Analysis of Loratadine by Potentiometry and Reverse-Phase High Performance Liquid Chromatography

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Abstract

A non-aqueous titration method was developed to assay Loratadine bulk active and a High Performance Liquid Chromatography (HPLC) method was developed to determine Loratadine's manufacturing impurity. The HPLC method was also suitable for simultaneously assay and related substance determination of Loratadine pharmaceutical preparations.

In the tritation method, glacial acetic acid was chosen as an amphiprotic solvent. Loratadine ionised in glacial acetic acid; the conjugated base of acetic acid (Ac^-), was then titrated with standardised perchloric acid. The method was validated found to be precise, linear and robust. Reverse-phase HPLC method using a Novapak C18 column with a CH_3CN: 10mM K_2HPO_4 (pH 7.7) (50:50 v/v) mobile phase, showed good separation of Loratadine and its degradation products. The method was validated and performed satisfactorily with respect to specificity, precision, accuracy, linearity, robustness and ruggedness.

The quantitation limit was 0.1 μg/mL with a RSD of 7.9% and the detection limit was 0.02 μg/mL with a RSD of 10.7% with six consecutive injections of 20μL injection volume.

The described methods have been demonstrated to be useful for the determination of Loratadine assay and its degradation products or manufacturing impurities in the active raw material and pharmaceutical preparations.

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