# SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

**Program Code: 885 M. Pharm. (Pharmaceutical Analysis & Quality Assurance)**

**2015 – 16**

## SEMESTER - I

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Hours/Week</th>
<th>Credits</th>
<th>Marks</th>
<th>Duration of Exam</th>
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<tr>
<td>PY.09.884.11.T</td>
<td>Pharmaceutical Analytical Techniques</td>
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**SEMESTER - II**

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* Discipline Centric – Pharmaceutical Packaging Technology / Drug Polymer Technology; Open – Quality Assurance & Management.

## SEMESTER – III

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510 24 300 17

Chairperson, BoS
Head of the Department
Dean of the Faculty
PHARMACEUTICAL ANALYTICAL TECHNIQUES

<table>
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<tr>
<th>Scheme of Instruction</th>
<th>Scheme of Examination</th>
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<td>Total Duration</td>
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Course Objectives:
To familiarize students in conventional and modern techniques of analysis used in different areas of pharmacy.
To understand the experimental concepts, the procedures and safety considerations in a quality control laboratory.
To give training in use of the technique and its applications in day to day practice.
To build on the basics learned at UG level and give latest advances in the area.

Course Outcomes:
By pursuing this course students are prepared for:
- Research and Development
- Food, Bio and Pharma Industries
- Clinical Research and Quality Control Administration

Unit - I :


Unit - II :

Mass Spectrometry: Basic principles Mass Spectrometry. Ionization techniques (El and CI), Mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes and Mc-Lafferty Rearrangement, Nitrogen Rules, Relative abundances of isotopes and their contribution to characteristic peaks and molecular formula determination.

Unit - III :
Chromatographic Techniques: General Principles, Classification of Chromatographic Methods Thin Layer Chromatography, Paper Chromatography and Column Chromatography and Methods based on Mechanism.

Gas Chromatography: Instrumentation, Column efficiency parameters, derivatization methods, applications in Pharmaceutical Analysis.

Unit - IV:

**Electrophoresis:** Principles, Instrumentation and Applications of Moving Boundary Electrophoresis Zone Electrophoresis (ZE), Isoelectric Focusing (IEF), Continuous Electrophoresis (Preparative) and Capillary Electrophoresis. SDS Gel Electrophoresis and Blotting Techniques.

**Radio Immuno Assay (RIA) and ELISA:** RIA- General Principles, Scope of Limitations of Insulin and Digitalis, ELISA - Instrumentation, Principle and Application for Analysis of Drugs

Unit - V:

**X-Ray Spectroscopy:** Origin of X-rays, basic aspects of crystals, X-ray crystallography, Miller indices, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

**Thermal Analytical Techniques:** Principles, Theory and Application of Thermal Analysis (DSC, DTA and TGA)

**Books and References:**
PHARMACEUTICAL PRODUCT DEVELOPMENT

Course Objectives:
This subject imparts overall theoretical knowledge on formulation development of dosage forms and its stability. The student learn about various physical and pharmaceutical parameter/properties of raw materials, drug substances and excipients to be studied and optimized in the pharmaceutical product development.

Course Outcomes:
The students after undergoing their course work shall become thorough in understanding the influence of various physical and pharmaceutical properties of drug substance, raw material and excipients. They shall become aware of various parameters to be studied and number of experiments to be conducted to develop the optimized formulation.

Unit - I: Pre-formulation (API): Influence of melting point, dissolution constant, pharmaceutical salts and hygroscopicity, physical forms of drugs, Methods of preparation and characterization.


Unit - II: Formulation Additives: Study of different types of additives e.g. antioxidants and preservatives, coloring and flavoring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents.

Pre-formulation (Excipients Science): Tablet excipients, factors influencing selection of excipients, directly compressible excipients, co-processing of excipients, determination of functionality tests of excipients, flow properties, compression properties, drug-excipient compatibility, methods of evaluations;

Unit - III:
Solubility: Importance, experimental determination, aqueous solubility aspects in pre-formulation, intrinsic solubility, phase-solubility analysis, pH solubility profile.


Unit - IV:

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & Tablets). Solid state stability and shelf life assignment. Stability Protocols and Reports;
Unit - V :


**Novel Drug Products:** Nano-Pharmaceuticals - Generation and Significance of Nano-suspensions, Nano-gels, Nano-carrier Systems;

**Books and References:**

QUALITY CONTROL OF HEALTH RELATED PRODUCTS

Scheme of Instruction

| Total Duration : 60 Hrs. |
| Hours/Week : 4 Hrs. |
| Credits : 4 |
| Instruction Mode : Lecture |
| Course Code : PY.09.885.13.T |

Scheme of Examination

| Max. Marks : 100 |
| Mid Semester : 20 |
| Quiz : 05 |
| End Semester : 75 |
| Exam Duration : 3 Hrs. |

Course Objectives:

This subject is aimed at giving knowledge about different quality control tests for analysis of cosmetics, Herbal products, Biological products, food constituents and Nutraceuticals. This knowledge will be helpful in evaluation/quality control of prepared finished products. Students know about procedures and different guidelines used for analysis of health related products.

Course Outcomes:

After the students have undergone the course work, they shall become acquainted with application of principles of pharmaceutical analysis for quality control of various products as mentioned in the above units.

Unit - I :

Quality Control of Cosmeceuticals: Hair care products (shampoo and hair dyes), baby care products (Oils, Creams, Powders and Shampoos), Personal Hygiene Products (shaving creams, after shave lotions and soaps), eye care products (eye shadows, eye liners, and eye brow pencils).

