**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)**
**COURSE STRUCTURE AND SYLLABUS**

**I YEAR I SEMESTER**

| Code | Group | Subject | L | P | Credits |
|---|---|---|---|---|---|
| | | Modern Pharmaceutical Analytical Techniques | 3 | 0 | 3 |
| | | Advanced Biostatistics and Research Methods | 3 | 0 | 3 |
| | | Pharmaceutical Management – I (General & Personnel) | 3 | 0 | 3 |
| | | Total Quality Management | 3 | 0 | 3 |
| | | Drug Regulatory Affairs (National and international Regulatory aspects) | 3 | 0 | 3 |
| | Lab | Modern Pharmaceutical Analytical Techniques Lab | 0 | 3 | 2 |
| | Lab | Pharmaceutical Management Lab | 0 | 3 | 2 |
| | | Seminar | - | - | 2 |
| | | Total Credits | 15 | 6 | 21 |

**I YEAR II SEMESTER**

| Code | Group | Subject | L | P | Credits |
|---|---|---|---|---|---|
| | | Intellectual Property Rights and Drug Regulatory Affairs | 3 | 0 | 3 |
| | | Pharmacological Screening Methods and Clinical Research | 3 | 0 | 3 |
| | | Pharmaceutical Management– II (Production, Marketing, Finance & Project) | 3 | 0 | 3 |
| | | Analytical Method Validation, Copy Rights and Trade marks | 3 | 0 | 3 |
| | | Pharmaceutical Market Research and Analysis | 3 | 0 | 3 |
| | Lab | Analytical Method Validation Lab | 0 | 3 | 2 |
| | Lab | Pharmaceutical Market Research and Analysis Lab | 0 | 3 | 2 |
| | | Seminar | - | - | 2 |
| | | Total Credits | 15 | 6 | 21 |

**II YEAR - I Semester**

| Code | Group | Subject | L | P | Credits |
|---|---|---|---|---|---|
| | | Comprehensive Viva | - | - | 2 |
| | | Project Seminar | 0 | 3 | 2 |
| | | Project work | - | - | 18 |
| | | Total Credits | - | 3 | 22 |

**II YEAR - II Semester**

| Code | Group | Subject | L | P | Credits |
|---|---|---|---|---|---|
| | | Project work and Seminar | - | - | 22 |
| | | Total Credits | - | - | 22 |

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PM&RA)**

## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

**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.

**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**

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

**UNIT III**

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

**UNIT IV**

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

**UNIT V**

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

**Outcome:** The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories involved 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.

**Text books**

1) Instrumental Methods of Chemical Analysis by B.K Sharma

2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar

**References:**

1. Organic spectroscopy by William Kemp
2. Quantitative Analysis of Drugs by D. C. Garrett
3. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
4. Spectrophotometric identification of Organic Compounds by Silverstein
5. HPTLC by P.D. Seth
6. Indian Pharmacopoeia 2010
7. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
8. Introduction to instrumental analysis by Robert. D. Braun

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PM&RA)**

## ADVANCED BIOSTATISTICS AND RESEARCH METHODS

**Objective:** The student shall know the introduction, scope of biostatistics and Research work, calculation and present of all data. It also informs the students, how the present research work writing and correlating.

**UNIT I**

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

**UNIT II**

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

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

**UNIT III**

**Measures of Correlation and Regression:** Experimental designing, planning of an experiment, replication and randomization. Probit analysis.

**Probability rules:** Binomial, Poison and Normal distribution.

**Hypothesis testing:** Student't' test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

**UNIT IV**

Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review,
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal
Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

**UNIT V**

The research report paper writing/ thesis writing
Different parts of the research paper

1. Title-Title of project with authors' name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology- subject, apparatus, instrumentation and procedure
5. Results – tables, graphs figure and statistical presentation
6. Discussion support or non support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata
11. Importance of Spell check for entire projects
12. Uses of footnotes

**Outcome:** The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

**Text Books**

1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White "Research Methods" ( Cengage learning India Pvt. Ltd)

**Reference Books**

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8 Research methods and Quantity methods by G.N.Rao
9. Fundamentals of Biostatistics by Khan and Khanum
10. Research Methodology by RK Khanna bis and Suvasis Saha
11. A practical approach to PG dissertation.

