ABSTRACT

Many cases of instability and incompatibility of drugs can have an impact on the quality of treatment and failure to achieve the desired therapeutic effect. This research aims to determine the potential instability and incompatibility of the compounded preparation of ketotifen fumarate and cyproheptadine HCl by carrying out the test method that has been validated. The type of this research is descriptive and non-experimental. This research carried out instability and incompatibility tests of the compounded preparation. The stability test used UV-Vis spectrophotometry combined with chemometrics. The prediction models were built from the actual concentration obtained from the validated reverse-phase high-performance liquid chromatography (HPLC) method. Incompatibility test by evaluating chemical functional groups using Fourier-Transformed Infrared (FT-IR). This research produces an analytical method stability and incompatibility of the mixture of ketotifen fumarate and cyproheptadine HCl in the powdered preparation. The research results show that the organoleptic test met the criteria on days 1, 5, 7, 10, 14, and 21 but did not meet the criteria on days 28,42,56,70,90. The moisture content test obtained during the period of storage meets the criteria. The spectra results show that there is no incompatibility in mixed preparations. A decrease in the concentration of more than 10% from the initial concentration was cyproheptadine HCl on the 70^{th} and 90^{th} day while ketotifen fumarate on the 90^{th} day. The beyond-use date of the ketotifen fumarate was 74 days and cyproheptadine HCl was 48 days.

Keywords: instability, incompatibility, ketotifen fumarate, cyproheptadine HCl, validation