Sri Indu Institute of Pharmacy

(An Autonomous Institution Under UGC, New Delhi)
Accredited by NAAC (Grade "A")
Recognized Under Section 2(f) of UGC Act 1956
Approved by PCI – New Delhi, Affiliated to JNTUH- Hyderabad.
Sheriguda (V), Ibrahimpatnam (M), R.R. Dist-501510, Telangana State, India.
Website: www.siip.ac.in. Email: siipoffice@siip.ac.in., Phone: +91-9391537555

MASTER OF PHARMACY (M.PHARMACY) COURSE
PHARMACEUTICS SPECIALISATION

R25-ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

FOR

I & II YEAR M.PHARM COURSE

(Batches Admitted from 2025-26 Academic Year)

PRINCIPAL
SRI INDU INSTITUTE OF PHARMACY
(An Autonomous Institution Under JNTUH)
Sheriguda (V), Ibrahimpatnam (M),
Sheriguda (V), Ibrahimpatnam (M), Hyderabad-501510

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MASTER OF PHARMACY (M.PHARMACY) COURSE
PHARMACEUTICS SPECIALISATION

CHOICE BASED CREDIT SYSTEM (CBCS)

R-25 REGULATIONS AS PER JNTUH, Hyderabad.

ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS FOR M.PHARMACY I & II Years

UNDER AUTONOMOUS STATUS FOR THE BATCHES ADMITTED FROM THE ACADEMIC YEAR 2025-2026

Note: Academic Regulations here under are subjected to amendments as may be made by the Academic Council of the Institute from time to time as per the JNTUH directives. Any or all such Amendments will be effective from such date and to such batches of Students (including those already undergoing the Program) as may be decided by the Academic Council timely.

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VISION

- To inculcate excellence in various fields of Pharmacy and mould the Institution as Center of Excellence in terms of Academics and Advanced Pharmaceutical Research"
- To evolve into a center of excellence in Science and Technology through creative and innovative practices in teaching, learning, promoting academic achievement & research excellence to produce internationally accepted, competitive and world class professionals, who are psychologically strong and emotionally balanced imbibed with social consciousness and ethical values.

MISSION

- Committed to impart quality Pharmacy Education and Research for Students to be competent globally"
- To provide high quality academic programs, training activities, research facilities and opportunities supported by incessant "Industry – Institute" interaction which is aimed at promoting Employability, Entrepreneurship, Leadership and Research aptitude among students that can contribute to the economic and technological development of the Region, State and the Nation.

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PROGRAM OUTCOMES (PO's)

PO's FOR M.PHARM (PHARMACEUTICS)	
PO1	Focuses on research and course work relating to development and production of various dosage forms.
PO2	Promotes multidisciplinary team-based approach to drug delivery, embracing a variety of activities in the area of drug formulation and delivery.
PO3	Major area of emphasis includes drug disposition and its kinetics
PO4	The department works towards research in the areas of formulation optimization and characterization of solid, liquid and semisolid dosage forms.

PROGRAM SPECIFIC OUTCOMES (PSO'S)

PSO'S OF M.PHARMACY COURSE	
PSO1	To set forth theoretical and practical knowledge among students in the various fields of pharmaceutical sciences , pharmaceutics , pharmaceutical chemistry , pharmacology and pharmacognosy.
PSO2	To ameliorate practical skills of students through industrial training and research to confront the pharmaceutical field.
PSO3	To acquaint the students with fundamental regulatory aspects of pharmaceutical Professionals, Industry, Education and Practice.
PSO4	To boost knowledge and skills on criteria for selection of drugs, dose calculations, dose adjustments by applying biopharmaceutics theory, pharmacokinetic and bioequivalence models which gives technical skill knowledge, invitro invivo studies using computer simulations and population modellings.
PSO5	To expand the knowledge in technical and professional careers in various pharmaceutical industry/institution/health care system through concurrent

	meticulous education.
PSO6	To plan the modern tools to integrate health care systems. Design an effective product with commercial advantage and societal welfare, execute risk and become an entrepreneur.

PSO'S OF M.PHARMACY (PHARMACEUTICS)	
PSO1	Will develop an ability to undertake multidisciplinary tasks in the pharmaceutical quality system.
PSO2	Can identify and resolve the research problems by utilizing the technical skill gained through training and experimentation.
PSO3	Execute team based research to implement innovative solutions in the area of formulation, quality assurance and technology transfer.
PSO4	Know the basic and advanced scientific facts and principles along with skills in design and development of novel drug delivery systems.

PROGRAM EDUCATIONAL OUTCOMES (PEO'S)

PEO'S OF M.PHARMACY COURSE	
PEO1	To provide extensive and advanced proficiency in pharmaceutical education leading to M. Pharm.
PEO2	To expertise the apprentice in the field of pharmacy to contribute in the social health care system.
PEO3	To doctrine the ground work for handling the infrastructure which is included in research aptitude in pharmaceutical sciences
PEO4	To imprint leadership and entrepreneurship capabilities in future pharmacy professionals

PEO's of M. PHARMACY (PHARMACEUTICS)	
PEO1	To inculcate the knowledge of formulation and designing of dosage forms
PEO2	To discipline the values of pharmacy in turning a chemical entity into a dosage form.
PEO3	To embed the awareness of dispensing the dosage forms with proper and lawful prescription
PEO4	To design and evaluate Novel Drug Delivery Systems

COURSE OUTCOMES OF M.PHARM (PHARMACEUTICS)
R22 REGULATIONS

M.PHARMACY (PHARMACEUTICS) I YEAR I SEMESTER	
COURSE CODE: PC I	**MODERN PHARMACEUTICS I**
CO1	To know about the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility
CO2	To apply ICH guidelines and evaluate drug, drug excipients compatibility
CO3	To apply the statistical design in different formulations.
CO4	To attain the knowledge of about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques.
CO5	To know the different physical properties in preformulation.
COURSE CODE: PC II	**APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS**
CO1	To understand various ADME parameters
CO2	To understand factors effecting bioavailability and stability of dosage forms.
CO3	To know the parameters for the disposition, absorption and Michaelis-Menton constants for non- linear kinetics
CO4	To know Drug interactions and problems associated in pharmacokinetic parameters.
CO5	To know bioequivalence studies and protocols to bioequivalence studies.
PE I	**ADVANCED PHYSICAL PHARMACEUTICS**
CO1	Deduce the factors affecting dissolution, and solubility in related *invitro* and *invivo* correlations.
CO2	Have knowledge about stability calculations, shelf-life calculations and accelerated stability studies.
CO3	Anticipating the analysis of particle size, solid dispersion, physics of tablets, polymer classification and its applications.
CO4	Understand rheology, absorption, related to liquids and semi-solid dosage forms.
COURSE CODE: PE I	**DRUG REGULATORY AFFAIRS**
CO1	Know about different competent regulatory authorities globally
CO2	To be aware of technical aspects pertaining to the marketing authorization application (MAA)
CO3	To know about regulatory guidelines framed by regulatory authorities.
CO4	Be familiar with GMP and ICH guidelines for stability testing
CO4	To escalate the knowledge of students in various quality control and

	regulatory aspects.
COURSE CODE: PE I	**TOTAL QUALITY MANAGEMENT**
CO1	To learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc
CO2	To become a perfect budding pharmacist.
CO3	To acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.
COURSE CODE: PE II	**ARTIFICIAL INTELLIGENCE IN FORMULATION AND PROCESS DEVELOPMENT**
CO1	The scope and significance of AI, ML, and DL in pharmaceutical formulation and identify appropriate algorithms for data analysis.
CO2	To Apply AI tools to monitor, predict, and optimize pharmaceutical manufacturing processes such as blending, granulation, and coating.
CO3	To Build and interpret neural network models and neuro-fuzzy systems for formulation prediction, optimization, and control.
CO4	To Implement machine learning techniques in the design and 3D printing of personalized drug delivery systems.
CO5	Evaluate real-time industry case studies to understand the practical impact of AI in formulation settings.
PE II	**PHARMACEUTICAL VALIDATION**
CO1	Be acquainted with the knowledge of validation of instruments and equipment's.
CO2	Carry out validation of manufacturing processes
CO3	Interpretation of various methods of validation.
CO4	Application of various methodologies in pharmaceutical validation.
PE II	**STABILITY OF DRUGS AND DOSAGE FORMS**
CO1	To characterize the evaluation of stability of solutions, solids and formulations against adverse conditions.
CO2	Competency of students to retain stability and storage conditions.
CO3	Proficiency of students in retaining the efficacy of the pharmaceutical products.
CO4	Knowledge on methods of sampling and tests for various cosmetics according to bureau of Indian standards.
COURSE CODE: MC	**RESEARCH METHODOLOGY AND IPR**
CO1	To analyze the research related information.
CO2	Follow research ethics
CO3	Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
CO4	Understanding that when IPR would take such important place in

	growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
CO5	Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits
CO6	To emphasize the need of information about intellectual property rights among students.
CO7	Figure out research problems and formulations.
CO8	Investigations of solutions research problems, data collection, analysis and interpretation of data.
COURSE CODE: LAB I	**MODERN PHARMACEUTICS I LAB**
CO1	To execute the preformulation studies of solid dosage forms.
CO2	Calculate the effect of compressional force on tablet disintegration time.
CO3	Preparation and evaluation of beta cyclodextrin complexes of new drugs
CO4	Perform accelerated stability testing of different tablets.
COURSE CODE: LAB II	**APPLIED BIO PHARMACEUTICS AND PHARMACOKINETICS LAB**
CO1	Computation of pharmacokinetic parameters of one compartment oral data and two compartment IV data.
CO2	Calculation of bioavailability and bioequivalence studies.
CO3	Evaluation of drug protein binding analysis.
CO4	Construction of calibration curves of different API's by UV/HPLC/HPTLC**.**
COURSE CODE: AUDIT COURSE I	**ENGLISH FOR RESEARCH PAPER WRITING**
CO1	To know how to improve writing skills and level of readability.
CO2	Fathom the skills needed when writing Title Ensure the good quality of paper at very first submission.
CO3	Ascertain about what to write in each section.
CO4	Flourish with skills needed when writing methods, results, conclusions etc.
AUDIT COURSE I	**DISASTER MANAGEMENT**
CO1	Learn to demonstrate and critical understanding of key concepts in disaster risk reduction and humanitarian response.
CO2	Critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
CO3	Planning and programming in different countries, particularly their

	home country or the countries they work in.
CO4	Critically understand the strengths and weakness of disaster management approaches.
AUDIT COURSE I	**SANSKRIT FOR TECHNICAL KNOWLEDGE**
CO1	To obtain working knowledge in illustrious Sanskrit,the scientific language in the world.
CO2	Learning of Sanskrit to improve brain functioning.
CO3	The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature.
CO4	Learning of Sanskrit to develop the logic in mathematics, science, and other subjects enhancing the memory power.
AUDIT COURSE I	**VALUE EDUCATION**
CO1	Sympathize value of education and self-development.
CO2	Imbibe good values in students.
CO3	Developing the overall personality.
CO4	learn the importance of character and competence.
M.PHARMACY (PHARMACEUTICS) I YEAR II SEMESTER	
COURSE CODE: PC III	**MODERN PHARMACEUTICS II**
CO1	Perceive the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenteral, aerosols, cosmetics and nutraceuticals.
CO2	Distinguish Formulation approaches, preparation & method of manufacturing labelling & Q.C. of anti-ageing products, sun screen lotion and fairness creams.
CO3	Overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.
CO4	Advances in propellants, metered dose inhaler designs, manufacture and quality control.
COURSE CODE: PC IV	**ADVANCED DRUG DELIVERY SYSTEMS**
CO1	Selection of the drugs for CDDS design of the formulation
CO2	fabrication of systems of above drug delivery systems with relevant applications.
CO3	Biochemical and molecular biology approaches to controlled drug delivery of Bioadhesive drug delivery systems
CO4	Drug targeting to particular organs lungs , brain etc
COURSE CODE: PE III	**INDUSTRIAL PHARMACY**
CO1	Explain the machinery involved in milling, mixing, filtration and drying used in production of pharmaceutical materials.
CO2	Learn salient features of GMP, TQM applicable in industry.
CO3	Understand the effluent treatments and prevention of pollution.

CO4	Evaluate the validation of analytical methods and processes.
PE III	**HERBAL COSMETICS**
CO1	Gain knowledge on classification, economic aspects and regulatory provisions related to manufacture of cosmetics.
CO2	Get exposed to processes involved in manufacturing of herbal cosmetics related to skin.
CO3	Brief account on herbal extracts and herbal products of cosmetic importance.
CO4	Elaborative study of formulations related to hair care with regard to their composition and claims for various herbs used in them.
PE III	**PHARMACEUTICAL MANGEMENT**
CO1	Useful for the students to know how to manage a pharma industry.
CO2	Aids the students to develop leadership qualities, communication and interpersonal skills.
CO3	Helps to understand the concepts of managerial control and its importance in pharma industry.
CO4	Helps the students to understand various managerial functions and professional skills required for a dynamic profession.
COURSE CODE: PE IV	**NANO BASED DRUG DELIVERY SYSTEMS**
CO1	Able to apply the properties related to the fabrication of nano pharmaceuticals.
CO2	Be aware of molecular formulations based on nano technology and science behind them.
CO3	Be able to select the right kind of materials and evaluate the product.
CO4	Improvements to medical or molecular imaging using nano technology.
PE IV	**NUTRACEUTICALS**
CO1	Recognise the occurrence and characteristic features of phytochemicals as nutraceuticals.
CO2	Know the importance of nutraceuticals in various common problems with the concept of free radicals.
CO3	Acknowledge the role of antioxidants in free radical induced disease conditions.
CO4	Expose to various food laws and regulations, health claims and dietery supplement claims.
PE IV	**CLINICAL RESEARCH AND PHARMACOVIGILANCE**
CO1	Demonstrate the types of clinical trial designs
CO2	Execute safety monitoring, reporting, and close out activities
CO3	Explain the regulatory requirements for conducting clinical trial
CO4	Explain the responsibilities of key players involved in clinical trials
CO5	Execute safety monitoring, reporting and close-out activities

CO6	Explain the principles of Pharmacovigilance
CO7	Detect new adverse drug reactions and their assessment
CO8	Perform the adverse drug reaction reporting system and communication in pharmacovigilance.
COURSE CODE: LAB III	**MODERN PHARMACEUTICS-II LAB**
CO1	To evaluate the effect of surfactant in invitro drug release.
CO2	Preparation and evaluation of film coated, floating, fast dissolving and chewable tablets.
CO3	To formulate and evaluate cold cream, vanishing cream, foundation and cleansing creams.
CO4	Preparation of oral care products like mouth washes.
COURSE CODE: LAB IV	**ADVANCED DRUG DELIVERY SYSTEMS LAB**
CO1	Study on diffusion of drugs through various polymeric membranes.
CO2	Preparation and evaluation of enteric coated pellets.
CO3	To formulate and evaluate sustained release oral matrix and reservoir systems.
CO4	Compare invitro dissolution profiles of various sustained release products available in the market.
	MINI PROJECT WITH SEMINAR
CO1	Allows the students to study, do research and act by themselves using their abilities.
CO2	Improves communication skills and networking with others.
CO3	Helps in gaining expert knowledge and renewing motivational confidence.
CO4	Provides latest information in the field of science and technology.
COURSE CODE: AUDIT COURSE II	**CONSTITUTION OF INDIA**
CO1	Understanding the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
CO2	Confer the intellectual origins of the frame work of argument that informed the conceptualization of social reforms leading to revolution in India.
CO3	Dissertate the circumstances surrounding the foundation of the congress socialist party under the leadership of Jawaharlal Nehru and eventual failure of the proposal of direct elections through adult suffrage in the Indian constitution.
CO4	Discuss the passage of the Hindu Code Bill of 1956.
AUDIT COURSE II	**PEDAGOGY STUDIES**
CO1	Figure out what pedagogical practices are being used by teachers in formal and informal class rooms in developing countries.
CO2	The evidence on the effectiveness of these pedagogical practices, in

	what conditions and with what population of learners.
CO3	How can teacher education, school curriculum and guidance materials best support effective pedagogy?
CO4	Identify critical evidence gaps to guide the development.
AUDIT COURSE II	**STRESS MANAGEMENT BY YOGA**
CO1	Develop healthy mind in a healthy body thus improving social health.
CO2	Improve efficiency
CO3	overcome stress.
CO4	To get well acquinted with types of pranayama.
AUDIT COURSE II	**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**
CO1	Study of Shrimad-Bhagwad-Geeta help the student in developing his personality and achieve the highest goal in life.
CO2	Study of neethishatakam will help in developing versatile personality of students.
CO3	To awaken wisdom in students.
CO4	To became a person with stable mind, pleasing personality and determination.
M.PHARMACY (PHARMACEUTICS) II YEAR I SEMESTER	
COURSE CODE: PE V	**BIOSTATISTICS**
CO1	Discuss the basic concept and importance of statistical analysis.
CO2	Explain various methods of testing hypothesis.
CO3	Dissert the methods of collection of data, analysis and interpretation.
CO4	To understand the basic aspects of statistics such as central tendency, dispersion and correlation.
PE V	**SCALE UP AND TECHNOLOGY TRANSFER**
CO1	Manage the scale up process in pharmaceutical industry.
CO2	Assist in technology transfer.
CO3	To establish safety guidelines which prevent industrial hazards.
CO4	Be aware of process validation.
PE V	**PRODUCTION AREA DESIGN AND PACKAGING DEVELOPMENT**
CO1	To elaborate the current good manufacturing practices.
CO2	To maximise knowledge on pharmaceutical packaging and design.
CO3	To familiarise the packaging of solids, semisolids, parenterals, ophthalmic and aerosols.
CO4	To be acquainted with components of packaging and packaging materials.
COURSE CODE: DISSERTATION	**DISSERTATION WORK REVIEW II**

CO1	Search and evaluate the available literature in your given subject or chosen topic area
CO2	Read the selected articles thoroughly and evaluate them
CO3	Organise the selected papers by looking for patterns and by developing sub topics
CO4	Analyse critically a segment of published body of knowledge through summary
M.PHARMACY (PHARMACEUTICS) II YEAR II SEMESTER	
COURSE CODE: DISSERTATION	**DISSERTATION WORK REVIEW III**
CO1	Apply knowledge and understanding in relation to the agreed area of study
CO2	Communicate in written form by integrating, analysing and applying key texts and practices
CO3	Demonstrate advanced critical research skills in relation to career development
CO4	Integrate the theory and practice in evaluation
COURSE CODE: DISSERTATION	**DISSERTATION VIVA VOCE**
CO1	Demonstrate knowledge in the program domain
CO2	Presenting views cogently and precisely
CO3	Exhibit professional etiquette suitable for career progression
CO4	Exhibit sustained curiosity and have an attitude of attention in detailing of the project

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ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS FOR M.PHARMACY I & II Years – I TO IV SEMESTERS

UNDER AUTONOMOUS STATUS FOR THE BATCHES ADMITTED FROM THE ACADEMIC YEAR 2025-2026

PRELIMINARY DEFINITIONS AND NOMENCLATURE

- "Autonomous Institute / College" means an institute / college designated as autonomous institute / college by the UGC, New Delhi and JNTUH Statutes, 2023.
- "Academic Autonomy" means freedom to a College in all aspects of conducting its academic programs granted by the University for promoting excellence.
- "Commission" means University Grants Commission (UGC), New Delhi.
- "University" means the Jawaharlal Nehru Technological University, Hyderabad.
- "Institute/College" means SRI INDU INSTITUTE OF PHARMACY, Hyderabad unless indicated otherwise by the context.
- "Programme" means: Master of Pharmacy (M.Pharmacy) degree programme.
- "Course" or "Subject" means a Theory or Practical subject, identified by its course–number and course-title.
- T – Tutorial, P – Practical, D – Drawing, L - Theory, C – Credits.

