3rd World Congress on
NATURAL PRODUCTS CHEMISTRY AND RESEARCH
&
12th WORLD PHARMA CONGRESS
October 16-18, 2017 Budapest, Hungary

Hot-Melt Extrusion: A cost effective approach leading to enhancement of bioavailability and acceleration of drug product development process via turning poorly water soluble drugs into viable therapeutics

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For orally administered drugs, water solubility and permeability are the rate-limiting factors to achieve their desired concentration in systemic circulation for the pharma¬cological 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 of drug product developmental process facing by formulation scientist. 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. 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 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 improv¬ing the bioavailability of drugs due to its wide applications, simple pro¬cess and low cost. HME is an efficient technology for producing solid molecular dispersions with considerable advantages including the absence of solvents, few processing steps, and con¬tinuous 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 non-infringing strategies for product developments.

Biography

Devendra Ridhurkar works as a Senior Scientist at Egis Pharmaceu¬ticals PLC, Budapest, Hungary with a focus towards development of platform and other emerging technologies in innovative and complex generic formulations. Before Egis, he worked at Dr. Reddy's Laboratories, India. He has served as a Scientist at IPCA laboratories, Macleods Pharmaceuticals and Alkem laboratories, India. He has 11 years of experience in drug products development, using different approaches and various technologies which include hot melt extrusion (HME), gastro-retentive drug delivery systems, and nanotechnology and cyclodextrin complexation. He is an expert in materializing the design of experiments (DOE) and quality by design (QBD). He obtained his MPharm and PhD in Pharmaceutics from Indian Institute of Technology, Banaras Hindu University, India. He has five patents and published eight peer-reviewed papers in reputed national and international journals. He has attended and presented his research work at various national and international conferences.

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