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Freeze-Drying; Table of Contents; Preface; Preface to the First Edition; 1 Foundations and Process Engineering; 1.1 Freezing; 1.1.1 Amount of Heat, Heat Conductivity, Heat Transfer and Cooling Rate; 1.1.2 Structure of Ice, Solutions and Dispersions; 1.1.3 Influence of Excipients; 1.1.4 Freezing of Cells and Bacteria; 1.1.5 Methods of Structure Analysis; 1.1.5.1 Measurements of Electrical Resistance (ER); 1.1.5.2 Differential Thermal Analysis (DTA); 1.1.5.3 Cryomicroscopy; 1.1.5.4 Differential Scanning Calorimetry (DSC); 1.1.5.5 Nuclear Magnetic Resonance; 1.1.5.6 Thermomechanical Analysis (TMA); 1.1.5.7 Dielectric Analysis (DEA); 1.1.5.8 X-ray Diffractometry-Raman Spectroscopy; 1.1.6 Changes of Structure in Freezing or Frozen Products; 1.2 Drying; 1.2.1 Main Drying (Sublimation Drying); 1.2.2 Secondary Drying (Desorption Drying); 1.2.3 Temperature and Pressure Measurement; 1.2.4 Water Vapor Transport During Drying; 1.2.5 Collapse and Recrystallization; 1.2.6 Drying Processes Without Vacuum; 1.3 Storage; 1.3.1 Measurement of the Residual Moisture Content (RM); 1.3.1.1 Gravimetric Method; 1.3.1.2 Karl Fischer (KF) Method; 1.3.1.3 Thermogravimetry (TG, TG/MS); 1.3.1.4 Infrared Spectroscopy; 1.3.2 Influence of Vial Stoppers on the Residual Moisture Content; 1.3.3 Qualities of the Dry Substances and Their Changes; 1.4 References for Chapter 1; 2 Installation and Equipment Technique; 2.1 Freezing Installation; 2.1.1 Cooling by Liquids: Shell-freezing and Spin-freezing; 2.1.2 Cooled Surfaces; 2.1.3 Product in the Flow of Cold Air, Foaming and Freezing of Extracts and Pulps; 2.1.4 Droplet Freezing in Cold Liquids; 2.1.5 Freezing by Evaporation of Product Water; 2.2 Components of a Freeze-drying Plant; 2.2.1 Installations for Flasks and Manifolds; 2.2.2 Drying Chambers and Forms of Trays; Trays for Special Applications; 2.2.3 Shelves and their Cooling and Heating; 2.2.4 Water Vapor Condensers; 2.2.5 Refrigerating Systems and Refrigerants; 2.2.6 Vacuum Pumps; 2.2.7 Inlet Venting Filters; 2.2.8 Vacuum Measuring Systems; 2.2.9 Leak Rate Detection; 2.2.10 Process Control Systems; 2.2.11 Problems, Failures and Deviations; 2.3 Installations up to 10 kg Ice Capacity; 2.3.1 Universal Laboratory Plants; 2.3.2 Pilot Plants; 2.3.3 Manipulators and Stoppering Systems for Vials; 2.3.4 Cleaning Installations, Sterilization by Steam and Vaporized Hydrogen Peroxide (VHP®); 2.4 Production Plants; 2.4.1 Loading and Unloading Systems; 2.5 Production Plants for Food; 2.5.1 Discontinuous Plants; 2.5.2 Continuous Plants with Tray Transport; 2.5.3 Continuous Plants with Product Transport by Wipers or by Vibration; 2.6 Process Automation; 2.6.1 Prerequisites for Process and Related Plant Automation; 2.6.2 Control of the Process and Related Plant Data by Thermodynamic Data Measured During the Process: Thermodynamic Lyophilization Control (TLC); 2.6.2.1 Control of the Process Without Temperature Sensors in the Product

Sommario/riassunto

Many modern pharmaceutical and biological products, e.g. blood derivatives, vaccines, cytostatic drugs, antibiotics, bacteria cultures but also consumer goods such as soluble coffee are freeze-dried to transform perishable substances into a form that can be stored and reconstituted to their almost original state without loss of quality. The book describes the up-to-date fundamentals of freeze-drying, not just presenting the process in all its seven steps theoretically, but explaining it with many practical examples. Many years of experience in freeze-drying allow the authors to supply value