



Research Paper

Simultaneous Estimation of Montelukast Sodium and Levocetirizine HCl by RP-HPLC Method Development in Pharmaceutical Tablet Dosage Form

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ABSTRACT

The chromatographic analysis was performed by Hypersil BDS C18 ,250 × 4.6 mm, 5 μ particle size with mobile phase consisting of methanol and sodium hydrogen phosphate and orthophosphoric acid buffer (pH 7.0) in the ratio of 75:25 v/v, at a flow rate of 1.2 ml/min and eluents monitored at 230 nm. The method was validated for linearity, accuracy, precision, robustness and application for assay as per ICH guidelines. The retention times of montelukast and levocetirizine were 12.65 and 4.458 min, respectively. The calibration curves of peak area versus concentration, which was linear from 8-28μg/ml for montelukast and 4-14μg/ml for levocetirizine, had regression coefficient (r^2) greater than 0.998. The method had the requisite accuracy, precision, and robustness for simultaneous determination of montelukast and levocetirizine in tablets. The proposed method is simple, economical, accurate and precise, and could be successfully employed in routine quality control for the simultaneous analysis of montelukast and levocetirizine in tablets.

Key words : MON (Montelukast sodium), LEV (Levocetirizine hydrochloride), RP-HPLC (Reverse phase – High performance liquid chromatography) .ICH (International Conference on Harmonization), μ (Micron).

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