Unit - II :

Quality Control of Herbal Products: Quality control of crude drugs (WHO guidelines) - Determination of Ash value and extractive matter, foreign matter, bitter value, haemolytic activity, swelling index, foaming index, pesticide residues and MO's, UV and fluorescence analysis of powdered drugs, and micro-chemical tests.

Unit - III :

Quality Control of Biological Products: Biological assays of the following.
2. Enzymes: Streptokinase, Urokinase.
3. Antitoxins: Diphtheria, Tetanus.

Unit - IV :

Quality Control of Nutraceuticals: Vitamins (A, B1, B2, B12, C, D, E and K), Micro Nutrients and Health Supplements.

Unit - V :


Books and References:

# INSRUMENTAL METHODS OF ANALYSIS

## Scheme of Instruction

<table>
<thead>
<tr>
<th>Total Duration</th>
<th>Hours/Week</th>
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<td>4 Hrs.</td>
<td>4</td>
<td>Lecture</td>
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## Scheme of Examination

<table>
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<th>Max. Marks</th>
<th>Mid Semester</th>
<th>Quiz</th>
<th>End Semester</th>
<th>Exam Duration</th>
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<td>05</td>
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## Course Objectives:

This subject is aimed at giving in-depth knowledge about different instrument/equipment based analytical principles and their application in characterization of formulations, excipients, interaction & compatibility studies.

- To give more stress on application based knowledge than instrumentation based one.
- To give hands on training on use of as many different sophisticated instruments as possible.

## Course Outcomes:

After the students have undergone this course, they shall acquire knowledge on theoretical aspects and interpretative skills of various instrumental methods of analysis. This knowledge and skills will help the students in understanding the application of these methods in formulation development of various dosage forms.

## Unit - I


## Unit - II

**Potentiometry and pHmetry:** Principles, Measurement and Applications – Potentiometry; Electrodes, Cells, Cell Potential, Measurement of pH, End Point Evaluation Methods, Null Point.

**Conductometry and Amperometry:** Principles, Instrumentation, Measurement and Applications - Conductivity Conductance, Equivalent and Molar Conductance, Wheatstone Bridge Principle and Amperometry.

## Unit - III

**Spectrophotometry:** Principles, Instrumentation and Applications of Raman, Laser, Plasma, Atomic Absorption Spectroscopy and Flame Photometry.

**Spectro-fluorimetry:** Theory, Instrumentation and Applications of Fluorescence, Phosphorescence, Chemiluminescence.

## Unit - IV

**Hyphenated Techniques:** Theory, Principle, Instrumentation and Applications LC-MS, GC-MS, MS-MS and LC-NMR in Pharmacy;

**Particles Size Analysis:** Theory, Principle, Instrumentation and Applications of Zetameter, Photon Correlation Spectroscopy, Counter-Counter Apparatus,

## Unit - V

**Pharmacopeial Methods of Analysis:** Physical Tests; Limit Tests; Special Tests; Dissolution Tests; Stability Tests; Miscellaneous Tests; Microbial Assays

**Sample Preparation for Analysis:** Different Techniques of Sample Preparation from Body fluids, Tissue Extracts, Cell culture Extracts and Phyto-chemical Extracts.
Books and References:
QUALITY ASSURANCE

Scheme of Instruction

<table>
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Scheme of Examination

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Course Objectives:

Achieve comprehensive understanding and acquiring professional competency in global quality standards systems and regulatory requirements in the pharmaceutical industry.

Develop and implement a robust quality assurance system in an organization towards quality excellence.

Course Outcomes:

This subject is aimed at giving knowledge about concepts of quality assurance,

- Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution,
- Address quality issues and provide solutions needed to attain quality leadership in an environment of continual improvement.
- Understand the importance of effective documentation and formula for various operating procedures in Pharmaceutical industry.

Unit - I :

Basic Quality Assurance Systems: Basic concept of quality control & quality assurance, functions, sources of variation, quality assurance for raw materials, APIs, packing materials & finished products (specifications, receipt, testing, sampling and certificate of analysis), production (change control, aseptic process control, temperature, pressure & humidity control tests, tests for air flow pattern, microbiological monitoring) buildings & facilities (design and construction features, construction materials, lighting, air handling systems, sanitation & maintenance) equipments (construction, cleaning and maintenance, calibration & handling).

Unit - II :

In-Process Quality Control: Importance, inspection, IPQC tests for tablets (weight variation, hardness, thickness, friability, disintegration tests and content uniformity), suspensions and emulsions (appearance and feel, volume check, viscosity, particle size distribution, electrical conductivity and content uniformity) and parenterals (pH, volume check, clarity, content uniformity, integrity of seals and particulate matter). Problems encountered and trouble shooting.

Unit - III :


Audits: GMP compliance audit, Definition summary, Audit policy, Internal and External Audits, Second Party Audits, External third party audits.

Unit - IV :


Documentation: Good Documentation Practices, Route Cause Analysis, Corrective Action Preventive Action (CAPA), Out of Specifications (OOS) and Out of Trend (OOT);
Unit - V:

**Impurity Profile:** Sources of impurities, their Effect on Drug Stability and Therapeutic Action. Determination of Impurities in Bulk Drugs and Formulation - Isolation, Characterization, Analytical Methods and Guidelines as per ICH and WHO for Impurity and Related Substances, Concept of Purity Angle, Threshold and Flag;

**Study of Compendia:** Evolution, Study of parts of Compendia like: Policies, General Notices, Monographs, Comparative Picture of IP, USP, BP.

