

The study on the Stability of a Drug. Can a Product have Life?

Xavier Solans, *Departament de Cristallografia, University of Barcelona, Spain*. E-mail: xavier@geo.ub.es

A product of a pharmaceutical company was received to make a study on the possible polymorph forms that this product could present. The first study was the characterization by XRPD, DTA, TG, IR spectroscopy and Raman scattering. The supplied product was crystallized and the crystal structure by single-crystal X-ray diffraction was determined. 567 different preparations in different conditions were made which were analyzed by XRPD, TG and DTA. These preparations were classified in three different clusters according to the XRPD patterns and melt/decomposition temperatures of the product. 58.3% of these preparations showed the supplied form, 25% in the second group and in the third 16.7%

At same time different bags, prepared in different years, were analyzed, being observed better the same variations in the patterns and in the melt/decomposition temperature that had been observed with the 567 preparations. The variations could also be ordered according to the time lapsed from their preparation.

The variations in the melt/decomposition temperature, enthalpy and entropy indicated that the product evolved with the time toward less stable states. The observation of the aging of the supplied product. The recovery of the aged phases by re-crystallization makes conclude that the product is not stable. The TG analyses show that the aged product doesn't have a losses of mass before to the melt temperature and the Rietveld analyses of all XRPD patterns show an increase of cell volume less than 15 \AA^3 , then the aging doesn't take place for the adsorption of other products: The width of the pattern peaks doesn't grow in the aged samples indicating that a lost of crystallinity doesn't take place.

Keywords: pharmaceutical crystallography, stability, polymorphs