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Abstract

This work aims to evaluate the effect of polymorphism on the physicochemical properties of meloxicam, which is an antipyretic and non-steroidal anti-inflammatory drug. Powder X-ray Diffraction, Infrared Spectroscopy with attenuated total reflectance, Thermogravimetric and Differential Scanning Calorimetry techniques were used for the polymorphic characterization. Comparative tests of solubility, intrinsic dissolution and dissolution profiles were performed on meloxicam active pharmaceutical ingredients (APIs) and formulated tablets, respectively. A polymorphic contamination (Forms I and III) was found in a studied meloxicam batch, which showed a higher solubility and greater intrinsic dissolution than those containing only the preconized form (Form I). Consequently, the dissolution profiles of the tablets that contained the polymorphic contamination showed higher drug release. Additionally, a thermal behavior study shows that MLX Form I and III are monotropy polymorphs being MLX Form III a metastable phase, which becomes MLX Form I at approximately 200 °C in solid state phase transition governed by kinetic variables. The kinetic of conversion of Form III to Form I in saturated solutions was also studied. These results illustrate the importance of the polymorphic characterization of meloxicam APIs and formulated tablets in order to avoid potential quality and efficacy problems of drug products.