Formulation and Analytical Development for Low-Dose Oral Drug Products

Description: Tested–and–proven strategies for developing and manufacturing low–dose oral drug products

Developing and commercializing a low–dose oral drug product presents a number of hurdles that can quickly offset the drug's benefits. Written by a team of leading scientists in drug development, this book collects and synthesizes the knowledge, techniques, and strategies needed for developing low–dose drugs successfully. With this book's practical support, readers can overcome the hurdles at all stages in drug development, from formulation to manufacturing and control to regulatory compliance.

Following an overview of the drug discovery and development process, the book is divided into four parts:

Part One examines formulation and process development of low–dose drugs, including theoretical considerations concerning the particle size of the drug substance and content uniformity, micronization of the drug substance, and manufacturing platform technologies.

Part Two focuses on challenges in analytical method development, including analytical control strategy, physical characterization of the micronized powder and the solid state of the active pharmaceutical ingredient in dosage forms, and cleaning verification of manufacturing equipment.

Part Three investigates containment technologies used in analytical laboratories and manufacturing plants.

Part Four deals with important regulatory considerations.

Readers learn how a variety of analytical methodologies are used in low–dose drug development, including dissolution testing, NMR, HPLC, and X–ray diffraction. Moreover, the book explains several possible manufacturing techniques, such as wet granulation, roller compaction, and direct compression alongside containment technologies for highly potent drugs. Case studies throughout the book demonstrate how particular strategies and techniques are applied in practice.

Pharmaceutical scientists as well as students will find overcoming the obstacles in developing low–dose drug products much easier when they have this book on hand to consult at all stages in the drug development and manufacturing process.

Contents:

Preface.

Foreword.

Contributors.


1.1 The Drug Discovery and Development Process.

1.2 Challenges and Strategies in Development of Low-Dose Drug Products.

1.3 Summary.

Acknowledgments.

References.

PART I: CHALLENGES AND STRATEGIES IN FORMULATION DEVELOPMENT OF ORAL LOW–DOSE DRUG PRODUCTS.

2. Challenges and Strategies in Formulation Development of Oral Solid Low–Dose Drug Products (Jack Y.
Zheng).

2.1 Introduction.

2.2 Current Regulatory Environment and Its Impact on New Drug Product Development.

2.3 Challenges in Developing Low–Dose Formulations.

2.4 Manufacturing Platforms for Low–Dose Drug Products.

2.5 Use of Experimental Design in Formulation and Process Development.

2.6 Containments.

2.7 Summary.

Acknowledgments.

References.

3. Particle Size of Drug Substance and Product Content Uniformity – Theoretical Considerations (Kevin C. Johnson).

3.1 Introduction.

3.2 Concept of Ideal Mixing.

3.3 Ideal Mixing Model Comparison with the Yalkowsky and Bolton Approach.

3.4 Experimental Support of Model Assumptions.

3.5 Analytical and Practical Considerations.

References.


4.1 Introduction.

4.2 Granulation Fundamentals.

4.3 Theory of Fluidization.

4.4 Formulation Development.

4.5 Process Development.

4.6 Summary.

References.


5.1 Introduction.

5.2 Granulation Mechanisms.

5.3 General Considerations on Wet Granulation.

5.4 Advantages and Disadvantages of Wet Granulation.

5.5 Use of Wet Granulation for Low–Dose Formulations.
5.6 Process-Induced Form Changes in Wet Granulation.

5.7 Concluding Remarks.

References.


6.1 Introduction.

6.2 Dry Granulation Process – Pros and Cons.

6.3 Overview of Dry Granulation Processes and Equipment Design.

6.4 Challenges for Low-Dose Product Development and their Assessment Methods.

6.5 Case Study: Formulation Challenges for Low-Dose Products.

6.6 Process Challenges During Dry Granulation Optimization for Low-Dose Products.

6.7 Conclusions.

Acknowledgments.

References.


7.1 Introduction.

7.2 Advantages of Direct Compression.

7.3 Challenges in Low-Dose Tablet Development Using Direct Compression.

7.4 Formulation Development for Low-Dose Drug Products Using Direct Compression.

7.5 Manufacturing Process Development for Low-Dose Drug Products.

7.6 Scale-Up for Blending Operation.

7.7 Formulation Examples for Direct Compression.

7.8 Conclusions.

Acknowledgments.

