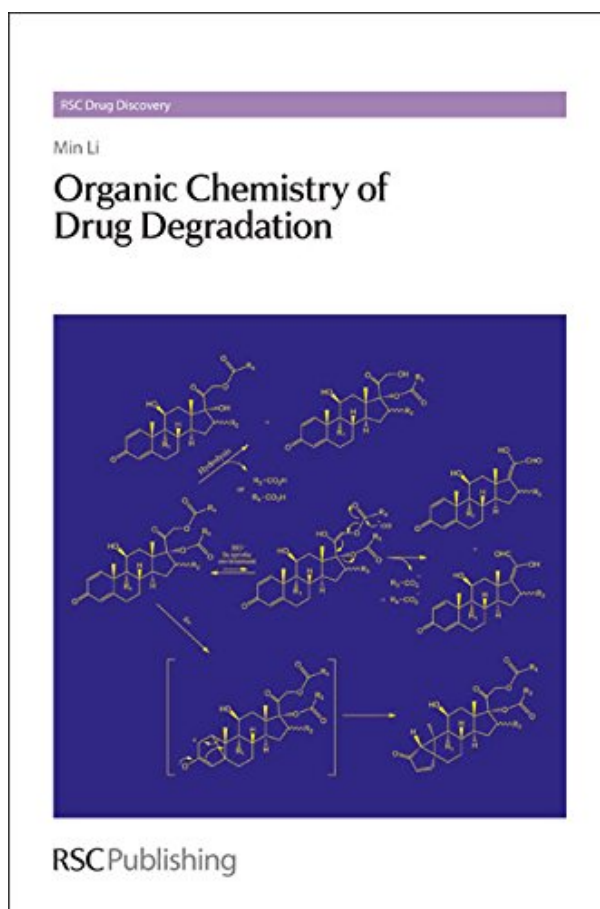


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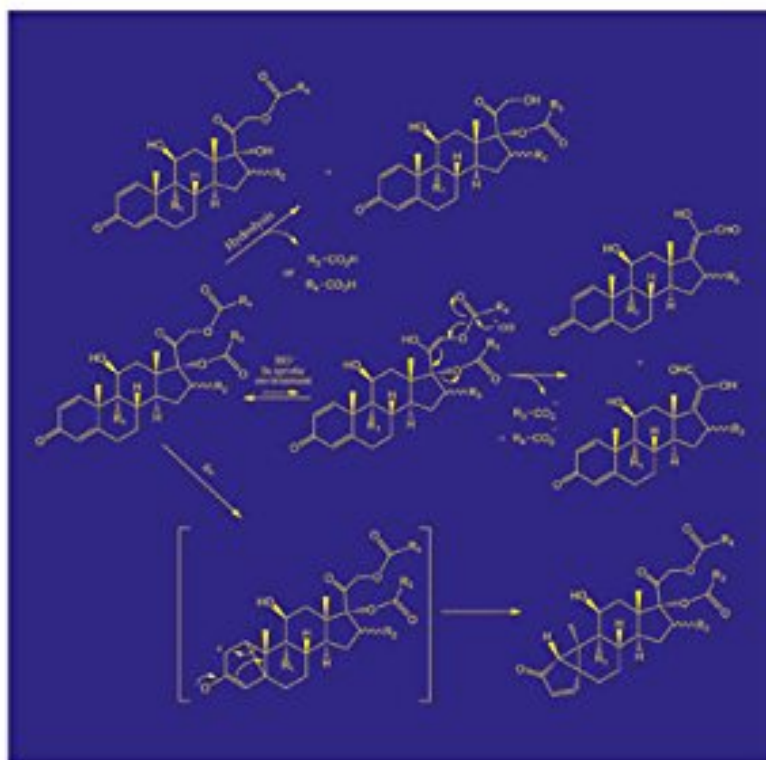
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Review

"Overall, *Organic Chemistry of Drug Degradation* is an interesting read and provides the reader with concise information and up-to-date knowledge on chemical as well as analytical aspects of drug degradation." (Prof. Dr. Mario Thevis, German Sport University Cologne (Germany) ChemMedChem, DOI: 10.1002/cmdc.201300109)

