### I YEAR I Semester

<table>
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<tr>
<th>Course Code</th>
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<td>Professional Core-I</td>
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<td>Professional Core-II</td>
<td>Quality control and Quality Assurance</td>
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| Professional Elective-I | 1. Quality Management Systems  
2. Pharmaceuticals and food Analysis  
3. Drug Regulatory Affairs | 3 | 0 | 0 | 3       |
| Professional Elective-II | 1. Product Development and Technology Transfer  
2. Advanced Pharmaceutical Analysis  
3. Pharmaceutical Management | 3 | 0 | 0 | 3       |
| Profession Elective-I | Research Methodology & IPR | 2 | 0 | 0 | 2       |
| Laboratory-I | Modern Pharmaceutical Analytical Techniques Lab | 0 | 0 | 4 | 2       |
| Laboratory-II | Quality Control and Quality Assurance Lab | 0 | 0 | 4 | 2       |
| Audit - I | Audit course - I | 2 | 0 | 0 | 0       |
| **TOTAL** | | **16** | **0** | **8** | **18** |

### I YEAR II Semester

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| Professional Elective-III | 1. Hazards and Safety Management  
2. Spectral Analysis  
3. Screening Methods in Pharmacology | 3 | 0 | 0 | 3       |
| Professional Elective-IV | 1. Audits and Regulatory compliance  
2. Herbal Drug Technology  
3. Stability of drugs and Dosage forms | 3 | 0 | 0 | 3       |
| Laboratory-III | Pharmaceutical Validation Lab | 0 | 0 | 4 | 2       |
| Laboratory-IV | Pharmaceutical Manufacturing Technology Lab | 0 | 0 | 4 | 2       |
| Mini Project with Seminar | | 2 | 0 | 0 | 2       |
| Audit - II | Audit Course - II | 2 | 0 | 0 | 0       |
| **TOTAL** | | **16** | **0** | **8** | **18** |
II YEAR I SEMESTER

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II YEAR II SEMESTER

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*For Dissertation Work Review - I, Please refer 7.8 in R19 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
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 methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II
b. HPLC: Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

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

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

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

1. Instrumental Methods of Chemical Analysis by B.K Sharma
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
12. HPTLC by P.D. Seth
13. Indian Pharmacopoeia 2007
14. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun
QUALITY CONTROL AND QUALITY ASSURANCE (Professional Core - II)

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

Course Outcome: Upon completion of this course the student should be able to:
- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

UNIT – I
Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT - II
cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

UNIT - III
Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

UNIT - IV

UNIT - V
Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of
waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCE BOOKS:
7. ICH guidelines
8. ISO 9000 and total quality management
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.
QUALITY MANAGEMENT SYSTEMS (Professional Elective - I)

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

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

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

UNIT - I

UNIT - II

UNIT - III

UNIT - IV
UNIT - V

TEXT BOOKS AND REFERENCES:
1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
4. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
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 analytical techniques 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 of analysis of food carbohydrates,
b. Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids

UNIT - II
a. Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.
b. Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT - III
Probiotics: Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT - IV
Definition, classification and principles and procedures involved in the quantitative determination of drugs from each category of both API and dosage forms (IP) of the following
- a. Analgesics & Antipyretics
- b. Antihypertensives
- c. Antihistamines
- d. Alkaloids
- e. Antibiotics
- f. Diuretics

UNIT - V
a. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
b. Analysis of fermentation products like wine, spirits, beer and vinegar.
  - Pesticides in food
  - And also student shall have knowledge in food regulations and legislations

TEXT BOOKS:
4) Analysis of Food constituents – Multon, Wiley VCH.
5) Dr. William Horwitz, Official methods of analysis of AOAC International

REFERENCE BOOKS:
1. Remington’s Pharmaceutical Sciences by Alfonso and Gennaro
4. Indian Pharmacopoeia 2012
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 to place the drug products in market for marketing approvals.

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

TEXT AND REFERENCE BOOKS:

1. Original laws published by Govt. of India.
3. Laws of Drugs in India by Hussain.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013
PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (Professional Elective-II)

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

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

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

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

UNIT - II.

