

PHARMACEUTICS (THEORY)

ER20-11T

Diploma in Pharmacy, First Year

As per PCI Education Regulations, 2020

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Preface

It gives us immense pleasure to present "Pharmaceutics (Theory)" for First Year Diploma in Pharmacy (D. Pharm.) students, meticulously prepared in accordance with the Pharmacy Council of India (PCI) Education Regulations (ER-2020). This book has been designed to provide students with a comprehensive understanding of the fundamental principles of pharmaceutics while developing the knowledge and practical insight required for pharmaceutical education and professional practice. Pharmaceutics is one of the most important branches of pharmaceutical sciences, serving as the foundation for the design, development, manufacturing, packaging, quality assurance, and delivery of medicines. A clear understanding of pharmaceutics enables students to appreciate how medicines are transformed from active pharmaceutical ingredients into safe, effective, stable, and patient-friendly dosage forms. This book comprehensively covers all the topics prescribed in the PCI syllabus, including the history of pharmacy profession in India, pharmacopoeias, pharmaceutical packaging materials, pharmaceutical aids, preservatives, unit operations, pharmaceutical dosage forms, pharmaceutical manufacturing plants, quality control, quality assurance, current Good Manufacturing Practices (cGMP), calibration, validation, and novel drug delivery systems. Each chapter has been presented in a systematic, student-friendly, and easy-to-understand manner with appropriate illustrations, tables, flowcharts, and examination-oriented explanations to facilitate effective learning. Special attention has been given to presenting complex pharmaceutical concepts in a simplified language without compromising scientific accuracy. The content has been carefully organized to strengthen conceptual understanding while simultaneously preparing students for university examinations, competitive examinations, and future professional responsibilities in the pharmaceutical industry, hospital pharmacy, community pharmacy, regulatory affairs, and research.

This book aims not only to help student's secure excellent academic performance but also to cultivate scientific thinking, professional ethics, and a deeper appreciation of the vital role pharmacists play in improving healthcare and ensuring patient safety. We sincerely hope that this textbook will serve as a valuable learning resource for Diploma in Pharmacy students, pharmacy teachers, academic institutions, and healthcare professionals. We also believe it will encourage learners to build a strong foundation in pharmaceutics and inspire them to pursue excellence in pharmaceutical sciences. Every effort has been made to ensure the accuracy and quality of the contents. Nevertheless, constructive suggestions and valuable feedback from readers, teachers, and professionals will always be welcomed and greatly appreciated for improving future editions of this book. We express our heartfelt gratitude to all our teachers, colleagues, students, reviewers, and well-wishers whose constant encouragement, support, and inspiration made this work possible. We dedicate this book to the pharmacy fraternity with the hope that it contributes meaningfully to pharmaceutical education and the advancement of healthcare.

With Best Wishes,

Authors

Bhavna D. Mahajan

Kunal S. Surwade

Pranjali T. Patil

How to use this book

The book serves three readers at once: the first-time learner, the reviser and the student preparing the night before an examination.

- Begin each chapter at its learning outcomes, which state exactly what you should be able to do afterwards, and test yourself against them at the end.
- Use the figures with the text, not instead of it. Every classification is drawn as a chart or tree and every method as a flowchart, so the picture and the words teach the same idea two ways.
- Treat the tables as revision aids, since a comparison table is the fastest way to fix a distinction the examiner will test.
- Work every calculation by hand. The worked examples, on the ball-mill critical speed, tablet weight variation, particle settling, suppository displacement value and injection isotonicity, are the ones the paper repeats.
- Learn the mnemonics and review grids, which are placed at the end of each chapter for last-minute recall.
- Work the self-assessment: the multiple-choice questions check recall, the short notes build the two-to-five mark answers, and the long-answer questions show what earns the marks.

Cross-references point back to where an idea was first taught, so you can follow the thread of the subject rather than treat each topic as separate.

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Abbreviations

- **API** — active pharmaceutical ingredient
- **BCG** — Bacille Calmette-Guérin (tuberculosis vaccine)
- **BP** — British Pharmacopoeia
- **cGMP** — current good manufacturing practice
- **CDSCO** — Central Drugs Standard Control Organisation
- **CR / SR** — controlled release / sustained release
- **DCGI** — Drugs Controller General of India
- **DPT** — diphtheria, pertussis and tetanus (vaccine)
- **DV** — displacement value
- **FBD** — fluidized bed dryer
- **GMP** — good manufacturing practice
- **HEPA** — high-efficiency particulate air (filter)
- **HLB** — hydrophilic-lipophilic balance
- **HPMC** — hydroxypropyl methylcellulose
- **ID / IM / IV / SC** — intradermal / intramuscular / intravenous / subcutaneous
- **IP** — Indian Pharmacopoeia
- **IPC** — Indian Pharmacopoeia Commission
- **IPRS** — IP Reference Substances
- **LAF** — laminar air flow
- **LAL** — Limulus amoebocyte lysate (bacterial endotoxin test)
- **NDDS** — novel drug delivery system
- **NF** — National Formulary
- **NPPA** — National Pharmaceutical Pricing Authority
- **o/w, w/o** — oil-in-water, water-in-oil
- **PCI** — Pharmacy Council of India
- **PEG** — polyethylene glycol (macrogol)
- **QA / QC** — quality assurance / quality control
- **SOP** — standard operating procedure
- **TDDS** — transdermal drug delivery system
- **USP-NF** — United States Pharmacopeia and National Formulary
- **WFI** — water for injection