

Abstract

High-performance liquid chromatographic technique for the determination of clotrimazole and its degradation products (2-chlorophenyl)-diphenyl methanol and imidazole in the formulation Clotrimazol spray 1 % was developed.

The presented thesis was focused to the selection of optimal column, composition of mobile phase, its pH and internal standard for the analysis of pharmaceutical formulation based on topically applied antifungal agent clotrimazole. Seven columns were tested in detail.

The tested columns were: Discovery HS F5 (5 μm , 150 x 4.6 mm); Chromolith[®] Performance, RP-18e (100 x 3 mm); ZIC[®] HILIC (3.5 μm , 50 x 2.1 mm); XTerra[®] RP 18 (5 μm , 100 x 3 mm); Discovery RP Amide C 16 (5 μm , 250 x 3 mm); Zorbax Extend-C18 (3.5 μm , 75 x 4.6 mm); Discovery ZR-PBD (5 μm , 150 x 4.6 mm).

HPLC was carried out using Discovery ZR- PBD column [5 μm , 150 x 4.6 mm]. This column is based on polybutadiene-coated zirconium oxide. A zirconium oxide is stable in the whole pH range with the high pressure and temperature up to 200°C.

Spectrophotometric detection at 210 nm was performed. The optimal mobile phase was a mixture of acetonitrile and water (pH 9.7) in the ratio of 50:50. The pH of the water component was finally adjusted to 9.7 with NH₄OH 25 %. The aqueous solution was filtered through 0.45 μm Millipore membrane filters.

The optimal injection volume was 3 μl and the optimal flow was 1 ml/min. Robustness of the method for correct internal standard selection was tested. Then ibuprofen was used as the internal standard. Analysis time was less than 4.5 min..

Keywords: Clotrimazole, (2-chlorophenyl)-diphenyl methanol, imidazole, HPLC