Ajit S. Narang · Sai HS. Boddu *Editors*

Excipient Applications in Formulation Design and Drug Delivery

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I dedicate this book to my teachers and mentors, who inspired the love of learning and believed in me more than I did; and to the support and sacrifices of my loved ones—my parents, brother, wife, children, and peers and colleagues—who have always inspired me to be and do the very best.

Ajit S. Narang

I dedicate this book to my parents, sisters, brother, wife and children for their unconditional love and support.

Sai HS. Boddu

Foreword

The study and use of pharmaceutical excipients is a living, ever evolving discipline. The excipients are not only routinely utilized in commercialized products and new products under development, but there is also constant research on their physiochemical properties, their influence on the biology of drug delivery, and the fundamental mechanisms that underlie material science. Excipients remain at the interface of fundamental and applied sciences, and often act as toolkits in the hands of an experimenter. This book is a humble attempt to gather any and all relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug delivery applications. We hope this book will appeal to a diverse group of students and researchers working with excipients.

Preface

In my role as an advanced drug delivery scientist and educator with keen interests in the fields of biopharmaceutics and drug targeting, I recognize the central role excipients play in all pharmaceutical drug applications. I am therefore happy to preface this book that addresses the fundamental science behind and the current understanding of excipient applications in such depth.

This book presents emerging research and perspectives on the use of excipients in pharmaceutical formulations. It also addresses some of the fundamental principles and key considerations related to the use of excipients such as compatibility studies, chemistry of drug-excipient interactions, and the mechanisms by which excipients may influence the biological response of drugs. The authors detail specialized applications such as the emerging field of characterizing the reactive impurities in excipients and harmonizing the composition profile of excipients from different sources and vendors. In the area of drug delivery, this book focuses on the role of excipients in modulating drug release, improving drug stability, and the development of bioequivalent and stable generic formulations.

Each chapter was contributed by chosen experts in their respective fields, and provides an in-depth perspective into a spectrum of excipient focused topics that are contemporary and highly relevant.

This book captures current topics of interest and the latest research updates in the field of pharmaceutical excipients; areas of interest to the biopharmaceutical industry users, excipient manufacturers, and regulatory bodies.

I give my best wishes to the reader and my hope that you get the best out of this book!

Gert Storm, Ph.D.,
Professor Biopharmaceutics/Targeted Nanomedicine
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Preface

It is my great pleasure to preface this book on the important technical considerations in the drug delivery applications of pharmaceutical excipients. Excipients play a vital role in drug products. In fact, almost no drug product can be made without excipients. At the same time, the information on excipients is scattered in the literature. The books currently available on excipients are very focused and provide general information. This book stands out in providing information relevant to students and scientists alike on the scientific considerations, methodologies, and approaches that one should take in judiciously selecting and utilizing excipients in pharmaceutical drug products.

My principal area of research is to develop an improved fundamental understanding of the role of surface properties in particle engineering and formulation. The use of excipients for the design and development of pharmaceutical dosage forms is certainly of great relevance and importance. I also have research interests in wetting, contact angles, surface energetics, physico-chemical properties of solids, and crystallization of both small and large (proteins) pharmaceutical molecules.

This book provides not only the technical and scientific depth needed for the students, educators, regulators, and the practicing scientists alike—it also provides focused and relevant information in one place, which makes this book a useful resource for frequent referral and use.

Happy reading!

Jerry Heng, Ph.D.
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Ajit S. Narang and
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