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

UNIT - IV

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

REFERENCES:
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
ADVANCED PHARMACEUTICAL ANALYSIS (Professional Elective - II)

Course Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications 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 the following 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 the following organic functional groups
A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl
E. Amino Acids

UNIT III

b. Principles and procedures involved in using the following reagents in the determination of pharmaceutical 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 - 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 limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

**TEXT BOOKS:**
1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners

**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.)
PHARMACEUTICAL MANAGEMENT (Professional Elective - II)

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

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

UNIT - I

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

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

UNIT - IV
Professional Managers: Tasks, responsibilities and skills needed. Leadership: Styles and managing change. Decision Making: Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.
Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT - V
Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc. Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

TEXT AND REFERENCE BOOKS:
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.
RESEARCH METHODOLOGY AND IPR

Course Objectives:

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

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

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

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

UNIT - II
Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III
Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV

UNIT - V
TEXT BOOKS:
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”

REFERENCES:
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 UV spectrophotometry
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, HPTLC Technique (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
LIST OF EXPERIMENTS:
1. QC tests for tablets and capsules (minimum 3 experiments)
2. QC tests for oral liquids and parenterals (minimum 3 experiments)
3. Forced degradation studies of some drugs.
4. Interpretation of spectras by IR, NMR and MASS
5. Estimation of drugs by specified colorimetric reagents
6. Assay of drug formulations using UV-Spectrophotometer (Any four)
7. Demonstration of functional groups of the given samples by IR Spectrophotometer.
8. Physicochemical tests for water
9. Solubility studies of weakly acidic and weakly basic drugs.
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD  
M.Pharm I Year II Sem (PHARMACEUTICAL QUALITY ASSURANCE)

PHARMACEUTICAL VALIDATION (Professional Core - III)

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

**Course Outcome:** Upon completion of the subject student shall be able to
- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments

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


**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**

**UNIT V**
*Analytical method validation*: General principles, Validation of analytical method as per ICH guidelines and USP.  
- Validate the manufacturing facilities

**REFERENCES:**
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam
Course Objectives: This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

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

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

UNIT - I

UNIT - II

UNIT - III

UNIT - IV
Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of

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

REFERENCES:
HAZARDS AND SAFETY MANAGEMENT (Professional Elective - III)

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

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

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

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

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

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

UNIT - IV
Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT - V
elements of safety Program and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

REFERENCES:
1. Y.K. Sing, Environmental Science, New Age International Pvt. Publishers, Bangalore
Course Objective: The students will acquire the knowledge about the various aspects of X-Ray diffraction methods, all types of IR methods, particle sizing methods, also DSC, DTA, TGA etc

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

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

UNIT - II
a. FT-NIR: Principle (overtones, combinations, fermi resonance, interferences etc.), instrumentation (dispersion spectrometer and FT-NIR), advantage, and disadvantage, qualitative and quantitative applications, including PAT and non-destructive analysis.

b. ATR: Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IR beam), advantages, and disadvantages, pharmaceutical applications.

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

UNIT - IV
a. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation, and Applications of fluorescence spectrophotometer.

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

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

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
12. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan
Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guidelines for handling animals and human and animal ethics for screening of drugs.

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

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

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

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

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

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

TEXT BOOKS:

REFERENCE BOOKS:
1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
AUDITS AND REGULATORY COMPLIANCE (Professional Elective-IV)

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

Course Outcome: Upon completion of this course the student should be able to
- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

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

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

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

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

UNIT - V

REFERENCES BOOKS:
HERBAL DRUG TECHNOLOGY (Professional Elective - IV)

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

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

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

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

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

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

UNIT - IV
b. Food Laws and Regulations, FDA, FPO, MPO, BIS, AGMARK.

UNIT - V
a) Natural colorants: Biological Source, coloring principles, chemical nature and usage of the following Annatto, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric

b) Natural sweeteners:
   i. Definition of nutritive and non-nutritive sweeteners, qualities of an ideal sweetner and sweetness potency.
   ii. Biological source, chemical nature, extraction details and usage of the following: Steviosides, Glycyrrhizin, Rebaudioside

REFERENCE BOOKS:
1. Textbook of Pharmacognosy by G.E. Trease, W.C. Evans, ELBS
2. Textbook of HPTLC by P.D. Seth.
3. Herbal Perfumes and cosmetics by Panda
4. Pharmacognosy by V.E Tyler, LR Brandy and JE Robbers (KM Varghese & co., Mumbai)
5. Natural Excipients by R. S Gaud, Surana.
6. Herbal Drug industry by RD Chowdary
7. Herbal Drug Technology by SS Agarwal
8. Pharmacognosy and Phytochemistry by VD Rangari.
9. Indian Pharmacopoeia
10. Dietetics by Sri Lakshmi
13. Research methods and Quantity methods by G. N. Rao
STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective – IV)

Course Objective: These topics are designed to impart specialized knowledge to preserve the properties of drugs and dosage forms during manufacture, storage, and shelf life. The understanding of properties and the evaluation of stability during storage, by solution and solid state, against several factors of 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 acyl transfers: Nature of reaction, structure, and utility, stabilization of pharmaceutical examples.

