



Original Article

Preformulation Studies for development of a generic capsule formulation of Celecoxib comparable to the branded (Reference) Product

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Abstract

This study aims to provide preformulation information, which is an essential part in the development of a robust formulation for generic celecoxib capsules. Various preformulation studies were carried out including drug characterization, Reference product characterization, Drug-Excipients compatibility studies. The physical properties of the drug like Solubility profile, Bulk / tapped densities, flow properties and particle size were also studied. The Celecoxib drug was found to be having good compatibility with majority of excipients studied. The drug is found to be of fluffy nature due to low density and the drug was also observed to be having very poor flow characteristic, hence it was concluded that direct filling of powder mixture into capsules was not possible. Therefore, wet granulation method was considered for granulation in-order to improve bulk density and flow-ability of blend.

Keywords: Preformulation, Generic formulation, Drug characterization, compatibility, bulk/tapped density, flow properties, wet granulation.

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