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 QUALITY ASSURANCE SPECIALIZATION

R25-ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

FOR

I & II YEAR M.PHARM COURSE

(Batches Admitted from 2025-26 Academic Year)

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

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MASTER OF PHARMACY (M.PHARMACY) COURSE
PHARMACEUTICAL QUALITY ASSURANCE SPECIALIZATION

CHOICE BASED CREDIT SYSTEM (CBCS)

R-25 REGULATIONS AS PER JNTUH, Hyderabad.

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

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

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

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VISION

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

MISSION

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

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PROGRAM OUTCOMES (PO's)

PO's of M.PHARM (PHARMACEUTICAL QUALITY ASSURANCE)	
PO1	Importance of quality ISO management systems
PO2	Knowledge on stability testing of drug and drug substances
PO3	Perception on analysis of issues in quality and quality evaluation of pharmaceuticals.

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 QUALITY ASSURANCE)	
PSO1	Be able to divulge the cognition in Modern Analytical techniques in various aspects of determination and validation of drugs and formulations.
PSO2	Will understand the importance of documentation, cGMP, GLP and certification applicable to pharmaceutical industries.
PSO3	Will expand the knowledge regarding the regulatory aspects in the pharmaceutical industries.
PSO4	Capable in managing various departments like QA, QC, RA, Production etc.

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 QUALITY ASSURANCE)	
PEO1	To divulge the cognition in Modern Analytical techniques in various aspects of determination and validation of drugs and formulations.
PEO2	To appreciate and understand the importance of documentation, cGMP, GLP and certification applicable to pharmaceutical industries.
PEO3	To inculcate the knowledge regarding the regulatory aspects in the pharmaceutical industries.
PEO4	To expertise the apprentice in managing various departments like QA, QC , RA, Production etc.

COURSE OUTCOMES OF M.PHARM (PHARMACEUTICAL QUALITY ASSURANCE) R25 REGULATIONS

M.PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE) I YEAR I SEMESTER	
COURSE CODE: PC I	**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**
CO1	Gain insight towards modern pharmaceutical analysis.
CO2	Apply knowledge in developing new methods for determination and validate procedures
CO3	Imply theories in the analysis of various bulk drugs and their formulations
CO4	Elaboration of knowledge in various instrumentation techniques
COURSE CODE: PC II	**PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE**
CO1	Understand the CGMP aspects in pharmaceutical industry
CO2	To appreciate the importance of documentation in pharmaceutical industry
CO3	To comprehend with the scope of quality certifications
CO4	Proficiency and responsibilities of QA and QC.
COURSE CODE: PE I	**QUALITY MANAGEMENT SYSTEMS**
CO1	To impart fundamental knowledge and concepts about various quality management principles
CO2	To encompass six system inspection model and concept of IPQC
CO3	ISO management systems
CO4	Analysis of issues in quality
CO5	Quality evaluation of pharmaceuticals
CO6	Look through ICH guidelines for stability testing of drug substances and drug products, risk management tools and HACCP
CO7	To study the tools for quality improvement and statistical approaches for quality.
PE I	**PHARMACEUTICALS AND FOOD ANALYSIS**
CO1	Application of various analytical techniques in determination of various food constituents and finished food products.
CO2	Able to apply analytical techniques in analysing food additives
CO3	Possess awareness on food regulations and legislations.
CO4	To analyse biomolecules in various food products
PE I	**DRUG REGULATORY AFFAIRS**
CO1	Mind full of technical aspects pertaining to the marketing authorization application.
CO2	Detail study of regulatory aspects that effect drug product design and

