Rajiv Gandhi Proudyogiki Vishwavidyalaya
M.Pharm. (Pharmaceutical Technology)
III Semester Course Contents

MPY 301 PT: STABILITY OF DRUGS AND DRUG PRODUCTS

UNIT – I

Overview of kinetic concepts : First, second and pseudo orders. Complex order kinetics:concepts; equations and their application. Series, consecutive and reversible reaction, steady state approximation. Stability prediction by pharmacist and calculation protocols.

UNIT – II

Temperature as a stress : Arrhenius theory, activation energy calculations, Q10 value calculations. Interpretation of kinetic data : Transition state theory, media effects, catalysis, pH effects. Some practical applications.

UNIT – III

Drug decomposition mechanisms :(a) Hydrolysis and acyltransfers : Nature of reaction, structure and utility, stabilization of pharmaceutical examples. (b) Oxidation : Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation (c) Photolysis : Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions. Solid state chemical decomposition Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state methods of stabilization.

UNIT – IV

Physical stability testing of dosage forms : (1) Solids – tablets, capsules, powder and granules (2) Disperse systems (3) Microbial decomposition (4) Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano- particles. Strategy and tactics of stability testing : (1) Regulatory requirements (2) Stability protocols (3) Experimental Design (4) Interpretation of data

REFERENCES:

1. Drug stability : Principles and practices by Jens T. Carstensen

2. Pharmaceutical Dosage Form Design : Tablets- Vol I,II & III by Lachmann.

3. Theory and Practice of Industrial Pharmacy by Lachman.

4. Stability Testing of Drug Products by W.Grimm.

5. Martin Physical Pharmacy – IVth Edition.

6. Physical Pharmaceutics by Manavalam and Ramaswamy.

7. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

Rajiv Gandhi Proudyogiki Vishwavidyalaya
M.Pharm. (Pharmaceutical Technology)
III Semester Course Contents

MPY 302 PT: ACTIVE PHARMACEUTICAL INGREDIENTS MANUFACTURING TECHNOLOGY

UNIT I

Introduction to basic pharmaceutical and fine chemical chemistry: Definitions of basic pharmaceuticals, intermediates, fine chemicals, heavy chemicals. Technology involved in manufacturing of pharmaceuticals. Unit processes in synthesis, biochemical processes in synthesis.

UNIT II

Unit processes: Study of the following chemical processes (with references to reagents, mechanisms, equipments and manufacture of drugs given below): Acylation, esterification, alkylation, amination, halogenation, hydrolysis, nitration, oxidation and reduction.

UNIT III

Industrial processes & scale up techniques, Industrial manufacturing methods and flow charts of Sulphamethoxazole, Ciprofloxacin, Benzocaine, Adrenaline, Rifampicin, Aspirin and Pentothal sodium.

UNIT IV

Bioethics and Bio-Safety Health hazards in manufacturing facility, The forms of Atmospheric contaminants, Chemical mixtures, Detection and sampling, Atmospheric contamination, industrial noise, criteria for hearing damage, Noise measuring instruments, effects of sound and ultrasound, the control of noise, vibration, Radiation Hazards, Radiation detection and measurement, personal protection, eye protection, Types of eye protection equipment. Finger & Arm protection, Foot & leg protection. Environmental protection laws related to industry.

Reference

- M.G. Larians: Fundamentals of Chemical Engineering Operations.
- W. L. Badger and Banchero: Introduction to Chemical Engineering.
- L. Lachman-The Theory and Practice of Industrial Pharmacy.
- Ganderton G.: Unit Processes in Pharmacy.
- Groggin P. K.: Unit Processes in Organic Synthesis.
- Marshall Sitting: Organic Chemical Processes.
- Dryden C. L.: Outlines of Chemical Technology

Rajiv Gandhi Proudyogiki Vishwavidyalaya
M.Pharm. (Pharmaceutical Technology)
III Semester Course Contents

MPY 303 PT : PHARMACEUTICAL PACKAGING TECHNOLOGY

Unit I

Functions of packaging, Packaging management, Package development, packaging and stability, packaging specification, Regulatory aspects of pharmaceutical packaging. Packaging material science: Basic materials used in packaging, their properties, method of manufacturing and applications-Paper, Plastics, Glass, Metal, and Elastomers.

Unit II

Containers and closures: Closure Systems: Basis of closure system, Types/mechanism of closure system, Sealing and adhesion techniques, Materials used for closure systems.

Introduction and applications of Glass containers, Plastic containers, Collapsible tubes, Plastic tubes, Aerosol containers, Closures, Liners, and Rubber stoppers.

Introduction and applications of Form-Fill-Seal (FFS) technology.

Unit III

Packaging techniques and machineries: Tamper resistant and child resistant packages: Introduction, method of preparation, and applications of Blister and Strip packs, Film Wrappers, Bubble packs, Shrink seals, Sachet and Pouches, Tape seals, Breakable caps, Sealed tubes, Aerosol containers, etc.

Unit IV

Quality control and quality assurance of packaging materials: Detection of defects in packaging materials, Quality testing of formed packs, Quality testing of containers and closures, Testing of child resistance and temper evidence property of packaging materials. Quality control tests for containers and closures as per Indian Pharmacopoeia.

Unit V

Legal and regulatory requirements: Requirements of labels and labeling as per Drug & Cosmetics act and rules. Product / patient information literatures. Regulatory aspects of storage, handling and distribution of packaging materials with special emphasis on cGMP and cGLP requirements.

Books recommended:

1. Dean, D.A.; Evans, E.R.; and Hall I.H., *Pharmaceutical Packaging Technology.*
2. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, *The Theory and Practice of Industrial Pharmacy.*
3. *Drug and cosmetic Act and Rules.*

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M.Pharm. (Pharmaceutical Technology)
III Semester Course Contents

MPY 304 PT : INDUSTRIAL PHARMACY

1. Pharmaceutical factory location: Selection of plant location, factors affecting plant location, layout facilities, type of layout along with their merits and limitations. Preparation of qualitative and quantitative departmental layout with equipment required for different dosage form like tablets, hard and soft gelatin capsules, liquid and sterile products.

2. Pilot plant scale up techniques: Significance, pilot study of some important dosage forms such as tablet capsule and liquid orals, discussion on important parameter such as formula, equipment, product uniformity and stability, raw material process and physical layout, personnel requirement and reporting responsibilities, SUPAC guideline.

3. Compaction and compression: Compaction of powder with particular reference to distribution and measurement of forces within the powder mass undergoing compression including physics of tablet compression, effect of particle size ,moisture content, lubrication etc. on the strength of tablets.

4. Fundamental of industrial management: Introduction to production and operation, management, definition, scope and objectives of operation management, functions of operation manager, nature and type of operations, integration of operations management with other functional areas, organization of production/operations function, project design and management.

5. Production Management: Introduction, production planning, production control, manufacturing system, product design, product development, material handling, productivity, production order, work study, maintenance management, preventive and breakdown maintenance.

6. Industrial hazards, safety, pollution control and effluent treatment: Introduction, factory acts and rules, fundamentals of accident prevention, elements of safety program and safety management, electrical hazards, chemical hazards and management of overexposure chemicals, gas hazards' and handling of gases, dust explosion and its control, fire prevention and control.

7. Material management: Introduction, objective, purchasing, store keeping, inventory control, technique of inventory control, ABC concept, economic order quantity, inventory management system, sales forecasting and cost control.

Books Recommended

- Lachman "The theory and Practice of Industrial Pharmacy
- Remingtons "Pharmaceutical Sciences"
- Bentley's Pharmaceutics.
- Pilot plants model and scale-up methods, by Johnstone and Thring.
- GMP practices for pharmaceutical –James Swarbrick.
- How to practice GMPs by P.P.Sharma.
- Chemical Engineering Plant Design by Vibrant.
- Pharmaceutical Process Validation by Loftus and Nash.