**Books and References:**

7. Mehra ML. Good Manufacturing Practices (GMP), University Book Agency.
9. D.A. Berry, Statistical Methodology in Pharmaceutical Science, Marcel Dekker, NY.
PHARMACEUTICAL ANALYTICAL TECHNIQUES

Course Objectives:
To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy.

Course Outcomes:
At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug products.

List of Experiments:

1. UV/Visible spectrum scanning of a few organic compounds for UV absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV Spectrophotometer in formulations (2 experiments).
4. Experiments based on the application of derivative spectroscopy (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
9. Any other relevant experiments based on theory.

Books and References:
PHARMACEUTICAL PRODUCT DEVELOPMENT

Scheme of Instruction

Total Duration : 60 Hrs.
Hours/Week : 4 Hrs.
Credits : 2
Instruction Mode : Practical
Course Code : PY.09.886.12.P

Scheme of Examination

Max. Marks : 100
Mid Semester : 20
Quiz : 05
End Semester : 75
Exam Duration : 6 Hrs.

Course Objectives:

To acquaint in analyzing the physical parameters required in pharmaceutical product development.

Course Outcomes:

To develop capacity to explain the differential principles applies to solve the physical parameters associated with product development.

List of Practical's:

1. Effect of surfactants on the solubility of drugs.
2. Effect of pH on the solubility of drugs.
3. Dissolution methods of transdermal drug delivery systems.
4. Dissolution studies of drug in three different biorelevant dissolution media (2 experiments).
5. Effect of solid dispersion and hydrotrropy on the dissolution.
6. Test for degradation of compounds using TLC for any two drugs.
7. Stability testing of solution and solid dosage forms for photo degradation (2 experiments).
8. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
9. Stability studies of drugs in dosage forms at 25 °C, 60% RH and 40 °C, 75% RH.
10. Compatibility evaluation of drugs and excipients.
11. Product development and protocol preparation using pre-formulation data for tablets and capsules.
12. Dissolution of drugs in different pH media for comparison of performance with innovator.

Books and References:
INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS

Course Objectives:
To make students familiar with the fundamental principles of IPR and Drug Regulatory Affairs

Course Outcomes:
On completion of the course the student would understand the principle and importance of IPR and Drug Regulatory Affairs in the Competitive World.
Further to familiarize with Safety and Pollution Control Regulations in addition to Other Product Regulations and Sustainable Development Principles.

Unit - I:

Unit - II:
International Patent Filing Procedures—Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system.

Unit - III:
ICH—Guidelines: Harmonization Efforts, Basic Principles (Quality, Safety and Efficacy), ICH Q11 (Quality Management Systems); Common Technical Document (CTD) and Generic Drug Products.
WHO—Guidelines: Sampling Operations
PICS Guidelines: Basic Requirements of Medicinal Products and APIs
OECD Guidelines: Clinical Studies

Unit - IV:
Regulatory Affairs: Indian Context- Drugs and Cosmetics Act 1940 and Rules 1945 with reference to Schedule M, U and Y. Drug Regulatory Controls and Authorities;
Important Regulations: Import and Export of Drugs; Preparation and Submission of Marketing Application of India, US and Europe; Approval and Appeals Present and Issues of Confidentiality.
Unit - V

**Industrial Safety Regulations**: Industrial Development & Regulation Act 1951, Industrial Hazards – Mechanical, Electrical, Chemical and Pharmaceutical (MSDS Preparation), Industrial Safety - Plant, Gas, Dust, Fire and Explosion, Safety Management. Monitoring & Prevention Systems,

**Pollution Control Regulations**: Pollution Control Act; Industrial Effluent Testing & Treatment. Control of Environmental Pollution, Water and Solid Waste in Formulation, Synthetic and Fermentation Plants.

**Other Product Regulations**: Prevention of Food Adulteration Act 1954; Consumer Protection Act

**Sustainable Development**: 10 Principles Bench Marked against leading International Standards;

**Books and References:**

8. Original Laws Published by Government of India.
9. Hussain. Law of Drugs in India.
10. Regulatory Guidelines Related to GMP by
   b. 21 Code of Federal Regulation, parts 210, 211 & 58. (US-FDA Guidelines)
   c. MHRA, UK Guidelines on GMP
   d. GMP Guidelines by Medicines Control Council of South Africa
   e. Schedule M of D & C Act
13. PICS Guidelines (Website: http://www.picscheme.org/)
15. Relevant OECD Guidelines (Website: http://www.ingentaconnect.com/content/oecd/16073/2001/00000001/00000004
# Analytical Method Validation

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<td>PY.09.885.22.T</td>
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## Course Objectives:

Develop and validate analytical and bioanalytical methods for pharmaceuticals vis-a-vis regulatory compliance. Understand the latest internationally recognized standards and developments in analytical assurance.

## Course Outcomes:

To equip students with comprehensive knowledge on regulatory aspects of analytical techniques.

### Unit - I

**Analytical Validation:** Introduction; History; Definition; Types of Validation; Prospective Validation, Retrospective Validation, Concurrent Validation, Revalidation, Validation Master Plan and Validation Protocol.

### Unit - II

**Analytical Procedures Validation:** Needs, Types, Accuracy, Precision, Linearity, Robustness, Specificity, Ruggedness, System suitability Parameters, LOQ, and LOD; Sources of Errors, Use of Significant Figures and their Correct Usage as per ICH Guidelines, USP requirement of Analytical Validation Different Category of Assays.