	pharmaceutical and bulk drug manufacture
CO3	Appraised of different competent regulatory authorities globally.
CO4	Well versed with quality, safety and legislation for cosmetic products and herbal products.
COURSE CODE: PE II	**PRODUCT DEVELPOMENT AND TECHNOLOGY TRANSFER**
CO1	To elucidate necessary information to transfer technology of existing products between various manufacturing places
CO2	To be familiar with development and informational content for IND, NDA, ANDA, and SNDA.
CO3	To know the concept, significance, design and layout of pilot plant scale up studies.
CO4	To be aware of pharmaceutical dosage form and their packaging requirements
PE II	**PHARMACEUTICAL ANALYSIS**
CO1	Perception on qualitative determination of various organic compounds
CO2	Knowledge on principles and procedures involved in determination of organic functional groups.
CO3	Accomplished with spectral analysis, dissolution parameters and microbial assays.
CO4	Performing different tests on excipients such as bulk density, particle size distribution etc.
PE II	**PHARMACEUTICAL MANAGEMENT**
CO1	Help students to know how to manage a pharma industry and its various departments.
CO2	Aids the students to develop leadership qualities, communication and interpersonal skills, decision making and motivation.
CO3	Management helps to understand the concept of managerial control, its levels and role , importance in pharma industry.
CO4	Allows the students to develop various managerial functional and professional skills required for a dynamic professional
COURSE CODE: MC	**RESEARCH METHODOLOGY AND IPR**
CO1	To analyse the research related information.
CO2	To emphasise the need of information about intellectual property rights among students.
CO3	Figure out research problems and formulations.
CO4	Investigation of solutions, research problems, data collection, analysis and interpretation of data.
CO5	Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
CO6	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
CO7	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.
COURSE CODE: LAB I	**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB**
CO1	Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC techniques
CO2	To identify different functional groups and incompatibilities by FTIR
CO3	To perform simultaneous estimation of multicomponent containing formulations by UV spectrophotometry
CO4	To calibrate glass ware, pH meter, UV visible spectrophotometer, FTIR Spectrophotometry, HPLC
COURSE CODE: LAB II	**QUALITY CONTROL AND QUALITY ASSURANCE LAB**
CO1	Conduct solubility studies of weekly acidic and weekly basic drugs.
CO2	Interpret spectra's by IR, NMR and MASS .
CO3	Perform QC test for tablets, capsules, oral liquids and parenterals.
CO4	Demonstration of functional groups of the given samples by IR spectrophotometer**.**
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	Flourishwith 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 QUALITY ASSURANCE) I YEAR II SEMESTER	
COURSE CODE: PC III	**PHARMACEUTICAL VALIDATION**
CO1	Able to explain the concept of validation.
CO2	Carry out validation of manufacturing process.
CO3	Apply the knowledge of validation to instruments and equipment's.
CO4	Acquainted with cleaning validation and analytical method validation.
COURSE CODE: PC IV	**PHARMACEUTICAL MANUFACTURING TECHNOLOGY**
CO1	Impart knowledge and skills necessary to train the students with industrial activities during pharmaceutical manufacturing.
CO2	Will be familiar with the principles and practices of aseptic process technology.
CO3	Have a better understanding of principles and instrumentation of quality by design and process analytical technology in pharmaceutical manufacturing.
CO4	Able to understand the common practice in pharmaceutical industry developments, plant layout and production planning.
COURSE CODE: PE III	**HAZARDS AND SAFETY MANAGEMENT**
CO1	Should disclose environmental problems among learners.
CO2	Develop an attitude of concern for the industrial environment.
CO3	Ensure safety standards in pharmaceutical industry.
CO4	Empower ideas to clear mechanism and management in different kinds of hazard management system.
PE III	**SPECTRAL ANALYSIS**
CO1	Acquire the knowledge about various aspects of X-Ray diffraction methods.
CO2	Knowledge on various spectral aspects of IR and ATR.
CO3	Familiar with principles , instrumentation and applications of potentiometer.
CO4	Principles, interference and applications of flame emission spectroscopy.
PE III	**SCREENING METHODS IN PHARMACOLOGY**

CO1	Know various techniques for screening of drugs for different pharmacological activities.
CO2	Aware of guidelines and regulations for screening new drug molecules on animals.
CO3	Notice the guidelines for handling animals and animal ethics for screening of drugs.
CO4	Care handling and breeding techniques of laboratory animals.
COURSE CODE: PE IV	**AUDITS AND REGULATORY COMPLIANCE.**
CO1	Capable of understanding the importance of auditing.
CO2	Have sound knowledge on methodology of auditing.
CO3	Understand the process of auditing in pharmaceutical industries.
CO4	Be competent with the planning process, responsibilities and administration**.**
PE IV	**HERBAL DRUG TECHNOLOGY**
CO1	Acquire knowledge on the preparation and standardization of herbal preparations.
CO2	Expose to various research institutions of natural products.
CO3	Acquinted with method of extraction, preparation and purification of herbal extracts.
CO4	Aware of colorants and sweeteners of natural origin.
PE IV	**STABILITY OF DRUGS AND DOSAGE FORMS**
CO1	Describe the evaluation of stability of solutions, solids, and formulations against adverse conditions.
CO2	Able to suggest the measures to retain stability and storage conditions for reataining the efficacy of drug products.
CO3	To know various drug decomposition mechanisms and stabilization of pharmaceuticals.
CO4	To understand the method of analysis in determination of quality of cosmetics in the finished forms and legislation of cosmetic products.
COURSE CODE: LAB III	**PHARMACEUTICAL VALIDATION LAB III**
CO1	Calibration of electronic balance and PH metre.
CO2	Qualification of pharmaceutical testing equipment like dissolution, disintegration and friability apparatus.
CO3	Preparation of batch manufacturing and master formula records.
CO4	Validation of analytical methods in processing area.
COURSE CODE: LAB IV	**PHARMACEUTICAL MANUFACTURING TECHNOLOGY LAB**
CO1	To study the design of sterile and non sterile plant layouts.
CO2	To prepare checklist for water for injection and sterile production area.
CO3	To perform stability study of tablet dosage forms.
CO4	To formulate and evaluate enteric coated pellets.

