

Development and Evaluation of Mesalamine—Glutamine Cocrystal Tablets for Colon Specific Delivery

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ABSTRACT

The objective of the work was to develop the co-crystal formulation of mesalamine with glutamine. It was done to enhance dissolution rate, solubility and physicochemical properties to be used in pharmaceutical composition (tablet) for colon targeting. Co-crystal preparation was carried out by liquid assisted grinding method using glutamine as a co-crystal former (1:1 stoichiometric ratio) and acetonitrile as a solvent giving maximum solubility and dissolution rate. The formation of the co-crystals was confirmed by Fourier Transform – Infra Red spectrometry, Differential Scanning Calorimetry and Powder X-Ray Diffraction. Pre-compression studies included measurement of bulk density, tapped density, angle of repose, Hausner's ratio and compressibility index. The tablets were prepared by direct compression. Post compression parameters for uncoated tablets included hardness, size and thickness, friability and weight variation. Enteric-

coated tablets were prepared by dip-coating process using Eudragit RSPO, Triethyl citrate and isopropyl alcohol mixture as coating solution. The coated tablets were further evaluated for disintegration and dissolution testing. All the results were found to be under specified limits. Finally, co-crystal tablets were compared with marketed formulation. *In vitro* dissolution rate of optimized mesalamine co-crystal tablet was comparatively higher than marketed formulation, which reflects improvement in solubility. Glutamine has good anti-inflammatory property. Formulation with glutamine as co-crystal added more efficacies to mesalamine for treatment in colon related inflammatory diseases. It was concluded that stable co-crystals of mesalamine -glutamine having better anti-inflammatory property, increased solubility and improved *in vitro* dissolution of mesalamine can be successfully prepared.

KEYWORDS: Mesalamine; Co-crystal; Colon targeting; Enteric coating; Glutamine.