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Foundations and Advances in Pharmaceutical Sciences

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PREFACE

Pharmaceutical sciences continue to evolve through the integration of natural product research, drug design, formulation development, and pharmacological evaluation. The increasing complexity of healthcare demands a multidisciplinary understanding of medicines, from their origin and development to their therapeutic application and regulatory evaluation. This book, *Integrated Pharmaceutical Sciences: From Natural Sources to Therapeutic Applications*, was prepared to provide a concise and structured overview of major domains within pharmaceutical sciences.

The book presents fundamental and applied concepts related to pharmacognosy, pharmaceutics, pharmaceutical chemistry, and pharmacology in an integrated manner. Each chapter has been designed to provide clear academic content with emphasis on practical relevance, recent developments, and current pharmaceutical approaches. Topics included range from natural drug sources and phytochemicals to novel drug delivery systems, toxicological screening, regulatory aspects, nanotechnology, and personalized medicine.

This book is intended for undergraduate and postgraduate students, researchers, and academic professionals seeking a compact interdisciplinary resource in pharmaceutical sciences. The contributors have aimed to maintain scientific accuracy while presenting the material in a concise and accessible format.

We hope this book will contribute to academic learning and encourage further exploration in the field of pharmaceutical sciences.

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Chapter – 13

Regulatory Aspects of Herbal and Synthetic Drugs

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13.1. Introduction

Pharmaceutical regulation is the legal and scientific framework that governs the development, testing, manufacturing, and marketing of medications. The primary objective is to protect public health by ensuring that all therapeutic products are safe, effective, and of high quality. This regulatory oversight applies to both highly purified synthetic drugs and complex herbal formulations. The mechanisms and standards applied to these two categories differ significantly due to their distinct physical and chemical characteristics. Synthetic drugs are typically single chemical entities with defined molecular structures and predictable pharmacological profiles. Herbal medicines are complex mixtures of hundreds of secondary metabolites with inherent natural variability. Regulatory agencies must adapt their evaluation paradigms to accommodate these differences while maintaining rigorous safety standards.

The historical evolution of pharmaceutical regulation is punctuated by public health crises. The elixir sulfanilamide tragedy in the United States and the global thalidomide disaster forced governments to enact stringent laws requiring pre-market proof of safety and efficacy. These events established the modern regulatory