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 QUALITY ASSURANCE) 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 QUALITY ASSURANCE) II YEAR II SEMESTER	
COURSE CODE: DISSERTATION	**DISSERTATION WORK REVIEW III**
CO1	Apply knowledge and understanding in relation to the agreed area of study

CO2	Communicate in written form by integrating, analysing and applying key texts and practices
CO3	Demonstrate advanced critical research skills in relation to career development
CO4	Integrate the theory and practice in evaluation
COURSE CODE: DISSERTATION	**DISSERTATION VIVA VOCE**
CO1	Demonstrate knowledge in the program domain
CO2	Presenting views cogently and precisely
CO3	Exhibit professional etiquette suitable for career progression
CO4	Exhibit sustained curiosity and have an attitude of attention in detailing of the project

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

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

PRELIMINARY DEFINITIONS AND NOMENCLATURE

- "Autonomous Institute / College" means an institute / college designated as autonomous institute / college by the UGC, New Delhi and JNTUH Statutes, 2023.
- "Academic Autonomy" means freedom to a College in all aspects of conducting its academic programs granted by the University for promoting excellence.
- "Commission" means University Grants Commission (UGC), New Delhi.
- "University" means the Jawaharlal Nehru Technological University, Hyderabad.
- "Institute/College" means SRI INDU INSTITUTE OF PHARMACY, Hyderabad unless indicated otherwise by the context.
- "Programme" means: Master of Pharmacy (M.Pharmacy) degree programme 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) STUDENTSWITH EFFECT FROM THE ACADEMIC YEAR 2025-26 (R-25) AT PAR WITH

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
(Established by Act No. 30 of 2008)
Kukatpally, Hyderabad, Telangana (India).

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

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

2.0 Eligibility for Admissions

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

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

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

3.0 M. Pharm. Programme Structure

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

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

3.3 Semester Scheme

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

3.3.1 Credit Courses

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

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

3.3.2 Course Classification

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

S.No.	Broad Course Classification	Course Group/ Category	Course Description
1	Core Courses (CoC)	PC - Professional Core	Includes courses related to the Specialization in Pharmacy
		Dissertation	Major Project
		Mini Project/ Seminar	Mini Project/Seminar based on core contents related to the Specialization in Pharmacy
2	Elective Courses (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 carriedout based on the average of the marks secured in the two Mid-Term Examinations conducted and assignments. The first Mid-Term examinations shall be conducted in middle of the Semester and second Mid-Term examinations during the last week of instruction. Each Mid-Term Examination shall be conducted for a total duration of 120 minutes with Part-A as compulsory section consisting of 5 questions carrying 2 marks each (10 marks), and Part-B with 3 questions to be answered out of 5 questions, each question carrying 5 marks (15 marks). Five marks in each course are allotted for the assignments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8.0 Re-Admission/Re-Registration

8.1 Re-Admission for Discontinued Student

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

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

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

9.0 Examinations and Assessment - The Grading System

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

9.2 As a measure of the student‟s performance, a 10-point Absolute Grading System using

the following percentage of marks and the corresponding letter grades are followed:

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

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

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

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

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

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

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

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

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

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

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

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

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

Illustration of calculation of SGPA

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

SGPA = 179/21 = 8.52

Illustration of calculation of CGPA

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

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

10.0 Award of Degree and Class

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

10.2 Award of Class

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

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

11.0 Withholding of Results

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

12.0 General

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

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

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

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

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

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

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

S.No	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1.(a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject to the examination (theory or practical) in which he is appearing but has notmade use of (material shall include any markson 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 anycandidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. Incase of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of materialrelevant to the subject to the examination (theory or practical) in which the candidate isappearing.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.

