

Methods in Pharmacology
and Toxicology

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Sanjay Bajaj
Saranjit Singh *Editors*



Methods for Stability Testing of Pharmaceuticals

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Methods for Stability Testing of Pharmaceuticals

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Preface

We, as pharmaceutical scientists, have always seen stability testing as a vital part of any drug development process. From the very basic level of experimentation, like stability of suspensions and emulsions in undergraduate laboratory, to stability testing of active pharmaceutical ingredients and conventional products containing them, and further to highly technical novel drug delivery systems, a thorough investigation on stability of every kind of product is desired for the benefit of the patients. Every product is supposed to be labeled with a valid expiry date and storage conditions, which are established through systematic stability studies. Due to many product failures and recalls happening for the reasons of instability, carrying out a successful stability program in the pharmaceutical industry has become very vital. Stability testing hence has to be a very well-organized activity, supported with due resources, which even stands up to critical regulatory scrutiny.

A lot of information, literature articles, and books regarding stability testing are already available, and lots of regulatory efforts have been made for harmonization of the stability testing requirements within different countries and regions. As this book is a part of the series *Methods in Pharmacology and Toxicology*, it was the intention of the editors to seek methods and protocols related to different aspects of stability programs that are followed practically in development laboratories in industry. Considering the fact that regulatory guidelines provide few experimental details, implementation of a successful stability program requires critical and logical thinking that is beyond the regular documented protocols and methods. Therefore, we have made efforts to collect the experiences from 15 organizations belonging to 9 different countries to encapsulate not all, but many, aspects of the stability testing program. We expect that this treatise will be a useful addition to the existing armamentarium of resources available to stability testing personnel, and even to students, owing to coverage of first-hand experience of international experts with many years of bench experience. Of course, making the experts agree to pen down their vital experience is always a herculean task, but we are fortunate that each contributor to this volume gave his/her best. The editors have full appreciation for each one of them. It is anticipated that the treatise will be found useful and interesting by the readers.

Of course, the editors also thankfully received great support from their families and all others connected with this compilation.

Chandigarh, India
Punjab, India

Sanjay Bajaj
Saranjit Singh

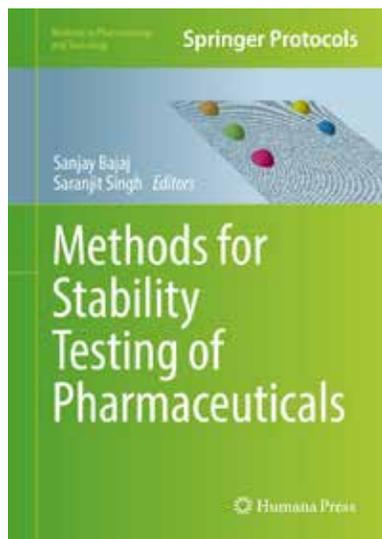
Contents

| | |
|---|------|
| <i>Preface</i> | v |
| <i>Editor's Note</i> | vii |
| <i>Acknowledgments</i> | ix |
| <i>Contributors</i> | xiii |
| | |
| 1 Regulatory Guidelines on Stability Testing and Trending of Requirements | 1 |
| <i>Dilip Kumar Singh, Saranjit Singh, and Sanjay Bajaj</i> | |
| 2 The Stability Dossier: Common Deficiencies and Ways to Improve | 31 |
| <i>Paul Marshall</i> | |
| 3 In Silico Drug Degradation Prediction | 53 |
| <i>Mohammed A. Ali, Rachel Hemingway, and Martin A. Ott</i> | |
| 4 Forced Degradation and Long-Term Stability Testing for Oral Drug Products: A Practical Approach | 75 |
| <i>Markus Zimmer</i> | |
| 5 A Model Approach for Developing Stability-Indicating Analytical Methods | 99 |
| <i>Peter Persich, Mario Hellings, Shalu Jhajra, Pradeep Phalke, and Koen Vanhoutte</i> | |
| 6 Protocols for Characterization of Degradation Products with Special Emphasis on Mutagenic Degradation Impurities | 123 |
| <i>Steven Hostyn, Peter Persich, Shalu Jhajra, and Koen Vanhoutte</i> | |
| 7 Stability Studies: Facility and Systems | 143 |
| <i>Ashish Gogia and Sumathi V. Rao</i> | |
| 8 User Requirements and Implementation of a Risk-Based, Compliant Stability Management System | 175 |
| <i>Susan Cleary, Parsa Famili, and Pedro Jorge</i> | |
| 9 Stability Considerations in the Life Cycle of Generic Products | 195 |
| <i>Sanjay Bajaj, Srinivasan Rajamani, and Mona Gogia</i> | |
| 10 Predictive Stability Testing Utilizing Accelerated Stability Assessment Program (ASAP) Studies | 213 |
| <i>Helen Williams</i> | |
| 11 Statistical Methods and Approaches to Avoid Stability Failures of Drug Product During Shelf-Life | 233 |
| <i>B. V. Suresh Kumar, Priyank Kulshrestha, and Sandeep Shiromani</i> | |
| 12 Estimation of Stability Based on Monitoring of Shipment and Storage | 261 |
| <i>Manuel Zahn</i> | |
| 13 Stability Testing Parameters and Issues for Nanotechnology-Based Drug Products | 293 |
| <i>Kamla Pathak and Satyanarayan Pattnaik</i> | |

| | | |
|----|---|-----|
| 14 | Stability Testing Issues and Test Parameters for Herbal Medicinal Products | 307 |
| | <i>Gulshan Bansal, Jasmeen Kaur, Nancy Suthar, Sarabjeet Kaur, and Rahul Singh Negi</i> | |
| 15 | Stability Testing Considerations for Biologicals and Biotechnology Products | 335 |
| | <i>Christine P. Chan</i> | |
| | <i>Index</i> | 349 |

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