**Development and Validation of Analytical Method for The Simultaneous Estimation of Montelukast sodium and Desloratadine in Bulk and In Their Tablet Dosage Form**

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## ABSTRACT

A simple, accurate, precise and stability Indicating RP-HPLC method was developed and validated for simultaneous estimation of Montelukast sodium and Desloratadine in bulk and in their tablet dosage form. The RP-HPLC method has shown adequate separation for Montelukast sodium and Desloratadine from its degradation products. The separation was achieved on a Hypersil BDS $C_{18}$ (250mm X 4.6mm i.d., 5µm particle size) with an isocratic mixture of phosphate buffer : Methanol pH 3.5 adjusted with orthophospharic acid in the ratio of 60:40 v/v. The mobile phase at a flow rate of 1.0ml/min, Injection volume 20µl and wavelength of detection was kept at 246nm. The retention time for Montelukast

sodium and Desloratadine was 6.773±0.1min and 2.763±0.1min, respectively. The linearity of the proposed method was investigated in the range of 10-30µg/ml and 5-15µg/ml for Montelukast sodium and Desloratadine, respectively. Correlation coefficient was 0.998 and 0.998 for Montelukast sodium and Desloratadine, respectively. The limit of detection was 0.34µg/ml and 0.226µg/ml for Montelukast sodium and Desloratadine, respectively and the limit of quantification was 1.040µg/ml and 0.687µg/ml for Montelukast sodium and Desloratadine, respectively. Force degradation study was carried out on combined dosage form as per ICH guideline and it was exposed to hydrolysis (acid and base hydrolysis), oxidative ,thermal and sunlight conditions to apply stress. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision, and robustness for estimation of Montelukast sodium and Desloratadine in commercially available tablet dosage form and results were found to be satisfactory. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

**Key words:** Montelukast sodium, Desloratadine, Stability indicating RP-HPLC method, Force degradation