3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate, who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course bythe candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered Against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the 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 debarredfor 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.

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

8.	Possess any lethal weapon or firearm in theexamination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also 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 periodof not less than one year

SRI INDU INSTITUTE OF PHARMACY

M.PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)

R25 COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2025-26 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques	3	1	0	4
Professional Core-II	Pharmaceutical Quality Control & Quality Assurance	3	1	0	4
Professional Elective-I	1. Quality Management Systems 2. Drug Regulatory Affairs 3. Pharmaceutical Food Analysis	3	1	0	4
Professional Elective-II	1. Product Development & Technology Transfer 2. Advanced Pharmaceutical Analysis 3. Pharmaceutical Management	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory- I	Modern Pharmaceutical Analytical Techniques Lab	0	0	6	3
Laboratory- II	Pharmaceutical Quality Control & Quality Assurance 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	Pharmaceutical Validation	3	1	0	4
Professional Core-IV	Pharmaceutical Manufacturing Technology	3	1	0	4
Professional Elective-III	1. Hazards and Safety Management 2. Spectral Analysis 3. Screening Methods in Pharmacology	3	1	0	4
Professional Elective-IV	1. Audits and Regulatory Compliance 2. Herbal Drug Technology 3. Stability of Drugs and Dosage Forms	3	1	0	4
Laboratory- III	Pharmaceutical Validation Lab	0	0	6	3
Laboratory- IV	Pharmaceutical Manufacturing Technology Lab	0	0	6	3
	Mini project	2	0	0	2
Audit - II	Audit Course - II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

II YEAR I Semester

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

II YEAR II Semester

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

***For Dissertation Work Review - I, Please refer 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

Open Electives:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Professional Core - I)

Course Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principals involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on themechanism of separation

a. **Column Chromatography:** Adsorption and partition, theory, preparation, procedure and methodsof detection
b. **Thin Layer Chromatography:** Theory, preparation, procedures, detection of compounds
c. **Paper Chromatography:** Theory, different techniques employed, filter papers used, qualitativeand quantitative detection

UNIT II

a. **Gas chromatography:** Introduction, fundamentals, instrumentation, columns: preparation andoperation, detection, derivatization.
b. **HPLC:** Basic parameters, Principles and instrumentation, solvents and columns used,
   Operational modes, detection and applications of HPLC
c. **HPTLC:** Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. **UV-Visible spectroscopy:** Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes,
   Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. **IR spectroscopy:** Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect (NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

REFERENCE BOOKS:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog,
   F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
5. Vogel‟s Text book of Quantitative Chemical Analysis by A.I. Vogel
6. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
7. Organic Chemistry by I. L. Finar
8. Organic spectroscopy by William Kemp
9. Quantitative Analysis of Drugs by D. C. Garrett
10. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
11. Spectrophotometric identification of Organic Compounds by Silverstein
12. HPTLC by P.D. Seth
13. Indian Pharmacopoeia 2007
14. High Performance thin layer chromatography for the analysis of medicinal plants by EikeReich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun
16. A Textbook of Analytical Chemistry by Y. Anjaneyulu, K. Chandrasekhar, Valli Manickam,Pharmed Press.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE
(Professional Core - II)

Course Objective: 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 Outcomes:

1. The study of this subject builds the confidence in the minds on the students to develop andformulate high quality pharmaceutical products.
2. The students will know about the organization and personnel of an industry.
3. To know about packaging and labeling in industry.
4. To know about SOPs followed as per regulations.

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, sterilize 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,

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 QualitySpecifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related MaterialVol. 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
6. A Textbook of Pharmaceutical Quality Assurance by K. P. R. Chowdary, Pharmamed Press.

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,

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
QUALITY MANAGEMENT SYSTEMS (Professional Elective - I)

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

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

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

UNIT I

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

UNIT II

Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

UNIT III

Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause,

Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

UNIT IV

Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

UNIT V

Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

TEXT AND REFERENCE BOOKS:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By AlEndres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases,By Jiju Antony; David Preece, Routledge, 2002
3. Pharmaceutical Quality Assurance and Management, K. P. Bhusari, Pharmamed Press.
4. 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
5. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books,2001
6. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997
7. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
8. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
9. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
DRUG REGULATORY AFFAIRS (Professional Elective - I)

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

Course Outcomes:

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

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and 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 andLoan 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 ina developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drugmanufacture, regulatory drug analysis.

