



Pharmaceutical Stress Testing: Predicting Drug Degradation, Second Edition (Drugs and the Pharmaceutical Sciences)

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The second edition of **Pharmaceutical Stress Testing: Predicting Drug Degradation** provides a practical and scientific guide to designing, executing and interpreting stress testing studies for drug substance and drug product. This is the only guide available to tackle this subject in-depth. The Second Edition expands coverage from chemical stability into the physical aspects of stress testing, and incorporates the concept of *Quality by Design* into the stress testing construct / framework. It has been revised and expanded to include chapters on large molecules, such as proteins and antibodies, and it outlines the changes in stress testing that have emerged in recent years.

Key features include:

- A renowned Editorial team and contributions from all major drug companies, reflecting a wealth of experience.
- 10 new chapters, including Stress Testing and its relationship to the assessment of potential genotoxic degradants, combination drug therapies, proteins, oligonucleotides, physical changes and alternative dosage forms such as liposomal formulations
- Updated methodologies for predicting drug stability and degradation pathways
- Best practice models to follow
- An expanded Frequently Asked Questions section

This is an essential reference book for Pharmaceutical Scientists and those working in Quality Assurance and Drug Development (analytical sciences, formulations, chemical process, project management).

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