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

UNIT - III
Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers, and stabilizers in Pharmaceutical formulation.
Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE, and Membrane filtration. Factors affecting extraction of drugs.

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

UNIT - V
Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions, and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.
Stability studies: Concept of stability studies.
a) cGMP & ICH guidelines for Accelerated stability Testing.
b) Interaction of containers & closure Compatibility Testing.
REFERENCE BOOKS:
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
LIST OF EXPERIMENTS:
1. Calibration of Electronic Balance and pH meter,
2. Validation of analytical methods (2 Experiments)
3. Validation of processing area
4. Cleaning validation of one equipment
5. Validation of granulation process
6. Validation of the following equipment
   a. Autoclave
   b. Hot air oven
   c. Tablet compression machine
   d. Dryer
7. Qualification of pharmaceutical testing equipment (Dissolution testing apparatus, friability apparatus, Disintegration testing)
8. Cleaning validation of any 2 analytical instruments
9. Preparation of Master Formula Record.
10. Preparation of Batch Manufacturing Record
JAWAHarlAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmaceutical Quality Assurance)

PHARMACEUTICAL MANUFACTURING TECHNOLOGY LAB (Laboratory – IV)

LIST OF EXPERIMENTS:
1. Preparation of four different types of semisolid dosage forms and their evaluation (2 experiments)
2. Comparative evaluation of different marketed products (tablets, capsules) of the same API (4 experiments)
3. Stability study testing of tablet dosage forms (any three products)
4. Preparation and evaluation of enteric coated pellets/tablets
5. Case study of application of QbD
6. Check list for sterile production area
7. Check list for water for injection
8. Design of plant layout-sterile and non-sterile
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

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, Poisson and Normal distribution.

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

UNIT - V
Hypothesis testing: Student 't' test, Chi square test,
Non-Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCE BOOKS:
1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
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, parental 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, parental, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

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

UNIT III

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

REFERENCES:
1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
Course Objectives: The student shall learn about Industrial area design, Current good manufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

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

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

UNIT II

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

UNIT V

REFERENCES:
1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. Gilbert Banker and Christopher Rhodes. Modern Pharmaceutics.
3. Aulton's Pharmaceutics: The design and Manufacture of Medicine
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 very first-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:

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:
Prerequisite: None

Course Objectives: Students will be able to
- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

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

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

UNIT-II:
Repercussions of Disasters and Hazards:

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:

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:
2. Sahni, Pardeep Et. Al. (Eds.),” Disaster Mitigation Experiences and Reflections”, Prentice Hall of India, New Delhi.
SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

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

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

UNIT-I:
Alphabets in Sanskrit,

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

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

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

TEXT BOOKS/ REFERENCES:
1. “Abhyaspustakam” – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. “Teach Yourself Sanskrit” Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
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:

UNIT-II:

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

UNIT-IV:

UNIT-V:

TEXT BOOKS/ REFERENCES:
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:

UNIT-II:

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:

UNIT-V:
TEXT BOOKS/ REFERENCES:
1. The Constitution of India, 1950 (Bare Act), Government Publication.
Prerequisite: None

Course Objectives: Students will be able to:
- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DFID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Students will be able to understand:
- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

UNIT-I:

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

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

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

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

TEXT BOOKS/ REFERENCES:
Prerequisite: None

Course Objectives:
- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Students will be able to:
- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

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

UNIT-II:
Yam and Niyam.

UNIT-III:
Do’s and Don’t’s in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

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

TEXT BOOKS/ REFERENCES:
1. “Yogic Asanas for Group Training-Part-I”: Janardan Swami Yogabhyasi Mandal, Nagpur
2. “Rajayoga or conquering the Internal Nature” by Swami Vivekananda, Advaita Ashrama
   (Publication Department), Kolkata
PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS  
(Audit Course - I & II)

Prerequisite: None

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

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

UNIT-I:
Neetisatakam-Holistic development of personality
- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:
Neetisatakam-Holistic development of personality
- Verses- 52,53,59 (dont’s)
- Verses- 71,73,75,78 (do’s)

UNIT-III:
Approach to day to day work and duties.
- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

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

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

TEXT BOOKS/ REFERENCES:
1. “Srimad Bhagavad Gita” by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari’s Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.