



Practical Guide to Hot-Melt Extrusion: Continuous Manufacturing and Scale-up

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Over the past few decades, hot-melt extrusion (HME) techniques have been shown to exhibit remarkable potential for the manufacture of various pharmaceutical products. HME is an emerging processing technology used primarily for the manufacture of pharmaceutical solid dispersions. It combines the advantages of a solvent-free process with fewer production steps making it suitable for easy to scale-up and continuous manufacturing applications. A single unit HME based operation, employing heat and mechanical shear, has displayed a significant potential to retain the stability even of thermo-labile therapeutics e.g., proteins. HME has now explicitly been established from a quality-by-design viewpoint for in-line data monitoring as per the recent guidelines issued by the US Food and Drugs Administration (FDA).

This book will focus primarily on the foregoing subject areas and will be of significant interest to a broad/interdisciplinary readership across the industries and academia for (but not limited to) the following reasons:

- Emerging HME processes and applications for multiple drug delivery.
- Solid-state engineering, solubility enhancement, controlled release, taste masking and sustained release case studies from a continuous manufacturing view-point.
- Means to explore the potential of continuous manufacture of co-crystals for promoting solvent free production methods.
- Scale-up case study and issue considerations and studies on the regulatory guidelines (FDA) for continuous manufacturing involving emerging HME techniques.

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