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The United States Food and Drug Administration (FDA) and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation (ICH) be isolated and characterized. Identifying process-related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms. When this process is performed at an early stage, there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high-quality drug product.

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This book, therefore, has been designed to meet the need for a reference text on the complex process of isolation and characterization of process-related (synthesis and formulation) impurities and degradation products to meet critical regulatory requirements. It's objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates, drug substances, and drug products. The book outlines impurity identification processes and will be a key resource document for impurity analysis, isolation/synthesis, and characterization.

- Provides valuable information on isolation and characterization of impurities.
- Gives a regulatory perspective on the subject.
- Describes various considerations involved in meeting regulatory requirements.
- Discusses various sources of impurities and degradation products.

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This laboratory guide represents a growing collection of tried, tested and optimized laboratory protocols for the isolation and characterization of eukaryotic RNA, with lesser emphasis on the characterization of prokaryotic transcripts. Collectively the chapters work together to embellish the RNA story, each presenting clear take-home lessons, liberally incorporating flow charts, tables and graphs to facilitate learning and assist in the planning and implementation phases of a project. RNA Methodologies, 3rd edition includes approximately 30% new material, including chapters on the more recent technologies of RNA interference including: RNAi; Microarrays; Bioinformatics. It also includes new sections on: new and improved RT-PCR techniques; innovative 5' and 3' RACE techniques; subtractive PCR methods;

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methods for improving cDNA synthesis. * Author is a well-recognized expert in the field of RNA experimentation and founded Exon-Intron, a well-known

biotechnology educational workshop

center * Includes classic and

contemporary techniques * Incorporates

flow charts, tables, and graphs to facilitate

learning and assist in the planning phases

of projects

A comprehensive overview of

biodegradable polymers, covering

everything from synthesis,

characterization, and degradation

mechanisms while also introducing useful

applications, such as drug delivery

systems and biomaterial-based

regenerative therapies. An introductory

section deals with such fundamentals as

basic chemical reactions during

degradation, the complexity of biological

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environments and experimental methods for monitoring degradation processes. The result is a reliable reference source for those wanting to learn more about this important class of polymer materials, as well as scientists in the field seeking a deeper insight.

This handbook series includes several naturally occurring chemicals that exhibit biological activity. These chemicals are derived from plants, insects, and several microorganisms. Volume II of this series is devoted to methods for isolation and identification for pest control technology. Methods for isolation and characterization are very important for gaining knowledge on how to discover these chemicals when present in such minute amounts (ppm to ppb levels) in nature. Several chemical and biological methods have been developed for

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Handbook of Methods in Aquatic Microbial Ecology is the first comprehensive compilation of 85 fundamental methods in modern aquatic microbial ecology. Each method is presented in a detailed, step-by-step format that allows readers to adopt new methods with little difficulty. The methods represent the state of the art, and many have become standard procedures in microbial research and environmental assessment. The book also presents practical advice on how to apply the methods. It will be an indispensable

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reference for marine and freshwater research laboratories, environmental assessment laboratories, and industrial research labs concerned with microbial measurements in water.

A comprehensive overview of biodegradable polymers, covering everything from synthesis, characterization, and degradation mechanisms while also introducing useful applications, such as drug delivery systems and biomaterial-based regenerative therapies. An introductory section deals with such fundamentals as basic chemical reactions during degradation, the complexity of biological environments and experimental methods for monitoring degradation processes. The result is a reliable reference source for those wanting to learn more about this important class of polymer materials, as

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well as scientists in the field seeking a deeper insight.

The Handbook of Laboratory Animal Bacteriology, Second Edition provides comprehensive information on all bacterial phylae found in laboratory rodents and rabbits to assist managers, veterinary pathologists and laboratory animal veterinarians in the management of these organisms. The book starts by examining the general aspects of bacteriology and how to sample and identify bacteria in animals. It then describes the most relevant species within each phylum and discusses the impact they may have on research. Emphasizing those bacteria known to interfere with research protocols, the book offers methods for isolation and differentiation among related bacteria. It discusses where to purchase reagents for rodent bacteriology and outlines standards

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bacteria Provides information on a range

of bacteria interfering with animal models

for human disease, not only for those

bacteria which cause disease in laboratory

animal colonies Includes new figures in

color and with enhanced resolution The

book is essential reading for those

interested in the management of organisms

known to interfere with the colony health

of rabbits and rodents used in research

protocols—including facility managers,

clinical veterinarians, veterinary

pathologists, and researchers.

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The functional analysis of plant-microbe interactions has re-emerged in the past 10 years due to spectacular advances in integrative study models. This book summarizes basic and technical information related to the plant growth promoting rhizobacteria (PGPR) belonging to the genus *Azospirillum*, considered to be one of the most representative PGPR last 40 years. We include exhaustive information about the general microbiology of genus *Azospirillum*, their identification strategies; the evaluation of plant growth promoting mechanisms, inoculants technology and agronomic use of these bacteria and some special references to the genetic technology and use.

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