PHARMSOL NEWS

HOT MELT TECHNOLOGY - NOVEL SOLVENT FREE APPROACH

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One of the biggest challenges faced today by the pharmaceutical industry lies in enabling the delivery of difficult-to-solubilize molecules. Approximately 40% of currently marketed drugs are classified as poorly soluble (BCS Class II/IV), and more than 70% of drugs in development are poorly soluble, representing an increasing industry challenge to develop formulations for poorly soluble drugs.

Several methods such as solid dispersion (SD), complexation, lipid-based systems, micronization, and co-crystals are being developed to improve the solubility of poorly soluble drugs. Recently, solid dispersion is one of the most widely used and successful techniques in formulation development.

Most of the techniques involved in improving solubility involves the use of organic solvents which is discouraged in many countries due to environmental issues and also it impacts the stability of the finished product. HME being a solvent free/solvent less technique offers unique advantages in this regard.

HOT MELT EXTRUSION—INTRODUCTION

Hot melt extrusion (HME) is a technology gaining interest in the pharmaceutical industry as a novel technique to generate physically stable and processable forms of APIs.

The mechanism of HME is to disperse APIs in the polymer matrix at the molecular level to form solid dispersions or solid solutions.

The increased use of HME technology in the pharmaceutical industry is its capability of *continuous manufacturing with the solvent-less processing and the versatility of the downstream processing of extrudates into final dosage forms*.

APPLICATIONS

⇒ Taste making
⇒ Oro-dispersible forms/Floating formulations
⇒ Controlled/ sustained/ Enteric/ Targeted drug delivery system
⇒ Transdermal drug delivery
⇒ Implants/rings
⇒ Abuse deterrent/tamper resistance

MERITS

⇒ Enhances the bioavailability of poorly soluble components
⇒ Solvent free technology
⇒ Continuous process

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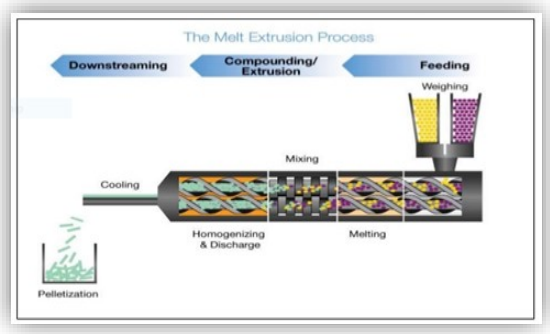
⇒ Better content uniformity
⇒ Enhances compressibility of API
⇒ Improves Stability



Product Development of hot-melt extrusion (HME)- based formulations divided into three stages:

Preliminary extrusion tests: Mainly involve in-depth evaluation of physicochemical properties of the drug and potential polymers like solubility, prediction of glass transition temperature (Tg) and interaction between the components.

Process development: To access extrudability, in vitro/in vivo release and physical stability which involves selection of optimal processing parameters which requires experiments used to assess the manufacturability, BE and stability of Amorphous SDs prepared by HME.

Process optimization: The main HME process parameters recommend for evaluation are Residence time, temperature profile, screw design, specific energy, feeding configuration, downstream processing and the impact of upscale.

Process development & Scale up requires careful analysis of the influence of not only each variable but also interactions between variables, because they influence crucial attributes of the product.

Conclusion:

Selection of suitable processing parameters and carefully optimized conditions may prove HME as a novel processing.

HME is the only solvent-free technology utilizing SDs, which is scalable and fast, which allows a continuous process.

How PharmSol can help you?

⇒ ***Development and tech transfer of poorly soluble drugs formulations.***

⇒ ***Reformulation of approved products for solvent free or cost effective approach***

⇒ ***Get in touch with our experts info@pharm-sol.com***