### Unit - III

**Development of Analytical Method Validation:** Introduction, Calibration, Performance, Maintenance and Validation of various Analytical Instruments such as Analytical Balance, UV-Visible Spectrophotometer, FT-IR Spectrophotometer, GC, HPLC, GC-MS and LC-MS.

### Unit - IV

**Drug Analysis in Biological Matrices:** Selection and Quantification of Biological sample, Extraction of Drugs by Various Methods as LLE, SPE and Membrane Filtration, Factors affecting Extraction of Drugs;

**Bio Analytical Method Validation:** Full Validation; Partial Validation and Cross-Validation.

### Unit - V

**Utilities Validation Methods:** Methods of Validation for the Following Utilities – Pharmaceutical Water Systems – DM Water Validation, AHU Validation, HVAC System and Sterilization Validation;

**Cleaning Validation (CV):** Validation of Cleaning Process; Elements of Validation Protocol; Determination of Acceptable Limits for Cleaning Process; Factors to consider in setting the Limits; Numerical Calculation of Limits.

## Books and References:

7. Mehra ML. Good Manufacturing Practices (GMP), University Book Agency.
QUALITY CONTROL METHODS

Scheme of Instruction

Total Duration : 60 Hrs.
Hours/Week : 4 Hrs.
Credits : 2
Instruction Mode : Practical
Course Code : PY.09.885.23.T

Scheme of Examination

Max. Marks : 100
Mid Semester : 20
Quiz : 05
End Semester : 75
Exam Duration : 6 Hrs.

Course Objectives:

To equip student to be professionally competent to achieve global quality standards in the pharmaceutical industry.

Course Outcomes:

At the end of the course the student is able to apply the knowledge of quality control methods to enhance the market value of the drug products

Unit - I :

Qualitative Analysis Functional Groups of APIs: Analytical principles, procedures and applications involved in the use of the following reagent based function group analysis.

a) MBTH (3-methyl-2-benzothiazoline hydrazone).
b) Folin – Ciocalteu (FC) reagent.
c) 2,6- Dichloroquinone chlorimide.
d) 2,3,5- Triphenyl tetrazolium salt.
e) 1,2- naphtho quininone -4- sulfonate.
f) Bratton-Marshall reagent.
g) PDAC (P-Dimethyl amino cinnamaldehyde).
h) PDAB (P-Dimethyl amino benzaldehyde).

Unit - II :

Quantitative Analysis of Functional Groups: Principles and Procedures involved in Quantitative Determination of the following functional groups:

A) Hydroxy B) Aldehyde C) Ketone D) Amine E) Methoxy F) Ester G) Carboxyl

Unit - III

Quantitative Analysis of Drugs in Dosage Forms: Principles and procedures involved in the analysis of drugs in dosage forms:

A) Anti-bacterial (penicillins, erythromycin) and fluoroquinolones
B) Steroids (cholesterol, progesterone, and androsterone);
C) Anti-inflammatory drugs (nimusuline, diclofenac. Ibuprofen and indomethacin);
D) Anti-hypertensive drugs (propranolol, levodopa); and
E) Anti-diarrhoeals (metronidazole, tinidazole).

Unit - IV :

Quality Control of Excipients: Tests related to excipients (disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives) such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range, including preservative challenge test.
Unit - V :


Books and References:

7. Indian Pharmacopoeia. Controller of Publication, Delhi, 2007
Biological Standardization

Scheme of Instruction

<table>
<thead>
<tr>
<th>Total Duration</th>
<th>Hours/Week</th>
<th>Credits</th>
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Scheme of Examination

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<td>05</td>
<td>75</td>
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Course Objectives:

To train students about various biological evaluation methods & the significance of such tests.

To impart knowledge about official / non-official methods of evaluation for a wide range of drug dosage forms.

To give them training in carrying out some of these techniques in the laboratory.

Course Outcomes:

At the end of the course the student acquire the wide exposure to students in the area of New Chemical Entity pre-clinical evaluations and related areas.

Unit - I : Detailed Study of Principles and Procedures Involved in Bioassay of

1. Heparin, Insulin, Posterior Pituitary; 2. Diphtheria, Typhoid

Unit - II : Principles and Procedures involved in Biological Tests of the following


Unit - III : Microbiological Assay

1. Vitamins - Cyano-cobalamine; 2. Antibiotics such as Neomycin Sulfate; 3. Vaccine - Diphtheria

Unit - IV : Biological Assay and Pyrogen Assay

Overview, types – direct, indirect and assay based on quantal responses, parallel line bioassays, bench top and primary bioassay screening, statistical principles in bioassay- randomization, replication and elimination of variation; Preservative efficacy, Antimicrobial Effectiveness testing as per USP; Evaluation of Oxytocin, Rabies Vaccine and Tetanus Antitoxin; Production, Chemistry, Properties and Tests of Bacterial Pyrogens and Endotoxin;

Unit - V : Bioassay of Biologics


Books and References:

1. Indian Pharmacopoeia 2007, Controller of Publications, Govt. of India, New Delhi.
2. Bochman & Hassan, Pharmaceutical Analysis, edited by Higuchi.
4. RV Smith, JT Stewart, Textbook of Biopharmaceutical Analysis.
6. British Pharmacopoeia, Department of Health, UK.
ELECTIVE

PHARMACEUTICAL PACKAGING TECHNOLOGY

Scheme of Instruction

Total Duration : 60 Hrs.
Hours/Week : 3 Hrs.
Credits : 3
Instruction Mode : Lecture
Course Code : PY.09.885.25.T

Scheme of Examination

Max. Marks : 100
Mid Semester : 20
Quiz : 05
End Semester : 75
Exam Duration : 3 Hrs.

