Stability Indicating Methods for the Determination of Loratadiane in the Presence of its Degradation Product

Amr Mohamed Badawy, N.A. El Ragehy, A.M. Badawey and S.Z. El Khateeb

Professor of Analytical Chemistry

Abstract

Four stability-indicating procedures have been suggested for determination of the non sedating antihistaminic agent loratadine. Loratadine being an ester undergoes alkaline hydrolysis and the corresponding acid derivative is produced as a degradation product. Its identity was confirmed using IR and MS. The first procedure is based on determination of loratadine by HPLC with detection at wavelength, 250 nm. Mobile phase is acetonitrile:orthophosphoric acid (35:65) using benzophenone as an internal standard. Sensitivity range is ± ȝg/ml. Second determination is a densitometric procedure based on determination of loratadine in the presence of its degradate at Ȝ nm using the mobile phase; methanol:ammonia (10:0.15). Sensitivity range is 1.25–7.50 μg per spot. The third procedure is a spectrophotometric one where a mixture of loratadine and its degradate are resolved by first derivative ratio spectra. Sensitivity range is found to be 3.00–22.00 μg/ml, upon carrying out the measurements at wavelengths 236, 262.4 and 293.2 nm. The fourth procedure is based on second derivative spectrophotometry, where D2 measurements are carried out at Ȝ 266 nm. The sensitivity range is 3.00–22.00 μg/ml. The validity of the described procedures was assessed by applying the standard addition technique. Statistical analysis of the results have been carried out revealing high accuracy and good precision. The suggested procedures could be used for determination of loratadine both in pure and dosage forms, as well as in the presence of its degradate.

Journal of Pharmaceutical and Biomedical Analysis - 2002, June