

In vitro Disaggregation and Dissolution of Four IR Lamotrigine Solid Dosage Forms

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Abstract : Lamotrigine is a phenyltriazine used in the treatment of epilepsy and bipolar disorder type I. The purpose of this study was to test and compare various solid forms of immediate release (IR) lamotrigine products, at different strengths, in order to study their disaggregation and dissolution behavior. IR products are designed to release their active substance promptly after administration. Concentration of hydrochloric acid in gastric juice is about 0.1-0.001 M, so FDA (Food and Drug Administration) recommends, for lamotrigine regular tablets, dissolution tests in HCl 0.1 M. To investigate the pH dependency of drug release in the entire gastrointestinal tract, we worked at two additional media with different pH values (4.5 and 6.8), that reflect conditions in it. To afford acceptable dissolution rates, tablets must disintegrate. Disaggregation of constituent particles increases the surface area and substantially increases the dissolution rate. For this reason availability of an active substance from tablets depends on its ability to disintegrate fast in dissolution media. pH of gastrointestinal fluid affects drug absorption by conditioning its solubility and dissolution, but also tablet disintegration may be influenced by it. To obtain information about the quantitative relationship between different mixture components, Nuclear Magnetic Resonance (NMR) spectroscopy was used. We also investigate tablet hardness. The investigation carried out confirms pH 1.2 as the ideal environment for the immediate availability of the active substance.

Keywords : dissolution, disaggregation, Lamotrigine, bioequivalence

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