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Impact of Drying on the Final Quality of Rice Grains; 2.6 Conclusion; References; 3 Characterization and Control of Physical Quality Factors During Freeze-Drying of Pharmaceuticals in Vials; 3.1 Introduction 3.2 Characterization Methods of the Key Quality Factors During Freeze-Drying of Pharmaceuticals in Vials 3.2.1 State Diagram, Melting Curves, Vitreous Transition, Collapse Temperature; 3.2.2 Characterization Methods: DSC, MDSC, Freeze-Drying Microscopy; 3.2.3 Ice Structure and Morphology: Cold Chamber Optical Microscopy; 3.2.4 Heat Flux Heterogeneity in the Sublimation Chamber; 3.2.5 Permeability of Freeze-Drying Cake: Pressure Rise Tests; 3.2.6 Estimation of Mean Product Temperature; 3.3 Influence of Freezing and Freeze-Drying Parameters on Physical Quality Factors 3.3.1 Influence of Freezing Protocol on Ice Morphology 3.3.1.1 Influence of Freezing Rate; 3.3.1.2 Influence of Vial Type and Filling Height; 3.3.1.3 Annealing; 3.3.2 Controlled Nucleation; 3.3.2.1 Controlled Nucleation by Ultrasound Sonication; 3.3.2.2 Effect of Ultrasound on Structural and Morphological Properties; 3.3.3 Relationship between Nucleation Temperatures and Sublimation Rates; 3.3.4 Freeze-Dried Cake Morphology; 3.3.4.1 Water Vapor Mass Transfer Resistance; 3.3.4.2 Freeze-Dried Layer Permeability; 3.3.5 Importance of Temperature Control 3.3.6 Influence of Operating Conditions on Sublimation Kinetics 3.4 Product Quality and Stability During Drying and Storage; 3.4.1 Product Quality and Formulation; 3.4.2 Product Quality and Polymorphism; 3.5 Conclusions; References; 4 In-Line Product Quality Control of Pharmaceuticals In Freeze-Drying Processes; 4.1 Introduction; 4.2 Control of the Freezing Step; 4.3 Monitoring of the Primary Drying; 4.3.1 Monitoring of Single Vials; 4.3.2 Monitoring of a Group of Vials; 4.3.3 Monitoring of the Whole Batch; 4.3.3.1 Detection of the Endpoint of the Primary Drying 4.3.3.2 Monitoring the Primary Drying Using the Measurement of the Sublimation Flux

Sommario/riassunto

This five-volume series provides a comprehensive overview of all important aspects of modern drying technology, concentrating on the transfer of cutting-edge research results to industrial use. Volume 3 deals with product quality and formulation. Biochemical, physical, and mechanical transformations which can occur during drying are described as well as methods for monitoring product quality such as process analytical technology. The preservation of desired product properties is discussed in detail for foods and biomaterials, freeze-dried active pharmaceutical ingredients, and highly porous