UNIT IV

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

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

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

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

TEXT AND REFERENCE BOOKS

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
PHARMACEUTICAL FOOD ANALYSIS (Professional Elective-I)

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

Course Outcome: At completion of this course student shall be able to understand various analyticaltechniques in the determination of

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

UNIT I

a. **Carbohydrates:** Classification and properties of food carbohydrates, General methods ofanalysis of food carbohydrates,
b. **Proteins**: Chemistry and classification of amino acids and proteins, Physico-Chemical propertiesof protein and their structure, general methods of analysis of proteins and amino acids

UNIT II

Probiotics: Definition, history, importance, mode of action, identification advantages anddisadvantages of probiotics. Applications of Probiotics

UNIT III

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation ofvegetable oils, Determination of adulteration in fats and oils.

UNIT IV

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay ofvitamins of B-series

UNIT V

a. **General Analytical methods** for milk, milk constituents and milk products like ice cream, milkpowder, butter, margarine, cheese including adulterants and contaminants of milk.
b. **Analysis of fermentation products** like wine, spirits, beer and vinegar.

TEXT BOOKS:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone,Edinburgh London, 1976

2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers,Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International
6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

REFERENCE BOOKS:

1. Remington‟s Pharmaceutical Sciences by Alfonso and Gennaro
2. Food Chemistry and Nutrition: A Comprehensive Treatise, Sumathi S, Pharmamed Press
3. David Pearson. The Chemical Analysis of Foods, 7th ed., Churchill Livingstone, Edinburgh,1976.
4. Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston,1974
5. Indian Pharmacopoeia 2012

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (Professional Elective - II)

Course Objective: This topic will impart the knowledge about principles of drug discovery developmentof INS, NDA and ANDA. This also gives the information about pre-formulation studies, protocols of stability studies, pilot plant scale up and packaging of pharmaceuticals.

Course Outcomes: Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actualmanufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between variousmanufacturing places

UNIT I

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

UNIT II

Pre-formulation studies: Introduction/concept, organolepti properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre- formulation protocol, Stability testing during product development.

UNIT III

Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

UNIT IV

Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packagingsystems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packingmaterials.

UNIT V

Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

REFERENCE BOOKS:

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G.Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy.Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rdEdition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea& Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn (1995) OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way „Pure and applied Pharmacy" by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition (Reprint 2006). Taylor and Francis. London and New York.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)
ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - II)

Course Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications ofthe important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are alsodiscussed.

Course Outcome: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

UNIT I

Principles and procedures involved in the determination of the official compounds in IP with the followinganalytical techniques:

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods
E. Neutralization
F. Acid – Base

UNIT II

A detailed study of the principles and procedures involved in the quantitative determination of thefollowing organic functional groups

A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl
E. Amino Acids

UNIT III

a. Reference Standards: Types, preparation methods and uses.
b. Principles and procedures involved in using the following reagents in the determination ofpharmaceutical dosage forms official in IP
   a. MBTH (3-methyl-2-benzothiazolone hydrazone)
   b. F.C. Reagent (Folin-Ciocalteu)
   c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
   d. 2, 3, 5 - *tri*Phenyltetrazolium salt
   e. 2,6 *di* -ChloroquinoneChlorimide
   f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
   g. Carr – Price Reagent
   h. 2,4 - DNP

UNIT IV

a. Analysis of Excipients: Tests related to excipients such as bulk density, tapped density, particlesize distribution, pH, moisture content, viscosity (dynamic), loss on drying, ash content, conductivity.

b. Excipients of interest: Disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT V

a. Dissolution Tests: Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated, uncoated, enteric coated, gelatin capsules etc.

b. Microbiological assays and Biological tests: Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

TEXT BOOKS:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

REFERENCE BOOKS:

1. Remington‟s Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

SRI INDU INSTITUTE OF PHARMACY
M. Pharm I Year I Sem (Pharmaceutical Quality Assurance)
PHARMACEUTICAL MANAGEMENT (Professional Elective - II)

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

Course Outcomes:

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

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

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives,

interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

TEXT AND REFERENCE BOOKS:

