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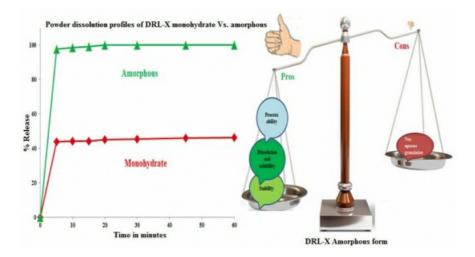
Advantages of amorphous DRL-X over the marketed form

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Solubility and dissolution play a pivotal role in an oral drug bioavailability. In addition to this pharmaceutical process parameters are also crucial for physical stability and drug development. DRL-X is a tyrosine kinase inhibitor drug belonging to Biopharmaceutics Classification System (BCS) class II. An amorphous form of DRL-X is prepared using spray drying technique and characterized by PXRD, DSC, and TGA etc. Various pharmaceutical properties of this amorphous form is compared against the marketed form of DRL-X. Current study indicates an enhanced apparent solubility over biological pH range 1.2 to 6.8, improved dissolution rate and IDR (Intrinsic Dissolution Rate) in OGD (Office of Generic Drugs) media for the synthesized amorphous form of DRL-X. Further this amorphous form is a stable glass with high glass transition temperature providing a better physical stability. This is further supported by the evidence of better tolerance to high compression, milling and aqueous granulation processes. Discovery of a novel amorphous form of DRL-X showing better physical stability, enhanced apparent solubility and dissolution will be a part of the presentation/discussion.

[1] Zografi, G. & Newman, A. (2017). J. Pharm. Sci. 106, 5-27.



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