- a) Milk and Dairy Products: General analytical methods for milk and its constituents (ice cream, milk powder, butter, margarine, cheese) including adulterants and contaminants.
- b) Fermentation Products: Analysis of products like wine, spirits, beer, and vinegar.

Unit 5: Pesticide Analysis and Food Regulations 12 Hours C104T5 , C104T6

- a) Pesticide Analysis: Impact of pests on food, pesticide use in agriculture, pesticide cycle, analysis of organophosphorus and organochlorine pesticides, and determination of residues in grains, fruits, vegetables, milk, and milk products.
- b) Food Legislation: Emphasis on regulatory standards such as BIS, Agmark, FDA, and US-FDA regulations.

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

RMACEUTICAL ANALYSIS PRACTICALS - II (MPA 105P)

Modern Pharmaceutical and Analytical Techniques

1. Analysis of Pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer **C105P1**
2. Simultaneous estimation of multicomponent formulations by UV spectrophotometry
3. Experiments based on HPLC **C105P2**
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulfate by fluorimetry **C105P3**
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by instrumental techniques
8. Colorimetric determination of drugs using different reagents **C105P1**

Advanced Pharmaceutical Analysis

9. Assay of official compounds by different titrations
10. Quantitative determination of hydroxyl group **C105P6**
11. Quantitative determination of amino group **C105P6**
12. Impurity profiling of drugs **C105P6**

Pharmaceutical Validation C105P4

13. Calibration of glassware
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Protocol and performance of analytical method validation **C105P4**

Food Analysis C105P5

21. Determination of total reducing sugars

22. Determination of proteins
23. Determination of saponification value, iodine value, peroxide value, acid value in food products
24. Determination of fat content and rancidity in food products
25. Analysis of natural and synthetic colors in food
26. Determination of preservatives in food
27. Determination of pesticide residue in food products
28. Analysis of vitamin content in food products
29. Determination of density and specific gravity of foods
30. Determination of food additives

2nd Semester

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Scope

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

Objectives

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic
- compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

THEORY

60Hrs

1 Unit 1: High-Performance Liquid Chromatography (HPLC) and Advanced Techniques (12 hours) C201T1

- a) HPLC Principles and Instrumentation: Principle, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injectors, detectors, columns, column problems, gradient HPLC, and HPLC solvents.
- b) Troubleshooting and Method Development: Sample preparation, method development, troubleshooting.
- c) New Developments in HPLC: Ultra and nano liquid chromatography in pharmaceutical analysis.
- d) Chiral Analysis in HPLC: Immobilized polysaccharide CSPs, advancements in enantiomeric separations, revised phase chiral method development, HILIC approaches.
- e) Preparative HPLC: Principles and practical aspects.

Unit 2: Biochromatography and Gas Chromatography (GC) (12 hours) C201T2

- a) Biochromatography Techniques: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography - general principles, stationary phases, and mobile phases.
- b) Gas Chromatography: Principles, instrumentation, derivatization, headspace sampling, GC columns, detectors, and quantification.
- c) High-Performance Thin Layer Chromatography (HPTLC): Principles, instrumentation, and pharmaceutical applications.

Unit 3: Advanced Chromatography Techniques and Capillary Electrophoresis (CE) (12 hours) C201T3

- a) Supercritical Fluid Chromatography (SFC): Principles, instrumentation, and pharmaceutical applications.
- b) Capillary Electrophoresis (CE): Overview of CE in pharmaceutical analysis, basic configuration, characteristics, principles, and various modes of CE.
- c) Method Development in CE: General considerations, use of crown ethers as buffer additives, and CE-MS hyphenation.

Unit 4: Mass Spectrometry (MS) and Hyphenated Techniques (12 hours) C201T4

- a) Mass Spectrometry Principles and Instrumentation: Theory, different ionization methods (electron impact, chemical, field, FAB, MALDI, APCI, ESI, APPI).
- b) MS Fragmentation and Analysis: Fragmentation rules, metastable ions, isotopic peaks, and MS applications.
- c) Advanced MS Techniques: LC-MS hyphenation, DART-MS analysis.
- d) Mass Analyzers and MS/MS Systems: Types of analyzers (Quadrupole, TOF, FT-ICR, ion trap, Orbitrap), MS/MS systems (Tandem: QqQ, TOF-TOF, Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap).

Unit 5: Nuclear Magnetic Resonance (NMR) Spectroscopy (12 hours) C201T5, C201T6

- a) NMR Principles and Instrumentation: Quantum numbers, principle, instrumentation, solvent requirements, relaxation processes, and NMR signal characteristics.
- b) Chemical Shift and Coupling: Chemical shift, factors affecting it, spin-spin coupling, and coupling constant.
- c) Advanced NMR Techniques: Nuclear magnetic double resonance, FT-NMR with reference to ¹³C NMR, spin-spin and spin-lattice relaxation.
- d) NMR Applications: ¹³C NMR, 1-D and 2-D NMR (NOESY, COSY techniques), interpretation and applications in pharmaceutical analysis.
- e) LC-NMR Hyphenation: Principles and applications in complex mixture analysis.

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. 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.
8. Organic Spectroscopy by Donald L. Pavia, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

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

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY

60Hrs

1 Unit 1: Introduction to Bioanalytical Methods and Drug Extraction (12 hours) C202T1

Extraction of Drugs and Metabolites from Biological Matrices: General need, principle, and procedures in bioanalytical methods.

- a) Protein precipitation
- b) Liquid-liquid extraction
- c) Solid phase extraction
- d) Novel sample preparation approaches

Bioanalytical Method Validation: USFDA and EMEA guidelines for method validation in bioanalysis.

Unit 2: Biopharmaceutical Considerations in Drug Bioavailability (12 hours) C202T2

- a) Biopharmaceutical Factors Affecting Drug Bioavailability: Introduction to key factors affecting drug bioavailability.
- b) In Vitro Testing for Bioavailability: Dissolution and drug release testing & Alternative methods of dissolution testing transport models
- c) Biopharmaceutics Classification System (BCS): Solubility: Experimental methods for solubility testing, Permeability: In-vitro, in-situ, and in-vivo methods

Unit 3: Pharmacokinetics, Toxicokinetics, and Drug Interactions(12 hours) C202T3

- a) Pharmacokinetics and Drug Interactions: Fundamental considerations of pharmacokinetics and pharmacodynamics (PK-PD interactions).
- b) Protein-binding interactions
- c) Tissue-binding interactions
- d) Cytochrome P450-based drug interactions
- e) Transporter-linked drug interactions
- f) Toxicokinetics: Importance and application in preclinical studies.
- g) Microsomal assays
- h) Evaluation in toxicokinetic studies
- i) LC-MS in Bioactivity Screening and Proteomics: Application of LC-MS for bioactivity screening and proteomic analysis.