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

SRI INDU INSTITUTE OF PHARMACY
M. Pharm I Year I Sem (Pharmaceutical Quality Assurance)
RESEARCH METHODOLOGY AND IPR

Course Objectives:

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

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

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

UNIT I

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

UNIT II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format 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
4. Intellectual Property Rights in Pharmaceutical Industry B Subba Rao, Pharmamed

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
7. Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Quality Assurance)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (Laboratory – I)

LIST OF EXPERIMENTS:

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption,calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLCTechnique (2-3 experiments)
6. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

SRI INDU INSTITUTE OF PHARMACY
M. Pharm I Year I Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB (Laboratory – II)

LIST OF EXPERIMENTS:

1. QC tests for tablets and capsules (minimum 3 experiments)
2. QC tests for oral liquids and parenterals (minimum 3 experiments)
3. Forced degradation studies of some drugs.
4. Interpretation of spectras by IR, NMR and MASS
5. Estimation of drugs by specified colorimetric reagents
6. Assay of drug formulations using UV-Spectrophotometer (Any four)
7. Demonstration of functional groups of the given samples by IR Spectrophotometer.
8. Physicochemical tests for water
9. Solubility studies of weakly acidic and weakly basic drugs.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)
PHARMACEUTICAL VALIDATION (Professional Core - III)

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

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

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

UNIT I

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

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

UNIT II

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

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

UNIT III

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

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

UNIT IV

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

UNIT V

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

- Validate the manufacturing facilities

REFERENCE BOOKS:

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

Sci. Series,Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A.Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (MarcelDekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud,Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and JamesAgalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, HeimanLam

M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)
PHARMACEUTICAL MANUFACTURING TECHNOLOGY (Professional Core–IV)

Course Objectives: This course is designed to impart knowledge and skills necessary to train thestudents with the industrial activities during Pharmaceutical Manufacturing.

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

- The common practice in the pharmaceutical industry developments, plant layout andproduction planning
- Will be familiar with the principles and practices of aseptic process technology, non-sterilemanufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD)and process analytical technology (PAT) in pharmaceutical manufacturing

UNIT I

Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

UNIT II

Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). Advanced sterile product manufacturing technology: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

UNIT III

Non-sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process- quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and palletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other

specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Problems encountered.

UNIT IV

Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

UNIT - V

Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbDfor Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCE BOOKS:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed.,Varghese Publishers, Mumbai1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. PublicationsPvt. Ltd, Noida,2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms:tablets Vol. I-III, 2nded., CBS Publishers & distributors, New Delhi,2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th Inc, New York, 2005. ed., Marcel Dekker
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi,1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor &Francis, 1st Edition.UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc.New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, NewJersey, 2008.

SRI INDU INSTITUTE OF PHARMACY
M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)
HAZARDS AND SAFETY MANAGEMENT (Professional Elective - III)

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

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

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazardmanagement system
- Teach the method of Hazard assessment, procedure, methodology for provide safeindustrial atmosphere.

UNIT I

Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d)
Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II

Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non-sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

UNIT IV

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system

mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V

Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergencyservices.

REFERENCE BOOKS:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute ofChemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013,India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T. S. S. Dikshith, CRCpress
5. Safety and Health in Industry: A Handbook by AM Sarma, BS Publications

SRI INDU INSTITUTE OF PHARMACY
M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)
SPECTRAL ANALYSIS (Professional Elective - III)

Course Objective: The students will acquire the knowledge about the various aspects of X-Ray diffraction methods, all types of IR methods, particle sizing methods, also DSC, DTA, TGA etc

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

UNIT I

X-Ray diffraction methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal techniques, single crystal diffraction, power diffraction, structural elucidation, and applications.

UNIT II

a. **FT-NIR:** Principle (overtones, combinations, fermi resonance, interferences etc.), instrumentation (dispersion spectrometer and FT-NIR), advantage, and disadvantage, qualitative and quantitativeapplications, including PAT and non-destructive analysis.
b. **ATR:** Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IRbeam), advantages, and disadvantages, pharmaceutical applications.

UNIT III

Electrometric Techniques: Principle, instrumentation and applications of Potentiometer, Amperometer, Conductometer and Polarography.

UNIT IV

a. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation, and Applications of fluorescence spectrophotometer.
b. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle,Instrumentation, Interferences, and applications.

