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 ANALYSIS 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 ANALYSIS 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 ANALYSIS)	
PO1	Understand the basic concepts and advances in analytical techniques and theoretical skills of various analytical instruments.
PO2	Skills in selecting suitable techniques for analysis of drugs and pharmaceuticals.
PO3	To apply the knowledge learnt in developing a new procedure of their own design.

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 ANALYSIS)	
PSO1	Can apply the principals involved in determination with addition to theoretical aspects, basic practical knowledge in modern analytical techniques.
PSO2	Will be able to apply various analytical techniques in determination of food constituents and finished food products.
PSO3	Can comprise the aspects of spectral analysis, dissolution parameters etc. and quantitative determination of various organic compounds.
PSO4	Will acquire knowledge on various types of phytoconstituents on the basis of chemistry data.

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 ANALYSIS)	
PEO1	To understand and apply the principals involved in determination with addition to theoretical aspects, basic practical knowledge in modern analytical techniques.
PEO2	To include application of various analytical techniques in determination of food constituents and finished food products.
PEO3	To embed and comprise the aspects of spectral analysis, dissolution parameters etc. and quantitative determination of various organic compounds.
PEO4	To acquire knowledge on various types of phytoconstituents on the basis of chemistry data.

COURSE OUTCOMES OF M.PHARM (PHARMACEUTICAL ANALYSIS)

R25 REGULATIONS

M.PHARMACY (PHARMACEUTICAL ANALYSIS) 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 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, Pesticides in food.
CO3	Able to apply analytical techniques in analysing Pharmaceuticals (API & Dosage forms)
CO4	Possess awareness on food regulations and legislations
COURSE CODE: PE I	**ADVANCED PHARMACEUTICAL ANALYSIS**
CO1	Perception on qualitative determination of various organic compounds
CO2	Accomplished with spectral analysis, dissolution parameters and microbial assays.
CO3	Knowledge on principles and procedures involved in determination of organic functional groups.
CO4	Performing different tests on excipients such as bulk density, particle size distribution etc.
PE I	**DRUG REGULATORY AFFAIRS**
CO1	Mind full of technical aspects pertaining to the marketing authorization application.
CO2	Detailed 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.
PE I	**PHYTOCHEMISTRY**
CO1	Comprehension on various types of phytoconstituents present in plants

CO2	Detailed study of isotropic tracer techniques.
CO3	Lead structure selection process and optimization.
CO4	Separation of phytoconstituents by vaccum and flash column chromatography.
COURSE CODE: PE III	**PHARMACEUTICAL VALIDATION**
CO1	Explain the aspect of validation
CO2	Carryout validation of manufacturing processes
CO3	Apply the knowledge of validation to instruments and equipment
PE II	**COSMETICS AND COSMECEUTICALS**
CO1	To know regarding regulatory biological aspects of cosmetics, excipients used for various formulations.
CO2	Designing of cosmeceuticals and herbal products.
CO3	Factors affecting microbial preservatives efficacy.
CO4	Sunscreen's classifications and regulatory aspects.
PE II	**STABILITY OF DRUGS AND DOSAGE FORMS**
CO1	Describe the evaluation of stability of solutions, solids and formulations against adverse conditions.
CO2	Be able to suggest retain stability and storage conditions for retaining the efficacy of the dosage forms.
CO3	Have overview on physical stability of novel drug carriers, liposomes, niosomes and nano particles.
C04	Quantitative determination of preservatives, antioxidants, colouring materials, emulsifiers and stabilizers used in pharmaceutical formulations.
COURSE CODE: MC	**RESEARCH METHODOLOGY AND INTELLECTUAL PROPERTY RIGHTS**
CO1	To scrutinize the research related information.
CO2	To accentuate the need of information about intellectual property rights among students.
CO3	Inspect out research problems and formulations.
CO4	Investigations 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	To study Incompatibility studies
CO2	Identification of functional groups and determination by FTIR
CO3	Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC
CO4	Estimation of multi component containing formulations by UV Spectrophotometry.
COURSE CODE: Lab II	**PHARMACEUTICAL AND FOOD ANALYSIS LAB**
CO1	Determination of fat content and rancidity in food products
CO2	Determination of pesticide residue in food products
CO3	Assay of analgesics and antipyretic drugs(API dosage forms) official in IP
CO4	Determination of saponification value, iodine value, peroxide value, acid value in food products.
COURSE CODE: AUDIT COURSE I	**ENGLISH FOR RESEARCH PAPER WRITING**
CO1	To know how to improve writing skills and level of readability.
CO2	Comprehend the skills needed when writing Title Ensure the good quality of paper at very first submission.
CO3	Ascertain about what to write in each section.
CO4	Flourish with skills needed when writing methods, results, conclusions etc.
AUDIT COURSE I	**DISASTER MANAGEMENT**
CO1	Learn to demonstrate and critical understanding of key concepts in disaster risk reduction and humanitarian response.
CO2	Critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
CO3	Planning and programming in different countries, particularly their home country or the countries they work in.
CO4	Critically understand the strengths and weakness of disaster management approaches.
AUDIT COURSE I	**SANSKRIT FOR TECHNICAL KNOWLEDGE**
CO1	To obtain working knowledge in illustrious Sanskrit, the scientific language in the world.
CO2	Learning of Sanskrit to improve brain functioning.
CO3	The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature.
CO4	Learning of Sanskrit to develop the logic in mathematics, science, and other subjects enhancing the memory power.
AUDIT COURSE I	**VALUE EDUCATION**