Unit 4: Cell Culture Techniques in Bioanalytical Studies(12 hours) C202T4

- a) Basic Cell Culture Techniques:
- b) Equipment used in cell culture labs
- c) Cell culture media, types of cell cultures, and general procedures
- d) Isolation, subculture, and cryopreservation of cells

- e) Cell Characterization and Applications:
- f) Characterization of cells and their bioanalytical applications
- g) Principles and applications of cell viability assays (MTT assays)
- h) Flow cytometry: Principles and applications in bioanalysis

Unit 5: Metabolite Identification and Bioavailability/Bioequivalence Studies (12 hours) C202T5& C202T6

- a) Metabolite Identification: In-vitro and in-vivo approaches for metabolite identification
- b) Protocols and sample preparation
- c) Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID)
- d) Regulatory perspectives on metabolite identification
- e) Drug Metabolizing Enzymes and Metabolite Assays: In-vitro assays for drug metabolites and metabolizing enzymes.
- f) **Drug Product Performance:** Bioavailability and bioequivalence studies, Methods for assessing bioavailability, Design and evaluation of bioequivalence studies, Crossover study designs, biosimilars, and clinical significance of bioequivalence

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassan, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

Scope

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

Objectives

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

- The cGMP aspects in a pharmaceutical industry

- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments

THEORY

60 hrs

12Hrs

1. Unit 1: Introduction to Quality Control and Quality Assurance (12 hours) C203T1

- a) Concept and Evolution: Fundamental concepts of quality control and quality assurance in the pharmaceutical industry.
- b) Good Laboratory Practices (GLP): Scope of GLP, key definitions, and roles of the Quality Assurance Unit. Protocols for non-clinical testing, animal house control, and report preparation.
- c) Overview of ICH Guidelines: QSEM with special focus on the Q-series for quality management.

Unit 2: Good Manufacturing Practices (GMP) and cGMP Guidelines(12 hours) C203T2

cGMP Guidelines according to Various Standards like Schedule M, USFDA (including CDER and CBER), PIC, WHO, and EMEA guidelines covering

- a) Key aspects: organizational roles, personnel responsibilities, training, hygiene, and personal records.
- b) Facility requirements: drug industry location, plant layout, construction, maintenance, sanitation, environmental control, and sterile area maintenance.
- c) Contamination Control and Warehousing: Control of contamination and Good Warehousing Practice.
- d) Quality by design(QbD): Introduction to principles , software tools, application in analytical procedures.
- e) CPCSEA guidelines for managing animal facilities in pharmaceutical contexts.

Unit 3: Quality Control in Raw Materials, In-Process, and Finished Products(12 hours) C203T3

Quality Control of Raw Materials and Finished Products: Procedures for raw material analysis, finished product testing, and packaging material inspection.

- a) Developing specifications (ICH Q6 and Q3) and purchase specifications for maintenance of stores.
- b) In-Process Quality Control (IPQC): IPQC and finished product quality control for formulations (tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic, and surgical products).
- c) Standards for IPQC according to Indian, US, and British pharmacopoeias.(how to refer pharmacopoeias)
- d) Quality Control for Packaging:Testing for containers, closures, and secondary packaging materials.

Unit 4: Documentation and Records in the Pharmaceutical Industry(12 hours) C203T4

Types of Documentation:

- a) Three-tier documentation: Policy, Procedures, and Work Instructions, along with formats and record maintenance.
- b) Documentation Standards:How to maintain, retain, and retrieve documents; preparation of Standard Operating Procedures (SOPs).

- c) Master Formula Record, Batch Formula Record
- d) Quality Audit Plan and Reports.
- e) Specifications and test procedures, protocols and reports, Distribution Records Electronic Data.

**Unit 5: Manufacturing Operations and Quality Control in Production(12 hours)
C203T5& C203T6**

- a) Manufacturing Operations and Sanitation: Sanitation practices, control of mix-ups and cross-contamination, and processing of intermediates and bulk products.
- b) Packaging Operations and Product Release: Steps in packaging, IPQC, release of finished products, and management of process deviations.
- c) Production Control: Charge-in of components, production time limitations, drug product inspection, calculation of yields, and expiry date calculation.
- d) Process review: Production record review, change control, sterile product management, aseptic process control, and packaging quality.

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 compendium 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, Excipients 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, Nilesch 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.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY

60Hrs

1. Unit 1: Herbal Remedies - Toxicity and Regulations (12 hours) C204T1

- a) Comparison of herbal remedies with conventional drugs, evaluating the efficacy of herbal medicine products, validation of herbal therapies, and pharmacodynamic and pharmacokinetic issues in herbal treatments.
- b) Regulatory Guidelines: WHO and AYUSH guidelines for herbal drug standardization.

Unit 2: Adulteration and Deterioration of Herbal Drugs (12 hours) C204T2

- a) Introduction to adulteration and substitution of herbal drugs, types and causes of adulteration, measures for controlling adulteration, sampling procedures, and determination of foreign matter.
- b) Techniques like DNA fingerprinting, identification of contaminants (heavy metals, pesticides, phototoxins, microbial).
- c) Regulatory Guidelines: Understanding the regulatory requirements for establishing herbal drug industries, including global marketing management, Indian and international patent laws for herbal drugs and natural products.

Unit 3: Testing and Standardization of Natural Products (12 hours) C204T3& C204T4

- a) The impact of herbal medicine on clinical laboratory testing, screening for adulterants using modern analytical instruments, regulations for dispensing herbal drugs, and stability testing of natural products.
- b) Pharmacopoeial Comparisons: Comparative study of herbal drug monographs as outlined in IP, USP, Ayurvedic, American, British, Siddha, and Unani pharmacopoeias, with WHO guidelines on quality assessment of herbal drugs.

Unit 4: Herbal Drug-Drug and Food Interactions (12 hours) C204T5

- a) WHO and AYUSH guidelines for the safety monitoring of natural medicines.
- b) Spontaneous reporting schemes for adverse reactions to bio drug –drug and bio drug – food interactions with suitable examples and
- c) Challenges in monitoring the safety of herbal medicines

Unit 5: Evaluation and Quality Control of Cosmetic Products (12 hours) C204T6

- a) Analytical methods for evaluating cosmetic raw materials and finished products , including determining acid, ester, saponification, iodine, and peroxide values, and

assessing rancidity, moisture, ash, volatile matter, heavy metals, powder fineness, density, and viscosity.