References.

8 Reduction of Particle Size of Drug Substance for Low-Dose Drug Products (Christopher L. Burcham, Paul C. Collins, Daniel J. Jarmer, and Kevin D. Seibert).

8.1 Introduction.

8.2 Reduction of Particle Size of Drug Substance by Milling Technologies.

8.3 Reduction of Particle Size of Drug Substance Using Crystallization Technologies.

8.4 Scale-Up Considerations.

8.5 Emerging Technologies and Future Directions.
Acknowledgments.

References.


9.1 Introduction.

9.2 Classification of Pharmaceutical Excipients in Solid Dosage Forms.

9.3 Physicochemical Attributes of Pharmaceutical Excipients.

9.4 Regulatory Status and Excipient Quality.

9.5 Summary.

Acknowledgments.

References.

PART II: CHALLENGES IN ANALYTICAL METHOD DEVELOPMENT FOR ORAL LOW–DOSE DRUG PRODUCTS.


10.1 Introduction.

10.2 Case Study 1: Drug Adsorption to Surfaces.

10.3 Case Study 2: Challenges Due to Nondrug–Related Impurities.

10.4 Case Study 3: HPLC Purity Method Development Challenges for a Fixed Combination Product Containing a Low–Dose Active Ingredient and a High–Dose Active Ingredient.

10.5 Case Study 4: Small Volume Dissolution Testing.

10.6 Summary.

Acknowledgments.

References.


11.1 Introduction.

11.2 Overview of Dissolution Testing.

11.3 Dissolution Method Development.

11.4 Dissolution Method Development for Low–Dose Oral Drug Products.

11.5 Summary.

References.

12. Analysis of Physical Transformation of API During Manufacture and Storage (Gregory A. Stephenson).

12.1 Introduction.

12.2 Discussion of Solid–State Forms.
12.3 Monitoring Processing Steps.
12.4 Measuring Transitions and Solid-Form Transformations in the Low-Dose Tablet.
12.5 Common Methods Used for Examination of Solid Forms.
12.6 Conclusions.

References.

13.1 General Issues in the Physical Characterization of Micronized Powders Used in Low-Dose Formulations.
13.2 Particle Size Analysis.
13.3 Specific Surface Area Analysis.
13.4 Summary.

References.

14.1 Introduction.
14.2 Importance of Excipient Absorbance Background to Low-Dose Impurity Analysis.
14.3 Factors Affecting Excipient Absorbance Background.
14.4 Use of Excipient Library.
14.5 Conclusions.

Acknowledgments.

References.

15. Cleaning Verification for Highly Potent Compounds (Brian W. Pack).
15.1 Introduction.
15.2 Cleaning Validation vs Cleaning Verification.
15.3 Acceptance Limit Calculations.
15.4 Analytical Method Validation.
15.5 General Analytical Techniques.
15.6 Analytical Techniques for Low-Dose Compounds.
15.7 Conclusions.

Acknowledgments.

References.

PART III: CONTAINMENT TECHNIQUES FOR HIGHLY POTENT PHARMACEUTICAL COMPOUNDS.

16 Containment Challenges and Strategies for Potent Compounds in the Pharmaceutical Industry (Victoria Cathcart, Sarah Jones, Beverly Nickerson).
16.1 Introduction.
16.2 Safe Exposure Control Levels–Bands, Limits, and Handling Guidance.
16.3 The Hierarchy of Workplace Controls.
16.4 Case Studies.
16.5 Summary.
Acknowledgments.
References.

17. Sample Handling and Containment in Analytical Testing Laboratories (David Pattavina, Nancy Sage, and Beverly Nickerson).
17.1 Introduction.
17.2 Sample Handling Considerations.
17.3 Handling Potent Compounds in Standard Analytical Laboratories.
17.4 Handling Potent Compounds in a Containment Laboratory.
17.5 Additional Considerations for Handling Potent Materials.
17.6 Summary.
Acknowledgments.
References.

PART IV: REGULATORY CONSIDERATIONS IN THE DEVELOPMENT OF LOW–DOSE DRUG PRODUCTS.
18.1 Introduction and Overview.
18.2 Three–Pronged Approach to Low–Dose Formulations.
18.3 Pharmaceutical Development Report.
18.4 Facility Controls for Highly Potent Drugs.
18.5 Conclusion.
References.
Index.

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