

Industrial Pharmacy and Facility Design

Course Code: BP803T

A Textbook for Bachelor of Pharmacy, Semester VIII

As per new PCI Syllabus 2026 (NEP 2020)

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Preface

This book has been written for students of the Bachelor of Pharmacy programme studying *Industrial Pharmacy and Facility Design* (BP803T) in the eighth semester, and for the teachers who guide them. The subject occupies a distinctive place in the curriculum. Where earlier courses treat the science of individual dosage forms, this course treats the industrial system that turns a proven formulation into a marketed medicine: the regulatory framework that governs development, the scale-up and technology transfer that move a product from the bench to the plant, and the design of the facilities and utilities in which medicines are actually made.

The book follows the prescribed syllabus unit by unit, but it is written around a single connecting idea, that quality is designed into a product and its process and then protected at every subsequent stage, rather than tested in at the end. Each regulatory requirement is presented together with the reason it exists and the way a plant demonstrates that it has been met, so that the student reads the syllabus not as five disconnected topics but as one continuous account of how a medicine of assured quality is made.

The treatment is pitched for a final-year undergraduate. Definitions are stated precisely, classifications are given in full, and the distinctions that examinations test are dwelt upon, while routine matter is treated briskly. Every chapter opens with learning outcomes tied to the course outcomes, develops the topic with original figures and worked examples drawn from manufacturing practice, and closes with a summary and a graded self-assessment of short-answer, long-answer and multiple-choice questions with model answers, so that the book serves the first-time learner, the reviser, and the examinee from the same pages.

Facts, figures and regulatory requirements have been drawn from the prescribed references and from the current ICH, WHO, ISO and Schedule M standards, and the reader is reminded that precise compendial and regulatory values should always be confirmed against the current editions. Every figure and table in the book is original, prepared to be clear in print. It is hoped that the book will help students not merely to pass the examination but to understand the industrial and regulatory logic of pharmaceutical manufacture, which they will meet again throughout their professional lives.

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Course Objectives and Outcomes

Course Objectives. The objectives of this course are to introduce the regulatory guidelines (ICH, WHO, Schedule M, cGMP and SUPAC) governing formulation development, stability testing and scale-up; to develop an understanding of industrial product development, including pilot plant operations, scale-up and platform technologies; to explain the principles and procedures of technology transfer from research and development to commercial production, including documentation, quality risk management and regulatory compliance; to introduce the design and operational requirements of sterile and non-sterile pharmaceutical facilities, including layout, utilities and contamination control; and to familiarise students with modern facility-design concepts such as modular cleanrooms, isolators, automation and advanced contamination control.

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

CO1 interpret the regulatory guidelines (ICH, WHO, Schedule M, SUPAC) relevant to product development, stability studies and manufacturing

CO2 explain pilot plant operations and scale-up strategies for solid, liquid and semisolid dosage forms

CO3 describe the processes, documentation and quality-management principles of technology transfer from research and development to manufacturing

CO4 design and evaluate facility layouts and utility systems for sterile and non-sterile manufacturing in accordance with cGMP and global cleanroom standards

CO5 assess modern facility-design approaches, including modular cleanrooms, automation and validation systems, for efficient and compliant manufacturing.

Syllabus

Unit I (12 hours). Regulatory guidelines for formulation development: ICH Q8, Quality by Design and optimisation (fundamental terminology, process and applications); ICH guidelines for stability testing. Industrial aspects of product development: pilot plant and scale-up, general considerations including personnel, space and raw-material requirements; scale-up considerations for solids, liquid orals and semisolids and the relevant documentation; SUPAC guidelines; introduction to platform technology.

Unit II (9 hours). Technology development and transfer: WHO guidelines for technology transfer, terminology, the transfer protocol, quality risk management, transfer from research and development to production (process, packaging and cleaning), granularity of the transfer process (active ingredient, excipients, finished products, packaging materials), documentation, premises and equipment, qualification and validation, quality control and analytical method transfer; technology transfer agencies in India (APCTT, NRDC, TIFAC, BCIL, TBSE/SIDBI); technology-transfer-related documentation, confidentiality agreement, licensing, memoranda of understanding, and legal issues.

Unit III (9 hours). Facility considerations, non-sterile: facility design according to Schedule M for various dosage forms; water purification system design and operation, storage, distribution and validation, and the different types of water; steam and clean-steam systems, compressed air, vacuum and cleaning-in-place, and the industry standards for water and steam systems; effluent testing facility design and significance; layout design for non-sterile dosage forms (process flow); cleaning and disinfection protocols, cleaning types (A, B and C), and cleaning validation methods and acceptance criteria.

Unit IV (9 hours). Facility considerations, sterile: overview of sterile manufacturing, layout as per Schedule M and cGMP, the cleanroom concept and the importance of sterility and contamination control, sterilisation-in-place, efficient material and personnel flow, zoning and segregation, and cleanroom classifications from the FDA, EMA, WHO and

ISO; heating, ventilation and air-conditioning (HVAC): significance, components and testing, including HEPA efficiency and integrity testing; parameters for the qualification and validation (routine monitoring) of a clean area.

Unit V (6 hours). Advances in facility design: the modular concept of manufacturing facilities, with significance and examples; advances in cleanroom technology, pass-through chambers, isolators and modular cleanrooms; automation and robotics in pharmaceutical manufacturing operations.

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