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Application of hot melt extrusion technology in development of solid dispersion systems for poorly water-soluble drugs

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The majority of new chemical entities (NCE) emerging from the drug discovery pipeline in the pharmaceutical industry during the past 2 to 3 decades have been extremely water-insoluble. The development of such compounds into orally bioavailable dosage forms is very challenging due to poor dissolution rates. One technique that has extensively been investigated in recent years to increase dissolution rates of poorly water-soluble drugs is a solid dispersion, where compounds are dispersed either molecularly or in the amorphous state in water-soluble carriers. Several methods for the preparation of solid dispersion, such as melt filling to form semisolid matrices, spray drying of organic solutions, melt extrusion, etc., have been reported in the literature. There are, however, major challenges in the successful application of such solid dispersion technologies because of inadequate drug-carrier miscibility, need for large volumes of organic solvents to dissolve drugs and carriers when solid dispersions are prepared by spray drying, thermal degradation during the manufacture of solid dispersion by the melt extrusion process and physical instability of dosage forms due to recrystallization of drug from solubilized or amorphous states and so forth. For these reasons, the commercial success of the solid dispersion technology has been rather limited as only a small number of drug products prepared by solid dispersion have been marketed despite extensive research in this area for the past 50 years. This presentation will elaborate how hot melt extrusion has in recent years emerged as the most viable and practical method for the development of solid dispersions. In particular, the following topics will be covered: (a) identification of potentially suitable polymers by drug-polymer miscibility testing, (b) determination of processing conditions by rheological analysis, (c) effects of the presence of drugs, plasticizers, surfactants, etc., on glass transition temperature, viscosity and extrudability of polymers and, thus, lowering processing temperatures of solid dispersions and (d) effect of surfactants on drug release from solid dispersions.

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