

Module Name: Dosage form Sciences

Module Number: 09

Course Title: Integrated Physical Pharmacy and Pharmaceutics II

Course Code: Phar2092

Course EtCTS: 9

Contact Hours: 243

Prerequisite: Integrated Physical Pharmacy and Pharmaceutics I

Co-requisite: None

Course Description:

The design of the course is based on the integration of the study of physico-chemical principles of pharmacy with the formulation, preparation and stabilization of semisolid and solid pharmaceutical dosage forms. In line with this, the course deals with scientific principles related to thermodynamic and electrical properties of colloidal systems, and diffusion and dissolution theories associated with drug release kinetics from dosage forms. The module is also designed to enable students apply these theories and principles for the formulation and production of semisolid and solid dosage forms in the practical compounding sessions and thereafter during their professional career. The principles of drug degradation mechanisms, rate and kinetic theories of chemical reactions are also included for their application in the determination of product shelf-life and stability studies. The applications of pharmaceutics in cosmetics, overview of radiopharmaceuticals and veterinary dosage forms are also included.

Course Objectives:

Upon completion of this course, students will be able to:

- Apply the physicochemical, electrical and thermodynamic properties of colloidal particles for the formulation of acceptable disperse systems
- Develop the knowledge and skills of formulation, compounding and dispensing of semisolid and solid dosage forms
- Select and characterize appropriate formulation excipients and packaging materials for pharmaceutical dosage forms and labeling thereof

- Describe the theories of diffusion and dissolution and apply for the determination of drug release kinetics from a dosage form
- Describe the different approaches of product stability studies and determine the shelf-life and expiry date of pharmaceutical products
- Identify the different types of formulation incompatibilities and their effect on the physicochemical and therapeutic performance of products
- Describe the different types of radiopharmaceuticals and their application, handling and storage precautions
- Apply the knowledge and skills of pharmaceutics in cosmetics
- Identify the important considerations while dealing with veterinary dosage forms

Course Content:

1. Semisolid dosage forms (14 hrs)

- Introduction
- Classification of semisolids
- Desired properties of semisolids

Ointments and Pastes (6 hrs)

- Introduction (Definitions, Properties and applications)
- Formulation (ideal properties of bases, types of bases)
- Preparation of ointment and pastes
- Packaging, labeling and storage

Creams (2 hrs)

- Introduction (Definition, types and properties of creams)
- Formulation
- Methods of preparation
- Packaging, labeling and storage

Gels (3 hrs)

- Introduction (Definition and applications)
- Classification
- Formulation (Gelling agents, factors affecting gelation)
- Syneresis and swelling of gels
- Preparation of gels

- Packaging, labeling and storage
2. Suppositories and Pessaries (7 hrs)
- Introduction (Definition and applications)
 - Formulations (desirable properties of bases, classification of bases, other excipients)
 - Preparation of suppositories
 - Calibration of moulds, determination of displacement value
 - Methods of preparation: fusion and compression
 - Packaging, labeling and storage
3. Micromeritics (8hrs)
- Particle size and size distribution
 - Methods for determination of particle size and size distribution
 - Particle shape and surface area
 - Methods for determination of surface area
 - Derived properties of powders (densities, porosity, packing arrangement, flowability)
4. Powders and granules (4 hrs)
- Powders as a dosage forms
 - Introduction (definition, classification and applications)
 - Preparation (size reduction, mixing and packing)
 - Challenges of powder dosage forms; eg, eutectic mixtures
 - Granules as dosage forms
 - Granulated preparations
 - Effervescent granules and methods of preparations
5. Diffusion and Dissolution (6 hrs)
- Introduction (osmosis, dialysis, diffusion)
 - Fick's law of diffusion (steady state, diffusion through a membrane)
 - Applications of diffusion
 - Dissolution of particles (Noyes-whetney equation, factors affecting dissolution)
 - Intrinsic dissolution rate
 - Sink conditions, Lag time and burst effects

- Hixon-crowel equation
6. Kinetics and Drug Stability (10 hrs)
- Introduction
 - Rates and orders of reactions
 - Physical degradation
 - Chemical degradation (mechanisms and stabilization approaches)
 - Factors affecting stability of drugs
 - Influence of temperature on reaction rates (Arrhenius equation)
 - Stability study (real time and accelerated stability study)
 - Prediction of shelf life
7. Introduction to radiopharmaceuticals (2 hrs)
- Formulation aspects, stability and handling of radiopharmaceuticals
8. Incompatibilities in formulation (2 hrs)
9. Cosmetics (9 hrs)
- Introduction
 - Hair cosmetics
 - Skin cosmetics
 - Deodorants and antiperspirants
 - Oral care products
 - Nail products
 - Eye cosmetics
 - Lip products
10. Veterinary dosage forms (4 hrs)

Mode of Delivery

- Illustrated lecture: 64 hrs
- Demonstration and Practical session: 48 hrs
- Report writing: 15 hrs
- Home Study: 70 hrs
 - Assignment: 17 hrs
 - Presentation: 15 hrs

Mode of Assessment

- Written mid exam: 30%
- Practical skill and competency based exams: 25 %
- Assignments (Group and/or individual): 10%
- Written final exam: 35%

Course Policies:

- Students are expected to have 100% attendance and to read all reading assignments in advance
- Students must attend and perform 100% of the practical laboratory sessions
- Student should submit all group and/or individual assignments and laboratory reports on due date
- Student should take all continuous assessments as scheduled
- Student should do his/her own work and actively participate during the presentation.

References

1. P. J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences, 5th Edition, Lippincott Williams & Wilkins, Philadelphia, 2006.
2. M. J Wilson K, Pharmaceutical Compounding and Dispensing, Pharmaceutical press, 2006.
3. L. V Allen, N. G Popovich, H. C Ansel, Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th edition, Lippincott Williams & Wilkins, 2004.
4. J. E Thompson and L. Davidow, a Practical Guide to Contemporary Pharmacy Practice, 2nd edition, Lippincott Williams & Wilkins, 2003.
5. A. Martin, J. Swarbrick and A. Cammarata, Physical Pharmacy, 3rd Edition, Lea & Febiger, Philadelphia, 1983.
6. A. T. Florence and D. Attwood, Physico-chemical Principles of Pharmacy, Macmillan Publishers Ltd., London, 1981
7. S. C. Wallwork and D. J. W. Grant, Physical Chemistry for Students of Pharmacy and Biology, 3rd Edition, Longman Group Ltd., London, 1977.
8. M. E. Aulton, Pharmaceutics: the science of dosage form design, 2nd ed., Churchill Livingstone, Edinburgh, 2002.
9. Hardee, G. E. and Baggot, J. D., Development and Formulation of Veterinary Dosage Forms, 2nd ed. Marcel Dekker, Inc. New York, 1998.
10. Breuer, M. M., Cosmetic Science, Academic Press, London, 1978.