

Introduction to Pharmaceutical Dosage Form II (Theory)

BP504T

A Textbook for B. Pharm Semester V

*As per the new Pharmacy Council of India (PCI) Syllabus
2026 (NEP 2020)*

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Preface

This book covers the theory of Pharmaceutical Dosage Form II as set out in the PCI syllabus for the fifth semester of the B. Pharm. programme. The subject completes the student's first full pass through the major dosage forms, taking up the liquid, pressurised and semisolid preparations that the earlier course on solid dosage forms did not treat.

The book is built on a single idea: that a dosage form is best understood as a stability problem solved by a physicochemical principle, and then carried from the bench formula through manufacture to the compendial test that releases it. A suspension settles, and Stokes' law and the theory of flocculation explain how the formulator slows and controls that settling. An emulsion cracks, and the theories of emulsification and the hydrophile–lipophile balance explain how an emulsifying agent holds it together. A metered-dose inhaler must place a drug in the deep lung, and the aerodynamic particle size decides whether it succeeds. A drug must cross the skin, and the structure of the stratum corneum decides whether it can. Throughout, the aim is that the student should be able to justify each excipient and each test, not merely list them.

The treatment is faithful to the syllabus and close to the university examination. Each chapter states its learning outcomes, develops the theory in a definition-led academic style, illustrates every classification and every method with an original figure or table, works through the calculations the subject demands, and closes with a graded self-assessment whose questions mirror the pattern of the question paper and whose model answers show what earns the marks. A student who works through this book, its figures and its problems should be prepared for the paper.

The five units of the syllabus are developed across seven chapters. Units carrying the widest range of distinct content, the monophasic liquids and the semisolids, are treated in two chapters each; the biphasic liquids and the pressurised forms in one each. Terms are defined once, where they first arise, and used consistently thereafter, so that the seven chapters read as one book.

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Course Objectives

The objectives of this course are to:

1. Understand the principles of formulation and development of monophasic liquid dosage forms, including solvent selection and solubility enhancement techniques.
2. Acquire knowledge of biphasic liquid dosage forms, including physicochemical principles, formulation strategies, manufacturing processes, and stability considerations.
3. Develop competence in pressurised dosage forms such as aerosols, metered-dose inhalers, and dry powder inhalers, with emphasis on formulation design, device components, manufacturing, and quality evaluation.
4. Understand the formulation, manufacturing, and evaluation of semisolid dosage forms, with emphasis on drug permeation through the skin and factors affecting topical drug delivery.
5. Gain exposure to advanced drug delivery systems such as nanosuspensions, nanoemulsions, SMEDDS/SNEDDS, xerogels, and emulgels for improved therapeutic performance.

Course Outcomes

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

1. Explain the fundamental principles, classification, formulation requirements, and quality aspects of monophasic and biphasic liquid dosage forms.
2. Formulate, manufacture, and evaluate monophasic and biphasic liquid preparations, including solutions, syrups, elixirs, suspensions, and emulsions, using appropriate excipients and processing techniques.
3. Apply physicochemical principles such as solubility enhancement, Stokes' law, DLVO theory, and emulsification theories to design stable liquid dosage forms and assess their stability and performance.
4. Design and evaluate pressurised and inhalation dosage forms, including aerosols, metered dose inhalers, and dry powder inhalers, by selecting suitable formulation components, devices, and quality control parameters.
5. Formulate, evaluate, and justify the use of semisolid and advanced drug delivery systems—including ointments, creams, gels, suppositories, nanosuspensions, nanoemulsions, SMEDDS/SNEDDS, xerogels, and emulgels—for enhanced drug delivery, stability, and patient compliance.