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ACADEMIC REGULATIONS OF M.PHARMACY COURSE (REGULAR/FULL TIME) STUDENTSWITH EFFECT FROM THE ACADEMIC YEAR 2025-26 (R-25)

AT PAR WITH

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by Act No. 30 of 2008)

Kukatpally, Hyderabad, Telangana (India).

Academic Regulations of M.Pharm. (Regular/Full Time) Programmes, 2025-26 (R25)(CBCS)
(Effective for the students admitted into I year from the Academic Year 2025-26 and onwards)

1.0 Jawaharlal Nehru Technological University Hyderabad (JNTUH) offers **Two** Years (**Four** Semesters) full-time Master of Pharmacy (M. Pharm.) Degree programmes, under Choice Based Credit System (CBCS) at its non-autonomous constituent and affiliated colleges in different specializations.

2.0 Eligibility for Admissions

2.1 Admission to the M. Pharm. programme shall be made subject to eligibility, qualification and specializations prescribed by the University from time to time, for each specialization under each M. Pharm. programme.

2.2 Admission to the post graduate programme shall be made on the basis of either the merit rank or Percentile obtained by the qualified student in the relevant GPAT Examination/ the merit rank obtained by the qualified student in PGECET, entrance test conducted by Telangana Government for M. Pharm. programmes / an entrance test conducted by JNTUH/ on the basis of any other exams approved by the University, subject to reservations as laid down by the Govt. from time to time.

2.3 The medium of instruction for all PG programmes will be English only.

3.0 M. Pharm. Programme Structure

3.1 The M. Pharm. Programmes of JNTUH are of Semester pattern, consisting of **Two** academic years, each academic year having **Two** Semesters (Odd and Even Semesters). The student shall not take more than **four** academic years to fulfill all the academic requirements for the award of M. Pharm. degree from the date of commencement of first year first semester, failing which the student shall forfeit the seat in M. Pharm. programme.

3.2 **UGC/PCI** specified definitions/descriptions are adopted appropriately for various terms and abbreviations used in these PG academic regulations, as listed below:

3.3 Semester Scheme

There shall be a minimum of 15 weeks of instruction, excluding the mid-term and semester-end exams. Around 15 instruction hours, 30 instruction hours and 45 hours of learning need to be followed per one credit of theory course, practical course and project/field-based learning respectively. Each Semester shall have 'Continuous Internal Evaluation (CIE)' and 'Semester End Examination (SEE)'. Choice Based Credit System (CBCS) and Credit Based Semester System (CBSS) are taken as 'references' for the present set of Regulations.

3.3.1 Credit Courses

All courses are to be registered by the student in a semester to earn credits which shall be assigned to each course in an L: T: P: C (Lecture Periods: Tutorial Periods: Practical Periods: Credits) structure based on the following general pattern:

- One credit for one hour/week/semester for theory/lecture (L) courses
- One credit for two hours/ week/semester for laboratory/ practical (P) courses or tutorials (T)
- One credit is allocated for three hours per week in a semester for Project/Mini-Project session.

3.3.2 Course Classification

All courses offered for the Post-Graduate Programme in Pharmacy (M. Pharm. Degree Programme) are broadly classified as follows. The University follows in general the guidelines issued by PCI/UGC.

S.No.	Broad Course Classification	Course Group/ Category	Course Description
1	Core Courses (CoC)	PC - Professional Core	Includes courses related to the Specialization in Pharmacy
		Dissertation	Major Project
		Mini Project/ Seminar	Mini Project/Seminar based on core contents related to the Specialization in Pharmacy
2	Elective Courses (EıE)	PE - Professional Electives	Includes elective courses related to the Specialization in Pharmacy
		OE - Open Electives	Elective courses which include inter-disciplinary courses or courses in an area outside the Specialization in Pharmacy
3	Audit Courses	--	Non-Credit Audit Courses

4.0 Course Registration

4.1 A faculty advisor/ mentor shall be assigned to a specified numbers of students belong each specialization, who will advise on M. Pharm. Course Structure, Curriculum, Choices/Options for Courses, based on their individual competencies, progress, fulfilment of pre-requisites and interest.

4.2 The academic section of the college invites registration forms from students before the beginning of the semester through on-line registration, ensuring date and time stamping. The online registration requests for semester courses shall be completed two weeks before the commencement of SEEs (Semester End Examinations) of the preceding semester.

4.3 A Student can apply for on-line Registration, only after obtaining the written approval from his Faculty Advisor, which should be submitted to the College Academic Section through the Head of Department (a copy of it being retained with Head of Department, Faculty Advisor and the Student).

4.4 If the Student submits ambiguous choices or multiple options or erroneous entries during on-line Registration for the Course(s) / Course(s) under a given/ specified Course Group/ Category as listed in the Course Structure, only the first mentioned Course in that Category will be taken into consideration.

4.5 Course Options exercised through on-line Registration are final and cannot be changed, nor can they be inter-changed; further, alternate choices also will not be considered. However, if the Course that has already been listed for Registration by the University in a Semester could not be offered due to unforeseen or unexpected reasons, then the Student will be allowed to have alternate choice either for a new Course, if it is offered, or for another existing Course (subject to availability of seats). Such

alternate arrangements will be made by the Head of Department, with due notification and time-framed schedule, within the first week from the commencement of Class-work for that Semester.

5.0 Attendance Requirements

Attendance is calculated for each course separately. Promotion/ detention rules are applied course- wise.

5.1 Attendance in all classes (Lectures/Laboratories) is compulsory. The minimum required attendance in each theory course including the audit courses should be 80%. The attendance of mid-term examination / Laboratory etc. at the rate of two periods of attendance for each theory course shall be considered, if the student appears for the mid-term examination of that course. This attendance should also be included in the fortnightly upload of attendance to the University. The attendance of mandatory audit courses should be uploaded separately to the University. A student shall not be permitted to appear for the Semester End Examinations (SEE), if his attendance is less than 80%.

5.2 A student's Seminar report and presentation on Mini Project shall be eligible for evaluation, only if the student obtain a minimum of **80%** of attendance in Seminar presentation classes on Mini Project during that Semester.

5.3 Condoning of shortage of attendance up to a maximum of 10% (considering the days of attendance in sports, games, NCC, NSS activities and Medical grounds) in each course (Theory/Lab/Mini Project/ Seminar) of a semester shall be granted by the College Academic Committee on genuine reasons.

5.4 A prescribed fee per course shall be payable for condoning shortage of attendance after getting the approval of College Academic Committee for the same. The condonation fee particulars need to be displayed in website/portal of the college. The College Academic Committee shall maintain relevant documents along with the requests from the students.

5.5 Shortage of Attendance below 70% in any course shall in **no case be condoned.**

5.6 A Student, whose shortage of attendance is not condoned in any Course(s) (Theory/Lab/Mini Project /Seminar) in any Semester or having the attendance less than 70 percentage, shall be detained in that course and is not eligible to write Semester End Examination/Evaluation of that Course. Such students have to seek re-registration for those Course(s) in subsequent Semesters, and attend the same as and when offered.

5.7 A student fulfills the attendance requirement in the present semester, shall not be eligible for readmission into the same semester.

5.8 A student shall put in a minimum required attendance in at least **three theory courses (excluding *audit* course)** in first Year I semester for promotion to first Year

II Semester. Same criteria shall be followed for promotion from first Year II semester to second Year I Semester.

6.0 Academic Requirements

The performance of the candidate in each semester shall be evaluated course-wise, with a maximum of 100 marks per course (theory / practical), based on Internal Evaluation and Semester End Examination. The following academic requirements must be satisfied, in addition to the attendance requirements mentioned in clause no. 5.

6.1 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to each course, if he secures not less than **40%** of marks (**28** out of **70** marks) in the Semester End Examination, and a minimum of **50%** of marks in the sum total of CIE (Continuous Internal Evaluation) and SEE (Semester End Examination) taken together. In terms of Letter Grades and this implies securing **'D'** Grade or above in a course.

6.2 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **Mini Project**, if student secures not less than **50%** marks (i.e. 50 out of 100 allotted marks). The student would be treated as failed, if student (i) does not submit a report on Mini Project or does not make a presentation of the same before the evaluation committee as per schedule or (ii) secures less than 50% marks in Mini Project evaluation. The failed student may reappear once for the above evaluation, as and when they are scheduled again; if the student fails in such „one reappearance" evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.

