

**DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR
SIMULTANEOUS ESTIMATION OF MONTELUKAST SODIUM AND
OLOPATADINE HYDROCHLORIDE AS API AND ITS
DOSAGE FORM**

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ABSTRACT

A First order derivative spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Montelukast Sodium and Olopatadine Hydrochloride in API and Dosage form. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of Montelukast Sodium and Olopatadine Hydrochloride. The method employed First order derivative method based on the measurement of absorbance at two wavelengths, 316.63 and 302.40 nm, ZCP of Montelukast Sodium and Olopatadine Hydrochloride respectively. The calibration curve was linear in a concentration range of 10-60 µg/ml for Montelukast Sodium and 5-30 µg/ml for Olopatadine Hydrochloride. The RP-HPLC method has shown adequate separation of Montelukast Sodium and Olopatadine Hydrochloride in bulk and its Dosage form. The separation was achieved on a Phenomenex luna ODS C18 (250mm X 4.6 mm i.d., 5 µm particle size) with an gradient system of Methanol:Water(pH 6.5) in the ratio of 90:10 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection

used was 302nm. The retention time for Olopatadine Hydrochloride and Montelukast Sodium was obtained as 2.420 ± 0.1 min and 5.254 ± 0.05 min, respectively. The linearity of the proposed method was investigated in the range of 10-60 μ g/ml and 5-30 μ g/ml for Montelukast Sodium and Olopatadine Hydrochloride respectively. Correlation coefficient was 0.999 and 0.9995 for Montelukast Sodium and Olopatadine Hydrochloride respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Montelukast Sodium and Olopatadine Hydrochloride.

Key words: Montelukast Sodium, Olopatadine Hydrochloride, First order derivative method, RP-HPLC, Validation.