Pharmaceutics Theory and Practical

for First Year Diploma in Pharmacy

aims to bridge the existing gap of long-felt demand for budding pharmacy technocrats, academicians and pharmacists, especially the young students of pharmacy. It will serve as an excellent textbook for the first year students of Diploma in Pharmacy. The text has been written precisely according to the latest syllabus prescribed by Pharmacy Council of India, covering Course Codes ER20-11T and ER20-11P. Due attention has been given to discuss all the topics thoroughly pertaining to theory and practical aspects of the subject.

The main objective of the book is to explain the fundamentals of pharmaceutics in the simplest possible language, easy for the students to understand. The textbook keeps a balance between the basic essentials and advanced areas of knowledge, apart from the usual topics.

Efforts have been made to focus mainly on the primary aspects for students of pharmacy undergoing diploma course as per PCI Course Regulation 2020. The book covers a wide range of areas in brief and contains a comprehensive description. The basic text in simple language not only deals with the basic concepts but also emphasizes technical and practical aspects of the subject. The most distinguishing feature of the book is ample 'long-answer' type questions, objective questions and experiments in pharmaceutics are highly obliging for the readers.

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Dr Agarwal has worked on taste masking techniques at F&D department of IPCA Labs, Mumbai. He has an excellent track record in academic institutions of high repute like IFTM, Moradabad, and SGIT, Ghaziabad, and is actively engaged in teaching, research, administration and service to pharmacy professionals.

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As per the latest syllabus prescribed by Pharmacy Council of India

Gaurav Agarwal

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Contents

Syllabus

THEORY

Course Code: ER20-11T 75 Hours (3 Hours/week)

Scope

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

Course Objectives

This course will discuss the following aspects of pharmaceutical dosage forms:

1. Basic concepts, types and need.
2. Advantages and disadvantages, methods of preparation/formulation.
3. Packaging and labelling requirements.
4. Basic quality control tests, concepts of quality assurance and good manufacturing practices.

Course Outcomes

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

1. Describe about the different dosage forms and their formulation aspects.
2. Explain the advantages, disadvantages, and quality control tests of different dosage forms.
3. Discuss the importance of quality assurance and good manufacturing practices.

Chapter	*Topics*	*Hours*
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	7
2	**Packaging materials:** Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials	5

(Contd.)

Chapter	*Topics*	*Hours*
3	**Pharmaceutical aids:** Organoleptic (colouring, flavouring, and sweetening) agents **Preservatives:** Definition, types with examples and uses	
4	**Unit operations:** Definition, objectives/applications, principles, construction, and workings of: **Size reduction:** Hammer mill and ball mill **Size separation:** Classification of powders 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	9
5	**Tablets:** Coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multilayered, etc.)	8
	Capsules: Hard and soft gelatine capsules	4
	Liquid oral preparations: Solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution	6
	Topical preparations: Ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries	8
	Nasal preparations, Ear preparations	2
	Powders and granules: Insufflations, dusting powders, effervescent powders, and effervescent granules	3
	Sterile formulations: Injectables, eye drops and eye ointments	6
	Immunological products: Sera, vaccines, toxoids, and their manufacturing methods.	4
6	Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants Quality control and quality assurance: Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation	5
7	**Novel drug delivery systems:** Introduction, classification with examples, advantages, and challenges	

PRACTICAL

Course Code: ER20-11P **75 Hours (3 Hours/week)**

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.
    - Emulsion: Castor oil emulsion, cod liver 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 granules, dusting powder.
    - Sterile injection: Normal saline, calcium gluconate injection.
    - Hard gelatine capsule: Tetracycline capsules.
    - Tablet: Paracetamol tablets.

3. Formulation of at least five commonly used cosmetic preparations, e.g. cold cream, shampoo, lotion, toothpaste etc.
4. Demonstration on various stages of tablet manufacturing processes.
5. Appropriate methods of usage and storage of all dosage forms including special dosage such as different types of inhalers, spacers, insulin pens.
6. 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, their 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, alligation, 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.