UNIT V

FT- Raman: Principle (absorption, diffraction, scattering and emission of wave, molecular interaction), instrumentation (Dispersive Raman, FT-Raman), advantage and disadvantage, pharmaceutical applications including detection of counterfeit

REFERENCE BOOKS:

1. Instrumental Methods of Chemical Analysis by B. K. Sharma
2. Organic spectroscopy by Y. R. Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors

4. Vogel‟s Text book of Quantitative Chemical Analysis by A. I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J. B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P. D. Seth
12. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)
SCREENING METHODS IN PHARMACOLOGY (Professional Elective - III)

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines andregulations for screening new drug molecules on animals.

UNIT I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert. A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heidelberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Guidelines and Screening Methods of Pharmacology by Surendra H. Bodakh, PharmamedPress.

REFERENCE BOOKS:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICHharmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India,Central drug standard control organization, New Delhi, Minister of Health-2001.

SRI INDU INSTITUTE OF PHARMACY
M. Pharm I Year II Sem (Pharmaceutical Quality Assurance)
AUDITS AND REGULATORY COMPLIANCE (Professional Elective - IV)

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

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

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT - I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT - II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT - III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT - IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT - V

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

REFERENCES 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. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loanaStefan, Jacobus F. Van Staden. Taylor and Francis (2005).

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)
HERBAL DRUG TECHNOLOGY (Professional Elective - IV)

Course Objectives: Helps the students in getting exposed to methods of extraction, preparation and purification of herbal extracts. To acquire knowledge on the preparation and standardization of herbal preparation. They will expose to various research institutions of natural products.

Course Outcomes: Helps the students to understand the organization and research of natural products in herbal drugs industries

UNIT I

Equipment for preparing herbal extracts: Process and equipments- Name of the equipment and itsuses with merits and demerits in each of the following unit operations in the extraction process.

1. Size reduction
2. Filtration
3. Evaporation/Distillation
4. Drying of extracts
5. Solvent recovery

UNIT II

Definition, classification of natural excipient: Sources, Chemical nature, Description parameters Pharmaceutical uses and storage conditions of following Natural excipients, Binding agents, disintegrating agents, diluents, emulsifying agents: Acacia, Tragacanth, Alginates, CMC, Gelatin, Pectin, Lactose, Starches, Talc, Ointment bases, suppository bases and Hardening agents: Beeswax,Cocoa butter, Lanolin, Hard paraffin

UNIT III

Methods of preparation and Evaluation of Herbal Tablets, Capsules, Ointments and other dosage forms. Study of any three formulations under each category with respect to their formulas and claims for various herbs used in them

UNIT IV

a. Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, healthclaims, Dietary Supplements Claims.
b. Food Laws and Regulations, FDA, FPO, MPO, BIS, AGMARK.

UNIT V

a) Natural colorants: Biological Source, coloring principles, chemical nature and usage of thefollowing Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric

b) Natural sweeteners:

i. Definition of nutritive and non-nutritive sweeteners, qualities of an ideal sweetener

andsweetness potency.

ii. Biological source, chemical nature, extraction details and usage of the following: Steviosides,Glycyrrhizin, Rebaudoside

REFERENCE BOOKS:

1. Textbook of Pharmacognosy by G. E. Trease, W. C. Evans, ELBS
2. Textbook of HPTLC by P.D. Seth.
3. Herbal Perfumes and cosmetics by Panda
4. Pharmacognosy by V.E Tyler, LR Brandy and JE Robbers (KM Varghese & co., Mumbai)
5. Natural Excipients by R. S Gaud, Surana.
6. Herbal Drug industry by RD Chowdary
7. Herbal Drug Technology by SS Agarwal
8. Herbal Drug Technology by SL Deore, Pharmamed Press.
9. Pharmacognosy and Phytochemistry by VD Rangari.
10. Indian Pharmacopoeia
11. Dietetics by Sri Lakshmi
12. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman andSchwartz.
13. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
14. Research methods and Quantity methods by G. N.Rao

SRI INDU INSTITUTE OF PHARMACY
M.PharmI Year II Sem (Pharmaceutical Quality Assurance)
STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective –IV)

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

Course Outcome: 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 ofPharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical,Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions ofpharmaceutical interest, prevention of photolytic reactions.