6.3 A student shall be deemed to have satisfied the academic requirements and earned the credits allotted to **seminar**, if student secures not less than 50% marks i.e. 50 out of 100 allotted marks. The student would be treated as failed, if student (i) does not submit a report on seminar as prescribed or does not make a seminar presentation before the evaluation committee as per schedule or (ii) secures less than 50% (i.e. < **50** marks out of **100**) marks in the seminar evaluation. The student failed in seminar evaluation may reappear once for it, as and when it is scheduled again. If the student fails in such one reappearance evaluation also, the student has to reappear for the same in the next subsequent semester, as and when it is scheduled.

6.4 A student shall register for all courses for total of **98** credits as specified and listed in the course structure for the chosen specialization, put in the required attendance and fulfill the academic requirements for securing **98** credits obtaining a minimum of **'D'** Grade or above in each course, and shall **pass all the audit courses** to complete the M. Pharm. program successfully.

Note: (1) The SGPA will be computed and printed on the grades memo only if the candidate passes in all the courses offered and gets minimum 'D' grade in all the courses.

(2) CGPA is calculated only when the candidate passes in all the courses offered in all the semesters

6.5 Marks and Letter Grades obtained in all those courses covering the above specified **98** credits alone shall be considered for the calculation of final CGPA, which will be indicated in the Grade Card of second year second semester.

6.6 When a student is detained due to shortage of attendance in any course(s) in any semester, no Grade allotment will be made for such course(s). However, he is eligible for re-registration of such course(s) in the subsequent semester(s), with the academic regulations of the batch into which he is re- registered, by paying the prescribed fees per course and earn credits.

6.7 A student eligible to appear for the Semester End Examination in any course, but absent from it or treated as failed (failing to secure **'D'** Grade or above), may reappear for that course at the supplementary examination as and when conducted. In such cases, his Internal Marks assessed earlier for that course will be carried over, and added to the marks secured in the supplementary examination, for the purpose of evaluating his performance in that course.

6.8 A Student who fails to earn **98** credits as per the specified course structure, and as indicated above, within **four** academic years from the date of commencement of his first year first semester, shall forfeit his seat in M. Pharm. programme and his admission **shall stand cancelled.**

7.0 Evaluation - Distribution and Weightage of Marks:

The performance of a student in each semester shall be evaluated course- wise (irrespective of credits assigned) for a maximum of 100 marks. The performance of a student in every theory course will be evaluated for 100 marks**.**

7.1 For theory courses, 30 marks shall be awarded for Continuous Internal Evaluation (CIE) and 70 marks shall be awarded for the performance in the Semester End Examination (SEE).

7.1.1 The Continuous Internal Evaluation for each course shall be carriedout based on the average of the marks secured in the two Mid-Term Examinations conducted and assignments. The first Mid-Term examinations shall be conducted in middle of the Semester and second Mid-Term examinations during the last week of instruction. Each Mid-Term Examination shall be conducted for a total duration of 120 minutes with Part-A as compulsory section consisting of 5 questions carrying 2 marks each (10 marks), and Part-B with 3 questions to be answered out of 5 questions, each question carrying 5 marks (15 marks). Five marks in each course are allotted for the assignments.

7.1.2 The details of the Question Paper pattern for Semester End Examination (SEE) are given below:

The Semester End Examination will be conducted for 70 marks. It consists of two parts: i) Part A for 20 marks and ii) Part B for 50 marks

- Part A is compulsory and consists of five questions, one from each unit and carrying four marks each.
- Part B consists of five questions carrying 10 marks each. There will be two questions from each unit and only one should be answered.

7.2 For practical courses there shall be a Continuous Internal Evaluation (CIE) during the semester for 30 marks and 70 marks for semester end examination (SEE).

7.2.1 **The rubrics for the** 30 marks internal evaluation is as follows:

1. A write-up on day-to-day experiment in the laboratory (in terms of aim, components/procedure, expected outcome) which shall be evaluated for 10 marks
2. 10 marks for viva-voce in the course concerned.
3. Internal practical examination conducted by the laboratory teacher concerned shall be evaluated for 10 marks.

7.2.2 The Semester End Examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University.

In the Semester End Examination held for 3 hours, the rubrics for a total of 70 marks are as shown below:

1. 15 marks for Synopsis
2. 40 marks for experiment
3. 15 marks for viva-voce on concerned laboratory course

A student has to secure 50 marks out of 100 (i.e. 50% marks) allotted for CIE and SEE taken together.

7.3 There shall be Mini Project during I year II semester. There shall be only i**nternal evaluation in** Mini Project for 100 marks. Student shall carryout the mini project in consultation with the mini project supervisor which may include critically reviewing the literature, project implementation and submit it to the department in the form of a report and shall make an oral presentation before the Departmental Academic Committee (DAC) consisting of Head of the Department, Mini Project supervisor and two other senior faculty members of the department. DAC will review the progress of the mini project during the presentations and evaluate the same for 50 marks. Mini Project Viva Voce will be evaluated by the DAC for another 50 marks before the semester-end examinations. The student has to secure a minimum of 50% of marks in this internal evaluation, to be declared passed. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.4 There shall be one seminar each during I Year I Semester & I Year II Semester. **100** marks are allotted for each of the Seminars. There shall be only i**nternal evaluation in Seminar.**

7.4.1 For **Seminar course**, the student in consultation with the seminar supervisor shall collect the information on a specialized topic, prepare a report, and submit it to the department. The Departmental Academic Committee (DAC) consisting of Head of the Department, seminar supervisor and two other senior faculty members of the department will evaluate the seminar report for 100 marks before the semester end examinations. The student has to secure a minimum of 50 marks (i.e. 50% marks) to be declared as passed. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.5 There shall be comprehensive viva-voce during II year I semester. It is an **external evaluation course** of 100 marks. It shall be evaluated by the committee consisting of an external examiner, Head of the Department, and two other senior faculty members of the department before the semester-end examinations. The external examiner shall be appointed from the cluster/other colleges which will be decided by the examination branch of the University. The student has to secure a minimum of 50 marks (i.e. 50% of the marks) to be declared as passed. If he fails to obtain the minimum marks, he has to reappear for the same as and when scheduled.

7.6 Every candidate shall be required to submit a dissertation on a topic approved by the Dissertation Review Committee.

7.7 A Dissertation Review Committee (DRC) shall be constituted with the Head of the Department as Chairperson, Dissertation Supervisor and one senior faculty member of the Department offering the M. Pharm. programme.

7.8 Registration of Dissertation Work: A candidate is permitted to register for the Dissertation Work after satisfying the attendance requirement in all the courses, both theory and laboratory.

7.9 After satisfying the above clause, the candidate in consultation with his Dissertation Supervisor, the title, objective and plan of action of his Dissertation work must be finalized and present before the Dissertation Review Committee (DRC), which is termed as in Dissertation Work Review–I, for approval within four weeks from the commencement of Second year First Semester. Only after obtaining the approval of the DRC, the student can initiate the Dissertation work. Dissertation Work Review–I does not carry any credits.

7.10 If a candidate wishes to change his supervisor or topic of the Dissertation, he can do so with the approval of the DRC. However, the DRC shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of Dissertation proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

7.11 A candidate shall submit his Dissertation progress report in two stages at least with a gap of **three** months between them.

7.12 The work on the Dissertation shall be initiated at the beginning of the II year and the duration of the Dissertation is two semesters. A candidate is permitted to submit Dissertation only after successful completion of all theory and practical courses with the approval of DRC not earlier than 40 weeks from the date of approval of the Dissertation work. For the approval of DRC the candidate shall submit the draft copy of thesis to the Head of the Department and make an oral presentation before the DRC.

7.13 The Dissertation Work Review - II in II Year I Sem. carries internal marks of 100. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate the work for the other 50 marks. The Supervisor and DRC will examine the Problem Definition, Objectives, Scope of Work, Methodology Adopted, Literature Survey in the same domain and progress of the Dissertation Work.

7.14 The Dissertation Work Review - III in II Year II Sem. carries 100 internal marks. Evaluation should be done by the DRC for 50 marks and the Supervisor will evaluate it for the other 50 marks. The DRC will examine the overall progress of the Dissertation Work and decide whether or not the Dissertation is eligible for final submission.

7.15 The evaluation of each of Dissertation Work Review – II and Dissertation Work Review - III by the DRC shall be carried out as per the criteria given below:

Objective(s) of the work done	- 5 Marks
Methodology adopted	- 15 Marks
Results and Discussions	- 25 Marks
Conclusions and Outcomes	- 5 Marks
Total	**- 50 Marks**

7.16 A candidate has to secure a minimum of 50% of marks to be declared successful in each of Dissertation Work Review — II and Dissertation Work Review - III. If he fails to obtain the required minimum marks, he has to reappear for the same Dissertation Work Review as and when conducted.

7.15 Dissertation Evaluation (Viva Voce) shall be done in II Year II Sem. There shall be external marks of 100 and it is evaluated by the external examiner. The evaluation shall be done as per the criteria given below:

Presentation of work	- 40 Marks
Communication skills	- 20 Marks
Viva-Voce	- 40 Marks
Total	**- 100 Marks**

The candidate has to secure a minimum of 50% marks in Dissertation Evaluation (Viva-Voce) examination. If he fails to obtain the required minimum marks, he has to reappear for the same as and when conducted.

