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**A Textbook of  
Industrial Pharmacy II  
for B.Pharm. VII Semester**

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**(As Per PCI Syllabus)**



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**Editors**

**Dr. Rashmi Madhariya**

**Prof. (Dr.) Alpana Ram**

**Dr. K. Kesavan**



**RENU PUBLISHERS**

New Delhi, Kolkata

This First Edition published in 2026

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**Title:** A Textbook of Industrial Pharmacy II for B.Pharm. VII Semester

**Editors:** Dr. Rashmi Madharia, Prof. (Dr.) Alpana Ram and Dr. K. Kesavan

**Description:** First edition | Renu Publishers 2026 | Includes bibliographical references and index.

**Identifiers:** ISBN 9789392597688 (Print) | 9789392597190 (eBook)

**Cover Design:** Renu Publishers

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# Preface

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This book, *Industrial Pharmacy II*, is prepared meticulously to align with the syllabus prescribed by the Pharmacy Council of India (PCI) for Bachelor of Pharmacy (B.Pharm) students. Industrial Pharmacy is a crucial branch of pharmaceutical sciences that bridges the gap between drug discovery and patient care by focusing on the development, manufacturing, quality control, and regulatory aspects of pharmaceutical products. This book, *Industrial Pharmacy II*, is designed to build upon the foundational concepts introduced in the earlier course and to provide a comprehensive understanding of advanced industrial pharmacy topics for Bachelor of Pharmacy students.

This book covers advanced concepts such as scale-up techniques, technology transfer, process validation, packaging technology, stability studies, quality assurance, and regulatory aspects, all of which are crucial for producing safe, effective, and high-quality medicines. The content is structured to cover the latest guidelines and good manufacturing practices (GMP) recommended by the PCI and relevant regulatory bodies, including the Central Drugs Standard Control Organization (CDSCO).

Each chapter is designed to facilitate clear understanding by combining theoretical knowledge with practical examples, illustrations, and review questions, encouraging critical thinking and application of concepts. This approach aims to equip students not only to excel in their academic examinations but also to prepare them for the dynamic challenges of the pharmaceutical industry.

We sincerely hope this book will serve as a comprehensive learning tool for students, academicians, and industry professionals, supporting the growth of competent pharmacy graduates who can contribute effectively to the pharmaceutical sector.

Constructive feedback from readers will be welcomed to enhance the quality of future editions.

***Editors***

**Dr. Rashmi Madharia**

**Prof. (Dr.) Alpana Ram**

**Dr. K. Kesavan**

## **INDUSTRIAL PHARMACY II (THEORY)**

### **Scope**

This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

### **Objectives**

**Upon completion of the course, the student shall be able to:**

1. Know the process of pilot plant and scale-up of pharmaceutical dosage forms.
2. Understand the process of technology transfer from lab scale to commercial batch.
3. Know different Laws and Acts that regulate pharmaceutical industry.
4. Understand the approval process and regulatory requirements for drug products.

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