Syllabus

Unit	Topics	No. of lectures
I	Monophasic Liquids & Pressurised Dosage Forms Foundations: Need, advantages/limitations; monophasic vs biphasic; solubility-enhancement techniques. Vehicles & solvents: Pharmaceutical waters (types; manufacturing & Quality Control of Purified/Distilled); classes of solvents as per toxicity. Formulation & manufacturing: Raw-material considerations and additives; processing; Quality Control of solutions/syrups/elixirs; powders for reconstitution as solutions. Measuring, filling & packaging: Techniques; container–closure integrity; automation in liquid manufacturing.	06 Hours
II	Biphasic Liquids - Suspensions Formulation & manufacturing: Additives; classification of suspending agents; IPQC & Quality Control; instabilities and packaging. Advances: Nanosuspensions; dry powder for reconstitution as suspensions; raft-forming systems.	06 Hours
III	Biphasic Liquids - Emulsions Formulation & manufacturing: Additives; classification of emulsifying agents; IPQC & Quality Control; instabilities and packaging. Advances: Nano-emulsions, micro-emulsions, SMEDDS/SNEDDS (overview, applications).	06 Hours
IV	Pressurized dosage forms (Aerosols/MDIs) Concepts; propellant classification/selection; valves & containers; formulation, manufacturing, and Quality Control (leak, spray pattern, delivered dose, particle-size/aerodynamic performance). Dry Powder Inhalers: valves & containers; formulation, manufacturing, and Quality Control.	06 Hours
V	Semisolid Dosage Form Theory of Semisolid Dosage Forms: Definition & Purpose, Drug Permeation Pathways through skin, Factors affecting	06 Hours

	Permeation, Permeation enhancers: Physical and Chemical. Types of semisolid dosage form: Ointments: Base Selection, Formulation, Manufacturing and Evaluation Creams: Formulation, Manufacturing and Evaluation Gels/Jellies: Formulation, Manufacturing and Evaluation. Pastes: Formulation, Manufacturing and Evaluation Suppositories and Pessaries: Formulation, Manufacturing and Evaluation Advances: Xerogels, emulgels (overview, applications).	
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How to Use This Book

Each chapter opens with a short list of **learning outcomes** tied to the official Course Outcomes of the subject. Every outcome is both taught in the chapter and tested in its self-assessment, so the list doubles as a revision checklist.

The **main text** develops each topic in the order: definition, classification, mechanism or principle, and application. Key terms are set in **bold** where they are first defined. **Figures** and **tables** are numbered by chapter (Figure 3.2, Table 3.1) and are referred to by number at the point in the text where they teach; they are not decoration, and a topic is often best revised from its figure. **Quick-recall boxes** hold a definition, a formula or an examination key in a form that can be memorised.

For calculation topics, a **worked example** is given in full before the theory it illustrates, and the self-assessment then ramps from worked problems through partly-worked to independent problems, each with a complete recomputed solution. A consolidated **formula sheet** at the back of the book collects every equation used.

The **self-assessment** at the end of each chapter carries short-answer questions, long-answer (essay) questions, multiple-choice questions and, where the subject demands, numerical problems, all with model answers. Genuinely high-yield topics are tagged honestly so that a student revising under time pressure can see where to spend attention first.

Abbreviations and Symbols

Abbreviation	Meaning
CMC	Critical micelle concentration
CO	Course outcome
DLVO	Derjaguin–Landau–Verwey–Overbeek (theory)
DPI	Dry powder inhaler
DV	Displacement value
HFA	Hydrofluoroalkane
HLB	Hydrophile–lipophile balance
ICH	International Council for Harmonisation
IP	Indian Pharmacopoeia
IPQC	In-process quality control
MDI	Metered-dose inhaler
MMAD	Mass median aerodynamic diameter
o/w	Oil-in-water
PDE	Permitted daily exposure
PEG	Polyethylene glycol (Macrogol)
QC	Quality control
SMEDDS	Self-microemulsifying drug delivery system
SNEDDS	Self-nanoemulsifying drug delivery system
TOC	Total organic carbon
w/o	Water-in-oil
WFI	Water for Injection
C	Volume/weight of pure base one mould cavity holds (displacement calc.)
D	Weight of drug per suppository
F	Sedimentation volume
J	Steady-state flux (Fick's first law)
η	Viscosity
ζ	Zeta potential

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