7.16 Dissertation Work Reviews - II and III shall be conducted in phase I (Regular) and Phase II (Supplementary). Phase II will be conducted only for unsuccessful students in Phase I. The unsuccessful students in Dissertation Work Review - II (Phase II) shall reappear for it at the time of Dissertation Work Review - III (Phase I). These students shall reappear for Dissertation Work Review - III in the next academic year at the time of Dissertation Work Review - II only after completion of Dissertation Work Review - II, and then Dissertation Work Review - III follows. The unsuccessful students in Dissertation Work Review - III (Phase II) shall reappear for Dissertation Work Review - III in the next academic year only at the time of Dissertation Work Review - II (Phase I).

7.17 After approval from the DRC, a soft copy of the thesis should be submitted for Anti-Plagiarism check and the plagiarism report should be submitted to the University and be included in the final thesis. The Thesis will be accepted for submission, if the similarity index is less than **30%**. If the similarity index is more than the required percentage, the student is advised to modify accordingly and re-submit the soft copy of the thesis after one month. The maximum number of re-submissions of thesis after plagiarism check is limited to two. The candidate has to register for the dissertation work and work for two semesters. After three attempts, the admission is liable to be cancelled. The college authorities are advised to make plagiarism check of every soft copy of dissertation before submissions.

7.18 Three copies of the Dissertation certified by the supervisor shall be submitted to the College/School/Institute for the evaluation.

7.19 The dissertation shall be adjudicated by an external examiner selected by the University. For this, the Principal of the College/School/Institute shall submit a panel of **three** examiners from among the list of experts in the relevant specialization as submitted by the supervisor concerned and Head of the Department.

7.20 If the report of the external examiner is unsatisfactory, the candidate shall revise and resubmit the dissertation. If the report of the examiner is unsatisfactory again, the dissertation shall be summarily rejected. Subsequent actions for such dissertations may be considered, only on the specific recommendations of the external examiner and /or Dissertation Review Committee. No further correspondence in this matter will be entertained, if there is no specific recommendation for resubmission.

7.21 If the report of the examiner is satisfactory, the Head of the Department shall coordinate and make arrangements for the conduct of Dissertation Viva-Voce examination. The Dissertation Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who adjudicated the Thesis. The student has to secure a minimum of 50% of marks in Dissertation Evaluation (Viva-Voce) examination.

7.22 If the student fails to fulfill the requirements as specified earlier, he will reappear for the Dissertation Viva-Voce examination only after three months. In the reappeared examination also, if he fails to fulfill the requirements, he will not be eligible for the award of the degree, unless he is asked to revise and resubmit his Dissertation Work by the board within a specified time period (within **four** years from the date of commencement of his first year first semester).

7.23 The Dissertation Viva-Voce External examination marks must be submitted to the University on the day of the examination.

7.24 For audit courses, a student has to secure 50 marks out of 100 marks (i.e. 50% of the marks) in the continuous internal evaluation for passing the course. These marks should also be uploaded along with the internal marks of other courses.

7.25 No marks or letter grades shall be allotted for audit courses. Only Pass/Fail shall be indicated in Grade Card.

8.0 Re-Admission/Re-Registration

8.1 Re-Admission for Discontinued Student

A student, who has discontinued the M. Pharm. degree programme due to any reason whatsoever, may be considered for '**readmission'** into the same degree programme (with the same specialization) with the academic regulations of the batch into which he gets readmitted, with prior permission from the authorities concerned.

8.2 If a student is detained in a course (s) due to shortage of attendance in any semester, he may be permitted to **re-register** for the same course(s) in the same category (core or elective group) or equivalent course, if the same course is not available, as suggested by the Board of Studies of that department, as and when offered in the subsequent semester(s), with the academic regulations of the batch into which he seeks re-registration, with prior permission from the authorities concerned.

8.3 A candidate must re-register for failed courses within four weeks of commencement of the class work and secure the required minimum attendance. In the event of the student taking this chance, his Continuous Internal Evaluation marks obtained in the previous attempt stands cancelled.

9.0 Examinations and Assessment - The Grading System

9.1 Grades will be awarded to indicate the performance of each student in each Theory Course, Lab/ Practical, or Mini Project, Seminar, Dissertation, etc., based on the percentage of marks obtained in Continuous Internal Evaluation (CIE) and Semester End Examination (SEE), both taken together, as specified in clause 7 above, and the corresponding Letter Grade shall be given.

9.2 As a measure of the student‟s performance, a 10-point Absolute Grading System using the following percentage of marks and the corresponding letter grades are followed:

% of Marks Secured in a Course (Class Intervals)	Letter Grade	Grade Points
Greater than or equal to 90%	O (Outstanding)	10
80 and less than 90%	A (Excellent)	9
70 and less than 80%	B (Good)	8
60 and less than 70%	C (Fair)	7
50 and less than 60%	D (Average)	6
Below 50%	F (FAIL)	0
Absent	Ab	0

9.3 A student obtaining **'F'** Grade in any Course is deemed to have „failed" and is required to reappear as „Supplementary Candidate" for the Semester End Examination (SEE), as and when conducted. In such cases, his Continuous Internal Marks (CIE Marks) in those courses will remain as obtained earlier.

9.4 If a student has not appeared for the examinations, **'Ab'** Grade will be allocated to him for any course and shall be considered „failed" and will be required to reappear as „Supplementary Candidate" for the Semester End Examination (SEE), as and when conducted.

9.5 A Letter Grade does not imply any specific marks percentage; it is only the range of percentage of marks.

9.6 In general, a student shall not be permitted to repeat any Course (s) only for the sake of „Grade Improvement" or „SGPA/ CGPA Improvement".

9.7 A student earns Grade Point (GP) in each Course, on the basis of the Letter Grade obtained by him in that Course. The corresponding „Credit Points" (CP) are computed by multiplying the Grade Point with Credits for that particular Course.

Credit Points (CP) = Grade Point (GP) x Credits …. For a Course

9.8 The Semester Grade Point Average (SGPA) is calculated by dividing the Sum of Credit Points secured from all Courses registered in a Semester, by the Total Number of Credits registered during that Semester. SGPA is rounded off to two Decimal Places. SGPA is thus computed as

$$\textbf{SGPA} = \{\sum_{i=1}^{N} C_i G_i\} \; / \; \{\sum_{i=1}^{N} C_i\} \textbf{ …. For each Semester,}$$

where „i" is the Course indicator index (taking into account all Courses in a Semester), „N" is the no. of Courses registered for the Semester (as specifically required and listed under the Course Structure of the parent Department), C_i is the no. of Credits allotted to the i^{th} Course, and G_i represents the Grade Points corresponding to the Letter Grade awarded for that i^{th} Course.

9.9 The Cumulative Grade Point Average (CGPA) is a measure of the overall cumulative performance of a student over all semesters considered for registration. The CGPA is the ratio of the total credit points secured by a student in all registered Courses in all Semesters, and the Total Number of credits registered in all the Semesters. CGPA is rounded off to two decimal places. CGPA is thus computed from the I Year Second Semester onwards, at the end of each Semester, as per the formula.

$$\textbf{CGPA} = \{ \sum_{j=1}^{M} C_j G_j \} / \{ \sum_{j=1}^{M} C_j \}$$

where „M" is the total no. of Courses (as specifically required and listed under the Course Structure of the parent Department) the Student has registered. C_j is the no. of Credits allotted to the j^{th} Course, and G_j represents the Grade Points corresponding to the Letter Grade awarded for that j^{th} Course. After registration and completion of I Year I Semester however, the SGPA of that Semester itself may be taken as the CGPA, as there are no cumulative effects.

Illustration of calculation of SGPA

Course	Credits	Letter Grade	Grade Points	Credit Points
Course 1	4	A	9	4 x 9 = 36
Course 2	4	O	10	4 x 10 = 40
Course 3	4	C	7	4 x 7 = 28
Course 4	3	B	8	3 x 8 = 24
Course 5	3	A	10	3 x 10 = 30
Course 6	3	C	7	3 x 7 = 21
	Total Credits = 21			Total Credit Points = 179

SGPA = 179/21 = 8.52

Illustration of calculation of CGPA

Course	Credits	Letter Grade	Grade Points	Credit Points
I Year I Semester				
Course 1	4	A	9	4 x 9 = 36
Course 2	4	A	9	4 x 9 = 36
Course 3	4	B	8	4 x 8 = 32
Course 4	3	O	10	3 x 10 = 30
Course 5	3	B	8	3 x 8 = 24
Course 6	3	D	6	3 x 6 = 18
I Year II Semester				
Course 7	4	B	8	4 x 8 = 32
Course 8	4	O	10	4 x 10 = 40
Course 9	4	A	9	4 x 9 = 36
Course 10	3	D	6	3 x 6 = 18
Course 11	3	C	7	3 x 7 = 21
Course 12	3	A	9	3 x 9 = 27
	Total Credits = 42			Total Credit Points = 350

CGPA upto II Year II Semester = 350/42 = 8.33

10.0 Award of Degree and Class

10.1 If a student who registers for all the specified Courses as listed in the Course Structure, satisfies all the Course Requirements, and passes the examinations prescribed in the entire M. Pharm. Programme, and secures the required number of **98** Credits (with CGPA □ 6.0), shall be declared to have qualified for the award of the M. Pharm. Degree in the chosen specialization of Pharmacy that he was admitted into.