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PM&RA)**

## PHARMACEUTICAL MANAGEMENT-I (GENERAL & PERSONNEL)

**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.

**UNIT I**

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

**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 Mangers; 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.

**Outcome**: 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.

**Text and reference books**

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.
11. Personnel Management and Industrial Relations by P. C. Tripathi.

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PM&RA)**

## TOTAL QUALITY MANAGEMENT

**Objective**: 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.

**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**

Good manufacturing practices: Organisation and personnel, responsibilities, training, hygiene.
Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination.
Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP).
Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.
Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.,
Packaging and labeling control, line clearance, reconciliation of labels, cartons and other packaging materials.
Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, regents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house.
Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities.
Finished products release, quality review, quality audits, batch release document.

**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 teratoginicity. 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.

**Outcome**: 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.

**Text and reference books**

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
2. Quality Assurance of Pharmaceuticals–A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.

4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by Sadhan K.Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance.
9. USP.
10. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
11. Quality assurance and quality management in pharmaceutical industry by Y.Anjaneyulu and Marayya

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PM&RA)**

## DRUG REGULATORY AFFAIRS
## (NATIONAL AND INTERNATIONAL REGULATORY ASPECTS)

**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.

**UNIT I**

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)
The Narcotics Drugs and Psychotropic Substances Act.
Medicinal and Toilet Preparations (Excise Duties) Act, 1955. The Pharmacy Act, 1948.

**UNIT II**

The Drugs and Cosmetics Act, 1940 and Rules there under. Recent amendments to Drugs and Cosmetic Act and other relevant rules.
Drugs (Price Control) Order in force. Loan license (contract manufacture). Certification and licensing procedures.

**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 & Health Care Products | CEP/COS |

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.

**Outcome:**

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

**Text and reference books**

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PM&RA)**

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB**

**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. Estimation of multi components formulation by UV of two different methods
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. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.



**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – I Sem M.Pharm (PM&RA)**

**PMRA - 1.7**
**PHARMACEUTICAL MANAGEMENT LAB**

**Practical work shall be carried out based on the theory syllabus.**

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PM&RA)**

## INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS

**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 filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

**Intellectual Property Rights:**

**UNIT I**

a) 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**

a) History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
b) Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
c) Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
d) Patent filing procedure under PCT, advantages, patent search and literature

**UNIT III**

a) Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
b) Background, Salient Features and Impact of International Treaties / Conventions like
    i. Paris Convention, Berne convention
    ii. World Trade Organization (WTO)
    iii. World Intellectual Property Organization (WIPO)
    iv. Trade Related Aspects of Intellectual Property Rights (TRIPS)
    v. Patent Co-operation Treaty (PCT), Mandrid Protocol

**Regulatory Affairs**

**UNIT IV**

a) National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
b) USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

**UNIT V**

a) Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
b) ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10.

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

**Recommended Books:**


1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India
3. Manual of Patent Office Practice and Procedure -2010
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
8. New drug approval process,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
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

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PM&RA)**

## PHARMACOLOGICAL SCREENING METHODS AND CLINICAL RESEARCH

**Objective:** The students is going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

**UNIT I**

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

**UNIT II**

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

**UNIT III**

Toxicity tests: OECD guidelines, determination of LD50, acute, subacute and chronic toxicity studies.

**UNIT IV**

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

**UNIT V**

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

**Outcome:** The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

**Text Books:**

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

**Reference Books:**

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized Tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trails on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PM&RA)**

## PHARMACEUTICAL MANAGEMENT-II
## (PRODUCTION, MARKETING, FINANCE & PROJECT)

**Objective:** To know the pharmaceutical product management, planning, marketing accounts and finance. They also know the Inventory control, concept and techniques to improve production In packaging, marketing, sale and accounting.

