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Nota di contenuto	Hot-melt Extrusion: Pharmaceutical Applications; Contents; List of Contributors; Preface; 1. Single-screw Extrusion: Principles; 1.1 Introduction; 1.2 Ideal Compounding; 1.3 Basics of the Single-screw Extruder; 1.3.1 Screw Feed Section; 1.3.2 Screw Compressor Section; 1.3.3 Screw Metering Section; 1.3.4 Mixers; 1.3.5 Limitations of Conventional Single-screw Mixers; 1.4 SSE Elongational Mixers; 1.5 Summary; References; 2. Twin-screw Extruders for Pharmaceutical Hot- melt Extrusion: Technology, Techniques and Practices; 2.1 Introduction; 2.2 Extruder Types and Working Principle 2.3 Individual Parts of a TSE 2.3.1 Drive Unit; 2.3.2 Screws; 2.3.3 Screw Elements; 2.3.4 Distributive Flow Elements; 2.3.5 Discharge Feed Screw; 2.3.6 Barrel; 2.4 Downstreaming; 2.5 Individual Processing Sections of the TSE; 2.5.1 Feeding Section; 2.5.2 Conveying/Melting Section; 2.6 Feeding of Solids; 2.7 TSE Operating Parameters; 2.7.1 Filling Level; 2.7.2 Screw Speed; 2.7.3 Feed Rate; 2.7.4 Residence Time

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	Distribution; 2.7.5 Effect of Screw Speed and Feed Rate on Melt Temperature 2.8 Setting up an HME Process using QbD Principles 2.8.1 Understanding Knowledge Space; 2.8.2 Defining Design Space; 2.8.3 Determining Control Space; 2.9 Summary; References; 3. Hot-melt Extrusion Developments in the Pharmaceutical Industry; 3.1 Introduction; 3.2 Advantages of HME as Drug Delivery Technology; 3.3 Formulations used for HME Applications; 3.3.1 Active Pharmaceutical Ingredient; 3.3.2 Solid Dispersions; 3.3.3 Bioavailability Improvement; 3.3.4 Controlled Delivery Systems; 3.3.5 Plasticizers; 3.4 Characterization of Extrudates; 3.4.1 Thermal Analysis; 3.4.2 Atomic Force Microscopy 3.4.3 Residence Time 3.4.4 Spectroscopic Techniques; 3.4.5 X-ray Diffraction (XRD); 3.4.6 Microscopy; 3.4.7 Drug Release; 3.5 Hot-melt Extruded Dosage Forms; 3.5.1 Oral Drug Delivery; 3.5.2 Films; 3.5.3 Vaginal Rings and Implants; 3.6 A View to the Future; References; 4. Solubility Parameters for Prediction of Drug/Polymer Miscibility in Hot- melt Extruded Formulations; 4.1 Introduction; 4.2 Solid Dispersions; 4.3 Basic Assumptions for the Drug-polymer Miscibility Prediction; 4.4 Solubility and the Flory-Huggins Theory; 4.5 Miscibility Estimation of Drug and Monomers; 4.6 Summary; References 5. The Influence of Plasticizers in Hot-melt Extrusion 5.1 Introduction; 5.2 Traditional Plasticizers; 5.3 Non-traditional Plasticizers; 5.4 Specialty Plasticizers; 5.5 Conclusions; References; 6. Applications of Poly(meth)acrylate Polymers in Melt Extrusion; 6.1 Introduction; 6.2 Polymer Characteristics; 6.2.1 Chemical Structure and Molecular Weight; 6.2.2 Glass Transition Temperature; 6.2.3 Plasticizers; 6.2.4 Thermostability; 6.2.5 Viscosity; 6.2.6 Specific Heat Capacity; 6.2.7 Hygroscopicity; 6.3 Melt Extrusion of Poly(methacrylates) to Design Pharmaceutical Oral Dosage Forms 6.4 Solubility Enhancement
Sommario/riassunto	"Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot- Melt Extrusion: Pharmaceutical Applications is an essential

multidisciplinary guide to the emerging pharmaceutical uses of this
processing technology for researchers in academia and industry
working in drug formulation and delivery, pharmaceutical engineering
and processing, and polymers and materials science"