

Industrial Pharmacy and Facility Design (Theory)

BP803T

A Textbook for B. Pharm Semester VIII

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

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Preface

This book is a course text for *Industrial Pharmacy and Facility Design* (BP803T), the theory paper of the eighth semester of the Bachelor of Pharmacy programme of the Pharmacy Council of India. It covers the prescribed syllabus in full and to the depth the university examination demands, treating each topic concisely and aligning the explanation with the question paper, so that a student who studies this book is prepared for the paper.

The subject is presented as a single argument rather than as five unconnected units. Its theme is that quality and sterility are built into a pharmaceutical product, its process, its transfer, and its facility by design, and are assured by understanding and control rather than by final inspection. The regulatory guidance of ICH, the WHO, and Schedule M, the engineering of utilities and cleanrooms, and the advances in modular and automated facilities are shown to be expressions of this one idea. The connections between the units are drawn out at each stage, so that the design space of Unit I reappears in the control strategy transferred in Unit II, the qualification sequence of Unit II is applied to the water systems of Unit III and the clean areas of Unit IV, and the contamination control of Units III and IV reaches its conclusion in the isolators of Unit V.

Every chapter opens with learning outcomes traced to the official Course Outcomes, develops the content with original figures and comparison tables, works through the calculations the subject requires with their full steps, and closes with a graded self-assessment of short-answer, long-answer, and multiple-choice questions with model answers, framed in the style of the university paper.

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Course Objectives

The objectives of this course are to:

1. Introduce regulatory guidelines such as ICH, WHO, Schedule M, cGMP, and SUPAC governing pharmaceutical formulation development, stability testing, and scale-up processes.
2. Develop an understanding of industrial product development processes including pilot plant operations, scale-up considerations, and platform technologies used in pharmaceutical manufacturing.
3. Explain the principles and procedures involved in technology transfer from research and development to commercial production, including documentation, quality risk management, and regulatory compliance.
4. Introduce the design and operational requirements of pharmaceutical facilities for sterile and non-sterile manufacturing, including layout planning, utilities, and contamination control systems.
5. Familiarize students with modern pharmaceutical facility design concepts such as modular cleanrooms, isolators, automation, and advanced contamination control technologies to ensure product quality and regulatory compliance.

Course Outcomes

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

1. Interpret regulatory guidelines (ICH, WHO, Schedule M, SUPAC) relevant to pharmaceutical product development, stability studies, and manufacturing processes.
2. Explain pilot plant operations and scale-up strategies for the development of solid, liquid, and semi-solid pharmaceutical dosage forms.
3. Describe the processes, documentation, and quality management principles involved in technology transfer from R&D to manufacturing.
4. Design and evaluate facility layouts and utility systems for sterile and non-sterile pharmaceutical manufacturing in accordance with cGMP and global cleanroom standards.
5. Assess modern pharmaceutical facility design approaches, including modular cleanrooms, automation, and validation systems, to ensure efficient and compliant manufacturing operation.

Syllabus

Unit	Topics	No. of lectures
I	Regulatory guidelines for formulation Development: ICH Q8, QbD and optimization (Fundamental terminologies, process and applications) ICH guidelines of stability testing Industrial aspects of Product development: Pilot Plant and Scale up: General considerations including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology	12 Hours
II	Technology development and transfer: WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials), Documentation, Premises and equipments, qualification and validation, quality control and analytical method transfer TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI TT related documentation - confidentiality agreement, licensing, MoUs, legal issues	09 Hours
III	Facility Considerations: Non sterile: Facility design according to schedule M for various dosage forms Water purification system: design and operation, Storage, distribution, and validation of water systems. Different types of waters Steam systems and Clean Steam, Compressed air, Vacuum, CIP. Industry standards for water and steam systems Effluent testing facility: Design and significance Layout design for various non-sterile dosage forms (Process flow) Cleaning and disinfection protocols, cleaning types (Type A, B and C), Cleaning validation methods and acceptance criteria	09 Hours

IV	Facility considerations: Sterile: Overview of sterile pharmaceutical manufacturing: layout as per schedule M and cGMP, clean room concept - Importance of sterility and contamination control, SIP, efficient material and personnel flow to maintain sterility, zoning and segregation, Guidelines, standards and Cleanroom classifications from FDA, EMA, WHO and ISO Heating, ventilation and air conditioning system (HVAC): Significance, components, testing (including efficiency and integrity testing of HEPA) Parameters for qualification and validation (routine monitoring) of clean area	09 Hours
V	Advances in facility design: Modular concept of manufacturing facilities with significance and suitable examples Advances in clean room technology: pass-through chambers, isolators, Modular cleanrooms Automation and robotics in pharmaceutical manufacturing operations	06 Hours

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List of abbreviations

Abbreviation	Expansion
AHU	Air handling unit
API	Active pharmaceutical ingredient
CIP	Clean-in-place
CMA	Critical material attribute
CPP	Critical process parameter
CQA	Critical quality attribute
DQ, IQ, OQ, PQ	Design, installation, operational, performance qualification
GMP	Good manufacturing practice
HEPA	High efficiency particulate air (filter)
HVAC	Heating, ventilation and air conditioning
ICH	International Council for Harmonisation
IP	Indian Pharmacopoeia
ISO	International Organization for Standardization
MACO	Maximum allowable carryover
PW	Purified Water
QbD	Quality by Design
QRM	Quality risk management
QTPP	Quality target product profile
RABS	Restricted access barrier system
RH	Relative humidity