- b) Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS
- c) Indian Standard specifications by BIS for sampling and testing various cosmetic finished products, including baby care, skincare, dental products, personal hygiene preparations, lipsticks, hair products, and skin creams.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmetic logy 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition.

PHARMACEUTICAL ANALYSIS PRACTICALS - I **(MPA 205P)**

1. Advanced Instrumental Analysis C205P1

1. Comparison of absorption spectra by UV and Woodward–Fieser rules
2. Interpretation of organic compounds by FT-IR **C204P2**
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals **C204P3**
6. Identification of organic compounds using FT-IR, NMR, CNMR, and Mass spectra

Modern Bioanalytical Techniques

7. Biomolecules separation utilizing various sample preparation techniques and quantitative analysis of components by gel electrophoresis
8. Biomolecules separation utilizing various sample preparation techniques and quantitative analysis of components by HPLC techniques **C204P4**
9. Isolation of analgesics from biological fluids (blood serum and urine)
10. Protocol preparation and performance of analytical/bioanalytical method validation **C204P5**
11. Protocol preparation for the conduct of BA/BE studies according to guidelines

Quality Control and Quality Assurance

12. In-process and finished product quality control tests for tablets, capsules, parenterals, and creams
13. Quality control tests for primary and secondary packing materials
14. Assay of raw materials as per official monographs **C204P5**
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record
17. Preparation of Batch Manufacturing Record

Herbal and Cosmetic Analysis C204P6

18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and developer in hair dye
20. Determination of foam height and SLS content of shampoo
21. Determination of total fatty matter in creams (soap, skin, and hair creams)
22. Determination of acid value and saponification value
23. Determination of calcium thioglycolate in depilatories

Semester III
MRM301T-Research Methodology & Statistics

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 (wilcoxon 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.

M.PHARMACY
PHARMACEUTICAL ANALYSIS

Course Number & Course Name	CO No	Course Outcome (CO)
MPA101T Modern Pharmaceutical Analytical Techniques	Upon completion of this course the graduate is able to	
	C101T1	To Recall the selected analytical spectrometric techniques and applications
	C101T2	To gain knowledge on interpretation of NMR spectra instrumentation, applications of ¹³ C & FT NMR
	C101T3	To remember different types of ionization and mass analysers in mass spectroscopy
	C101T4	To analyze pharmaceutical drugs using different chromatographic techniques
	C101T5	To choose different electrophoresis techniques for the separation of mixture of compounds
	C101T6	To elaborate the study in analysis by using X-ray crystallographic technique, potentiometry and thermal techniques
MPA102T Advanced Pharmaceutical Analysis	Upon completion of this course the graduate is able to	
	C102T1	To Classify the impurities in drug substance, new drug product And residual solvents as per ICH guidelines
	C102T2	To illustrate the identification of elemental impurities, analytical procedures and C, H, N, S analysis
	C102T3	To learn stability testing protocols with mechanistic and stability information
	C102T4	To assess the impurity profiling and degradant characterization and stability testing of phyto pharmaceuticals HPLC/HPTLC
	C102T5	To evaluate the biological vaccines, anti toxins antiserum as per pharmacopoeia
	C102T6	To estimate the drugs by immune assay procedures
MPA103T Pharmaceutical Validation	Upon completion of this course the graduate is able to	
	C103T1	To know why to perform validation and qualification studies
	C103T2	To get brief outline for qualification of glass ware and analytical instruments like FTIR, GC, HPLC, HPTLC, UV, pH
	C103T3	To develop knowledge regarding importance of cleaning Validation and utility system validation
	C103T4	To study analytical method validation, computerized system validation as per ICH / USP guidelines
	C103T5	To know basics of intellectual property
	C103T6	To maximize the knowledge regarding how to file a patent and its Procedure and significant of technology transfer in pharmaceutical industry .
MPA104T Food Analysis	Upon completion of this course the graduate is able to	
	C104T1	To recall the concepts of Biomolecules, their processing digestion Absorption and metabolism of carbohydrates and proteins

	C104T2	To explain different food constituents like lipids and vitamins
	C104T3	To identify food additives and to understand different techniques in determination of food additives
	C104T4	To analyse finished food products and fermentation products
	C104T5	To estimate the concentration of pesticide level in finished goods and Various foods and to explain the effect of pests and insects on various foods
	C104T6	To improve knowledge on food regulations and legislations and understand different analytical techniques in food processing
MPA105P Pharmaceutical Analysis Practical I	Upon completion of this course the graduate is able to	
	C105P1	To recall the assay of official compounds by different titrations
	C105P2	To illustrate the calibration /Validation of different analytical instruments with their compliance
	C105P3	To analyse the pharmacopoeial compounds and their formulations by Chromatographic and Spectroscopic techniques
	C105P4	To interpret the impurities and residual solvents by Impurity profiling of drugs
	C105P5	To determine the Physico-chemical properties of food products
	C105P6	To estimate the various constituents in food products
MPA201T Advanced Instrumental Analysis	Upon completion of this course the graduate is able to	
	C201T1	How the HPLC is applied for the analysis of enantiomers and the chiral compounds
	C201T2	To explain the different bio chromatography and gas chromatographic techniques
	C201T3	To apply knowledge of advanced chromatography techniques and CE-MS for the analysis of pharmaceutical compounds
	C201T4	To analyze the pharmaceutical drugs by using hyphenated mass Spectrometric techniques
	C201T5	To gain knowledge how to interpret NMR spectra for structural analysis
	C201T6	To maximize the knowledge about different types of NMR techniques like FTNMR, C13
MPA202T Modern BioAnalytical Techniques	Upon completion of this course the graduate is able to	
	C202T1	To choose various extraction procedures for the sample Preparation in bio-analytical method development and its validation according to USFDA and EMEA guidelines.
	C202T2	To explain Biopharmaceutical considerations and Biopharmaceutics classification system
	C202T3	To summarize the applications of pharmacokinetic and toxicokinetic studies

	C202T4	To classify various cell culture techniques and study of cell viability assays
	C202T5	To evaluate the metabolites and drug metabolizing enzymes
	C202T6	To predict the performance of drug product by bioequivalence studies

