

Development and Validation of Stability Indicating RP-HPLC Method for Estimation of Ketorolac and Fluoromethalone in Ophthalmic Formulations

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ABSTRACT

A simple, specific, accurate and stability-indicating reversed phase high performance liquid chromatographic method was developed for the simultaneous determination of ketorolac and fluorometholone in its ophthalmic formulation. ODS-BP hyperchrome C18 having 250 mm × 4.6 mm × 5µm with mobile phase composed of 0.2% Formic acid and 0.2% of TEA in water (pH adjusted to 5.0 with Formic Acid): Methanol (40:60 v/v) at flow rate of 1.0 ml/min, detection wavelength at 230 nm. The retention

times of ketorolac and fluorometholone were found to be 5.164 min and 2.969 min, respectively. Linearity was established for Ketorolac and fluorometholone in the range of 80-120 µg/mL and 16-24 µg/mL respectively. The percentage recoveries for ketorolac and fluorometholone were found to be in the range of 98-99% and 98-99% respectively. The LOD and LOQ for Ketorolac was found to be 5.14 and 15.5 µg/ml, and for fluorometholone 0.72 and 2.21 respectively.

KEYWORDS: Ketorolac, Fluorometholone, Degradation, RP-HPLC; Ophthalmic.