UNIT II

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

Physical stability testing of dosage forms:

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

UNIT III

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

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

SRI INDU INSTITUTE OF PHARMACY

M.Pharm I Year II Sem (PHARMACEUTICAL QUALITY ASSURANCE)

PHARMACEUTICAL VALIDATION LAB (Laboratory – III)

LIST OF EXPERIMENTS:

1. Calibration of Electronic Balance and pH meter,
2. Validation of analytical methods (2 Experiments)
3. Validation of processing area
4. Cleaning validation of one equipment
5. Validation of granulation process
6. Validation of the following equipment
    a. Autoclave
    b. Hot air oven
    c. Tablet compression machine
    d. Dryer
7. Qualification of pharmaceutical testing equipment (Dissolution testing apparatus, friabilityapparatus, Disintegration testing)
8. Cleaning validation of **any 2** analytical instruments
9. Preparation of Master Formula Record.
10. Preparation of Batch Manufacturing Record

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL MANUFACTURING TECHNOLOGY LAB (Laboratory – IV)

LIST OF EXPERIMENTS:

i. Preparation of four different types of semisolid dosage forms and their evaluation (2experiments)
ii. Comparative evaluation of different marketed products (tablets, capsules) of the same API (4experiments)
iii. Stability study testing of tablet dosage forms (any three products)
iv. Preparation and evaluation of enteric coated pellets/tablets
v. Case study of application of QbD
vi. Check list for sterile production area
vii. Check list for water for injection
viii. Design of plant layout-sterile and non-sterile

SRI INDU INSTITUTE OF PHARMACY
M.Pharm II Year I Sem (Pharmaceutical Quality

Assurance)BIOSTATISTICS (Professional Elective - V)

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

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

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

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

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

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

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

REFERENCE BOOKS:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm II Year I Sem (Pharmaceutical Quality Assurance)

SCALE UP AND TECHNOLOGY TRANSFER (Professional Elective - V)

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

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

UNIT I

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

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

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

REFERENCE BOOKS:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor

andFrancis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ.Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman Pharmaceuticaldosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
7. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
8. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.
9. Pharmaceutical Process Scale-up 2nd Ed. Levin Michael, CRC press

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

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

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

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

REFERENCE BOOKS:

1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of IndustrialPharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton‟s Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, NewYork, USA.
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 Quality Assurance)

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
5. Academic Writing,Ajay Semalty, Pharmamed Press

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Quality Assurance)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

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

UNIT-I:

Introduction:

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

Disaster Prone Areas in India:

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

UNIT-II:

Repercussions of Disasters and Hazards:

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

UNIT-III:

Disaster Preparedness and Management:

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

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation.

Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People‟s Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

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

TEXT BOOKS/ REFERENCES:

1. Disaster Management: Hazard and Risk Awareness – A Comprehensive Approach, N. V. S.Raju,BS Publications
2. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies ""NewRoyal book Company.
3. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall ofIndia, New Delhi.
4. 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 Quality Assurance)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

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

Course Outcomes: Students will be able to

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

UNIT-I:
Alphabets in Sanskrit,

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

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

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

TEXT BOOKS/ REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Quality Assurance)
VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

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

Course outcomes: Students will be able to

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

UNIT-I:

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

UNIT-II:

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

UNIT-III:

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

UNIT-IV:

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

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford UniversityPress, New Delhi
2. Indian Culture Values and Professional Ethics, P. S. R. Murty,BS Publications

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Quality Assurance)
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: HistoryDrafting 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: ZilaPachayat. Elected officials and their roles, CEO ZilaPachayat: 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 Quality Assurance)
PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

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

Course Outcomes: Students will be able to understand:

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

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework andterminologyTheories of learning, Curriculum, Teacher education.Conceptual framework, Researchquestions**.** Overview of methodology and Searching.

UNIT-II:

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

UNIT-III:

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

UNIT-IV:

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

UNIT-V:

Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

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

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

Prerequisite: None

Course Objectives:

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

Course Outcomes: Students will be able to:

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

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

UNIT-II:
Yam and Niyam.

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

UNIT-IV:
Asan and Pranayam

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

TEXT BOOKS/ REFERENCES:

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

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

Prerequisite: None

Course Objectives:

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

Course Outcomes: Students will be able to

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

UNIT-I:

Neetisatakam-Holistic development of personality

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

UNIT-II:

Neetisatakam-Holistic development of personality

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

UNIT-III:

Approach to day to day work and duties.

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

UNIT-IV:

Statements of basic knowledge.

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

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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