Poster Presentation

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Occurrence of polymorphism in famotidine raw materials

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Polymorphs are compounds with the same chemical composition, however the molecules are arranged in at least two different ways in the solid state. Famotidine is a histamine H2-receptor antagonist inhibitor of gastric secretion and widely used in gastric and duodenal ulcer disease. Two polymorphs are described for famotidine, A and B. The polymorph A is the most thermodynamically stable form and polymorph B is the kinetically favored form being marketed because it presents greater pharmacological activity. The aim of this study was to evaluate the occurrence of famotidine polymorphs in five raw materials acquired from different suppliers. The reference standard (USP) was also analyzed. All samples were characterized by powder X-ray diffraction (PXRD), infrared spectrophotometry (IR-ATR) and differential scanning calorimetry (DSC). PXRD analysis enables us to identify form B in five raw material samples and in the reference standard (USP). However, one of the raw materials additionally shows the presence of polymorphic form A. The DSC and IR-ATR techniques were essential to identify the polymorphic forms of famotidine confirming the results obtained by PXRD. Since the presence of polymorphs can compromise the effectiveness and safety of medicines and there is no official methodology of analysis and control of polymorphism in famotidine raw materials, the polymorphic contamination found in this study are being further analyzed and their physicochemical properties are being evaluated.

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