Drug Stability and Chemical Kinetics

Muhammad Sajid Hamid Akash •
Kanwal Rehman
Editors

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Springer

Editors
Muhammad Sajid Hamid Akash
Department of Pharmaceutical Chemistry
Government College University
Faisalabad, Pakistan

Kanwal Rehman
Department of Pharmacy
University of Agriculture
Faisalabad, Pakistan

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This book is dedicated
to
Our Beloved and Adorable Little Twinkles
Muhammad Aqdas Akash
&
Zainab Akash

Preface

Stability studies are essential for certifying safety, efficacy and quality of drug products to assess their shelf life. These studies assure that pharmaceutical products will exhibit constant efficacy under specified storage conditions. Developments in pharmaceutical industry show novel ways for preserving the quality of pharmaceutical preparations. Stability is vital for protection, value and quality of a drug. The investigation of drug stability is essential to improve quality, safety and efficacy. Drug toxicity and its adverse effects can be prevented by evaluating parameters related to stability. Upon storage, pharmaceutical products are vulnerable to chemical and physical degradation. These degradations alter pharmacological properties of a drug resulting in reduced benefits and increased toxicity. Physical factors that influence the stability of pharmaceuticals are heat, ionic strength, acid-base catalysis, solvent, light and radiations, oxygen, particle size distribution and moisture.

Advanced kinetic models are used to calculate the degradation rate of biological products, such as protein and virus-based vaccines and emulsion-based adjuvant vaccines. Statistical tools are used to select an optimal number based on variable parameters and analyse experimental data obtained from various steps of kinetic models.

This book "Drug Stability and Chemical Kinetics" provides an introduction to the principles of pharmaceutical analysis in drug stability and chemical kinetics, proposes guidelines for drug stability and stability testing, and mentions methods and protocols for drug stability studies and degradation factors of pharmaceutical products, including physical, chemical and microbial degradation as well as role of decomposition, catalysis and catalytic agents. Finally, it explains various kinetic models in drug stability prevention and therapeutic intervention.

This book provides comprehensive and up-to-date information regarding the principles of pharmaceutical analysis in drug stability and chemical kinetics.

There exists an enormous gap in knowledge between the fundamentals of drug stability and the role of chemical kinetics. This book aims to link the gap existing between drug stability as well as its factors and chemical kinetics as well as its factors. Therefore, this book provides better understanding about each vital component of drug stability and chemical kinetics.

By implication, chapters of this book mention the emerging areas of research in this field and various environmental factors that affect drug quality by physical or

chemical degradation. The book also discusses types and methods of stability tests and storage conditions as well as ICH and WHO guidelines.

This book includes in-depth assessments about various analytical methods and protocols for drug stability studies and factors involved in drug degradation by influencing its kinetic profile. We assure this book will inspire and show innovative paths of research to increase knowledge, awareness and responsiveness about drug stability studies.

Faisalabad, Pakistan Muhammad Sajid Hamid Akash
Faisalabad, Pakistan Kanwal Rehman

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Last but not least, we thank Springer Publishers for providing us the platform to publish this book and contribute essential information in this field.

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About the Editors

Muhammad Sajid Hamid Akash is currently working as Associate Professor and Chairman at Department of Pharmaceutical Chemistry, Government College University Faisalabad (GCUF), Pakistan. He received his bachelor and master degrees in pharmacy from Bahauddin Zakariya University, Multan, Pakistan, and PhD degree in pharmaceutical analysis from Zhejiang University, China. He has published more than 100 articles (with cumulative impact factor 250 with total citations of 3150) in internationally recognized peer-reviewed ISI-indexed journals. He has also published 40 book chapters and 3 books with international publishers. Currently, he is investigating various molecular and metabolic pathways to study the effect of endocrine disrupting chemicals (EDCs) and environmental contaminants (ECs) and their treatment strategies for these EDCs- and ECs-induced metabolic disorders funded by Higher Education Commission (HEC) of Pakistan. His research work is advanced and worthy of implementation in developing countries like Pakistan, where it can be most beneficial and economical especially for diabetic patients. Based on his significant scientific contributions in the field of pharmaceutical sciences, he has been awarded Research Productivity Award by Pakistan Council for Science and Technology (PCST), PAS Gold Medal by Pakistan Academy of Sciences and A.R. Shakoori Gold Medal by Zoological Society of Pakistan.

Kanwal Rehman is working as Assistant Professor at Department of Pharmacy in University of Agriculture, Faisalabad, Pakistan. She received her PhD in pharmacology and toxicology from Zhejiang University, Hangzhou, China, where she has done some excellent work by exploring the effect of arsenic compounds and their molecular mechanisms in arsenic-induced carcinogenic and anticancer effects. She displays a keen interest in the pathogenesis of metabolic disorders such as diabetes mellitus and obesity, and works on new therapeutic modalities for the treatment of these disorders. Her other notable work includes the detection of environmental pollutants and their cytotoxic effects. She has published nearly 90 articles with cumulative impact factor of 240. She has also published 40 book chapters and 3 books with international publishers. She is working on three research projects funded by Higher Education Commission (HEC) of Pakistan. Currently, she is investigating the role of pharmacogenomics based upon gene polymorphism on various molecular and metabolic pathways involved in mitogenic disorders, and

focusing on treatment strategies like natural biogenic compounds against different risk factors of metabolic disorders such as pancreatitis, cardiometabolic disorders and hormonal imbalance. Dr. Kanwal Rehman has also been awarded Research Productivity Award by Pakistan Council for Science and Technology (PCST), Pakistan.