MPA203T Quality Control and Quality Assurance	Upon completion of this course the graduate is able to	
	C203T1	To Define and describe fundamental principles of quality control, quality assurance, and Good Laboratory Practices (GLP).
	C203T2	To understand the guidelines for Good Manufacturing Practices (GMP) and contamination control as per various regulatory standards.
	C203T3	To Apply ICH guidelines and pharmacopoeial standards to ensure quality control of raw materials, finished products, and packaging.
	C203T4	To Analyze quality management documentation, including SOPs, master formula records, and batch records, for compliance with regulatory standards.
	C203T5	To Evaluate production processes and control measures for sterile product manufacturing and packaging operations.
	C203T6	Design and propose a comprehensive quality assurance framework for pharmaceutical production and process reviews.
MPA204T Herbal and Cosmetic Analysis	Upon completion of this course the graduate is able to	
	C204T1	To define herbal remedies, to recall efficacy and validation of herbal Products and to recall WHO and AYUSH guidelines
	C204T2	To explain adulteration and deterioration types causes and Determination techniques and to illustrate regulatory requirements for setting herbal drug industry
	C204T3	To experiment with the analytical techniques in testing of natural products and drugs
	C204T4	To compare methods in determination of herbal drugs in monographs of different pharmacopoeias
	C204T5	To determine the herbal drug-drug interactions according to WHO and AYUSH guidelines
	C204T6	To estimate cosmetic products, finished products and raw Materials for the presence of different impurities and chemical constituents to meet Specifications as per Bureau Indian standards
MPA205P Pharmaceutical Analysis Practical III	Upon completion of this course the graduate is able to	
	C205P1	To Demonstrate the ability to analyze pharmacopoeial compounds, multicomponent formulations, and drugs using UV-Vis spectrophotometry and colorimetric methods with various reagents
	C205P2	To Employ advanced chromatographic techniques, including HPLC and Gas Chromatography, for the quantification, separation, and impurity profiling of pharmaceutical compounds..
	C205P3	To Evaluate the applicability of fluorimetry and flame photometry for the estimation of specific analytes like riboflavin,

		quinine sulfate, sodium, and potassium in pharmaceutical and biological matrices.
	C205P4	To Develop and validate analytical methods by performing calibration of analytical instruments, including pH meters, UV-Vis spectrophotometers, FTIR, GC, and HPLC, and assess cleaning validation protocols
	C205P5	To Analyze food products for critical quality parameters such as reducing sugars, protein, fat content, natural and synthetic colors, preservatives, pesticide residues, and vitamin content using advanced instrumental techniques.
	C205P6	To Perform impurity profiling of drugs and quantitative determination of specific functional groups like hydroxyl and amino groups in pharmaceutical compounds using titrimetric and advanced instrumental methods..
MRM 301T Research Methodology and Biostatistics (Common for all specializations) (Theory)		Upon completion of this course the graduate is able to
	C301T1	To define the concepts of research methodology
	C301T2	To infer data using biostatistic techniques
	C301T3	To identify the importance of knowledge of medical research
	C301T4	To inspect the laboratory animal facilities
	C301T5	To know the importance of CPCSEA guidelines
	C301T6	To maximize the knowledge regarding declaration of Helsinki
Project Work (Common for all specializations)	PW1	To define the fundamentals , carry out the literature review on the proposed research work and identify the problem
	PW2	To summarise the requirements in the proposed research
	PW3	To develop the research hypothesis
	PW4	To take part in research experiments and documented
	PW5	To evaluate the work done by applying statistic tools
	PW6	To appraise societal application and appreciation

M. PHARM - PHARMACEUTICS

Program Outcomes (POs)

Upon the completion of the program, the graduate is able to

PO 1	In-Depth Knowledge: Acquire a deep understanding of the processes involved in pharmaceutical drug manufacturing and how to analyze their chemical composition
PO 2	Laboratory Expertise: Ability to perform experiments and operate instruments in the laboratory, which is crucial for creating and testing pharmaceuticals in a safe and efficient manner.
PO 3	Research and Innovation: Develop Skill in conducting research in pharmaceutical sector and generating novel and improved methods for the development and evaluation of medicines.
PO 4	Effective Problem-Solving: Ability to solve difficult problems that arise during the manufacturing and testing of drugs and integrate the same for enhancing the quality applying statistics and computer software tools.
PO 5	Collaborative Skills: Collaborate effectively with other healthcare professionals and researchers to enhance both pharmaceutical products and research initiatives.
PO 6	Clear Communication: Effective in communicating research findings and testing results using precise scientific language that the peers in the field can understand.
PO 7	Ethical Conduct: Adhere to ethical standards in the work, taking responsibility for ensuring the safety of pharmaceutical products for patients.
PO 8	Patient-Centered Approach: Prioritize the safety, effectiveness, and well-being of patients, makes utmost concern in pharmaceutical practices.
PO 9	Knowledge Sharing: Disseminate their discoveries by publishing articles in respected scientific journals and presenting the research work at academic and professional gatherings to improve methodologies within the field.
PO 10	Regulatory Adherence: Understanding and compliance with the established rules and regulations and quality standards in the pharmaceutical and healthcare sectors, ensuring the safety and quality of medications.
PO 11	Lifelong Learning: Ongoing learning and self-improvement even after completing studies, staying updated with the latest scientific knowledge and industry practices.

Program Specific Outcomes (PSO)

PSO 1	Advanced Formulation Expertise: Acquire an in-depth understanding of pharmaceutical drug manufacturing processes and formulation techniques, enable to design and create innovative drug delivery systems and dosage forms.
PSO 2	Research Pioneers: Excel in research and innovation within the field, demonstrating the ability to develop novel and improved methodologies for drug development and evaluation, contributing to advancements in pharmaceutical science.
PSO 3	Laboratory Proficiency: Demonstrate exceptional skills in laboratory techniques, particularly in the context of pharmaceutical formulation and drug analysis, ensuring the safe and efficient production and testing of medications.
PSO 4	Innovative Problem Solvers: Competent at solving complex challenges that may arise during drug manufacturing and testing, utilizing knowledge and laboratory expertise to find practical solutions and optimize pharmaceutical processes.

Program Educational Objectives (PEOs)

PEO 1	Comprehensive Expertise: Deep and comprehensive understanding of pharmaceutical drug manufacturing, chemical analysis, and formulation, equipping with the knowledge to excel in pharmaceutical research, production, and development.
PEO 2	Research and Innovation Leaders: Emerge as leaders in pharmaceutical research and innovation, consistently generating novel and improved methods for drug development and evaluation. Able to contribute significantly to the advancement of pharmaceutical science and the development of safer and more effective medicines.
PEO 3	Advanced Laboratory Proficiency: Proficient in utilizing advanced laboratory techniques and instrumentation, particularly in the realm of pharmaceutical formulation and drug analysis. This expertise enables to contribute safe and efficient pharmaceutical production, ensuring the highest quality medications.
PEO 4	Solutions-Oriented Problem Solvers: Develops exceptional problem-solving skills, particularly in addressing complex challenges during drug manufacturing and testing. And leverages the knowledge and laboratory expertise to find practical and innovative solutions that optimize pharmaceutical processes and ensure product quality and safety.
PEO 5	Effective Communicators and Collaborators: Effective communicators who conveys their research findings and testing results clearly to their peers and the broader scientific community. Also excel in collaborating with healthcare professionals and researchers to enhance pharmaceutical products and research initiatives, fostering teamwork and interdisciplinary approaches in the field.