Course Objectives:

To develop understanding and provide scientific basics of the packaging technology
To understand the types of packaging and improve the standards of packaging technology

Course Outcomes:

To appreciate the importance of Pharmaceutical Packaging Technology

Unit - I

Pharmaceutical Packaging: Purpose of packaging, prerequisites of an ideal package, various types of inner and outer packages used for different pharmaceutical dosage forms, selection of a suitable package, storage temperature, hazards encountered by the package during storage and distribution.


Flexible Packaging: Types of films, co-extruded films, foils, coating and laminates, shrink and stretch films.

Corrugated and Solid Fiber Boards and Boxes: Type of corrugation methods.

Caps and Closures: Types; caps, closures, liners, child resistant caps, elastomeric closures for parenterals,

Unit - II

Glass Containers for Pharmaceuticals: Glass types, their chemical performance, testing and quality control.

Plastics Containers for Pharmaceuticals: Classification of plastics, plastic polymers and their physicochemical, mechanical and biological properties; Additives and fabrication processes. Plastic container for parenterals and transfusion sterile drip kits. Quality control testing and biological toxicity.

Paper and Paper Board: Types of paper, folding cartons, quality control testing of paper and paper board.

Metal containers: Aluminum & Tin Plate Drums, Collapsible Tubes & Aerosol Containers, Lacquering, Coating & Lining.

Unit - III

Sterile product packaging: General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machinery. Limitations and merits of various packages. Evaluation of the sterile product packages.

Environmental Considerations: Packaging and recycling of packaging materials along with national and international regulations

Unit - IV

Packaging Machinery: Introduction, strip packaging machinery, form, fill and seal machines, liquid and solid filling machines, capping machines, machinery employed for liquid formulation packaging.

Advances in Packaging Technology: Blister packaging, tamper evident packaging systems, child resistant packaging, aerosol packaging, etc.
Unit - V

Labels and Labeling: Objectives and contents of a pharmaceutical label. Types of label (including bilingual label, bar code label, radiofrequency(RF) label, structured program label, in-mould label and decorative labels), legal requirements of labeling, packaging inserts and outserts. Adhesives and machinery employed for labeling. Concept of paperless labeling and new developments in labeling technologies.

Books and References:
6. Herrickson R. Remington The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 21st Ed.
ELECTIVE

QUALITY ASSURANCE AND MANAGEMENT

<table>
<thead>
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<th>Scheme of Instruction</th>
<th>Scheme of Examination</th>
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**Course Objectives:**

Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.

Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement. Understand the importance of effective management and documentation.

**Course Outcomes:**

To equip student to be professionally knowledgeable to sustain global quality standards and productive management output in the pharmaceutical industry.

**Unit - I:**


**Unit - II:**

**Equipment Qualification (EQ):** Design Qualification (DQ); Installation Qualification (IQ); Operating Qualification (OQ) and Performance Qualification (PQ)

**Standard Operating Procedures (SOP):** Operations like Cleaning, Filling, Drying, Compression, Coating, Disinfection, Sterilization, Membrane Filtration etc.

**Total Quality Management (TQM):** Principles, Elements of TQM, Continuous Improvement and Learning, Management Tools, Tools and Techniques of Quality, New Quality Tools and Techniques

**Unit - III:**

**Inventory Management:** Costs, Inventory Categories, Selective Inventory Control, Reorder Quantity Methods and EOQ, Inventory Models, Safety Stock-Stock Out, Lead Time–Reorder Time Methods, Modern Inventory Management Systems, Inventory Evaluation.

**Materials Management:** Introduction; Purchasing; Raw Materials; Packaging Materials; Intermediate and Bulk Products; Finished Products; Rejected and Recovered Materials; Recalled Products; Returned goods; Reagents and Culture Media; Waste Materials; Reference standards; Miscellaneous Materials;

**Unit - IV:**

**Human Resources Management:** Introduction; Qualification Experience and Training; Responsibilities and Key Personnel; Personal hygiene and clothing; Legal Aspects; Consultants

**Facilities Management:** Introduction; Principal Area; Plumbing and Drainage system; Lighting; Ventilation; Heating; Air-Conditioning; Sewage, Refuge and Disposal of Water; Washing and Toilet Facilities; Sanitation; Maintenance; Utilities; Water, Power, Steam; Vacuum; Air; Gases, etc.,
Unit - V:


Documentation and Records: Introduction; Specifications; Master Production and Control Record; Batch Production and Control Record; Important SOPs and Record; Change Control; Site Master File; Change control format; Product complaint document; Internal audit document; Product recall document; IPQC document; Material receipt; Sampling; Dispensing & Storage document;

Books and References:

7. Mehra ML. Good manufacturing practices (GMP), University Book Agency.

11. Regulatory Guidelines Related to GMP by
   b. 21 Code of Federal Regulation, parts 210, 211 & 58. (USFDA guidelines)
   c. MHRA, UK Guidelines on GMP
   d. GMP Guidelines by Medicines Control Council of South Africa
   e. Schedule M of D & C Act

# ELECTIVE
## DRUG POLYMER TECHNOLOGY

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**Course Objectives:**

*To know and understand the importance of polymers use in drug development*

**Course Outcomes:**

*To acquaint with the knowledge of significance of polymers in drug development.*

**Unit - I :**

**General Study of Polymer Science:** Classification of polymers, Macromolecules: structure and properties (molecular mass, molecular weight, distribution, conformation and configuration). Major strategies for synthesis of polymers, general methods of preparation of polymers like solution, bulk, suspension and emulsions, polymerizations with examples. Methods of polymer modification, Solid state properties of polymers, flow characteristics, crystallinity.