CO1	Sympathise value of education and self-development
CO2	Imbibe good values in students.
CO3	Developing the overall personality.
CO4	learn the importance of character and competence.
M.PHARMACY (PHARMACEUTICAL ANALYSIS) I YEAR II SEMESTER	
COURSE CODE: PC III	**ADVANCED INSTRUMENTAL ANALYSIS I**
CO1	Thorough knowledge on various spectral aspects of X ray, IR, SEM
CO2	Be familiar with principles, instrumentation of ORD
CO3	Overview on CE in pharmaceutical analysis
CO4	Principles, instrumentation, pharmaceutical application of supercritical fluid chromatography
COURSE CODE: PC IV	**MODERN BIOANALYTICAL TECHNIQUES**
CO1	Able to understand extraction of drugs from biological sources
CO2	Familiar with separation of drugs using different techniques
CO3	Know the guidelines for BA & BE studies
CO4	Well versed with automation and computer aided analysis in sampling
COURSE CODE: PE IV	**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.
PE III	**HERBAL COSMETICS**
CO1	Gain knowledge on classification, economic aspects and regulatory provisions related to manufacture of cosmetics.
CO2	Get exposed to processes involved in manufacturing of herbal cosmetics related to skin.
CO3	Brief account on herbal extracts and herbal products of cosmetic importance.
CO4	Elaborative study of formulations related to hair care with regard to their composition and claims for various herbs used in them.
PE III	**PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS**
CO1	Perceive various epidemiological methods and their applications.
CO2	Be able to understand fundamental principles of Pharmacoeconomics.
CO3	Should perform the key Pharmacoeconomics analysis methods.
CO4	Understand Pharmacoeconomics decision analysis methods and their applications.
PE IV	**ADVANCED INSTRUMENTAL ANALYSIS II**
CO1	Thorough knowledge on various electrochemical methods like

	fluorimetry, ELISA, RIA, etc.
CO2	Introduction and applications of conductometry
CO3	Methods of potentiometric titration to determine the end point
CO4	Working and applications of dropping mercury and rotating platinum electrodes
PE IV	**NUTRACEUTICALS**
CO1	Recognise the occurrence and characteristic features of phytochemicals as nutraceuticals.
CO2	Know the importance of nutraceuticals in various common problems with the concept of free radicals.
CO3	Acknowledge the role of antioxidants in free radical induced disease conditions.
CO4	Expose to various food laws and regulations, health claims and dietary supplement claims.
PE IV	**CLINICAL RESEARCH AND PHARMACOVIGILANCE**
CO1	**To explain the regulatory requirements for conducting clinical trials**
CO2	To demonstrate the types of clinical trial designs
CO3	Execute safety monitoring, reporting and close out activities
CO4	Explain the principles of Pharmacovigilance
	Perform the adverse drug reaction reporting systems and communication in pharmacovigilance
CO5	Detect new adverse drug reactions and their assessment
COURSE CODE: LAB III	**ADVANCED INSTRUMENTAL ANALYSIS I LAB**
CO1	To determine chlorides and sulphates by nephloturbidometry
CO2	To estimate riboflavin by flourimetry
CO3	To perform assay of official compounds by potentiometry and conductometric titrations
CO4	To determine phosphate interference on absorption of calcium
COURSE CODE: LAB IV	**PHARMACEUTICAL 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 parenteral.
CO4	Demonstration of functional groups of the given samples by IR spectrophotometer**.**
	MINI PROJECT WITH SEMINAR
CO1	Allows the students to study, do research and act by themselves using their abilities.
CO2	Improves communication skills and networking with others.
CO3	Helps in gaining expert knowledge and renewing motivational confidence.
CO4	Provides latest information in the field of science and technology.

