



Stability of Loratadine Tablets in Argentina

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SUMMARY. Stability of loratadine formulations can be affected when the product is exposed to high temperature and humidity. In this study, chemical and *in vitro* dissolution stability of loratadine (10 mg) tablets available in Argentina were assessed. Drug content and dissolution profiles were determined according to USP29, at time zero, and after 3 and 6 months of storage under ICH accelerated aging conditions (40 °C, 75 % RH). Dissolution efficiency and assay values were compared, both by mathematical and statistical methods, to assess interchangeability and stability during aging. After 180 days, most formulations evaluated showed statistically significant changes in the active ingredient and in the dissolution behaviour. Only formulation K did not meet the assay acceptance criteria.

KEY WORDS: Aging conditions, Dissolution, Loratadine, Stability, Tablets.

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