10.2 Award of Class

After a student has earned the requirements prescribed for the completion of the programme and is eligible for the award of M. Pharm. Degree, he shall be placed in one of the following three classes based on the CGPA:

Class Awarded	CGPA
First Class with Distinction	≥ 7.50
First Class	$6.50 \leq \text{CGPA} < 7.50$
Second Class	$6.00 \leq \text{CGPA} < 6.5$

11.0 Withholding of Results

If the student has not paid the dues, if any, to the University or if any case of indiscipline is pending against him, the result and degree of the student will be withheld and he will not be allowed into the next semester.

12.0 General

12.1 **Credit**: A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field work per week.

12.2 **Credit Point:** It is the product of grade point and number of credits for a course.

12.3 Wherever the words “he”, “him”, “his”, occur in the regulations, they shall include “she”, “her”.

12.4 The academic regulation should be read as a whole for the purpose of any interpretation.

12.5 In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the University is final.

12.6 The University may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the University.

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

S.No	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1.(a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form ofmaterial concerned with or related to the subject to the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination).	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. Incase of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject to the examination (theory or practical) in which the candidate isappearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.

3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate, who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course bythe candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the	Expulsion from the examination hall and cancellation of performance in that subject and
	question paper during the examination or answer book or additional sheet, during or after the examination.	All the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in Connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters tothe examiners or writes to the examiner Requesting him to award pass marks.	Cancellation of the performance in that subject.

6.	Refuses to obey the orders of the Chief Superintendent/Assistant– Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in- charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which inthe opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all othersubjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any par there of inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in theexamination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.

9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarredand forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

- Punishments to the candidates as per the above guidelines.
- Punishment for institutions: (if the squad reports that the college is also involved in encouraging malpractices)
- A show cause notice shall be issued to the college.
- Impose a suitable fine on the college.
- Shifting the examination centre from the college to another college for a specific periodof not less than one year.

SRI INDU INSTITUTE OF PHARMACY

M.PHARMACY (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)

R25 COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2022-23 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutics-I	3	1	0	4
Professional Core-II	Applied Biopharmaceutics and Pharmacokinetics	3	1	0	4
Professional Elective-I	1. Advanced Physical Pharmaceutics 2. Drug Regulatory affairs 3. Total Quality Management	3	1	0	4
Professional Elective-II	1. Artificial Intelligence in Formulation and Process Development 2. Pharmaceutical Validation 3. Stability of Drugs and Dosage Forms	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Modern Pharmaceutics – I Lab	0	0	6	3
Laboratory- II	Applied Biopharmaceutics and Pharmacokinetics Lab	0	0	6	3
Audit – I	Audit Course- I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	**16**	**4**	**16**	**26**

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Modern Pharmaceutics - II	3	1	0	4
Professional Core-IV	Advanced Drug Delivery Systems	3	1	0	4
Professional Elective-III	1. Industrial Pharmacy 2. Herbal Cosmetics 3. Pharmaceutical Management	3	1	0	4
Professional Elective-IV	1. Nano based Drug Delivery Systems 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Modern Pharmaceutics – II Lab	0	0	6	3
Laboratory- IV	Advanced Drug Delivery System Lab	0	0	6	3
	Mini Project	2	0	0	2
Audit – II	Audit Course- II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	TOTAL	**16**	**4**	**16**	**26**

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Scale up and Technology Transfer 3. Production area, Design and Packaging Development	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva voce	0	0	8	4
	Dissertation Work Review – II	0	0	24	12
	TOTAL	**6**	**2**	**32**	**24**

II YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	TOTAL	**0**	**0**	**44**	**22**

***For Dissertation Work Review - I, Please refer R25 Academic Regulations.Audit**

Audit Courses I & II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

Open Electives:

1. Entrepreneurship Management
2. Pharmaceutical administration
3. Cosmetic Science
4. Environmental and Health safety
5. Vaccines and Biologicals

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS –I (Professional Core-I)

Course Objectives: Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

Course Outcome: Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

UNIT I

Preformulation studies: Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies as per ICH**.**

UNIT II

Formulation development of solid dosage forms – I: New materials, excipient science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipient, co-processed materials, methods of preparation and evaluation.

UNIT III

Formulation development of solid dosage forms– II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.

Microencapsulation- types, methodology, problems encountered.

UNIT IV

Formulation development of soft and hard gelatin capsules: Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams,

factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

TEXT BOOKS

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman andSchwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman andLachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Pharmaceutical statistics by Bolton

REFERENCE BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington‟s Science and Practice of Pharmacy by A. Gennaro.
3. Ansel‟s Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and IsadoreKanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, VallabhPrakashan Delhi – 2013

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Core– II)

Course Objectives: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non- linear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

Course Outcomes: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non- linear kinetics.

UNIT I

a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
c. **Bioavailability:** Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo* Correlation analysis and Levels of Correlations.
d. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

a. Distribution: Apparent volume of distribution and its determination, factors affecting.
b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
c. Elimination: Over all apparent elimination rate constant, and half life.All the above under the following conditions:
    1. Intravenous infusion
    2. Multiple dose injections
d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

Pharmacokinetics – Absorption: Rate constants – Zero order, first order,Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration.

UNIT IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis- Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non- linear binding, and non-linearity of pharmacological responses.

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kineticsin GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence. Numerical problems associated with all units, if any.

TEXT BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, VallabhPrakashan.2010.
4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz, PharmamedPress

REFERENCE BOOKS

1. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
2. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Albert P. G

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHYSICAL PHARMACEUTICS (Professional Elective – I)

Course Objectives: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

Course Outcomes: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

UNIT I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT II

Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systemsand semisolids. Oscillatory testing, Creep measurement.

Characterization of API and excipients: Differential Scanning Calorimetry: Principle, thermaltransitions, advantages, disadvantages, instrumentation, applications and interpretations

X Ray Diffraction methods: Origin of x-rays, principle, advantages, disadvantages, instrumentation,applications and interpretations.

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid-state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) anddissolution equipment.

TEXT BOOKS:

1. Physical Pharmacy, 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman, Vol. 4.
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II.
4. Cartenson "Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, VallabhPrakashan Delhi – 2013.

REFERENCE BOOKS:

1. Dispersive systems I, II, and III.
2. Robinson. Controlled Drug Delivery Systems.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

DRUG REGULATORY AFFAIRS (Professional Elective-I)

Course Objectives: The topics which are present in the Drug regulatory affairs are very much usefulwhich increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcomes:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application(MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful toplace the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC& BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API‟s, Manufacturing Contract andLoan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC,Water Systems, Stores Managemant, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution ina developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drugmanufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, qualitycontrol, batch release documents, distribution records, complaints and recalls. Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product DirectorateDMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
    3) MHRA – Medicines and Health Care Products Regulatory Agency
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per theirspecific requirements.

TEXT AND REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Text Book of Forensic Pharmacy by C K Kokate, Pharmamed Press
6. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty,Vallabh Prakashan Delhi - 2013

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

TOTAL QUALITY MANAGEMENT (Professional Elective - I)

Course Objectives: Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

Course Outcomes: Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist. It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

UNIT - I

Concepts and Philosophy of TQM, GLP, GMP (orange guide).

UNIT – II

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

UNIT - III

Good manufacturing practices: Organization and personnel, responsibilities, training, hygiene. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP). Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms. Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc., Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities. Finished products release, quality review, quality audits, batch release document.

UNIT - IV

Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratoginicity. Animal

pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials. Quality assurance standards as per ISO.

UNIT - V

Globalization of drug industry, present status and scope of pharmaceutical industry in India. WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

TEXT AND REFERENCE BOOKS:

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
2. Quality Assurance of Pharmaceuticals–A Compendium of Guidelines and Related Materials,Vol.–1; WHO Publications.
3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney
   H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance, USP.
9. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
10. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu andmarayya
11. Total Quality Management, An integrated Approach by D. R. Kiran, BS Publications
12. Total Quality Management, 3rd edition by Joel E. Ross. CRC press

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

COSMETICS AND COSMECEUTICALS (Professional Elective - II)

Course Objectives:

- Understanding the fundamentals of Artificial Intelligence, Machine Learning, and Deep Learning in the context of pharmaceutical formulation
- Apply AI in pharmaceutical manufacturing through process analytical technology (PAT), real- time control, and smart manufacturing.
- Gain knowledge of Artificial Neural Networks and Neuro-Fuzzy Systems for formulation optimization and decision support.
- Explore the integration of Machine Learning in 3D printing of personalized dosage forms and process optimization.
- Analyze real-world case studies highlighting AI applications in formulation development, personalized medicine and AI-based devices

Course Outcomes: Upon completion of the course student shall able to

- CO1: Explain the scope and significance of AI, ML, and DL in pharmaceutical formulation and identify appropriate algorithms for data analysis.
- CO2: Apply AI tools to monitor, predict, and optimize pharmaceutical manufacturing processes such as blending, granulation, and coating.
- CO3: Build and interpret neural network models and neuro-fuzzy systems for formulation prediction, optimization, and control.
- CO4: Implement machine learning techniques in the design and 3D printing of personalized drug delivery systems.
- CO5: Evaluate real-time industry case studies to understand the practical impact of AI in formulation settings

UNIT I

Fundamentals of AI and ML in Pharmaceutics

Definition, scope and relevance of AI, ML, and Deep Learning

Types of data: Structured, unstructured, and big data preprocessing

Learning paradigms: Supervised, unsupervised, reinforcement learning

Tools & Platforms: Python, R, KNIME MATLAB, TensorFlow

Overview of models: SVM, Decision Trees, Random Forest, Neural Networks.

UNIT II

AI in Preformulation and Formulation Development:

Application of AI in preformulation studies: Solubility, compatibility, excipient screening. Design of Experiments (DoE) and AI-assisted QbD for optimizing formulations.

