



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 PHARMACEUTICAL REGULATORY AFFAIRS 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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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 imbued 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 of M.PHARM (PHARMACEUTICAL REGULATORY AFFAIRS)	
PO1	Knowledge gained in generic development strategies.
PO2	Analyze the post approval regulatory requirements for actives and drug products and submission of global documents in common technical document/eCTD formats
PO3	Apply the principles of regulatory affairs in drug development process, filing and approval, non-clinical and clinical drug development in global scenario.

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 (PHARMACEUTICAL REGULATORY AFFAIRS)	
PSO1	Can apply the principals involved in determination with addition to theoretical aspects, basic practical knowledge in modern analytical techniques. How to prepare for the readiness and implementation of fundamental aspects on various regulatory practices.
PSO2	Develop insight towards drug regulatory affair aspects in pharmaceutical industries.
PSO3	Interpret the values of total quality management in various quality control and regulatory facet.
PSO4	Should be capable of understanding complete particulars about validation, types, methodology and application.

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 (PHARMACEUTICAL REGULATORY AFFAIRS)	
PEO1	To prepare for the readiness and implementation of fundamental aspects on various regulatory practices.
PEO2	To increase the insight towards drug regulatory affair aspects in pharmaceutical industries.
PEO3	To expand the values of total quality management in various quality control and regulatory facet.
PEO4	To focus and retain purpose of understanding complete particulars about validation, types, methodology and application.

**COURSE OUTCOMES OF M.PHARM
(PHARMACEUTICAL REGULATORY AFFAIRS)
R25 REGULATIONS**

M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS) I YEAR I SEMESTER	
COURSE CODE: PC I	GOOD REGULATORY PRACTICE
CO1	The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
CO2	Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
CO3	Implement Good Regulatory Practices in the Healthcare and related Industries.
CO4	Prepare for the readiness and conduct of audits and inspections
COURSE CODE: PC II	DRUG REGULATORY AFFAIRS
CO1	To know the different competent regulatory authorities globally.
CO2	To be aware of technical aspects pertaining to the marketing authorization application (MAA)
CO3	The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals
CO4	Well versed with quality, safety and legislation for cosmetic products and herbal products.
COURSE CODE: PE I	INTELLECTUAL PROPERTY RIGHTS
CO1	Information regarding patent laws, IPR and drug regulation in India
CO2	To know patent filing procedures under PCT
CO3	Understand various types of IPR, Patentable subject, history of Indian patent protection
CO4	Gain knowledge on salient features and impact of international treaties or conventions like WTO, WIPO, TRIPS and PCT
PE I	TOTAL QUALITY MANAGEMENT
CO1	Establish regular guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc.
CO2	Acquire vast knowledge regarding the quality control aspects of different regulatory bodies.
CO3	Regulatory requirements of single dose and repeat dose toxicity studies
CO4	To escalate the knowledge of students in various quality control and regulatory aspects.