M. PHARM - PHARMACEUTICAL ANALYSIS

Program Outcomes (POs)

Upon the completion of the program, the graduate is able to

PO 1	In-Depth Knowledge: Acquire a deep understanding of the processes involved in pharmaceutical drug manufacturing and how to analyze their chemical composition
PO 2	Laboratory Expertise: Ability to perform experiments and operate instruments in the laboratory, which is crucial for creating and testing pharmaceuticals in a safe and efficient manner.
PO 3	Research and Innovation: Develop Skill in conducting research in pharmaceutical sector and generating novel and improved methods for the development and evaluation of medicines.
PO 4	Effective Problem-Solving: Ability to solve difficult problems that arise during the manufacturing and testing of drugs and integrate the same for enhancing the quality applying statistics and computer software tools.
PO 5	Collaborative Skills: Collaborate effectively with other healthcare professionals and researchers to enhance both pharmaceutical products and research initiatives.
PO 6	Clear Communication: Effective in communicating research findings and testing results using precise scientific language that the peers in the field can understand.
PO 7	Ethical Conduct: Adhere to ethical standards in the work, taking responsibility for ensuring the safety of pharmaceutical products for patients.
PO 8	Patient-Centered Approach: Prioritize the safety, effectiveness, and well-being of patients, makes utmost concern in pharmaceutical practices.
PO 9	Knowledge Sharing: Disseminate their discoveries by publishing articles in respected scientific journals and presenting the research work at academic and professional gatherings to improve methodologies within the field.
PO 10	Regulatory Adherence: Understanding and compliance with the established rules and regulations and quality standards in the pharmaceutical and healthcare sectors, ensuring the safety and quality of medications.
PO 11	Lifelong Learning: Ongoing learning and self-improvement even after completing studies, staying updated with the latest scientific knowledge and industry practices.

Program Specific Outcomes (PSO)

PSO 1	Advanced Analytical Proficiency: Attains an in-depth understanding of sophisticated analytical instrumentation and techniques used in pharmaceutical analysis, allowing students to precisely determine the chemical composition of pharmaceutical products.
PSO 2	Innovative Research in Analytical Science: Excel in conducting research and innovation in the field of pharmaceutical analysis with a focus on advanced instrumentation. Develops novel and improved methods for the precise evaluation of medicines, contributing to the advancement of analytical sciences in pharmaceuticals.
PSO 3	Mastery of Advanced Laboratory Instruments: Demonstrates exceptional expertise in operating and leveraging advanced laboratory instruments and equipment, essential for conducting high-precision pharmaceutical analysis safely and efficiently.
PSO 4	Strategic Problem Solvers in Analytical Challenges: Skilled at addressing complex issues that may arise during pharmaceutical analysis, utilizing their knowledge of advanced instrumentation to identify solutions and optimize analytical processes.

Program Educational Objectives (PEOs)

PEO 1	Advanced Analytical Proficiency: Achieve a deep and advanced understanding of analytical instrumentation and techniques in pharmaceutical analysis, enabling them to conduct precise chemical analyses of pharmaceutical products and contribute to the advancement of analytical sciences.
PEO 2	Innovative Research Leaders in Analytical Science: Emerge as leaders in pharmaceutical analysis research, consistently developing novel and improved methodologies for evaluating medicines. Their work will significantly advance the field of analytical sciences in pharmaceuticals.
PEO 3	Expert Users of Advanced Laboratory Instruments: Demonstrates exceptional expertise in operating and leveraging advanced laboratory instruments and equipment. The mastery of instruments is crucial for conducting high-precision pharmaceutical analysis safely and efficiently.
PEO 4	Strategic Problem Solvers in Analytical Challenges: Proficient in addressing complex issues that may arise during pharmaceutical analysis. Also employs knowledge of advanced instrumentation to identify solutions and optimize analytical processes to ensure the quality and safety of pharmaceutical products.
PEO 5	Effective Communicators and Collaborators in Analytical Research: Graduates will excel in communication, conveying their research findings and analytical results effectively to their peers and the broader scientific community. They will also demonstrate strong collaborative skills, working effectively with healthcare professionals and researchers to enhance pharmaceutical analysis and research initiatives, fostering interdisciplinary teamwork



Kommareddy Venkata Sadasiva Rao Siddhartha College of Pharmaceutical Sciences

(AUTONOMOUS)

Pinnamaneni Polyclinic Road, Siddhartha Nagar, Vijayawada - 520010, AP, INDIA

(Sponsors : Siddhartha Academy of General & Technical Education)

ISO 14001:2015, ISO 50001:2018&ISO 21001:2018 CERTIFIED INSTITUTION

Approved by AICTE, PCI, New Delhi, Govt. of Andhra Pradesh & Accredited by NAAC with 'A' Grade

Affiliated to Krishna University, Machilipatnam & Recognized as 2(f) under UGC Act 1956

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1.	ANTI-RAGGING COMMITTEE
2.	ANTI-RAGGING SQUAD
3.	INTERNAL COMPLAINT COMMITTEE
4.	GPAT COMMITTEE
5.	SC/ST WELFARE COMMITTEE
6.	INSTITUTION-INDUSTRY CELL
7.	GRIEVANCE REDRESSAL COMMITTEE
8.	INTELLECTUAL PROPERTY RIGHTS CELL
9.	EXAMINATION COMMITTEE
10.	DISCIPLINARY COMMITTEE
11.	SEXUAL HARASSMENT MONITORING COMMITTEE
12.	ICT & AUTOMATION AND WEBSITE COMMITTEE
13.	STUDENT WELFARE AMENITIES COMMITTEE
14.	WOMEN EMPOWERMENT CELL
15.	HANDBOOK AND MAGAZINE COMMITTEE
16.	TRAINING & PLACEMENT COMMITTEE
17.	SPORTS & CULTURAL COMMITTEE
18.	NSS PROGRAMME COMMITTEE
19.	INDUSTRIAL RESEARCH AND CONSULTATION COMMITTEE
20.	ALUMNI COMMITTEE
21.	PUBLIC RELATION, PRESS & MEDIA COMMITTEE
22.	LIBRARY COMMITTEE
23.	E-CELL
24.	ATTENDANCE COMMITTEE
25.	TIME-TABLE COMMITTEE
26.	INTERNAL QUALITY ASSURANCE CELL
27.	ELECTORAL LITERACY CLUB
28.	PROJECT REVIEW COMMITTEE
29.	PROGRAM ASSESSMENT COMMITTEE (PAO)
30.	KAPILA TEAM
31.	MODERATION COMMITTEE
32.	ACADEMIC CALENDAR COMMITTEE
33.	SCHOLARSHIP AWARENESS COMMITTEE



