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Method Development and Validation for the Simultaneous Estimation of Montelukast Sodium and Rupatadine Fumerate in Tablet Dosage form By RP-HPLC Method

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Abstract: *A simple, precise, cost effective stability indicating RP-HPLC method has been developed and validated for the determination of Rupatadine fumerate and Montelukast sodium in pharmaceutical compositions. Montelukast sodium was highly susceptible to acidic condition and photo degradation; while Rupatadine fumerate was moderately degrade under alkaline condition. Methods: The chromatographic separation was achieved on hibar R 250-4, C-18 columns (250mm ×4.6mm,5um) using a mobile phase consisting of Methanol:Water (90:10v/v) with ortho phosphoric acid at a flow rate of 1ml/min. Detection wavelength was found 252 nm. Results: The Retention times of Rupatadine and Montelukast were found 4.31 and 11.59 minute respectively. The method was found to be linear over the range of 15-40 µg/ml for both the drugs with correlation co-efficient (r2) 0.996 & 0.999 for Rupatadine and Montelukast respectively. Percentage recoveries obtained for both the drugs were 99.49-100.25% and 99.52-100.53% for Rupatadine and Montelukast respectively. The %RSD for precision and accuracy of the method was found to be less than 2%. Conclusion: The method was validated according to the ICH guidelines with respect to specificity, linearity, accuracy, precision and robustness. Developed HPLC method can resolve all decrement peak of both drug. So this method is stability indicating in nature. The method developed can be used for the routine analysis of Rupatadine and Montelukast from dosage form.*

Keywords: Montelukast Sodium, Rupatadinefumerate HPLC Analytical Method Develop Mentation etc.

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