Monitoring of Clotrimazole degradation pathway in presence of its co-formulated drug

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Abstract

Two stability-indicating chromatographic methods for the determination of clotrimazole and its two acid induced degradation products, with dexamethasone acetate without prior separation. First method depends on RP-HPLC utilizing ODS-3 Inertsil C18 column. Mobile phase consists of acetonitrile:phosphate buffer (pH 6.0) in ratio (65:35, v/v) with flow rate 1.5 mL/min and UV-detection at 220 nm. Linearity range 1.0–75.0 μg/mL for clotrimazole and 2.0–75.0 μg/mL for dexamethasone with mean percentage recovery of 99.49 ± 1.10 for CLT and 99.60 ± 1.06 for DA. Second method depends on HP-TLC. Developing system is composed of chloroform:ethyl acetate in the ratio of (5:3.5, v/v), scanned at 220 nm. Linearity range 1.0–12.0 μg/band for clotrimazole and 1.0–20.0 μg/band for dexamethasone with mean R% of 99.33 ± 0.76 for clotrimazole and 99.77 ± 0.99 for dexamethasone. Conditions and parameters affecting the separation of the cited components without interference of the degradation products are tested and optimized. Suitability of the methods for quantization of the drugs concentrations is proven by validation as instructed from the ICH. Validation results and statistical treatment of the data demonstrate reliability of these methods. Kinetics of acid degradation process of clotrimazole are investigated by the proposed HPLC method and the order rate constant, half life and shelf life are computed.

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