# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

## M.PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)

### R19 COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2019-20 Admitted Batch

### I YEAR I Semester

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>L</th>
<th>T</th>
<th>P</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Core-I</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Core-II</td>
<td>Quality control and Quality Assurance</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Elective-I</td>
<td>1. Quality Management Systems</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Pharmaceuticals and food Analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Drug Regulatory Affairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional Elective-II</td>
<td>1. Product Development and Technology Transfer</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Advanced Pharmaceutical Analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Pharmaceutical Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MC</td>
<td>Research Methodology &amp; IPR</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Laboratory-I</td>
<td>Modern Pharmaceutical Analytical Techniques Lab</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Laboratory-II</td>
<td>Quality Control and Quality Assurance Lab</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Audit</td>
<td>Audit course - I</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td>16</td>
<td>0</td>
<td>8</td>
<td>18</td>
</tr>
</tbody>
</table>

### I YEAR II Semester

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>L</th>
<th>T</th>
<th>P</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Core-III</td>
<td>Pharmaceutical Validation</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Core-IV</td>
<td>Pharmaceutical Manufacturing Technology</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Elective-III</td>
<td>1. Hazards and Safety Management</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Spectral Analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Screening Methods in Pharmacology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional Elective-IV</td>
<td>1. Audits and Regulatory compliance</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Herbal Drug Technology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Stability of drugs and Dosage forms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory-III</td>
<td>Pharmaceutical Validation Lab</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Laboratory-IV</td>
<td>Pharmaceutical Manufacturing Technology Lab</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td><strong>Mini Project with Seminar</strong></td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Audit</td>
<td>Audit Course - II</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td>16</td>
<td>0</td>
<td>8</td>
<td>18</td>
</tr>
</tbody>
</table>
Audit Courses 1 & 2
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
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 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-up 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.
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
PHARMACEUTICALS AND FOOD ANALYSIS (Professional Elective - I)

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
- 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
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 of vegetable oils, Determination of adulteration in fats and oils.

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

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.

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
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 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 Quality Control – Basic understanding for in-built quality.

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

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

UNIT V
Governing Regulatory Bodies across the globe.
Country Authority Submission
a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe
   1) European Medicines Agency (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:**
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 C. Complexometric
B. Oxidation-reduction 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 C. Carbonyl compounds
B. Esters 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 - tPhenyltetrazolium 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”.
**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
QUALITY CONTROL AND QUALITY ASSURANCE LAB (Laboratory – II)

LIST OF EXPERIMENTS:
1. QC tests for tablets and capsules (minimum 3 experiments)
2. QC tests for oral liquids and parenterals (minimum 3 experiments)
3. Forced degradation studies of some drugs.
4. Interpretation of spectras by IR, NMR and MASS
5. Estimation of drugs by specified colorimetric reagents
6. Assay of drug formulations using UV-Spectrophotometer (Any four)
7. Demonstration of functional groups of the given samples by IR Spectrophotometer.
8. Physicochemical tests for water
9. Solubility studies of weakly acidic and weakly basic drugs.
Prerequisite: None

Course objectives: Students will be able to:
- Understand 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:
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to
- learn to demonstrate a critical understanding of key concepts in disaster risk reduction 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.
REFERENCES:
2. Sahni, Pardeep Et. Al. (Eds.),” Disaster Mitigation Experiences and Reflections”, Prentice Hall of India, New Delhi.
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:
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:

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:

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:
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Quality Assurance)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

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

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

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

UNIT-II:
Yam and Niyam.

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

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 Yogabhysy 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 (don’ts)
- Verses- 71,73,75,78 (do’s)

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

UNIT-IV:
Statements of basic knowledge.
- Shrimad Bhagwad Geeta: Chapter 2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

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

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