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Hot-melt extrusion (HME) and its application for bioavailability improvement of poorly water soluble drugs

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Statement of the Problem: For orally administered drugs, water solubility and permeability are the rate-limiting factors to achieve their desired concentration in systemic circulation for the pharmacological response. Poor water solubility of new chemical entities belonging to biopharmaceutical classification system (BCS) class II and IV accounts for 40 to 70% incidence of delay or failure during the drug product development process. Therefore, turning poorly water soluble drugs into viable therapeutics is the recurring and most challenging aspect facing by formulation scientist for drug product development. Hence, the poor bioavailability of the drugs has intensified demand for technologies and methods in the pharmaceutical industries to overcome their traits and meet the aforesaid challenges.

Solution for the Problem: Development of the formulations of BCS class II and IV drugs by converting the poorly water-soluble crystalline form into a more soluble amorphous form within the polymeric blends that will enhance the solubility which in turn leads to the improved bioavailability. These formulations can be developed by adopting various solid dispersion technological approaches like hot-melt extrusion (HME), kneading technique, co-precipitation, co-grinding, spray-drying, lyophilization, melt agglomeration process and supercritical fluid process. Among all these approaches, solid dispersion prepared by HME has gained popularity in the pharmaceutical industry as a means of improving the bioavailability of drugs due to its wide applications, simple process and low cost.

Conclusion & Significance: HME is an efficient technology for producing solid molecular dispersions with considerable advantages including the absence of solvents, few processing steps, and continuous operation over solvent-based processes such as spray drying and co-precipitation. Also, HME is one of the recommended processes by FDA to encourage move from batch-to-continuous manufacturing. Moreover, it is a value addition to intangible property of organization and can be used as noninfringing strategies for product development.

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