**Unit - II :**

**Evaluation of Polymers in Solution:** Polymers in solutions; Solubility of polymers, methods of polymer characterization in solution (thermodynamics of polymer solutions). Viscosity and viscoelasticity of polymers, polyelectrolytes and polyampholytes, cross-linked polymers and polymer complexes.

**Unit - III :**

**Therapeutic Applications of Polymers:** Polymers for therapeutic applications, biocompatible and biodegradable polymers, biodegradability and biodegradability testing of polymers, applications of biodegradable polymers in parenterals and surgicals, polymer-drug conjugates, self-assembled polymeric carriers (polymeric micelles, polymer-coated liposomes, nanoparticles, microspheres, etc.)

**Unit - IV :**

**Bio interactions of Polymers:** Interactions of polymers with tissues and cells, Pharmacokinetics of polymer therapeutics, targeted polymer therapeutics, passive targeting of polymeric drugs, enhanced permeation and retention effect (EPR), functional excipients and biological response modifiers, polymeric immune-adjuvants and immune-modulators, stimuli responsive systems and intracellular drug delivery.

**Unit - V :**

**Polymer Drugs and Regulatory Issues:** Prospects of Polymer Drugs and Regulatory Challenges in Polymer Therapeutics

**Books and References:**

1. J. Brandrup, E. H. Immergut; Polymer Handbook; John Wiley and Sons
7. Biomedical Polymers and Polymer Therapeutics, Eds. E. Chiellini et. al., Kluwer Charles
8. G. Gebelein, T. C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
9. D. S. Soane; Polymer Applications for Biotechnology; Prentice Hall Inc.
11. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications.
12. P. J. Tarcha; Polymers for Controlled Drug Delivery; CRC Press.
15. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. A. V. Kabanov,
ANALYTICAL METHOD VALIDATION

Scheme of Instruction

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<th>Total Duration</th>
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Scheme of Examination

| Max. Marks | 100 |
| Mid Semester | 20 |
| Quiz        | 05  |
| End Semester | 75 |
| Exam Duration | 6 Hrs. |

Course Objectives:

To provide the basic principles involved in the Analytical Method Validation

Course Outcomes:

To understand the significance of Analytical Method Validation

1. Analytical method validation for the parameters accuracy, precision, repeatability, specificity, system suitability, selectivity and robustness for the following drugs/formulations by UV-Visible Spectroscopy and HPLC. (7 Expts)
   a. Paracetamol tablets
   b. Diclofenac sodium gel.
   c. Cetirizine syrup.
   d. Metronidazole infusion.
   e. Chloramphenicol capsules.
   f. Ibuprofen and Paracetamol tablets
   g. Paracetamol and Diclofenac sodium tablets.

2. Validation of following equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine

3. Validation of a processing area

4. Validation of at least two analytical instruments.

5. Cleaning validation of one equipment.

6. Identification of impurities in drug substances by TLC and LC method - Aspirin, Paracetamoland Ranitidine HCl. (3 Expts)

7. Stability indicating assays for Ranitidine HCl and Aspirin by LC method. (2 Expts)

8. Limit test for heavy metals of herbal preparations - Arsenic, lead, cadmium and mercury. (2 Expts)

9. Determination of residual solvents by GC. (2 Expts)

Books and References:

1. Ira R. Berry & Robert Nash, Pharmaceutical Process Validation, Second Edn, Marcel Dekker Inc.


QUALITY CONTROL METHODS

Scheme of Instruction

<table>
<thead>
<tr>
<th>Course</th>
<th>Total Duration</th>
<th>Hours/Week</th>
<th>Credits</th>
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Scheme of Examination

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<th>End Semester</th>
<th>Exam Duration</th>
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<tr>
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<td>05</td>
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<td>6 Hrs.</td>
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Course Objectives:

To learn and understand the conceptual and experimental basics of quality control methods

Course Outcomes:

To ensure the quality of drugs and drug formulations

List of Experiments:

1. Qualitative and Quantitative Analysis of Some Pharmaceutical Dosage Form using the following reagents and reactions.
   a. Oxidative Coupling Reaction using 3-Methyl – 2 – Benzothiazolinone hydrazone (MBTH)
   b. Condensation Reaction using the Reagent
   c. p-Dimethyl Amino Cinnamaldehyde (PDAC)
   d. Folin Ciocatecu (FC) Reagent
   e. Diazotization followed by Coupling Reaction
   f. Oxidation followed by Complexation Reaction
2. Analysis of Active Pharmaceutical Ingredients (API)
3. Quality Control Tests of Packaging Materials
4. Identification of Impurities and related substances in APIs (Albendazole, Metronidazole, Diclofenac, Paracetamol, Aspirin, Ibuprofen)
5. Detection and Quantitative Determination of Antioxidants and Preservatives
6. Effectiveness of Anti-Microbial Preservatives (Preservative Challenge Test)
7. Evaluation of Congealing Temperature, Gelling Temperature, and Swelling Temperature of Excipients
8. Determination of Viscosity of Excipients using Brook-Field Viscometer
9. Simultaneous Estimation of Drugs in fixed dose combinations
10. Experiments based on Gel Doc System for Protein based Drugs

Books and References:
SAIL

SCIENTIFIC AND TECHNICAL WRITING

Scheme of Instruction

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Scheme of Examination

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<td>Exam Duration</td>
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Course Objectives:

To be able to appreciate and understand importance of writing scientifically.