**UNIT I**

Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.

Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping.

Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

**UNIT II**

Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment. Product management. E-Pharma Marketing.

**UNIT III**

Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.

Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

**UNIT IV**

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm's stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management.

Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance.

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Evaluation of investment decisions by pay back period, accounting rate of return, net present value methods, break even analysis.

**UNIT V**

Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.

Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework. Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social. Risk analysis.

Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new issues, negotiations with FIs, FIIs, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

**Outcome:** Student will get knowledge about production management, production planning and control, design and development of packaging, marketing of pharmaceuticals.

**Text and reference books**

1. Financial Management by Johnson, R.W.; The Ronald Press.
2. Fundamental of Financial Management by Van Horne, J.C.; Prentice Hall of India (P) Limited.
3. Stock Exchange and Investment Analysis by Briston, R. J.
4. Indian Financial System by Khan, M. Y.; Tata McGraw Hill.
5. Tax Planning for Industrial Projects by Agarwal R. K.; Hind Law Publishers, New Delhi.
6. Project Management by Chaudhary, S.; Tata McGraw Hill.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner; CRS Publishers and Distributors, Delhi.
8. Financial Management by Gupta And Sharma I st Edition 1996.
9. Accounting for Management Planning and Control III rd Edition Richard M. Lynch
11. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
12. Business Organization and Management by Shukla M. C.; S. Chand and Company.
13. Business Organization and Management by Sherlakar S. A.; Himalaya.
14. Personnel Management by Filippo E. B.; McGraw Hill.
15. Marketing Management by Kotler Philip.; Prentice Hall of India.
16. Organizational Behavior by Rao and Narayan; Konark Publishers.
17. Personnel Management by Tripathi P. C.; S. Chand and Company.
18. Principle and Practice of Marketing in India by Memoria C. B.
19. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
20. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
21. Production and Operations Management by S.N.Chary

**M. PHARM. (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)-R13 Regulations**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**I Year – II Sem M.Pharm (PM&RA)**

## ANALYTICAL METHOD VALIDATION, COPY RIGHTS AND TRADE MARK

**Objective:** The students will know the validation guidelines, different methods of validation, implementation of validation. They also know about the law related to copyrights, trademarks and their implementation.

**UNIT I**
**Validation guidelines**
1. ICH Q2A: Text on validation of analytical procedures: Definitions and terminology (March 1995)
2. ICH Q2B: Validation of analytical procedures: Methodology (June 1997)
3. FDA: (Draft) Guidance for Industry: Analytical procedures and methods validation
4. Pharmacopoeias: USP and European Pharmacopoeia

**UNIT II**
**What methods to be validated?**
Defined for:
- identification
- quantitative tests for content of impurities
- limit tests for control of impurities
- quantitative tests for active moiety in drug substances and drug products

Referred to:
- dissolution testing
- particle size determination (drug substance)

**UNIT III**
**Implementation of Guidelines**
- Standard protocols
- Set up as procedures
- Mutual agreement on tests
- Mutual agreement on criteria
- Mutual agreement on documentation

==> MUTUAL DEVELOPMENT PROCEDURES (MDP)

**UNIT IV**
**Copyright:** Law relating to copyright in India. Copyright Act, 1957and its amendments. Subject matter of copyright protection. Rights of owners of copyrights. Infringement of copyright, remedies against infringement of copyright. Authorities and institutions under the copyright Act.
**Trade Marks:** The trade marks legislation in India. Service marks, certification Marks, Collective marks, Distinctiveness of Trade Marks, Distinct Marks. Subject matter of Trade marks. Acquisition of registered Trade Mark. Register and conditions for Registration. Infringement of Trade marks.