COURSE CODE: AUDIT COURSE II	CONSTITUTION OF INDIA
CO1	Understandinge the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
CO2	Confer the intellectual origins of the frame work of argument that informed the conceptualization of social reforms leading to revolution in India.
CO3	Dissertate the circumstances surrounding the foundation of the congress socialist party under the leadership of Jawaharlal Nehru and eventual failure of the proposal of direct elections through adult suffrage in the Indian constitution.
CO4	Discuss the passage of the Hindu Code Bill of 1956.
AUDIT COURSE II	**PEDAGOGY STUDIES**
CO1	Figure out what pedagogical practices are being used by teachers in formal and informal class rooms in developing countries.
CO2	The evidence on the effectiveness of these pedagogical practices, in what conditions and with what population of learners.
CO3	How can teacher education, school curriculum and guidance materials best support effective pedagogy?
CO4	Identify critical evidence gaps to guide the development.
AUDIT COURSE II	**STRESS MANAGEMENT BY YOGA**
CO1	Develop healthy mind in a healthy body thus improving social health.
CO2	Improve efficiency
CO3	overcome stress.
CO4	To get well acquinted with types of pranayama.
AUDIT COURSE II	**PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS**
CO1	Study of Shrimad-Bhagwad-Geeta help the student in developing his personality and achieve the highest goal in life.
CO2	Study of neethishatakam will help in developing versatile personality of students.
CO3	To awaken wisdom in students.
CO4	To became a person with stable mind, pleasing personality and determination.
M.PHARMACY (PHARMACEUTICAL ANALYSIS) 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 ANALYSIS) 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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R-25 REGULATIONS AS PER JNTUH, Hyderabad.

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

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

PRELIMINARY DEFINITIONS AND NOMENCLATURE

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

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

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

9.9 The Cumulative Grade Point Average (CGPA) is a measure of the overall cumulative

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

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

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 ≤ CGPA < 7.50
Second Class	6.00 ≤ CGPA < 6.5

11.0 Withholding of Results

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

12.0 General

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

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

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

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

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

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

MALPRACTICES RULES

DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

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

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

.6	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent/ any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults theofficer-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 subjectsthe candidate has already appeared including practical examinations and project work and shall not be permitted for the remainingexaminations of the subjects of that semester/year. The candidate is also debarredand forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has alreadyappeared 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 subjectand 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.

SRI INDU INSTITUTE OF PHARMACY

M.PHARMACY (PHARMACEUTICAL ANALYSIS)
R22 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2022-23 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Modern Pharmaceutical Analytical Techniques	3	1	0	4
Professional Core-II	Pharmaceutical Food Analysis	3	1	0	4
Professional Elective-I	1. Advanced Pharmaceutical Analysis 2. Drug Regulatory Affairs 3. Phytochemistry	3	1	0	4
Professional Elective-II	1. Pharmaceutical Validation 2. Cosmetics and Cosmeceuticals 3. Stability of Drugs and Dosage forms	3	1	0	4
	Research Methodology & IPR	2	0	0	2
Laboratory-I	Modern Pharmaceutical Analytical Techniques lab	0	0	6	3
Laboratory-II	Pharmaceutical food Analysis Lab	0	0	6	3
Audit - II	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	Advanced Instrumental Analysis – I	3	1	0	4
Professional Core-IV	Pharmaceutical Quality Control & Quality Assurance	3	1	0	4
Professional Elective-III	1. Modern Bio-analytical Techniques 2. Herbal Cosmetics 3. Pharmacoepidemiology & Pharmacoeconomics	3	1	0	4
Professional Elective-IV	1. Advanced Instrumental Analysis - II 2. Nutraceuticals 3. Clinical Research and Pharmacovigilance	3	1	0	4
Laboratory- III	Advanced Instrumental Analysis I Lab	0	0	6	3
Laboratory- IV	Pharmaceutical Quality Control & Quality AssuranceLab	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 PackagingDevelopment	3	1	0	4
Open Elective	Open Elective	3	1	0	4
Dissertation	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

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

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 principles 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 the mechanism 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, ***interpretation of spectra*** 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.

REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL FOOD ANALYSIS (Professional Core – II)

Course 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
- Pharmaceuticals (API & Dosage forms)
- 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 and disadvantages 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, BostonLondon, 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

REFERENCES:

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 edn, Churchill Livingstone, Edinburgh.
4. Nielsen S. Introduction to 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 Analysis)
ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - I)

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 of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

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 thefollowing analytical 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, particle size 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 limittests, 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.
7. Fundamentals of Analytical Chemistry, DK Sarkar, Pharmamed Press

REFERENCES:

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 Analysis)
DRUG REGULATORY AFFAIRS (Professional Elective - I)

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

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application(MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful 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 Licences – Test Lic., Import lic., for testing of drugs and API‟s, Manufacturing Contractand Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

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

UNIT III

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

UNIT IV

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

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe
   1) European Medicines Agency (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. 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 Analysis)
PHYTOCHEMISTRY (Professional Elective - I)

Course Objective: Helps the students to get exposed to natural product drug discovery and to perform quantitative and qualitative evaluation of herbal extracts. To understand the chemistry of important phytoconstituents of different categories.

Course Outcome: On the basis of chemistry data of phytoconstituents students will acquire knowledge on various types of phytoconstituents present in the plants.

UNIT I

Biosynthetic pathways and Radio tracing techniques: containing drugs:

a) Methods of Biogenetic Investigations, detailed study of isotropic tracer techniques.
b) Study of Biosynthetic pathways of of following phyto-pharmaceuticals: Atropine, Morphine,Cardiac glycosides and Flavonoids.

UNIT II

Drug discovery and development: Approaches to discovery and development of natural products as potential new drugs. Sourcing and archiving Natural products for discovery, evaluating natural products for therapeutic properties, Identifying the biologically active Natural products, the lead structure selection process and Optimization with suitable examples from the following source: artemesin, andrographolides.

UNIT III

a) Extraction/Isolation methods for specific Phytochemical groups, Choice of solvents and Interferingcompounds for general Isolation and purification of desired phytoconstituents.
b) Recent sophisticated extraction techniques like: Super critical fluid extraction and Ultra-sonicextraction. Separation of phytoconstituents by Vacuum and Flash column chromatography.

UNIT IV

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses of the followingphyto-pharmaceuticals:

a) Atropine, caffeine, Morphine and brief account on its derivatives and analogues
b) Camptothecin, Digoxin
c) Taxol, Podophyllotoxin

UNIT V

a. Natural colorants: Biological Source, colouring principles, chemical nature and usage of thefollowing Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric
b. Flavours and Perfumes: Sandal wood oil, Orange oil, Lemon oil, Palmarosa oil, Geranium oil.

REFERENCES:

1. Phytochemical methods of chemical analysis by Harbone

2. Modern methods of plant analysis- peach & M. V. Tracey Vol. 1 to VII
3. Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4. Thin layer chromatography by Stahl
5. Chemistry of natural products by Atur Rahman
6. Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7. Medicinal Chemistry Drug Discovery by Donald J, Abrahm,
8. Plant drug analysis by Wagner
9. Clarke‟s isolation & identification of drugs by AC Mottal
10. Chromatography of Alkaloids by Varpoorte Swendson
11. Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Pharmacognosy and Phytochemistry: A Comprehensive Approach, S L Deore, PharmamedPress
14. Medicinal chemistry and drug discovery by Burger‟s
15. Foye‟s Principles of medicinal chemistry.
16. Pharmacognosy and phytochemistry by Biren seth
17. Herbal Perfumes and cosmetics by Panda
18. Herbal Drug Technology by SS Agarwal
19. Pharmacognosy and Phytochemistry by VD Rangari.
20. Textbook of Pharmacognosy by G. E. Trease, W. C. Evans, ELBS

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Analysis)
PHARMACEUTICAL VALIDATION (Professional Elective - 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

REFERENCES:

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. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar,Pharmamed Press
6. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud,Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and JamesAgalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, HeimanLam

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Analysis)
COSMETICS AND COSMECEUTICALS (Professional Elective - II)

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

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

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products

UNIT I

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

UNIT II

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

UNIT III

Formulation Building blocks: Building blocks for different product formulations ofcosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheologicaladditives: classification and application. Antimicrobial used as preservatives, their merits anddemerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of amoisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. **Perfumes;** Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT IV

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

UNIT V

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

REFERENCES

1. Harry‟s Cosmeticology. 8th edition.
2. Poucher‟sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rdedition
5. Cosmeceuticals by Y Madhusudan Rao, Pharmamed Press
6. Cosmetic and Toiletries recent suppliers‟ catalogue.
7. CTFA directory.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year I Sem (Pharmaceutical Analysis)
STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective –II)

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.