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A clear understanding of the organic chemistry of drug degradation is essential for maintaining the stability, efficacy, and safety of a drug product throughout its shelf-life. During analytical method development, stability testing, and pharmaceutical manufacturing troubleshooting activities, one of the frequently occurring and usually challenging events is the identification of drug degradants and the understanding of drug degradation mechanisms and pathways. This book is written by a veteran who has first-hand experience in drug design and development, degradation mechanism studies, analytical development, and manufacturing process troubleshooting and improvement. The author discusses various degradation pathways with an emphasis on the mechanisms of the underlying organic chemistry, which will aid greatly in efforts of degradant identification, formulation and analytical development, and manufacturing process improvement. Organic reactions that are significant in drug degradation are discussed and illustrated with examples. The author brings the book to a close with two chapters on strategy for rapid elucidation of drug degradants and

control of drug degradation with regard to the current regulatory requirements and guidelines. One chapter that should be given special attention is the one on Oxidative Degradation. Oxidative degradation is one of the most common degradation pathways but perhaps the most complex of all. This chapter employs more than sixty drug degradation case studies with in-depth discussion on their unique degradation pathways. With increasing regulatory requirements on quality and safety of pharmaceutical products, this book will be an invaluable resource for pharmaceutical and analytical scientists as well as medicinal chemists.

About the Author

Dr. Min Li is an Associate Director at Analytical Chemistry in Development and Supply - Supply Analytical Sciences Department of Merck & Co., Inc. He has led technical teams of senior-level scientists (Senior and Principal Scientists) for various analytical and pharmaceutical manufacturing process investigation and troubleshooting, impurity peak identification, study of drug degradation mechanisms, analytical method development, validation, specification setting, and support for new drug filing. He graduated from Fudan University and received his Ph.D. in Organic Chemistry from Johns Hopkins University, followed by a postdoctoral research at University of Illinois at Chicago in medicinal chemistry. Dr. Li was a Principal Scientist at Roche (1995 - 1998), a Scientific Fellow at Merck (1998 - 2005), and a manager at Schering-Plough (2005 - 2010). He was president of Sino-American Pharmaceutical Professionals Association (SAPA) between 2003 and 2004. Dr. Li is the first/primary author of more than 40 publications in a multi-disciplinary arena including organic, medicinal, bioconjugate, and analytical chemistry, as well as mass spectrometry. He has been invited to present in numerous international scientific meetings and conferences.

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The vast majority of drugs are organic molecular entities. A clear understanding of the organic chemistry of drug degradation is essential to maintaining the stability, efficacy, and safety of a drug product throughout its shelf-life. During analytical method development, stability testing, and pharmaceutical manufacturing troubleshooting activities, one of the frequently occurring and usually challenging events would be the identification of drug degradants and understanding of drug degradation mechanisms and pathways. This book is written by a veteran of the pharmaceutical industry who has first-hand experience in drug design and development, drug degradation mechanism studies, analytical development, and manufacturing process troubleshooting and improvement. The author discusses various degradation pathways with an emphasis on the mechanisms of the underlying organic chemistry, which should aid greatly in the efforts of degradant identification, formulation development, analytical development, and manufacturing process improvement. Organic reactions that are significant in drug degradation will first be reviewed and then illustrated by examples of drug degradation reported in the literature. The author brings the book to a close with a final chapter dedicated to the strategy for rapid elucidation of drug degradants with regard to the current regulatory requirements and guidelines. One chapter that should be given special attention is Chapter 3, Oxidative Degradation. Oxidative degradation is one of the most common degradation pathways but perhaps the most complex one. This chapter employs more than sixty drug degradation case studies with in-depth discussion in regard to their unique degradation pathways. With the increasing regulatory requirements on the quality and safety of pharmaceutical products, in particular with regard to drug impurities and degradants, the book will be an invaluable resource for pharmaceutical and analytical scientists who engage in formulation development, analytical development, stability studies, degradant identification, and support of manufacturing process improvement. In addition, it will also be helpful to scientists engaged in drug discovery and development as well as in drug metabolism studies.

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As a scientist with more than 10 years of working experience in the pharmaceutical industry focusing on

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this book can be used as an excellent resource for drug product design

By Amazon Customer

A large amount of drug degradation questions were asked in FDA's deficient letter during my current job, I searched internet for some professional reference, then I found this book. This book gives not only a lot of practical drug degradation examples of current marketed medicine, but also gives insightful discussion of the mechanism of the drug degradation formation. In order to develop a high quality small molecular drug and deep understanding of current products, this book can be used as an excellent resource for drug product design. I highly recommend this book for both Academic and Pharmaceutical professionals.

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A great reference book in drug degradation.

By Amazon Customer

Organic Chemistry of Drug Degradation provides a thorough and in-depth review on degradation pathways and mechanisms that are most relevant to drug molecules. As a pharmaceutical scientist working in analytical development and drug metabolism, I found this book a great reference book, containing valuable information to gain knowledge on drug degradation and to have a better understanding on how such reactions might impact drug development. Scientists working in formulation, process and product development would also benefit from reading this book.

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