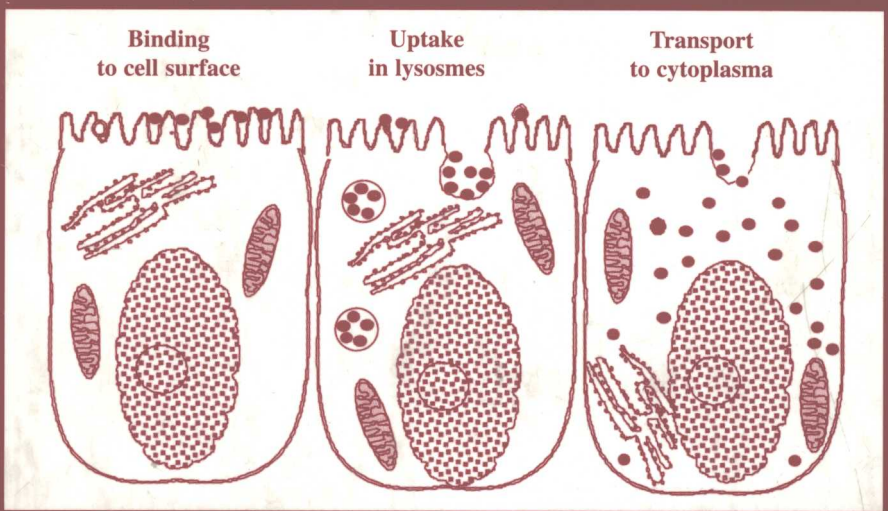
DRUGS AND THE PHARMACEUTICAL SCIENCES VOLUME 98

Bioadhesive Drug Delivery Systems

Fundamentals, Novel Approaches, and Development



edited by
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Preface

Our aim in writing *Bioadhesive Drug Delivery Systems* was to provide a comprehensive reference on bioadhesion covering basic concepts and methods for characterizing bioadhesive materials, novel biological approaches designed to improve vehicle targeting or enhance uptake, and practical topics addressing product development for clinical applications. Although the goal of bioadhesion research may be a marketable device, what is ultimately important is an understanding of the fundamental concepts involved in the mechanisms of adhesion, the biological interactions, and the practical application of bioadhesive carriers. In compiling the various chapters, our target was not to resolve the issues involved in bringing a product from bench to market, or to provide a "magic formula" to reduce costs during the process, but to expose the researcher, student, or industrial scientist to the wonderful possibilities of engineering, evaluating, and manufacturing bioadhesive materials. Some researchers may consider this book an excellent starting point to familiarize themselves with the field, while others may find it a source of new ideas for developing or characterizing innovative bioadhesive systems.

The book is divided into four parts: (I) Fundamentals of Bioadhesion, (II) Methods of Evaluating Bioadhesive Interactions, (III) Novel Concepts and Strategies for Bioadhesive Delivery Systems, and (IV) Development Issues of Bioadhesive Drug Delivery Systems: Products and Clinical Trials. Each chapter is devoted to a specific topic or concept and contains relevant literature reviews of the subject, supported by novel discoveries or ideas of the contributing authors.

Part I, Fundamentals of Bioadhesion, reviews both physicochemical fundamentals and biological aspects of bioadhesion. Here we discuss the theories and concepts developed to describe adhesive interactions and explain the relevant forces associated with bioadhesive bonding. Topics covered include mechanical and chemical bonding, polymer–mucus interactions, the effect of surface energy in bioadhesion, the role of polymer hydration or water movement, and mucus rheology. In addition, the anatomy

and physiology of target tissues as well as the molecular and intracellular mechanisms that may contribute to bioadhesion are discussed. Specific chapters are devoted to biochemical properties of mucus and glycoproteins, cell adhesion molecules, and cellular interactions with two- and three-dimensional surfaces.

Part II, Methods of Evaluating Bioadhesive Interactions, explains the more common techniques for bioadhesive analysis that have been adapted from traditional materials testing. Chapters are dedicated to unique and innovative systems specifically designed for characterizing adhesive interactions in biological settings. These topics include the use of microbalances and magnetic force transducers, the use of atomic force microscopy, direct measurements of molecular level adhesions, and methods to measure cell–cell interactions.

Part III, Novel Concepts and Strategies for Bioadhesive Delivery Systems, highlights the possibilities and goals of employing bioadhesive materials as drug carriers. The effects of prolonged residence time, minimized interfacial boundaries, and cellular interactions are discussed. Particular attention is devoted to receptor mediated bioadhesion, pharmaceutical transport from bioadhesive carriers, diffusion or penetration enhancers, and lectin-targeted vehicles.

Part IV, Development Issues of BDDS: Products and Clinical Trials, discusses a unique area that has not been covered in any previous bioadhesion text. The purpose of this section is to provide an illustrative overview of clinical bioadhesive applications. Chapters offer examples of vaginal, nasal, buccal, ocular, and transdermal drug delivery using bioadhesive carrier materials. Issues involved in product development, clinical testing, and production are described.

By dividing the text into four parts, we hope to introduce the reader to the various aspects and considerations involved in developing bioadhesive controlled-release systems, starting from pure scientific concepts based on theoretical ideas and ending with significant examples of specific applications. Bioadhesive polymers offer unique carrier characteristics for many pharmaceutics. They can be tailored to adhere to either the dermis or any mucosal tissue including those found in the eye and mouth, and throughout the respiratory, urinary, and gastrointestinal tracts. These materials can improve localization of delivered agents, enhance local bioavailability, decrease adverse systemic effects, and improve drug absorption and transport. Using bioadhesive materials, it may be possible to reformulate existing compounds to produce new and useful products while decreasing the overall cost in development. The focus of this text is on understanding the basic mecha-

nisms of bioadhesion and on how this knowledge can be applied toward engineering efficient bioadhesive carrier systems for delivering therapeutic agents.

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