AI in Process Analytical Technology (PAT)

Process Prediction Models – AI models to simulate and optimize blending, granulation, compression and coating

Machine Learning in 3D-Printing of Dosage Forms. Case studies.

UNIT III

Artificial Neural Networks and Neuro-Fuzzy Models in the Development of Pharmaceutical Products

Basics of neural networks: nodes, layers, weights, and activation functions, Supervised vs unsupervised learning, Types of ANN: Feedforward, Backpropagation, Deep neural networks, Concept of fuzzy logic, Adaptive Neuro-Fuzzy Inference Systems (ANFIS), Integration of neural networks with fuzzy logic, Applications in Formulation Development, Benefits, Challenges and Case studies.

UNIT IV

Pharmacokinetics, Biopharmaceutics & Stability Modeling

AI in pharmacokinetic and PBPK modeling: absorption, distribution, metabolism, and excretion (ADME), Tools: SimCyp, GastroPlus for modeling in vivo behavior of drug delivery systems, Neural networks for predicting shelf life and degradation kinetics, AI in enhancement of nanotechnology-based and targeted delivery systems, AI in IVIVC modeling and biopharmaceutic classification.

UNIT V

Case Studies and Emerging Trends

AI in personalized medicine and dose individualization AI in bioavailability prediction and IVIVC modeling

AI-driven 3D printing in drug formulation

AI in robotics in Nano-based drug delivery systems

Recent case studies: AI in vaccine development, COVID-19 models.

REFERENCE BOOKS:

1. Machine Learning for Drug Formulation and Process Development – Vijay Kumar Thakur (CRC Press)
2. Artificial Neural Networks: Applications in Chemical and Biological Engineering- S. Chakraverty, Smita Tapaswi, CRC Press, 2022
3. Artificial Intelligence in Drug Delivery – Abhay Shukla & Reinhold Kesharwani
4. A Handbook of Artificial Intelligence in Drug Delivery (2023), Philip, Shahiwala, Rashid, Faiyazuddin et al.
5. AI and ML in Pharmaceutical sciences-Harish Dureja.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL VALIDATION (Professional Elective - II)

Course Objective: 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.

Course Outcome: 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

UNIT I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.

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

UNIT IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place(CIP).

UNIT V

Analytical method validation: General principles, Validation of analytical method as per ICHguidelines and USP.

- Validate the manufacturing facilities

REFERENCE BOOKS:

1. 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, (MarcelDekker).
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 inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud,Interpharm Press
8. Pharmaceutical Facilities: Design, Layouts and Validation, 2nd Ed, Potdar, Pharmamed Press.
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and JamesAgalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, HeimanLam

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective - II)

Course Objectives: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding ofproperties and evaluation of stability during storage, by solution and solid state against several factorsof degradation.

Course Outcomes: The students should describe the evaluation of stability of solutions, solids andformulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT - I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization ofPharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical,Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions ofpharmaceutical interest, prevention of photolytic reactions.

UNIT - II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT - III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials,emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugsby various methods as LLE, SPE and Membrane filtration.Factors affecting extraction of drugs.

UNIT - IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT - V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

REFERENCE BOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry‟s Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of IndianStandards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W. Grimm.
11. Stability of Drugs and Dosage Forms by Yoshioka and Stella.,BSP Books

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today"s world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I:

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation,Necessary instrumentations

UNIT - II:

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III:

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format ofresearch proposal, a presentation and assessment by a review committee

UNIT - IV:

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT-V:

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science &engineering students""
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

REFERENCE BOOKS:

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in NewTechnological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)
MODERN PHARMACEUTICS – I LAB (Laboratory - I)

List of Experiments:

1. To carry out the preformulation studies of solid dosage forms**.**
2. To study the effect of compressional force on tablet disintegration time
3. To study the micromeritic properties of powders and granules
4. To study the effect of particle size on dissolution of capsules.
5. To study the effect of binders on dissolution of tablets
6. To study enteric coated tablets dissolution in relevant pH.
7. Accelerated stability testing of different tablets
8. Determination of first order, second order rate constants by acid and alkaline hydrolysis
9. Preparation and evaluation of beta cyclodextrin complexes of new drugs
10. Preparation of paracetamol tablets and comparison with marketed products
11. Design of experiments (DOE) in the optimization of an immediate release tablets.
12. Calculation of shelf life using accelerated stability data,

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS LAB (Laboratory- II)

List of Experiments:

1. Analysis of dissolution by various data-kinetic modeling.
2. Calibration curve of different API"s by UV/HPLC/HPTLC
3. Dissolution of immediate release, sustained release and delayed release.
4. Evaluation of drug-protein binding analysis
5. Assignment of numerical problems, one compartment and two compartment disposition,method of residuals, AUC and evaluation of pharmacokinetic parameters.
6. Calculation of Ka (absorption rate constant) absorption curve- Wagner nelson method , Loo-Riegel method.
7. Calculation of pharmacokinetics parameters of one compartment oral data and twocompartment IV data.
8. Construction of IVIVC from the data
9. Calculation of Urinary Pharmacokinetics
10. Calculation of Bioavailability and Bioequivalence Studies
11. Permeation studies of Franz diffusion cell
12. Drug Release from semisolids by Agargel method or Franz diffusion cell.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS - II (Professional Core - III)

Course Objective: The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control. The students alsounderstand about the cosmetics and nutraceuticals.

Course Outcomes: students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics andnutraceuticals.

UNIT I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

a. **Pilot plant:** Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.

b. **Scale up:** Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilization methods (Moist heat, dry heat, filtration, radiation, gaseous sterilization), product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV

a. **Cosmetics:** Formulation approaches, preparation & method of manufacturing labelling & Q.C. of anti-ageing products, sun screen lotion and fairness creams.

b. **Nutraceuticals:**

1. Introduction, source, manufacture and analysis of glucosamine & cartinine.
2. Monographs: General and specific properties of glucosamine & cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring,

microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

b. Air handling systems: Study of AHUs, humidity & temperature control.

TEXT BOOKS:

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington‟s Science and Practice of Pharmacy by A. Gennaro.
4. Ansel‟s Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr.
5. Nicholas G. Popovich, Howard C. Ansel.
6. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman andLachman.
7. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

REFERENCE BOOKS:

1. Bentley`s Text Book of Pharmaceutics by EA Rawlins.
2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Nutraceuticals, 2nd edition by Brian lock wood.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED DRUG DELIVERY SYSTEMS (Professional Core - IV)

Course Objectives: The students shall apply the pharmacokinetic and pharmacodynamic principlesin the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

Course Outcomes: Students will select the drugs for CDDS design of the formulation fabrication ofsystems of above drug delivery systems with relevant applications.

UNIT I

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

a. Controlled release oral drug delivery systems
b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation and applications of the following

a. Implantable Therapeutic systems
b. Transdermal delivery systems
c. Ocular and Intrauterine delivery systems
d. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oralimmunization, controlled release microparticles for vaccine development

UNIT III

Biochemical and molecular biology approaches for drug delivery using following technologies

a. Bioadhesive drug delivery systems
b. Nasal drug delivery systems
c. Drug delivery to Colon

UNIT IV

Biochemical and molecular biology approaches to control drug delivery of

a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealed erythrocytes

UNIT - V

Drug targeting to particular organs

a. Delivery to lungs
b. Delivery to the brain and problems involved
c. Drug targeting in neoplasams

TEXT BOOKS:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Advances in Drug Delivery, 4 Vol. set, Rao Madhusudan Y, Pharmamed Press
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
7. Oral Drug Delivery Technology, 2nded, by Aukunuru Jithan

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

INDUSTRIAL PHARMACY (Professional Elective - III)

Course Objectives: The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosage forms

Course Outcome: The students will explain the machinery involved in milling, mixing, filtration, dryingand packing material constructions used in the production of pharmaceutical materials. They also learn salient feature1s of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes

UNIT I

Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, granulation, drying and blending.

UNIT II

a. Materials of construction of pharmaceutical equipment and packaging materials: Study of the principles, production techniques in the large scale production of tablets, capsules, suspensions, liquid pharmaceuticals, ophthalmic products and sterile products.
b. Qualification of equipment (IQ, OQ, PQ)

UNIT III

Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

UNIT IV

Effluent Testing and Treatment: Effluent analysis, specifications and preventive measures water ofpollution, solid pollution, air pollution and sound pollution.

UNIT V

Validation: Regulatory basis, validation process for solid dosage forms, sterile products, and liquiddosage forms.

TEXT BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. willig.
3. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Pharmaceutical production management, C.V.S. Subrahmanyam, Vallabh Prakash.
6. Industrial Pharmacy: A Comprehensive Approach, D K Tripathi, Pharmamed Press.

REFERENCE BOOKS:

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, PeterHarriott.
2. Remington‟s Science and Practice of Pharmacy by A. Gennaro.
3. Bentley‟s Text book of Pharmaceutics by EA Rawlins.
4. CGMP, H.P.P. Sharma

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

HERBAL COSMETICS (Professional Elective - III)

Course Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

UNIT - I

Introduction: Herbal/ natural cosmetics, Classification & Economic aspects.Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involvedin the production of Herbal/natural cosmetics.

UNIT - II

a) Commonly used herbal cosmetics raw materials –water, preservatives, surfactants, oils /waxes, colors, and some functional herbs
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Molding,Packing.
c) General principles of quality control of herbal cosmetics

UNIT - III

Skin care Products: Physiology and chemistry of skin,Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, Face packs. Elaborative study of five formulations under each category with regard to their composition andclaims for various herbs used in them.

UNIT - IV

Hair care Products: Hair structure and its chemistry

Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Hair dyes, Creams, Oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT - V

Herbs in cosmetics:

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna, Turmeric, Liquorices, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

REFERENCE BOOKS:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P. Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL MANAGEMENT (Professional Elective - III)

Course Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

Course Outcomes:

- These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing, and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labsetc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through

various routessuch as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper &Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Pauland Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management 3rd Edition Harry A. Smith.
10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.
11. Personnel Management and Industrial Relations by P. C.Tripathi.
12. Pharmaceutical Industrial Management by G. Vidya Sagar, Pharmamed Press.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

NANO BASED DRUG DELIVERY SYSTEMS (Professional Elective - IV)

Course Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes – The students should be able to select the right kind of materials, able to developnano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT - I – Introduction to Nanotechnology

a. Definition of nanotechnology
b. History of nanotechnology
c. Unique properties and classification of nanomaterials
d. Role of size and size distribution of nanoparticles properties.
e. Marketed formulations based on nanotechnology and science behind them

UNIT - II – Synthesis of Nanomaterials Physical, chemical and biological MethodsMethods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferasomes, micelles, aquasomes and nanoemulsions

UNIT - III - Biomedical applications of Nanotechnology

a. Nanotechnology products used for in vitro diagnostics
b. Improvements to medical or molecular imaging using nanotechnology
c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT - IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT - V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, sizeseparation, stability, methods of analysis regarding integrity and release of drugs

TEXT AND REFERENCE BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Humanbody, Eiki Igarashi, CRC press. 2015

2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery,Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, TataMcGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U.Kulkarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao,Imperial College Press (2004)
6. Nano-Carrier Systems Theories, Methods & Applications, Amit K. Goyal, Goutam Rath,Pharmamed Press.
7. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry,Cambridge, UK (2005)
8. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V.Braun, Wiley - VCH Verlag, Weiheim (2003)
9. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley &Sons,2009
10. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
11. Introduction to Nano Science and Technologies, AnkaneyuluYerramilli, BS Publications. 2016

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations.

Course Outcomes: Helps the student to understand the importance of Nutraceuticals in variouscommon problems with the concept of free radicals

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soya bean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinalbenefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lactobacillum
f) Phytoestrogens: Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage.Free radicals involvement in other disorders. Free radicals theory of ageing.

b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C,

Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety.Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims,Dietary Supplements Claims

REFERENCE BOOKS:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T. Agusti and P. Faizal:BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A. Balch 2nd Edn., AveryPublishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - IV)

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

Course Outcomes: Upon completion of the course, the student shall be able to;

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

UNIT I

Regulatory Perspectives of Clinical Trials:

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

UNIT II

Clinical Trials: Types and Design:

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

UNIT III

Clinical Trial Documentation:

Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT IV

Basic aspects, terminologies and establishment of pharmacovigilance:

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety
data.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary,Pharmamed Press.
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS – II LAB (Laboratory- III)

List of Experiments:

1. Scale up calculations from R&D to pilot plant for the following unit operations
   a) Wet granulations using RMG/PLM
   b) Blending & Lubrications
   c) Film coating
2. Preparation of Injectables, Ampoules & Vials
3. Preparation of Ophthalmic products, Eye drops and Eye ointments
4. Preparation of Dry powder Inhalations
5. Formulation Development and Demonstration of function of DPI of marketed products
6. Formulation of Aerosol Demonstration of marketed products

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutics/Pharmaceutical Technology)

ADVANCED DRUG DELIVERY SYSTEMS LAB (Laboratory- IV)

List of Experiments:

1. Study on diffusion of drugs through various polymeric membranes (2 experiments)
2. Formulation and Evaluation of sustained release Oral Matrix Tablet (2 experiments)
3. Formulation and Evaluation of sustained release Oral Reservoir System (2 experiments)
4. Formulation and Evaluation of Microspheres / Microencapsules (2 experiments)
5. Study of in-vitro Dissolution of various SR products in market (2 experiments)
6. Formulation and Evaluation of Transdermal Films (2 experiments)
7. Formulation and Evaluation of Mucoadhesive System (2 experiments)
8. Preparation and Evaluation of Enteric Coated Pellets / Tablets (2 experiments)
9. Preparation and Evaluation of Liposomes, Niosomes and Nanoparticles

SRI INDU INSTITUTE OF PHARMACY
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)
BIOSTATISTICS (Professional Elective - V)

Course Objectives: The student shall know the introduction, scope of biostatistics and Researchwork, calculation and present of the data.

Course Outcomes: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data.

UNIT I
Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement andpresentation, formation of table and charts.

UNIT II
Measures of central tendency: computation of means, median and mode from grouped andungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and theircoefficients.

UNIT III
Measures of Correlation and Regression
Probability rules: Binomial, Poison and Normal distribution.

UNIT IV
Experimental designing, planning of an experiment, replication and randomization.
Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V
Hypothesis testing: Student „t" test, Chi square test,
Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCE BOOKS:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
6. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, KPRChowdary, Pharmamed Press.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)
SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

Course Objectives: This course is designed to impart knowledge and skills necessary to train thestudents to be on scale up, technology transfer process and industrial safety issues.

Course Outcomes: On completion of this course it is expected that students will be able to;

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

UNIT I

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

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

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

REFERENCE BOOKS:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor andFrancis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.

4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ.Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker,NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker,NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.\
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

SRI INDU INSTITUTE OF PHARMACY
M.Pharm II Year I Sem (Pharmaceutics/Pharmaceutical Technology)
PRODUCTION AREA DESIGN & PACKAGING DEVELOPMENT
(Professional Elective - V)

Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

Course Outcomes: At the end of the semester student will get an idea about Industrial area designand packaging of different formulations and its stability conditions.

UNIT I
Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II
Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III
Pharmaceutical packaging and Design: Introduction, Packaging system, Components of packaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV
Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V
Packaging of Solids, Semisolids, Parenterals, Ophthalmic and Aerosols: Introduction, Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCE BOOKS:

1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of IndustrialPharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton‟s Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New
6. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar, Pharmamed Press
7. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.
8. Remington: The Science and Practice of Pharmacy. 8. Michael E. Aulton, Kevin Tylor
9. Pharmaceutical Packaging Technology, UK jain, Pharmamed Press

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at veryfirst-time submission

UNIT-I:
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:
Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:
Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:
key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:
skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman‟sbook.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York DordrechtHeidelberg London, 2011

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)
DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction andhumanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice frommultiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance inspecific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countriesthey work in

UNIT-I:

Introduction:

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:

Repercussions of Disasters and Hazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:

Disaster Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People‟s Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies ""NewRoyal book Company.
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall ofIndia, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &DeepPublication Pvt. Ltd., New Delhi.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)
SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancingthe memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledgefrom ancient literature

Course Outcomes: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

UNIT-I:
Alphabets in Sanskrit,

UNIT-II:
Past/Present/Future Tense, Simple Sentences

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

UNIT-V:
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. "Abhyaspustakam" – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. "Teach Yourself Sanskrit" Prathama Deeksha-Vempati Kutumbshastri, Rashtriya SanskritSansthanam, New Delhi Publication
3. "India‟s Glorious Scientific Tradition" Suresh Soni, Ocean books (P) Ltd., New Delhi.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)
VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None
Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course outcomes: Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT-I:
Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:
Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration.Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:
Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:
Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:
Character and Competence –Holy books vs Blind faith. Self-management and Good health. Scienceof reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford UniversityPress, New Delhi

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals‟ constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

UNIT-I:
History of Making of the Indian Constitution: History Drafting Committee, (Composition &Working), **Philosophy of the Indian Constitution:** Preamble**,** Salient Features.

UNIT-II:
Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality**,** Right to Freedom**,** Right against Exploitation**,** Right to Freedom of Religion**,** Cultural and Educational Rights**,** Right to Constitutional Remedies, Directive Principles of State Policy**,** Fundamental Duties.

UNIT-III:
Organs of Governance: Parliament**,** Composition**,** Qualifications and Disqualifications**,** Powers and Functions**,** Executive**,** President**,** Governor**,** Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:
Local Administration: District‟s Administration head: Role and Importance, Municipalities:

Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:

Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy makingundertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms indeveloping countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions,and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum andguidance materials best support effective pedagogy?

UNIT-I:
Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT-II:
Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:
Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers‟ attitudes and beliefs and Pedagogic strategies.

UNIT-IV:
Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:
Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher

education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31(2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal ofCurriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher educationresearch project (MUSTER) country report 1. London: DFID.
4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, „learning to read" campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)
STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT-I:
Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:
Yam and Niyam.

UNIT-III:
Do`s and Don‟t‟s in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

UNIT-V:
i) Various yog poses and their benefits for mind & body
ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. „Yogic Asanas for Group Tarining-Part-I”: Janardan Swami Yogabhyasi Mandal, Nagpur 2.“Rajayoga or conquering the Internal Nature” by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutics/Pharmaceutical Technology)
PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality andachieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom) Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont‟s) Verses- 71,73,75,78 (do‟s)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

TEXT BOOKS/ REFERENCES:

1. “Srimad Bhagavad Gita” by Swami Swarupananda Advaita Ashram (Publication Department),Kolkata.
2. Bhartrihari‟s Three Satakam (Niti-sringar-vairagya) by P. Gopinath, Rashtriya SanskritSansthanam, New Delhi.