**UNIT V**
Trade mark laws and governing of trade marks, role of Indian trade mark office.

**Outcome:** Students will get knowledge about ICH guidelines for validation, FDA drafts and techniques which are used for validation and their implementation. They also know the rights and laws related to copyrights and trademarks.

**Text Books**

1. Ira R.Berry and R.A. Nash ( eds ) Pharmaceutical Process Validation, Marcel Dekker Inc, New York
2. Pharmaceutical Process Validation by Loftus and Nash.
3. Remington's Pharmaceutical Sciences, The science and practice of pharmacy, 20th Edition, Vol.I&II.
4. Quality Assurance of Pharmaceuticals –A compendium of guidelines- WHO publication.
5. Theory and practice of industrial pharmacy by Liberian and Lachman.
6. Pharmaceutical Process validation by Berry and Nash.
7. Intellectual properties rights by GB Reddy.

**Reference Books**


1. GMP by Sidney Herbal, Willing.
2. Quality Assurance Guide - Organization of Pharmaceutical products of India.
3. Drugs and Cosmetics Act 1969 and Rules 1945.
4. S.H. Willing M.M.T.Tuckerman, W.S.Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Decker Inc, M.New York.
5. P.P. Sharma, How to practice GMP's Vandhana Publications, Agra
6. Lippincott Williams Wilkins, Philadelphia, 2000
7. Quality assurance guide supplied by Organization of Pharmaceutical procedure of India.

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**I Year – II Sem M.Pharm (PM&RA)**

## PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS

**Objective:** students shall know the overview of global pharmaceutical market, growth calculations, innovator new drug evaluation, analysis of finished dosage forms and APIs. They also know about the pharmaceutical companies, R&D strengths, case study of companies.

**UNIT I**

- Introduction and overview of global pharmaceutical market
- Growth calculations based on Therapeutic category vs regions
- Innovator new drug candidate evaluation and strategic development cycle.
- Calculation of market promotion data
- Patent extension strategies
- Return on investment and R&D pipeline

**UNIT II**

Analysis of finished dosage forms based on

- Therapy
- Product
- Companies
- Quantity
- Value
- Country wise
- Region wise etc

Analysis of Active Pharmaceutical Ingredients based on

- Product,
- Quantities
- Value

Critical evaluation of databases for the global market research

- IMS
- Newport
- Export data etc

**UNIT III**

Lead analysis of Innovator vis-à-vis with Therapeutic Category & Generic drug makers vis-à-vis with Therapeutic Category

**UNIT IV**

Pharmaceutical Companies Portfolio, financials, R&D strengths and pipeline strength analysis

**UNIT V**

Case studies- Pharma growth stories of companies
Market research using SAS programmes on market trends
Multi Variate Analysis programmes to analyse in relationship between various factors governing the market growth.

**Outcome**: Students will have knowledge about global market, growth calculations depending on regions, market promotion datas, patent extensions, analysis of finished dosage forms and APIs. They also study data base related to strategies of companies.

**Text and Reference books**

1. Principles of Pharmaceutical Marketing by MICKEY SMITH
2. Principles and Practice of Drug Manufacturing Management by MD BURANDE
3. Pharmaceutical Market research and analysis by Donald R. Lehmann
4. Pharmaceutical Market in 21st Century by Mickey C. Smith

5. Pharmaceutical Marketing: A Practical Guide by Dimitris Dogramatzis
6. Strategic management of health care organizations by Linda E. Swayne, Walter Jack Duncan, Peter M. Ginter
7. Managing Health Care Business Strategy by George B. Moseley, III, George B. Moseley
8. Pharmaceutical Management by Sachin Atkar

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**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**I Year – II Sem M.Pharm (PM&RA)**

**ANALYTICAL METHOD VALIDATION – LAB**

**Practical work shall be carried out based on the theory syllabus.**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**
**I Year – II Sem M.Pharm (PM&RA)**

**PMRA – 2.7**
**PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS – LAB**

**Practical work shall be carried out based on the theory syllabus.**