Kommareddy Venkata Sadasiva Rao

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1. Anti-Ragging Committee

S.No.	Name of the member	Designation	Committee	Phone No.
1	Dr.A.Suneetha	Principal	Chairperson	9949185566
2.	Dr.RamanaiahGangireddy	Prof.&HoD	Co-ordinator	9848121188
3	Sri. K. Anil Kumar	Assistant Professor	Member	9440419934
4	Sri. S. VeerabhadraRao	Warden (Boys Hostel)	Member	7382732126
5	Smt. U. Susheela	Warden (Girls Hostel)	Member	9030534024
6	Sri.Ch.Prakash	Sub- Inspector of Police	Member	8317626066
7	Mrs.T. Sowjanya	Parent	Member	9164019649
8	Mr.SuraganiPranavSai	2 nd Year student	Member	9392784314
9	Ms. GolajapuJyothirmayee	2 nd Year student	Member	7981363782
10	Sri.G.SubbaRao	Senior Reporter	Member	6303353573
11	Smt. Vijayasree Gupta	PDC, NGO	Member	9885033567
12	Smt. A.PavaniKumari	Non-Teaching	Member	9866070299

2) Anti-Ragging Squad

S.No.	Name of the member	Designation	Email id
1	Dr. CH. Nagabhushanam	Assistant Professor	nagabhushanam_137@yahoo.co.in
2	Sri .K. Anil Kumar	Assistant Professor	kvsrkutumbalu@gmail.com
3	Sri. S. VeerabhadraRao	Warden(Boys Hostel)	kvsrsiddharthapharma@gmail.com
4	Smt. U. Susheela	Warden(Girls Hostel)	kvsrsiddharthapharma@gmail.com
5	Sri. L.VinayShekhar	Physical Director	kvsrsiddharthapharma@gmail.com

3) Internal Complaint Committee (ICC)

S.No.	Name of the member	Committee	Phone No.
1.	Dr. V. Karunasree	Chair person	9866901088
2.	Dr. M. Vijaya Lakshmi	Member	8501011122
3.	Dr. Ch. Nagabhusanam	Member	9951067030
4.	Mrs. M. Srilakshmi	Member	9247898900
5.	Mrs. P. V. Krishnaveni	Member	8331921420
6.	Ms. KonagalaArudra	Student	9346239427
7.	Ms. SohithaMulupuri	Student	8985890011
8.	Mr. Mohammad SalarAhamad	Student	9248760642

4) GPAT Committee

S.No	Name of the member	Designation	Phone No.
1	Dr. T. P.Rao	Co-ordinator	9441902645
2	Dr.V.Karunasree	Member	9866901088
3	Dr.B.Anupama	Member	9441813652
4	Dr. Ch. Nagabhushnam	Member	9951067036
5	Dr.Ch.Supriya	Member	9440966090

5) SC/ST Welfare Committee

S.No	Name of the member	Designation	Phone No.
1.	Dr.TSarala Devi	Co-ordinator	9849483034
2.	Smt. K.Jyothi	Member	9398222732
3.	Ms. J.Sowmya	Student Member	9032784384
4.	Mr. B.RajuNaik	Student Member	6281336920
5.	Mr. V.JaswanthRaju	Student Member	9502140548

6) Institution-Industry Cell

S.No.	Name of the member	Designation	Committee	Phone No.
1.	Dr. T. P. Rao	Associate Professor	Chair person	9441902645
2.	Dr. A. Bharathi	Associate Professor	Member	9393043134
3.	Dr. V KarunaSree	Associate Professor &HoD	Member	9866901088
4.	Dr. B. Anupama	Associate Professor &HoD	Member	9441813652
5.	Mr.A.Murali	Student	Member	8309424488
6.	Ms.D.NagaRamya	Student	Member	

7) Grievance Redressal Committee

S.No	Name of the Member	Present Designation	Committee	Phone No.
1.	Dr. A. Suneetha	Principal	Chairperson	9949185566
2.	Dr. G. Vijaya Kumar	Professor	Member	9989921747
3.	Dr. T. Sarala Devi	Assistant Professor	Member	9849483034
4.	Sri. A.V.S. Ravi Sainadh	Assistant Professor	Member	9618352952
5.	Ms. D.Keerthi	Student	Member	9966933318
6.	Mr.S.Hemanth Krishna	Student	Member	8688957820

8) Intellectual Property Rights Cell

S.No.	Name	Designation	Committee	Phone No.
1.	Dr.JyothirmayeeDevineni	Associate Professor	Chairperson	9866175359
2.	Dr. G. Ramanaiah	Associate Professor	Member	9848121188
3.	Dr. A. Bharathi	Associate Professor	Member	9393043134
4.	Ms. MounikaBai	Student	Member	8142235428
5.	Ms. M.Cherishma	Student	Member	9440250011

9) Examination Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr.A.Suneetha	Principal & Professor	Chairperson	9949185566
2.	Dr. M. VijayaLakshmi	Associate Professor	Member	8501011122
3.	Dr. K.Durga Prasad	Assistant Professor	Member	7306775758
4.	Dr.V.Narendra	Assistant Professor	Member	9618171818
5.	Smt. IswaryaObilineni	Assistant Professor	Member	7989552803
6.	Smt. A.LakshmiPavani	Assistant Professor	Member	9100199577
7.	Mr. P.Srinivasu	Assistant Professor	Member	9989092806

10) Disciplinary Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr. T .P.Rao	Associate Professor	Chairperson	9441902645
2.	Dr. V.Karunasree	Associate Professor	Member	9866901088
3.	Smt. R. Anusha	Assistant Professor	Member	7288967999
4.	Ms.D. GowriPriya	Student	Member	8185929971
5.	Ms.K. Heemanvi	Student	Member	9949119757
6.	Mr.T.SaiPraneeth	Student	Member	9164019649