- To develop competence in writing and abstracting skills.
- To write either a draft research proposal or a chapter of dissertation.

Course Outcomes:

Able to prepare a document with systematic approach.

Unit - I :

COLLECTION AND EVALUATION OF INFORMATION: Identification sources, searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

WRITING AS A MEANS OF COMMUNICATION: Different forms of scientific and technical writing: Articles in journals, Research notes and reports, Review articles, Monographs, Dissertations, Bibliographies.

How to formulate outlines: The reasons for preparing outlines

(i) as a guide for plan of writing (ii) as skeleton for the manuscript

Outline of topic, concept, sentence and combination of topic and sentence outlines

Unit - II :

DRAFTING TITLES, SUB TITLES, TABLES, ILLUSTRATIONS

- Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.
  - Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head
  - Appendices: use and guidelines

The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Re-reading

Checking: Organization, Headings, Content, Clarity and Grammar

Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE

Introduction, Review of Literature, Methodology, Results and Discussion

Content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

References:

SAIL

RESEARCH METHODOLOGY

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<td>: 1 Hr.</td>
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**Course Objectives:**

To give exposure on how to do literature survey for the project work.
To develop technical writing skills in the form of a research report.

**Course Outcomes:**

To able to organize the research in an effective fashion

**Unit – I**

**Basics of Research:** Definition, objectives, motivation, types of research and approaches; Descriptive research, conceptual, theoretical, applied and experimental.

**Formation of Research Problem:** Research Process: To determine what type of research to be done, plan of research work; Selection of research area, prioritization of research; Literature review: importance and methods, sources; Objectives and scope of work, developing research plan and schedule; Scheduling constraints, steps, problems in scheduling, limitations.

**Experimental Modeling:** Definition of experimental design, examples, single factor experiments, blocking and Nuisance factors, guidelines for designing experiments; General model of process: Input factors/ variables, Output parameters/ variables controllable/ uncontrollable variables, dependent/ independent variables, experimental validity; Introduction to Risk assessment, reliability, sustainability, and uncertainty.

**Unit – II**

**Analysis of Data:** Types of data: parametric and nonparametric, descriptive and inferential data; Collection of data: normal distribution, calculation of co-relation coefficient; Data processing: analysis, error analysis, meaning and different methods; analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity/nonlinearity of model, testing adequacy of model; Test to be used in data exploration and their choice; Introduction of software used in data analysis.

**Research Deliverables:** Various Forms of Publication: Thesis, paper, research proposal; Thesis Writing: Introduction, literature review/state-of-the-art, research approach (methodology), results/ findings, discussions, conclusions, scope for future work, references, appendices; Presentation: Poster, thesis, proposal, and paper.

**Ethical and Plagiarism issues in research:** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines/ herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments; Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography, end note.

**References:**

SAIL

TEACHING METHODOLOGY

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Course Objectives:

To acquaint with the basic tools of teaching to part of teaching profession

Course Outcomes:

Able to practice the teaching techniques for effective dissemination of knowledge

Unit - I :

Learning and Instruction: Principles of Instructional design and learning theory, Merrill’s five principles and Gagne’s condition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learning model of Kolb.

Curriculum Development: A six step approach. Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom’s Taxonomy, three domains of educational objectives.

Unit - II :

Assessment: Definition and methods, Georges Milers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.

Teaching Methods: Activities conducted individually, in pairs and in groups like self-introduction, peer introduction, group poster making, grammar and vocabulary games, etc. Discussions, Role play activities, Short presentations; Listening and viewing activities with follow up activities like discussion, filling up worksheets, writing exercises (using language lab wherever necessary/possible) etc.

References:

SAIL

ENTREPRENEURSHIP DEVELOPMENT

Scheme of Instruction

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Course Objectives:

To provide conceptual inputs regarding entrepreneurship management.
To sensitize and motivate the students towards entrepreneurship management.
To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.

Course Outcomes:

To develop management skills for entrepreneurship management

Unit - I

CONCEPTUAL FRAME WORK: Concept need and process in entrepreneurship development; Role of enterprise in national and global economy; Types of enterprise – Merits and Demerits, Government policies and schemes for enterprise development; Institutional support in enterprise development and management;

THE ENTREPRENEUR: Dynamics of Entrepreneurial Motivation: Concepts; Developing Entrepreneurial Competencies; Requirements and understanding the process of entrepreneurship development; self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur’s role.

Unit - II

LAUNCHING AND ORGANISING AN ENTERPRISE: Environment scanning – Information, sources, schemes of assistance, problems; Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis; Resource mobilization – finance, technology, raw material, site and manpower; Costing and marketing management and quality control; Feedback, monitoring and evaluation; Project work – Feasibility report; Planning, resource mobilization and implementation.