PE I	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.
COURSE CODE: PE II	STABILITY OF DRUGS AND DOSAGE FORMS
CO1	To epitomise 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.
PE II	PHARMACEUTICAL FORMULATION TECHNOLOGY
CO1	Shall explain the pre formulation parameters
CO2	Apply ICH guidelines and evaluate drug, drug excipients compatibility
CO3	Explain about formulation and development, use of excipients in tablets, powders, capsules, microencapsules and coating techniques
CO4	To learn and apply the statistical design in different formulations
PE II	DOCUMENTATION AND REGULATORY WRITING
CO1	To know the various documents pertaining to drugs in pharmaceutical industry
CO2	Understand the basics of regulatory compilation
CO3	Create and assemble the regulation submission as per the requirements of agencies
CO4	Follow up the submissions and post approval document requirements
COURSE CODE: MC	RESEARCH METHODOLOGY AND INTELLECTUAL PROPERTY RIGHTS
CO1	To scrutinize the research related information.
CO2	Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
CO3	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.
CO4	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.
CO5	To accentuate the need of information about intellectual property rights among students.
	Inspect out research problems and formulations.
CO6	Investigations of solution, research problems, data collection, analysis and interpretation of data.
COURSE CODE: Lab I	REGULATORY PRACTICE AND DOCUMENTATION LAB
CO1	Case studies of each of good pharmaceutical practices
CO2	Documentation of in process and finished products, quality control tests for solid, liquid, semisolid and sterile preparations
CO3	Preparation of SOP's, analytical reports included in stability and validation
CO4	Protocol preparation for documentation of various types of records like BMR, MFR, DR
COURSE CODE: Lab II	DRUG REGULATION AND REGISTRATION LAB
CO1	Includes case studies on change management, deviations and correctives and preventive actions
CO2	Deals with import of drugs for research and developmental activities
CO3	Preparation of regulatory submission using eCTD software
CO4	Documentation of raw materials, analysis as per official monographs
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	Sympathise 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 (PHARMACEUTICAL REGULATORY AFFAIRS) I YEAR II SEMESTER	
COURSE CODE: PC III	REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS
CO1	Know the regulatory requirements for biologics and vaccines.
CO2	Perceive the regulation for newly developed biologics and biosimilars.
CO3	Interpret the regulatory requirements of blood and /or its components including blood products and label requirements.
CO4	Well versed with preclinical and clinical development considerations of biologics
COURSE CODE: PC IV	REGULATORY ASPECTS OF MEDICAL DEVICES
CO1	Harmonization initiatives for approval and marketing of medical devices and IVDS.
CO2	Clinical evaluation and investigation of medical devices and IVDS.
CO3	Basics of medical devices and IVDs, process of development, ethical and quality considerations
CO4	Regulatory approval process for medical devices and IVD's in India, US, Canada
COURSE CODE: PE III	REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS
CO1	Know the regulatory requirements for nutraceuticals.
CO2	Understanding the regulation for registration and labelling of nutraceuticals and Europe
CO3	Understanding the global aspects of WHO guidelines on nutrition.
CO4	Involves the study of USFDA, Food safety modernization act
P E – III	PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
CO1	To know the various aspects of quality control and quality assurance

	aspects of pharmaceutical industries.
CO2	To know the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.
CO3	To develop and formulate high quality pharmaceutical products.
PE III	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.
COURSE CODE: 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 dietary 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	Detect new adverse drug reactions and their assessment
CO4	Perform the adverse drug reaction reporting system and communication in pharmacovigilance.
PE 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.
COURSE CODE: LAB III	REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS LAB
CO1	Comparison of clinical trial application requirements of US, EU, INDIA or Biologics
CO2	Understanding preparation of documents required for the approval of herbal products of diverse dosage forms as per regulation requirements.
CO3	To understand preparation of Biologics License Application.

CO4	Preparation of documents required for the approval of vaccine products
COURSE CODE: LAB IV	REGULATORY ASPECTS OF MEDICAL DEVICES LAB
CO1	Understand Audit checklist for Medical Device facility.
CO2	Understanding GMP of manufacturing of medical devices of diverse nature.
CO3	Preparation and submission of medical devices for approval.
CO4	Preparation and submission of nutraceuticals, devices for approval
COURSE CODE	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 acquainted 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 (PHARMACEUTICAL REGULATORY AFFAIRS) 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 subtopics
CO4	Analyse critically a segment of published body of knowledge through summary
M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS) 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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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 – 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 with its specialization.
- “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)
STUDENTS WITH 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

R-25 ACADEMIC REGULATIONS OF M.PHARM COURSE (2025-26 ACY)

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 (EtE)	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 carried out 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 **internal 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 **internal 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 |

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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

$$\text{SGPA} = \left\{ \sum_{i=1}^N C_i G_i \right\} / \left\{ \sum_{i=1}^N C_i \right\} \dots \text{For each Semester,}$$

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.

$$\text{CGPA} = \left\{ \sum_{j=1}^M C_j G_j \right\} / \left\{ \sum_{j=1}^M C_j \right\}$$

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	$4 \times 9 = 36$
Course 2	4	O	10	$4 \times 10 = 40$
Course 3	4	C	7	$4 \times 7 = 28$
Course 4	3	B	8	$3 \times 8 = 24$
Course 5	3	A	10	$3 \times 10 = 30$
Course 6	3	C	7	$3 \times 7 = 21$
	Total Credits = 21			Total Credit Points = 179

$$\text{SGPA} = 179/21 = 8.52$$

Illustration of calculation of CGPA

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

$$\text{CGPA upto II Year II Semester} = 350/42 = 8.33$$

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 of material 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. In case 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 is appearing.	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.

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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 by the 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 question paper during the examination or answer book or additional sheet, during or after the examination.	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.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.

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	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 in the 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 other subjects 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 part thereof 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.

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8.	Possess any lethal weapon or firearm in 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. 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 debarred and 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

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

R-25 ACADEMIC REGULATIONS OF M.PHARM COURSE (2025-26 ACY)

SRI INDU INSTITUTE OF PHARMACY
M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS)
R22 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	Good Regulatory Practices	3	1	0	4
Professional Core-II	Drug Regulatory Affairs	3	1	0	4
Professional Elective-I	1. Intellectual Property Rights 2. Total Quality management 3. Pharmaceutical Validation	3	1	0	4
Professional Elective-II	1. Stability of Drugs and Dosage Forms 2. Pharmaceutical Formulation Technology 3. Documentation and Regulatory Writing	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Regulatory Practice and Documentation Lab	0	0	6	3
Laboratory- II	Drug Regulation and Registration 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	Regulatory aspects of herbals and biologicals	3	1	0	4
Professional Core-IV	Regulatory aspects of medical devices	3	1	0	4
Professional Elective-III	1. Regulatory aspects of Foods and Nutraceuticals 2. Pharmaceutical Quality Control and Quality Assurance 3. Nano Based Drug Delivery Systems	3	1	0	4
Professional Elective-IV	1. Clinical Research and Pharmacovigilance 2. Nutraceuticals 3. Advanced Drug Delivery Systems	3	1	0	4
Laboratory- III	Regulatory aspects of herbals and biologicals lab	0	0	6	3
Laboratory- IV	Regulatory aspects of medical devices 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

R-25 ACADEMIC REGULATIONS OF M.PHARM COURSE (2025-26 ACY)

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 R22 Academic Regulations.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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
GOOD REGULATORY PRACTICE (Professional Core - I)

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

Course Outcome: At completion of this course it is expected that students will be able to understand

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
- Implement Good Regulatory Practices in the Healthcare and related Industries.
- Prepare for the readiness and conduct of audits and inspections.

UNIT I

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

UNIT II

Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards

UNIT III

Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

UNIT IV

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self- Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

UNIT V

Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types

R-25 ACADEMIC REGULATIONS OF M.PHARM COURSE (2025-26 ACY)

of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

TEXT AND REFERENCE BOOKS:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
DRUG REGULATORY AFFAIRS (Professional Core - II)

Course Objectives: The topics which are present in the Drug regulatory affairs are very much useful which 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 authorization application(MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place 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 Cosmetics 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 Licenses – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan license 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 Management, Effluent etc.)
5. Quality Assurance and Quality Control – Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a 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 drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, 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 Directorate DMF
- c. Europe
 - 1) European Medicines Agency (EMA/ National Authorities) EDMF
 - 2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
 - 3) MHRA – Medicines and Health Care Products Regulatory Agency
- b. Product Filing
- c. Responding Regulatory Deficiencies
- d. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific 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. Pharmaceutical Regulatory Affairs - Selected Topics, CVS
Subramanyam and JThimmasetty, Vallabh Prakashan Delhi – 2013

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
INTELLECTUAL PROPERTY RIGHTS (Professional Elective - I)

Course Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Course Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

UNIT - I

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non- Obviousness, Utility, enablement and Best mode),

UNIT - II

- a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
- b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
- c. Opposition - pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
- d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT - III

- a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
- b. Background, Salient Features and Impact of International Treaties / Conventions like
 1. Paris Convention, Berne convention
 2. World Trade Organization (WTO)
 3. World Intellectual Property Organization (WIPO)
 4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
 5. Patent Co-operation Treaty (PCT), Madrid Protocol

UNIT - IV

- a. PCT Application procedure and review procedure
- b. National phase application procedure for US & EU
- c. Patent prosecution procedure in US and EU
- d. WIPO and its role in IPR
- e. Hatch- Waxman provision for IPR

UNIT - V

- a. Patent in validation process in India, US and Europe
- b. IPR related to copyright, trade mark, trade secret and geographical indication.
- c. Patent application writing
- d. Claim construction and claims.

RECOMMENDED BOOKS:

1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
2. Draft manual of Patent Practice and Procedure -2008, The Patent Office, India
3. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press
4. Fundamentals of Patents and Patenting, Vivekananda Mandal, Pharmamed Press
5. Manual of Patent Office Practice and Procedure -2010
6. Original Laws Published by Govt. of India
7. Protection of Industrial Property rights by P. Das and Gokul Das
8. Law and Drugs, Law Publications by S.N. Katju
9. Laws of drugs in India, Hussain
10. New drug approval process, 5th edition, byGuarino
11. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
12. Drugs and Cosmetics act by Vijay Malik
13. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
14. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
15. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
16. Pharmaceutical Regulatory affairs –selected topics. CVS subhramanyam and J Thimmasettee. Delhi, Vallabh Prakashan, 2012

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
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 teratogenicity. 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 and marayya
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 (Pharmaceutical Regulatory Affairs)
PHARMACEUTICAL VALIDATION (Professional Elective - I)

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 ICH guidelines and USP.

- Validate the manufacturing facilities

REFERENCE BOOKS:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci.

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- 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 Intiaz Haider
 7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud,Interpharm Press
 8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) andJamesAgalloco (Ed.), Marcel Dekker, 2nd Ed.
 9. Analytical Method validation and Instrument Performance Verification by Churg Chan,HeimanLam

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
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 of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

Course Outcomes: The students should describe the evaluation of stability of solutions, solids and formulations 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 of Pharmaceutical 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 of pharmaceutical 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 drugs by 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. Sawnsen – 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.

SRI INDU INSTITUTE OF PHARMACY

M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

PHARMACEUTICAL FORMULATION TECHNOLOGY (Professional Elective - II)

Course Objective: Students will know the pre-formulation 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 pre-formulation 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

Pre-formulation: Goals of pre-formulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.

Flow of Powders: Physical properties and importance. Angle of repose, Carr's index, compressibility, bulk density, tapped density.

UNIT II

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

UNIT III

Tablets: Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.

Tablet coating: Types of coating, steps involved in coating process- pan coating and fluid bedcoating and problems associated with coating.

Hard Gelatin Capsules: General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

UNIT IV

Dissolution: Principles of dissolution, factors influencing dissolution, official methods and apparatus. Dissolution of immediate release, controlled release and delayed release products.

UNIT V

Stability testing: Chemical degradation and preventive measures. Various stability testing conditions and use of stabilizers in packing

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 and Schwartz.
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 and Lachman.
5. Pharmaceutical Dosage Form: Basics and Beyond, Kamlesh J. Wadher, Pharmamed Press
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
7. Pharmaceutical statistics by Bolton Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

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 Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
DOCUMENTATION AND REGULATORY WRITING (Professional Elective - II)

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

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

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

UNIT I

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

UNIT II

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). None CTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

UNIT III

Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third-party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

UNIT IV

Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

UNIT - V

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Affected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

TEXT AND REFERENCE BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Academic Writing, Ajay Semalty, Pharmamed Press
5. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
7. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
8. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
9. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
10. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
11. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
12. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
13. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
14. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
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 emphasize 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 of research 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 New Technological Age", 2016.
7. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

REGULATORY PRACTICE AND DOCUMENTATION LAB (Laboratory - I)

List of Experiments:

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR) Labeling comparison between brand & generics.
5. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
6. Case studies on response with scientific rationale to USFDA Warning Letter
7. Preparation of submission checklist of IMPD for EU submission.
8. Comparison study of marketing authorization procedures in EU.

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DRUG REGULATION & REGISTRATION LAB (Laboratory - II)

List of Experiments:

1. Case studies on Change Management/ Change control. Deviations and Corrective & Preventive Actions (CAPA)
2. Import of drugs for research and developmental activities
3. GMP Audit Requirements as per CDSCO
4. Preparation of checklist for registration of IND as per ICH CTD format.
5. Preparation of checklist for registration of NDA as per ICH CTD format.
6. Preparation of checklist for registration of ANDA as per ICH CTD format.
7. Comparative study of DMF system in US, EU and Japan
8. Preparation of regulatory submission using eCTD software
9. Documentation of raw materials analysis as per official monographs
10. Preparation of audit checklist for various agencies
11. Preparation of submission to FDA using eCTD software
12. Preparation of submission to EMA using eCTD software
13. Preparation of submission to MHRA using eCTD software

SRI INDU INSTITUTE OF PHARMACY

M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS (Professional Core - III)

Course Objective: This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Course Outcome: Upon the completion of the course the student shall be able to :

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

UNIT - I

India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

UNIT - II

USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

UNIT - III

European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ bio similarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.

UNIT - IV

Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorization, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network)

UNIT - V

Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.

TEXT AND REFERENCE BOOKS:

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

SRI INDU INSTITUTE OF PHARMACY

M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORY ASPECTS OF MEDICAL DEVICES (Professional Core - IV)

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

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

- Basics of medical devices and IVDs, process of development, ethical and quality considerations.
- Harmonization initiatives for approval and marketing of medical devices and IVDs.
- Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
- Clinical evaluation and investigation of medical devices and IVDs.

UNIT - I

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

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

UNIT - II

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

UNIT - III

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

UNIT - IV

European Union: Introduction, Classification, Regulatory approval process for Medical

Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

UNIT - V

ASIAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.

REFERENCE BOOKS:

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

SRI INDU INSTITUTE OF PHARMACY

M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (Professional Elective – III)

Course Objective: This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

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

- a. Know the regulatory Requirements for Nutraceuticals
- b. Understand the regulation for registration and labeling of Nutraceuticals and foodsupplements in India, USA and Europe.

UNIT - I

Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

UNIT - II

Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

UNIT - III

India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

UNIT - IV

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S

UNIT - V

European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

TEXT AND REFERENCE BOOKS:

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M.Hasler(Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around theWorld byDebasis Bagchi (Academic Press, Elsevier)
3. <http://www.who.int/publications/guidelines/nutrition/en/>
4. [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)5363_24_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)5363_24_EN.pdf)
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
(Professional Elective – III)

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

Course Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

UNIT I

- a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
- b. **Impurities in new drug products:** Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
- c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

UNIT II

- a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
- b. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

UNIT III

- a. Organization and personnel, responsibilities, training hygiene
- b. **Premises:** Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
- c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilizes in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT IV

- a. Packaging and labeling controls, line clearance and other packaging materials.
- b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufacture and controls on dosage forms

- a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,

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b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra
4. Pharmaceutical Process Validation by Berry and Nash
5. How to Practice GMP's – P.P. Sharma

REFERENCES BOOKS:

1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. SOP Guidelines by D.H. Shah
5. Quality Assurance Guide by OPPI
6. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D.Nally (Dec 26, 2006)
7. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.

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M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

NANO BASED DRUG DELIVERY SYSTEMS (Professional Elective – III)

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 develop nano 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 Methods Methods for synthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes, Niosomes, transferosomes, 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, size separation, stability, methods of analysis regarding integrity and release of drugs

REFERENCE BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in

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- the Humanbody, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatfroms 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, Ankaneyulu Yerramilli, BS Publications. 2016
 12. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

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 in pharmacovigilance

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 (Pharmaceutical Regulatory Affairs)

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 various common 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, Soyabean, Ginseng, Garlic, Broccoli, Ginkgo, Flaxseeds

UNIT II

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

- a) Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, lutein
- b) Sulfides: Diallylsulfides, Allyl trisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
- f) Phytoestrogens: Isoflavones, daidzein, Genistein, 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

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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., Avery Publishing 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

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M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

ADVANCED DRUG DELIVERY SYSTEMS (Professional Elective - IV)

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

Course Outcomes: Students will select the drugs for CDDS design of the formulation fabrication of systems 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, oral immunization, controlled release microparticles for vaccine development

UNIT III

Biochemical and molecular biology approaches to controlled drug delivery of

- 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 neoplasms

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. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Advances in Drug Delivery, Vol 1, 2, 3,4 by Y. Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORY ASPECTS OF HERBALS AND BIOLOGICAL LAB (Laboratory - III)

List of Experiments:

1. Preparation of Biologics License Applications (BLA)
2. Preparation of documents required for Vaccine Product Approval
3. Comparison of clinical trial application requirements of US, EU and India of Biologics
4. Preparation of Checklist for Registration of Blood and Blood Products
5. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
6. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
7. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
8. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
9. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
10. Preparation of document required for the approval of herbal products of diverse dosage forms (3 products) as per regulations requirements

Practical work shall be carried out based on the theory syllabus.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORY ASPECTS OF MEDICAL DEVICES LAB (Laboratory - IV)

List of Experiments:

1. Checklists for 510k and PMA for USmarket
2. Checklist for CE marking for various classes of devices for EU
3. STED Application for Class III Devices
4. Audit Checklist for Medical Device Facility
5. Clinical Investigation Plan for Medical Devices
6. Preparation and submission of medical devices for approval (3 products)
7. GMP of manufacturing of medical devices of diverse nature (3 products)
8. preparation and submission of nutraceuticals devices for approval (3 products)

Practical work shall be carried out based on the theory syllabus

SRI INDU INSTITUTE OF PHARMACY
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

BIostatISTICS (Professional Elective - V)

Course Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcome: 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 and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

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 (Pharmaceutical Regulatory Affairs)

SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

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

Course Outcome: 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, parenteral 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, parenteral, 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 vendor 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 sealing machine. 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 and Francis.

R-25 ACADEMIC REGULATIONS OF M.PHARM COURSE (2025-26 ACY)

3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese PublBombay.
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, Parenteral 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,
10. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

SRI INDU INSTITUTE OF PHARMACY
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

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 Outcome: At the end of the semester student will get an idea about Industrial area design and 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 Industrial Pharmacy.
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 (Pharmaceutical Regulatory Affairs)
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 (Pharmaceutical Regulatory Affairs)
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 and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific 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 countries they 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 (Pharmaceutical Regulatory Affairs)

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 enhancing the memory power
- ☐ The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from 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. “Abhyastakam” – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. “Teach Yourself Sanskrit” Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. “India’s Glorious Scientific Tradition” Suresh Soni, Ocean books (P) Ltd., New Delhi.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Regulatory Affairs)
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. Science of 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 University Press, New Delhi

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Regulatory Affairs)
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 (Pharmaceutical Regulatory Affairs)
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 making undertaken 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 in developing 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 and guidance 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 in-depth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the school 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 of Curriculum Studies*, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research 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 (Pharmaceutical Regulatory Affairs)

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 Training-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 (Pharmaceutical Regulatory Affairs)
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 and achieve 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 (don't'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: Chapter 2-Verses 56, 62, 68
- ☐ Chapter 12 -Verses 13, 14, 15, 16,17, 18
- ☐ Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- ☐ Chapter 2-Verses 17, Chapter 3-Verses 36,37,42,
- ☐ Chapter 4-Verses 18, 38,39
- ☐ Chapter 18 – 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 Sanskrit Sansthanam, New Delhi.