REFERENCES:

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

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

Course Objectives:

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

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

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

UNIT I

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

UNIT II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT III

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

UNIT IV

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

UNIT V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information

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

TEXT BOOKS:

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

REFERENCES:

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 Analysis)
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(2 experiments)
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 Analysis)
PHARMACEUTICAL FOOD ANALYSISLAB (Laboratory –II)

LIST OF EXPERIMENTS:

1. Determination of total reducing sugar
2. Determination of proteins
3. Determination of saponification value, Iodine value, Peroxide value, Acid value in foodproducts
4. Determination of fat content and rancidity in food products
5. Analysis of natural and synthetic colors & food additives in food
6. Determination of preservatives in food
7. Determination of pesticide residue in food products
8. Assay of any two Analgesic & Antipyretic drugs (API & dosage forms) official in IP
9. Assay of any two Antihistamines (API & dosage forms) official in IP
10. Assay of any two Diuretics (API & dosage forms) official in IP
11. Microbiological assay of any two Antibiotics official in IP

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS – I (Professional Core - III)

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

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, powder diffraction, structural elucidation and applications.

UNIT II

a. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
b. **Super critical fluid chromatography**: Principles, instrumentation, pharmaceutical applications.

UNIT III

Capillary Electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CEcharacteristics, principles of CE, methods and modes of CE. General considerations and method development in CE,

UNIT IV

a. **DSC:** Principle, thermal transitions, instrumentation (Heat flux and power-compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
b. **DTA**: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

UNIT V

Scanning electron microscope (**SEM**): Principles, Instrumentation and applications.
Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Analysis)
PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE (Professional Core – IV)

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

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

UNIT I

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

UNIT II

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

UNIT III

a. Organization and personnel, responsibilities, training hygiene
b. **Premises**: Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, 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 Pharmaceutical Process Validation by Berry and Nash
4. How to Practice GMP‟s – P.P. Sharma

REFERENCES:

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. Pharmaceutical Quality Assurance and Management, K. P. Bhusari, Pharmamed Press
5. SOP Guidelines by D.H. Shah
6. Quality Assurance Guide by OPPI
7. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D.Nally (Dec 26, 2006)
8. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30,Elsevier, 2005.

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Analysis)
MODERN BIO-ANALYTICAL TECHNIQUES
(Professional Core - IV)

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

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

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

UNIT I

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

UNIT II

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods.Permeability: In-vitro, in-situ and In-vivo methods.

UNIT III

Bioanalysis and bioanalytical method validation:

a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

UNIT IV

Pre-Formulation: A consideration of following characteristics of medicinal agents in their dosageform:

Physical characteristics-Particle size, polymorphism, crystal form, solubility, Interfacial tension, Saltformation, wetting of solids, flow characteristics, compressibility and Partition coefficient.

Chemical Characteristics-Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug –Excipient compatibility studies.

UNIT V

a. **Automation and computer-aided analysis, LIMS**: The concept of auto samplers and high throughput analysis, computer-controlled instrumentation and networked laboratory. Peculiarities of laboratory information management systems (LIMS).
b. **Drug Product Performance, In Vivo:** Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies.

REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Analysis)
HERBAL COSMETICS (Professional Elective - III)

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

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

Hair care Products: Hair structure and its chemistry

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

UNIT V

Herbs in cosmetics:

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

REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm. I Year II Sem (Pharmaceutical Analysis)
PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS
(Professional Elective - III)

Course Objective: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy productsand services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT I

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT II

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds‟ ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-

Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT V

Definition, Steps involved, Applications, Advantages and disadvantages of the following: Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts andPractice

SRI INDU INSTITUTE OF PHARMACY

M.Pharm Sem – II (PHARMACEUTICAL ANALYSIS)
ADVANCED INSTRUMENTAL ANALYSIS – II
(Professional Elective - IV)

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

Course Outcome: By the completion of topics the students will come out with the thorough knowledge of various electrochemical methods, flourimetry, AAS, RIA, ELISA etc. which help them in further projects works and also industrial opportunities

UNIT I

Polarography – Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.

Amperometry - Principles, instrumentation and applications including amperometric titrations.

UNIT II

a. **Potentiometry –** Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
b. **Conductometry–** Introduction, Conductivity cell, Conductometric titrations, applications

UNIT III

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugsthat can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

UNIT IV

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

UNIT V

a. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds,Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.
b. **ELISA:** Principle, types and application of ELISA

REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Analysis)
NUTRACEUTICALS (Professional Elective - IV)

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

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals

UNIT I

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

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

UNIT II

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

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

UNIT III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C,

Vitamin E, α-Lipoic acid, melatonin

c. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

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

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

REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Analysis)
CLINICAL RESEARCH AND PHARMACOVIGILANCE
(Professional Elective - IV)

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

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

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

UNIT I

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

UNIT II

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

UNIT III

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

UNIT IV

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

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance: International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, ArisG Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition,Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

SRI INDU INSTITUTE OF PHARMACY
M.Pharm I Year II Sem (Pharmaceutical Analysis)
ADVANCED INSTRUMENTAL ANALYSIS-I LAB (Laboratory –III)

LIST OF EXPERIMENTS:

1. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
2. Determination of compounds of sodium, potassium and calcium by Flame photometry.
3. Estimation of riboflavin/quinine sulphate by flourimetry
4. Assay of official compounds by potentiometric titrations **(Any 2)**
5. Assay of official compounds by conductimetric titrations **(Any 2)**
6. Demonstration on ELISA
7. Quenching of fluorescence
8. Perform phosphate interference on absorption of calcium

(Note: Minimum of two experiments covering each of the above-mentioned topics)

SRI INDU INSTITUTE OF PHARMACY

M.Pharm I Year II Sem (Pharmaceutical Analysis)

PHARMACEUTICAL QUALITY CONTROL AND QUALITY ASSURANCE LAB

LIST OF EXPERIMENTS:

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

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

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

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

UNIT I

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

UNIT II

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

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

UNIT III

Measures of Correlation and Regression

Probability rules: Binomial, Poison and Normal distribution.

UNIT IV

Experimental designing, planning of an experiment, replication and randomization.

Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V

Hypothesis testing: Student „t" test, Chi square test,

Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCES:

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 andCompany.
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.

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

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

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

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

UNIT I

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

REFERENCES:

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

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

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

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

Course Outcome: At the end of the semester student will get an idea about Industrial area 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.

REFERENCES:

1. Lachman; Lieberman Herbert A.; Kanig, The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton‟s Pharmaceutics: The design and Manufacture of Medicine
4. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
5. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester
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 Analysis)
ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course objectives: Students will be able to:

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

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

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

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

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

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

TEXT BOOKS/ REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Analysis)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

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

UNIT-I:

Introduction:

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

Disaster Prone Areas in India:

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

UNIT-II:

Repercussions of Disasters and Hazards:

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

UNIT-III:

Disaster Preparedness and Management:

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

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning,

People‟s Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

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

TEXT BOOKS/ REFERENCES:

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

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

Prerequisite: None

Course Objectives:

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

Course Outcomes: Students will be able to

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

UNIT-I:
Alphabets in Sanskrit,

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

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

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

TEXT BOOKS/ REFERENCES:

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

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

Prerequisite: None

Course Objectives: Students will be able to

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

Course outcomes: Students will be able to

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

UNIT-I:

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

UNIT-II:

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

UNIT-III:

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

UNIT-IV:

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

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Analysis)
CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

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

Course Outcomes: Students will be able to:

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

UNIT-I:

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

UNIT-II:

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

UNIT-III:

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

UNIT-IV:

Local Administration: District"s Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayat raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments),

Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:

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

TEXT BOOKS/ REFERENCES:

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

SRI INDU INSTITUTE OF PHARMACY
M.Pharm (Pharmaceutical Analysis)
PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

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

Course Outcomes: Students will be able to understand:

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

UNIT-I:

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

UNIT-II:

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

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the in depth 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 Analysis)
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 Analysis)
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- 26,28,63,65 (virtue)
- Verses- 29,31,32 (pride & heroism)

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.