GROWTH STRATEGIES AND NETWORKING: Performance appraisal and assessment; Profitability and control measures, demands and challenges; Need for diversification; Future Growth – Techniques of expansion and diversification, vision strategies; Concept and dynamics; Methods, Joint venture, co-ordination and feasibility study;

References:

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COMPUTATIONAL TECHNIQUES

Scheme of Instruction

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Course Objectives:

Learn the organization of a digital computer.
Learn to think logically and write pseudo code or draw flow charts for problems.

Course Outcomes:

Be familiar with the use of Office software.
Be exposed to presentation and visualization tools as well as problem solving techniques and flow charts.

Unit - I

Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.
Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).
Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).
Software: Idea of popular software’s like MS Office, structure drawing software’s, chemical structure visualizing software’s, statistical software’s & mathematical software, reference managing software’s (only introduction).

Unit - II

Web page design: Need, concept and use of HTML
Databases: Meaning, Need and creating table, record creating and maintenance.
Internet concept: History, creating internet connection, common problems & solutions.

References:

4. www.Pubmed.com
5. www.Pubchem.com
6. www.mdl.com
10. www.uspto.gov
11. www.esp.gov
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Laboratory Design, Safety and Management

Scheme of Instruction

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Course Objectives:

To expose them to existing national safety standards
To acquaint with Laboratory Design and Management

Course Outcomes:

On completion of the course the student will be able to perform the Experiments as per cGLP norms.

Unit - I
Lab Design Criteria; Codes, Standards and References; Architectural Considerations, Walls, Doors, Windows, Security, Ceiling, Flooring, Cleanability, Sinks, Storage, Exit Paths, Engineering Considerations – Electrical, Plumbing, Utilities – Air, Water, Steam and Gases, Heating, Ventilation, Air Conditioning and Fume Hoods; Laboratory Furniture Design and Location; General Laboratory Safety Practices; Standard Operating Procedures (SOP’s);

Unit - II:
Management of Analytical Laboratory: Organization of Laboratories based on their types, staffing, skill development and training, budgeting and financing, purchase of costly equipment, qualities of laboratory manager and management styles.
Laboratory Inspections: Internal inspection, external audit, concepts, preparing for inspections and audits.
Reference standards: Types, preparation, containers, labeling, storage and use.
Documentation: STPs: Certificate of Analysis (COA.), Laboratory Note Books: Typical Documents used in a GLP Laboratory including Standard Test Protocols (STP’s);

References:
1. Laboratory Design Guidelines – University of North Carolina, USA
2. Laboratory Design Hand Book
4. Laboratory Design and Construction Guidelines (2010) – Department of Environment, Health and Safety, University of South Carolina, USA
5. Laboratory Safety Design Guide,(2007) – Department of Environment, Health and Safety, University of California, USA
6. Laboratory Safety Guidance,(2011) – OSHA, USA
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Creativity and Innovation

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Course Objectives:
To impart the knowledge of various aspects of Creativity and Innovation

Course Outcomes:
On Completion of the course the student will be able to understand the significance of Creativity and Innovation.

Unit - I
The process of technological innovation - factors contributing to successful technological innovation - the need for creativity and innovation - creativity and problem solving – brain storming - different techniques.

Unit - II
Patents - Patent search - Patent laws - International code for patents

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Employability Skills

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Course Objectives:
To enhance the employability skills of learners with a special focus on presentation skills, group discussion and interview skills.
To enable them to improve their soft skills necessary for workplace contexts.
To equip them with effective communicative competence for a global reach.

Course Outcomes:
Participate in conversations both formal and informal, attend phone calls and interviews successfully.
Read different types of texts and listen to, and understand foreign accents.

Unit - I

SPEAKING SKILLS: Conversational skills (formal and informal contexts) - telephonic communication, attending job interviews (responding to FAQs) - taking part in GDs - making presentations.
WRITING SKILLS: Job applications - cover letter - resume - applying online - writing proposals - e-Mails - letters - reports - memos - minutes - blogging - tweeting - writing recommendations and instructions - writing for publications.
READING SKILLS: Vocabulary building - speed reading (skimming - scanning) - reading different genres of texts from newspapers to philosophical treatises - critical reading - effective reading strategies such as reading 'beyond the lines', summarizing, graphic organizers and distinguishing facts from opinions.

Unit - II

LISTENING/VIEWING SKILLS: Speeches of different nationalities with focus on American and British accent (TED talks, podcasts) - listening to lyrics - lectures - instructions - dialogues - news casting - talk shows - interviews (Hard talk, Devil’s Advocate)
SOFT SKILLS: Motivation - persuasive skills - negotiations - time management - emotional intelligence - stress management - creative and critical thinking.

References:

Web Sources:
1. www.humanresources.about.com
2. www.careerride.com
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INFORMATION SEARCH TECHNIQUES

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Course Objectives:
To learn the types of information searches and know the importance of search preparation
To establish the formulation of search strategies and understand the types of search techniques and also to make use of the search techniques in information retrieval
To identify the search techniques to various search tools

Course Outcomes:
Able to distinguish between simple, advanced and meta searches
Plan for a search session and formulate search strategies
Select the appropriate search tool for the required information
Apply the use of search techniques to various search tools

Unit - I :
Types of Searches:- Simple searching, Advanced searching and Meta searching, Keywords, Search preparation.
Search Strategy: Steps in developing search strategy, advantages of a search strategy

Unit - II :
Search Techniques: Boolean Logic, Parenthesis, Phrase searching, Truncation, Wildcards and Field searching
Application of Search Techniques: Searching from deep web sources eg Medline/PubMed; Searching from directories and search engines; and Searching in subject portals eg: HINARI

References:

Web Sources: