RAJIV GANDHI PROUDHYOGIKI VISHWAVIDYALAYA
M. Pharm (Pharmaceutical Technology)
II Semester Course Contents
MPY-201-PTch: PHYSICAL PHARMACEUTICS

Unit I

Particle Science and Powder Technology: Polymorphism, crystal structure, amorphous state, solid dispersions, particle size distribution, particle size analysis methods. Physics of compression, consolidation strength of granules, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet.

Unit II

Solubility and Dissolution: Solubility and solubilisation of drugs and effect of surfactants, co-solvents, complexation, drug derivatization and solid state manipulation. Theories of dissolution, factors affecting dissolution rate, official methods for measurement of dissolution rate. Drug release mechanisms: study of mechanistic realistic theories like Fick's law of diffusion, polymer swelling, polymer erosion/degradation, and study of empirical or semi-empirical mathematical models like Higuchi, Korsmeyer-Peppas, Hixon Crowell, Hopfenberg, Cooney model.

Unit III

Rheology: Instrumentation, rheological properties of disperse systems and semi solids. Newtonian, Non-Newtonian flow, Plastic behavior, Weissenberg effect, Transient deformations in shear (of liquids), Uniaxial extension, Secondary flow, Thixotropy and rheopexy, Non-linear elasticity, Viscoelastic behavior, Elastic solids, Hookean elastic material, Linear anisotropic materials, Limits of elasticity. Study of rheological plots, determination of Flow curve, yield point, 3-interval test (structural decomposition and regeneration), temperature swing test. Theories on physical stability of disperse systems, adsorption, wetting, crystal growth mechanisms, physical stability testing of emulsions and suspension.

Unit IV

Kinetics and Drug Stability: The chemical breakdown of drugs, Kinetics of chemical decomposition in solution, factors influencing drug stability of liquid dosage forms, factors influencing drug stability of solid dosage forms, stability calculations, rate equation, complex order kinetics, kinetics of some decompositions, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms, methods of physical stability testing: freeze-thaw methods, centrifugation method. ICH Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F guidelines for stability testing.

Unit V

Polymer Science: Polymer structure, properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, applications of polymers in pharmaceutical formulations, N-(2-Hydroxypropyl) methacrylamide, copolymer conjugates, functional PEG for drug delivery, pH-sensitive polymers for drug delivery, hydrogels for oral administration, hydrogels for the controlled release of proteins, thermosensitive biodegradable hydrogels for the delivery of therapeutic agents, recombinant polymers for drug delivery, polymeric micelles, block copolymers, graft copolymers.

References:

1. Physical Pharmacy; By Alfred Martin
2. Remington's Pharmaceutical Sciences.
3. Theory and Practice of Industrial Pharmacy; By Lachmann and Libermann.
4. Modern Pharmaceutics; By Gillbert and S. Banker.
5. Rheology Fundamentals; By Alexander Ya. Malkin.
6. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
7. Polymeric Drug Delivery Systems; By Glen S. Kwon
8. ICH quality guidelines, www.ich.org

30/04/2013

RAJIV GANDHI PROUDHYOGIKI VISHWAVIDYALAYA
M. Pharm (Pharmaceutical Technology)
II Semester Course Contents
MPY-202-PTch: NON-STERILE DOSAGE FORMS

Unit I

Tablet Manufacturing Technology: Modern approach to tablet product design, tablet compression tooling, preformulation studies, designing of tablets and their manufacturing, granulation technology, manufacturing problems, direct-compression process, direct-compression fillers, co-processed active ingredients, modification and integration of direct compression and granulation processes, inlay tablets, layer tablets, effervescent tablets, molded sublingual tablets, compressed sublingual tablets, buccal tablets, vaginal tablets, rectal tablets, Dispersible tablets, chewable tablets, mouth dissolving, mouth disintegrating tablets, and medicated lozenges.

Unit II

Powder & Tablet Coating Technology: Nonfunctional film coating, coating equipments, automated coating procedures, particle coating, Wurster processes, centrifugal powder coating, compression coating, functional film coating, spray drying, aqueous-phase separation, coacervation, nonaqueous-phase separation interfacial polymerization, sustained-release product designing through coating, novel polymeric coating materials.

Unit III

Capsules: Filling equipments and their operational aspects, filling operation, formulation aspects, special techniques involved in finishing of hard gelatin capsules. Study of DuoCap™, ENCODE™, DRcaps, Pearlcaps, Plantcaps™, Vcaps capsule technology. Soft gelatin capsule, methods of manufacturing, nature of capsule shell, nature of capsule content, filling operation, base adsorption consideration, physical stability of capsule and packaging. Non-gelatin capsules.

Unit IV

Pharmaceutical Dispersion Technology: DLVO theory, free energy considerations, stability considerations, manufacturing protocols, particle properties, solid-liquid interface, stabilization, rheological aspects, applications of surfactants and viscosity-imparting agents in dispersions, sedimentation control in dispersions, viscosity changes during product aging, flocculation and deflocculation phenomena, excipient compatibility, stabilization of dispersions, chemical and physical factors, structured vehicle. Formulation aspects of emulsion, microemulsion, multiple emulsions, gel emulsion, Formulation of antacid and clay products, aqueous oral suspensions, topical suspensions.

Unit V

Semi-solid products: Raw materials, formulation and manufacturing aspects, industrial processing, storage and packaging. Drug absorption from semisolid products, physicochemical characteristics of drug, suppository, machinery used in manufacturing, problems in manufacturing and trouble shooting.

References:

1. Theory and Practice of Industrial Pharmacy; By Lachman and Libermann.
2. Modern Pharmaceutics; By Banker and Rhodes.
3. Pharmaceutical Dosage Forms: Tablets. Second Edition, Vol. 1-3; By Lieberman, Lachman, and Schwartz
4. Pharmaceutical Dosage Forms: Disperse Systems. Volumes 1 & 2; By Lieberman, Rieger and Banker
5. Remington's Pharmaceutical Sciences.

30/04/2013

RAJIV GANDHI PROUDHYOGIKI VISHWAVIDYALAYA
M. Pharm (Pharmaceutical Technology)
II Semester Course Contents
MPY-203-PTch: STERILE DOSAGE FORMS

Unit I

Preformulation & Sterilization Techniques:

Preformulation in parenteral medication: physicochemical property of drug, accelerated stability evaluation, considerations for proteins and peptides, screening of parenteral packaging components.

Sterilization: Methods, product and package considerations, validation of sterilization, sterility testing.

Unit II

Formulation of Parenteral Products:

SVP and LVP: Introduction, formulation principles, formulation development, vehicle selection, antibacterial agents, buffers, tonicity modifiers, solution quality, effect of container over formulation, process effect, and stability evaluation. Parenteral products of proteins and peptides.

Ophthalmic, Nasal & Otic products: Pharmaceutical requirements, buffering, viscosity, bioavailability, specialized devices & packaging considerations.

Unit III

Lyophilization: General considerations of the process, formulation, freezing, primary drying, secondary drying, container closure system for lyophilization, equipment, properties of lyophilized products, components of a lyophilized product, role of water in lyophilization, lyophilization cycle, stability aspects, and application of thermal analytical methods in lyophilization.

Unit IV

Parenteral Product Packaging:

Glass: Manufacturing of glass containers, chemical and mechanical performance of glass as container for parenterals.

Plastics: Fabrication processes, plastics used in parenteral packaging.

Elastomeric Closures: Types of rubber used in parenteral packaging, closure design, rubber compounding, closure control, closure deisn qualification, regulatory considerations.

Unit V

Quality Assurance of Parenteral Products: Raw material control, chemical and microbial attributes of parenterals, sterility testing, pyrogen testing, preservative efficacy, particulate matter testing, regulatory and GMP considerations.

References:

1. Theory and Practice of Industrial Pharmacy; By Lachman and Libermann.
2. Modern Pharmaceutics; By Banker and Rhodes.
3. Pharmaceutical Dosage Forms: Parenteral Medications, Volume 1-3; By Avis, Lieberman, and Lachman.
4. Lyophilization: Introduction and Basic Principles; By Thomas A. Jenning
5. Remington's Pharmaceutical Sciences.

RAJIV GANDHI PROUDHYOGIKI VISHWAVIDYALAYA
M. Pharm (Pharmaceutical Technology)
II Semester Course Contents
MPY-204-PTch: NOVEL DRUG DELIVERY TECHNOLOGY

Unit I

Biopharmaceutical & Pharmacokinetic Considerations: Dosing regimen, loading and maintenance dose, one and two compartment models and first order absorption in multiple dosing. Intravenous infusion and first order absorption in multiple dosing. Application of pharmacokinetic principles in calculation of dose for sustained release dosage forms, calculation based on zero order release and first order release approximation. BCS system and development of IVIVC.

Unit II

Site Specific Oral Drug Delivery Systems: Designing of oral mucosal drug delivery systems, buccal patches /tablets, medicated chewing gum, and lozenges. Osmotic tablets, colonic drug targeting. Pulsincaps, hydrophilic sandwich, Eaglet technology, and Enterion technology. Targeting through Peyer's patches lymphatic system.

Unit III

Novel Oral Drug Delivery Technologies: Study of TIMERx®, MASRx®, COSRx®, RingCap®, Smartrix®, TheriForm®, DissoCubes®, Orasolv® and Durasolv® and other novel patented technologies developed for various controlled and sustained /fast release oral drug delivery systems.

Unit IV

Pelletization Technology: Designing of modulated release drug delivery systems by pelletization techniques: Layering, coating pan, Wurster coater, centrifugal granulation, extrusion-spheronization, cryopelletization, melt spheronization, and spray drying and spray congealing techniques.

Unit V

Modified Release Liquid Drug Delivery Systems: Dispersed and colloidal drug delivery systems. Sustained release suspensions, multiple emulsions, self emulsifying drug delivery systems (SEDDS), liquid crystals, in-situ gels.

References:

1. Gibaldi and Perrier, Pharmacokinetics
2. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics
3. Notari, Biopharmaceutics and Pharmacokinetics
4. Ritschel, Handbook of Pharmacokinetics.
5. Shargel, Applied Biopharmaceutics and Pharmacokinetics.
6. Banker and Rhodes, Modern Pharmaceutics.
7. Wise, Handbook of pharmaceutical controlled release technology.
8. Robinson and Lee, Controlled drug delivery: fundamentals and applications.
9. Wang, Sihaan, and Soltero, Drug delivery principles and applications.
10. Ghosh and Pfister, Drug delivery to oral cavity: molecules to market.
11. Rathbone, Hadgraft, and Roberts, Modified-release drug delivery technology.
12. Hinary, Lloyd, and Swarbrick, Drug delivery and targeting.