# M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS)

## 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>Good Regulatory Practice</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Core-II</td>
<td>Drug Regulatory Affairs</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Elective-I</td>
<td>1. Intellectual Property Rights</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Total Quality Management</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>3. Pharmaceutical Validation</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Elective-II</td>
<td>1. Stability of Drugs and Dosage forms</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Pharmaceutical Formulation Technology</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>3. Documentation and Regulatory Writing</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>MC</td>
<td>Research methodology and IPR</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Laboratory- I</td>
<td>Regulatory Practice and Documentation Lab</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Laboratory- II</td>
<td>Drug Regulation and Registration Lab</td>
<td>0</td>
<td>4</td>
<td>0</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><strong>TOTAL</strong></td>
<td><strong>16</strong></td>
<td><strong>0</strong></td>
<td><strong>8</strong></td>
<td><strong>18</strong></td>
<td></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>Regulatory aspects of medical devices</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Core-IV</td>
<td>Regulatory aspects of herbals and biologicals</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Elective-III</td>
<td>1. Regulatory aspects of food and Nutraceuticals</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Biostatistics and Research Methodology</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>3. Nano based Drug delivery systems</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Professional Elective-IV</td>
<td>1. Clinical research and Pharmacovigilance</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2. Nutraceuticals</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>3. Advanced Drug Delivery Systems</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Laboratory- III</td>
<td>Regulatory aspects of herbals and biologicals Lab</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Laboratory- IV</td>
<td>Regulatory aspects of medical devices Lab</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>--</td>
<td>Mini Project with Seminar</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><strong>Total</strong></td>
<td><strong>16</strong></td>
<td><strong>0</strong></td>
<td><strong>8</strong></td>
<td><strong>18</strong></td>
<td></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
GOOD REGULATORY PRACTICE (Professional Core - I)

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

Course Outcome: At completion of this course it is expected that students will be able to understand
- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
- Prepare for the readiness and conduct of audits and inspections.

UNIT - I

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

UNIT - III

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

UNIT - V
Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

TEXT AND REFERENCE BOOKS:
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance by Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol. 150.
6. Drugs & Cosmetics Act, Rules & Amendments
Course Objectives: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

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

UNIT I
Drug Regulatory Aspects (India)
1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC & BE studies
5. Various 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
INTELLECTUAL PROPERTY RIGHTS (Professional Elective - I)

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

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

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

UNIT - II

UNIT - III

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

UNIT - V
a. Patent in validation process in India, US and Europe
b. IPR related to copyright, trade mark, trade secret and geographical indication.
c. Patent application writing
d. Claim construction and claims.
RECOMMENDED BOOKS:
1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P. Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
10. Drugs and Cosmetics act by Vijay Malik
12. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
Course Objectives: Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

Course Outcomes: Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist. It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

UNIT - I
Concepts and Philosophy of TQM, GLP, GMP (orange guide).

UNIT – II
Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

UNIT - III

UNIT - IV
Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratogenicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials. Quality assurance standards as per ISO.

UNIT - V
Globalization of drug industry, present status and scope of pharmaceutical industry in India. WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

TEXT AND REFERENCE BOOKS:
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
8. OPPI-Quality Assurance, USP.
9. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
10. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu and marayya
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
- Carry out 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
STABILITY OF DRUGS AND DOSAGE FORMS (Professional Elective - II)

Course Objectives: 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 evaluation of stability during storage, by solution and solid state, against several factors of degradation.

Course Outcomes: The students should describe the evaluation of stability of solutions, solids, and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT - I
Drug decomposition mechanisms:
1. Hydrolysis and acyl transfers: Nature of reaction, structure and utility, stabilization of pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, interest inhibition of oxidation

UNIT - II
Solid state chemical decomposition: Kinetics 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:

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.
11. Stability of Drugs and Dosage Forms by Yoshioka and Stella.
PHARMACEUTICAL FORMULATION TECHNOLOGY (Professional Elective - II)

Course Objective: Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

Course Outcome: Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

UNIT - I:
Preformulation: Goals of preformulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.
Flow of Powders: Physical properties and importance. Angle of repose, Cars index, compressibility, bulk density, tapped density.

UNIT - II:

UNIT - III:
Tablets: Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.
Tablet coating: Types of coating, steps involved in coating process-pan coating and fluid bed coating and problems associated with coating.
Hard Gelatin Capsules: General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

UNIT - IV:

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

TEXT BOOKS:
1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
6. Pharmaceutical statistics by Bolton Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

REFERENCE BOOKS:
1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
5. Dispensing for Pharmaceutical Students by SJ Carter.
Course Objective: This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Course Outcomes: Upon completion of the course the student shall be able to,
- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

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

UNIT - II

UNIT - III

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

UNIT - V
TEXT AND REFERENCE BOOKS:
1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth,
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges,
   Stephen
5. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana
6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al
   Endres, Wiley, 2000
7. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases,
   By Jiju Antony; David Preece, Routledge, 2002
8. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and
   Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler;
   Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
9. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum
   Books, 2001
    By Christine Avery; Diane Zabel, Routledge, 1997
    Publications
13. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes,
    2009, ASQ Publications
    Program (MDSAP)
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:
REGULATORY PRACTICE AND DOCUMENTATION LAB (Laboratory - I)

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

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

UNIT-IV:

UNIT-V:

TEXT BOOKS/ REFERENCES:
JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm (Pharmaceutical Regulatory Affairs)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

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

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

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

UNIT-II:

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:
**Election Commission**: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.
TEXT BOOKS/ REFERENCES:
1. The Constitution of India, 1950 (Bare Act), Government Publication.
PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

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

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

UNIT-I:

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

UNIT-III:
Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the 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:


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

Prerequisite: None

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

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

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

UNIT-II:
Yam and Niyam.

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

UNIT-IV:
Asan and Pranayam

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

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