SILVER OAK UNIVERSITY

Silver college of Pharmacy (067)
Programme Name: D.Pharm (18)
Subject Name: Pharmaceutics
Subject Code: 1180672101
Year: I

Prerequisite:
This course is designed to impart basic knowledge and skills on the art and science of formulating and dispensing different pharmaceutical dosage forms.

Objective: Upon completion of this course the student should be able to:

1. This course will discuss the following aspects of pharmaceutical dosage forms
2. Basic concepts, types and need
3. Advantages and disadvantages, methods of preparation / formulation
4. Packaging and labelling requirements
5. Basic quality control tests, concepts of quality assurance and good manufacturing practices

Teaching Scheme:

Teaching Scheme				
L	T	P	Contact Hours	Credit
4	1	3	8	8

Content:

Unit No.	Contents	Teaching Hours	Weightage %
1	**History of the profession of Pharmacy in India** in relation to Pharmacy education, industry, pharmacy practice, and various professional associations. Pharmacy as a career **Pharmacopoeia:** Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia	07 Hrs	09%
2	**Packaging materials:** Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials	05 Hrs	07%
3	**Pharmaceutical aids:** Organoleptic (Colouring, flavouring, and sweetening) agents Preservatives: Definition, types with examples and uses	03 Hrs	04%
4	**Unit operations:** Definition, objectives/applications, principles,	09 Hrs	12%

	construction and workings of: **Size reduction:** hammer mill and ball mill **Size separation:** Classification powder according to IP, Cyclone separator, Sieves and standards of sieves **Mixing:** Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer **Filtration:** Theory of filtration, membrane filter and sintered glass filter **Drying:** working of fluidized bed dryer and process of freeze drying **Extraction:** Definition, Classification, method and applications		
5	**Tablets**: Coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi layered, etc.)	08Hrs	55%
	Capsules: Hard and soft gelatin capsules	04Hrs	
	Liquid oral preparations: Solution, syrup, elixir, emulsion suspension, dry powder for reconstitution	06Hrs	
	Topical preparations : Ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries	08Hrs	
	Nasal preparations, Ear preparations	02Hrs	
	Powders and granules: Insufflations, dusting powders, effervescent powders, and effervescent granules	03Hrs	
	Sterile formulations: Injectables, eye drops and eye Ointments	06Hrs	
	Immunological products: Sera, vaccines, toxoids and their manufacturing methods.	04Hrs	
6	**Basic structure, layout, sections and activities of pharmaceutical manufacturing plants Quality control and quality assurance**: Definition and concepts of quality control & quality assurance, current good manufacturing practice (cGMP), Introduction to concept of calibration and validation	05	07%
7	**Novel drug delivery systems:** Introduction, Classification with examples, advantages and challenges	05	07%
	Total	75 Hrs	100%

Course Outcome:

Sr. No.	CO statement
CO-1	Describe about the different dosage forms and their formulation aspects
CO-2	Explain the advantages, disadvantages, and quality control tests of different dosage forms
CO-3	Discuss the importance of quality assurance and good manufacturing practice

Teaching & Learning Methodology: -

The various methods or tools follows by the faculties to teach the above subject are:

1. Student centered learning
2. Experimental learning

List of Tutorials/Experiments:

Scope: This course is designed to train the students in formulating and dispensing common pharmaceutical dosage forms.

Course Objectives: This course will discuss and train the following aspects of preparing and dispensing various pharmaceutical dosage forms

1. Calculation of working formula from the official master formula
2. Formulation of dosage forms based on working formula
3. Appropriate Packaging and labelling requirements
4. Methods of basic quality control tests

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Calculate the working formula from the given master formula
2. Formulate the dosage form and dispense in an appropriate container
3. Design the label with the necessary product and patient information
4. Perform the basic quality control tests for the common dosage forms

Practicals:

1. Handling and referring the official references: Pharmacopoeias, Formularies, etc. for retrieving formulas, procedures, etc.
2. Formulation of the following dosage forms as per monograph standards and dispensing with appropriate packaging and labelling
    - **Liquid Oral:** Simple syrup, Piperazine citrate elixir, Aqueous Iodine solution, Strong Iodine solution
    - **Emulsion:** Castor oil emulsion, Cod liver oil emulsion, olive oil emulsion
    - **Suspension:** Calamine lotion, Magnesium hydroxide mixture
    - **Ointment:** Simple ointment base, Sulphur ointment
    - **Cream:** Cetrimide cream
    - **Gel: Sodium alginate gel**
    - **Liniment:** Turpentine liniment, White liniment BPC
    - **Dry powder:** Effervescent powder granule, Dusting powder
    - **Sterile Injection:** Normal Saline, Calcium gluconate Injection
    - **Hard Gelatine Capsule:** Indomethacin capsules, Tetracycline capsules
    - **Tablet:** Paracetamol tablet granules ready for compression.
3. Demonstration on various stages of tablet manufacturing processes (including coating Tablets, if possible)
4. Appropriate methods of usage, and storage of special dosage forms including different types of inhalers, spacers, insulin pens
5. Demonstration of quality control tests and evaluation of common dosage forms viz. tablets, capsules, emulsion, sterile injections as per the monographs

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Various systems of measures commonly used in prescribing, compounding and dispensing practices
2. Market preparations (including Fixed Dose Combinations) of each type of dosage forms, generic name, minimum three brand names and label contents of the dosage forms mentioned in theory/practical
3. Overview of various machines / equipments / instruments involved in the formulation and quality control of various dosage forms / pharmaceutical formulations.
4. Overview of extemporaneous preparations at community / hospital pharmacy vs. manufacturing of dosage forms at industrial level
5. Basic pharmaceutical calculations: ratios; conversion to percentage fraction, allegation, proof spirit, isotonicity

Field Visit

The students shall be taken for an industrial visit to pharmaceutical industries to witness and understand the various processes of manufacturing of any of the common dosage forms viz. tablets, capsules, liquid orals, injectables, etc. Individual reports from each student on their learning experience from the field visit shall be submitted.

Books Recommended: - (minimum 3 books)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Remington's Pharmaceutical Sciences.
3. The Extra Pharmacopoeia-Martindale.
4. Mehta RM. Pharmaceutics I. Delhi: Vallabh Prakashan
5. Practical manual for pharmaceutical dosage forms by Munira M. Momin
6. United States Pharmacopoeia (USP)
7. Subrahmanyam CVS. Textbook of physical pharmaceutics. 2nd ed. Delhi: Vallabh Prakashan

List of Open Source Software/learning website:

- http://silveroakuni.ac.in/video-lecture
- https://nptel.ac.in/
- https://nptel.ac.in/courses/112/105/112105124/