11) Sexual Harassment Monitoring Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr. T Sarala Devi	Assistant Professor	Chairperson	9849483034
2.	SK.Jareena	Assistant Professor	Member	9182798693
3.	Ms.S.L.S.MounicaPratyusha	Assistant Professor	Member	9100746956
4.	Ms..Ch.Abinaya	Student	Member	8374499523
5.	Ms.Ch. Jahnavi	Student	Member	9390875514
6.	Ms.S. Dattakshaya	Student	Member	7569812848

12) ICT & Automation and Website Committee

S.No.	Name of the Member	Committee	Designation	Phone No.
1.	Dr. K.Ravishankar	Assistant Professor	Chairperson	9492535524
2.	Smt. K.Pradeepthi	Assistant Professor	Member	7995851919
3.	Dr. P.Swetha	Assistant Professor	Member	9652141257
4.	Mr.J.Pransanth	Student	Member	9515423609
5.	Mr.P.SaiRohith	Student	Member	9166504870
6.	Ms. K. Himaja Rama Tulasi	Student	Member	9391461856

13) Student Welfare Amenities Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr.Ch.Nagabhushanam	Associate Professor	Chairperson	9951067030
2.	Ms. Jareena. Sk	Assistant Professor	Member	9182798693
3.	Smt. S.Pranathi	Assistant Professor	Member	9398541700
4.	Ms.Ch. Chaitanya Raj	Student	Member	7981134498
5.	Ms.P.RajaRasogna	Student	Member	6281492477
6.	Ms.Ch.Manogna	Student	Member	9908318199

14) Women Empowerment Cell

S.No	Name of the Member	Designation	Committee	Phone No.
1.	Dr. A. Suneetha	Principal	Chairperson	9949185566
2.	Dr. M.Vijayalakshmi	Associate Professor	Member	8501011122
3.	Smt. A. Lakshmi Pavani	Assistant Professor	Member	9100199577
4.	Ms. T .S.Mrinalini	Assistant Professor	Member	8977216085
5.	Smt. K.Sirisha	Assistant Professor	Member	9948438068
6.	Ms.A.Sowjanya	Assistant Professor	Member	7095237196
7.	Ms. P.Chaarishma	Student	Member	9966281111
8.	Ms.K.RenukaChowdary	Student	Member	8125885678

15) Handbook and Magazine Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr.N.Kanakadurga Devi	Associate Professor	Chairperson	9392418336
2.	Dr.D.Jyotirmayee	Associate Professor	Member	9866175359
3.	Dr. T.Sarala Devi	Assistant Professor	Member	9849483034
4.	Smt. P.LakshmiPrasanna	Assistant Professor	Member	7075667386
5.	Mr.Jonus Evangel Nakka	Student	Member	8688962081
6.	Ms.I.Pallavi	Student	Member	9642804888

16) Training & Placement Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr. Ch.Nagabhushanam	Associate Professor	Chairperson	9951067030
2.	Dr. T. P. Rao	Associate Professor	Member	9441902645
3.	Dr.Arifa Begum	Assistant Professor	Member	7013053774
4.	Smt. P.LakshmiPrasanna	Assistant Professor	Member	7075667386
5.	Ms. Sri RamyaRvs	Student	Member	9246629988
6.	Mr. K.Sai Praveen	Student	Member	9848053599

17) Sports & Cultural Committee

S.No.	Name of the Member	Committee	Designation	Phone No.
1.	Sri.L.VinaySekhar	Physical Trainer	Sports Coordinator	9966344779
2.	Ms T.S. Mrinalini	Assistant Professor	Chairperson	8977216085
3.	MsR.Triveni	Assistant Professor	Member	8897514894
4.	Ms. A.Sowjanya	Assistant Professor	Member	7095237196
5.	Mr.J. David Stephen Roy	Student	Member	8897989510
6.	Ms. S.Dattakshaya	Student	Member	7569812848

18) NSS Programmme Committee

S.No.	Name of the Member	Committee	Designation	Phone No.
1.	Sri.L.VinaySekhar	Physical Trainer	Chairperson	9966344779
2.	Dr.P.Swetha	Assistant Professor	Member	9652141257
3.	Ms.Jareena.sk	Assistant Professor	Member	9182798693
4.	Smt. S.Pranathi	Assistant Professor	Member	9398541700
5.	Mr. T.DurgaVeeraManikantaSathish	Student	Member	9618481115
6.	Mr. B.JithendraNath	Student	Member	9441624219

19) Industrial Research and Consultation Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr. A.Bharathi	Associate Professor	Chairperson	9393043134
2.	Dr. G. Vijaya Kumar	Professor	Member	9989921747
3.	Dr. M Vijayalakshmi	Associate Professor	Member	8501011122
4.	Dr. B. Anupama	Associate Professor	Member	9441813652
5.	Sri. A.V.S. Ravi Sainadh	Assistant Professor	Member	9618352952
6.	Dr.Arifa Begum	Assistant Professor	Member	9441822796

20) Alumni Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr.D. Jyothirmayee	Associate Professor	President	9866175359
2.	Mr.K.Vijaya Kishore	Assistant Professor	Vice President	9948442452
3.	Dr. B. Anupama	Associate Professor	Secretary	9441813652
4.	Dr. Ch. Nagabhushanam	Assistant Professor	Joint Secretary	9951067030
5.	Dr. K.Ravishankar	Assistant Professor	Treasurer	9492535524
6.	Smt.R.Anusha	Assistant Professor	Joint Secretary	7288967999
7.	Ms. S.L.S.MounicaPratyusha	Assistant Professor	Vice President	9100746956
8.	Ms. R.Manimala	Student	Member	9490062031
9.	Ms. D.GowriPriya	Student	Member	7207168919
10.	Mr. K. RevanthSrinadh	Student	Member	8883121999

21) Public Relation, Press& Media Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr. Ch. Nagabhushanam	Assistant Professor	Chairperson	9951067030
2.	Ms. R.Triveni	Assistant Professor	Member	8897514894
3.	Smt. AmaniPrasanna	Assistant Professor	Member	81254 38987
4.	Mrs.V.Indumathi	Lab Assistant	Member	8519930230
5.	Mrs.P.V.KrishnaVeni	Data Entry Opertor	Member	7013159045
6.	Ms. B.BhavyaThanusri	Student	Member	9885292999

22) Library Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1	Dr.A.Suneetha	Principal	Chairperson	9949185566
2	Dr.G.Vijay Kumar	Professor	Member	9989921747
3	Dr.RamaniahGangireddy	Professor	Member	9848121188
4	Dr. V.Karunasree	Associate Professor	Member	9866901088
5	Dr. B. Anupama	Associate Professor	Member	9441813652
6	Mrs.K.Saileela	Assistant Librarian	Member	9491346697

23)E-Cell

S.No.	Name of the Member	Designation	Committee	Phone No.
1	Mrs.IswaryaObilineni	Assistant Professor	Chair person	7989552803
2	Mr.K.Anil Kumar	Assistant Professor	Member	9440419934
3	Smt. K. Pradeepthi	Assistant Professor	Member	7995851919
4	Mr. P.Srinivasu	Assistant Professor	Member	9989092806
5	Ms. M.KeerthiPriya	Student	Member	6301212587
6	Ms. Ch.Sahithi	Student	Member	8074222488

24)Attendance Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr. A. Bharathi	Associate Professor	Chairperson	9393043134
2.	Dr. N.KanakaDurga Devi	Associate Professor	Member	9392418336
3.	Mrs. K.Jyothi	Assistant Professor	Member	9398222732
4.	Smt. R. Anusha	Assistant Professor	Member	7288967999
5.	Smt. K.Sirisha	Assistant Professor	Member	9948438068
6.	Ms. S.L.S. MounicaPratyusha	Assistant Professor	Member	9100746956

25) Time Table Committee

S.No.	Name of the Member	Designation	Committee	Phone No.
1.	Dr. M Vijayalakshmi	Associate Professor	Chairperson	8501011122
2.	Dr.V.Narendra	Assistant Professor	Member	9618171818
3.	Smt. A.LakshmiPavani	Assistant Professor	Member	9100199577
4.	Smt.R.Anusha	Assistant Professor	Member	7288967999
5.	Smt. S.Pranathi	Assistant Professor	Member	9398541700
6.	Smt. AmaniPrasanna	Assistant Professor	Member	81254 38987

26) IQAC Committee

1.	Chairman	Dr. A. Suneetha, Principal KVSR Siddhartha College of Pharmaceutical Sciences, Vijayawada.
2.	Coordinator	Dr. G. Vijayakumar, HoD Dept of Pharmacy Practice
3.	Members from Teaching Staff	Dr. K. Ravi Shankar, Asst. Professor Dr.P.Swetha, Asst. Professor Sri. A. V.S. Ravi Sainadh, Asst. Professor Smt. O.Iswarya, Asst. Professor
4.	Members from Administrative Staff	Mr. K. VenkataRao, Senior Asst Smt. P. V. Krishnaveni, Data Entry Operator
5.	Management Representatives	Sri. Ch.Arunkumar, Convenor Sri. P.Syama Krishna, Convenor Committee member
6.	Nominees from Local Society	Dr. Samaram, Member Smt. Kumari, Member
7.	Nominee from Student	Mr. T.SaiPraneeth, Student
8.	Nominee from Alumni	Mr.ChittineniManoj, MS
9.	Nominee from Industrialist	Mr.K.Manohar, Accurate Labs
10.	Nominees from Stakeholder	Mr.DanduVenkataSita Rama Rao, Parent

27) Electoral Literacy Club

S.No.	Name	Designation	Committee	Phone No.
1.	Dr. A. Bharathi	Professor	Coordinator	9393043134
2.	Dr. Ch. Nagabhushanam	Assistant Professor	Additional Coordinator	9951067030
3.	Smt.M. Sailaja	Lab Assistant	Assistant Co-ordinator	9440680379
4.	Mr. D. Vamsi Krishna	II Pharm D	Student Representative	9550260931
5.	Mr.V. BhanuVyshnavSai	II B. Pharmacy	Student Representative	9490823439

28) Project Review Committee

S.No.	Name of Members	Designation	Committee
1.	Dr. A. Suneetha	Principal	Chairperson
2.	Dr.G.Vijaya Kumar	Professor & HOD	Member
3.	Dr G. Ramanaiah	Professor & HOD	Member
4.	Dr.V. KarunaSree	Associate Professor & HOD	Member
5.	Dr. B. Anupama	Associate Professor & HOD	Member
6.	Dr.M.Vijaya Lakshmi	Associate Professor	Member
7.	Dr.Ch.Supriya	Associate Professor	Member

29) Program Assessment Committee

S.No.	Name of Members	Designation	Committee
1.	Dr. A. Suneetha	Principal	Chairperson
2.	Dr.M.Vijaya Lakshmi	Associate Professor	Member
3.	Dr.Ch.Supriya	Associate Professor	Member
4.	Dr. K.Ravishankar	Assistant Professor	Member
5.	Smt. A.LakshmiPavani	Assistant Professor	Member
6.	Dr. K.Durga Prasad	Assistant Professor	Member

30) KAPILA Team

S.No.	Name	Designation	Institute/Comp any	Contact No.
1.	Prof. SuneethaAchanti	Chairperson - Faculty Member(Principal/Director/Dean/ Vice Chancellor/SeniorFaculty member) having IP background knowledge	KVSRSCOPS	9949185566
2.	Dr.Ch. Nagabhushanam	Institute alumni/Industry expert	KVSRSCOPS	9951067030
3.	Venkateswara raoYarlagadda	Institutealumni/Industryexpert/IncubationHead/Technology transfer officerepresentative	Accurate labs	9100074414
4.	Dr. Ch. Divakarbabu	Legal Advisor/IPR expert	Siddhartha law college	7013539373
5.	Dr.Ch.Supriya	Faculty Member (Senior Faculty Member – Convenor Single Point of Contact)	KVSRSCOPS	9985969634

31) Moderation Committee

S.No.	Name of Members	Designation	Committee
1.	Dr. A. Bharathi	Professor	Chairperson
2.	Dr.T.Sarala Devi	Assistant Professor	Member
3.	Dr.Ch.Nagabhushanam	Assistant Professor	Member
4.	Smt. K.Pradeepthi	Assistant Professor	Member

32) Academic Calendar Committee

S.No.	Name of Members	Designation	Committee
1.	Dr. G. Ramana	Professor	Chairperson
2.	Dr.M.Vijaya Lakshmi	Associate Professor	Member
3.	Smt. R. Anusha	Assistant Professor	Member
4.	Dr.P.Swetha	Assistant Professor	Member
5.	Smt. A.LakshmiPavani	Assistant Professor	Member
6.	Smt. K. Pradeepthi	Assistant Professor	Member

33) Scholarship Awareness Committee

S.No.	Name of Members	Committee
1.	Dr. CH. Nagabhushanam	Chairperson
2.	Dr. M. VijayaLakshmi	Member
3.	Mrs. P. V. Krishnaveni	Member
4.	Ms. SohithaMulupuri	Student
5.	Ms. GolajapuJyothirmayee	Student

COURSES OFFERED

- PHARM D
- B.PHARMACY
- M.PHARM
 - PHARMACEUTICAL ANALYSIS
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