Development and Validation of Analytical Method for Simultaneous Estimation of Ambroxol Hydrochloride and Desloratadine in Bulk and Its Formulation

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ABSTRACT

A simple, specific, accurate and precise reverse phase high pressure liquid chromatographic(RP-HPLC) method has been developed for the simultaneous estimation of Ambroxol Hydrochloride(AMB) and Desloratadine(DES) in Bulk and its dosage form by reverse phase Phenomenex luna ODS C_{18}. The samples were analyzed by using Potassium dihydrogen phosphate buffer : Acetonitrile in the ratio of 50:50 v/v (pH adjusted to 4.0 with 1% v/v Orthophosphoric acid) as a mobile phase at the flow rate of 1 ml/min in isocratic mode and detection wavelength 247 nm. Both the drugs were eluted within 10 minutes and give sharp peak with high theoretical plate count and low tailing factor. The retention time for Ambroxol Hydrochloride and Desloratadine was found to be 3.687 and 5.997 min respectively. The validation was carried according to ICH guidelines. In linearity curve correlation coefficients for Ambroxol Hydrochloride and

Desloratadine were found to be 0.9965 and 0.9986 respectively. The percent recovery was 99.63% w/w for Ambroxol Hydrochloride and Desloratadine 99.96% w/w for indicating accuracy and reliability of method. The limit of detection was 12.51µg/ml and 0.6700µg/ml for Ambroxol Hydrochloride and Desloratadine, respectively and the limit of quantification was 37.91µg/ml and 2.03µg/ml for Ambroxol Hydrochloride and Desloratadine, respectively. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision and robustness for estimation of Ambroxol Hydrochloride and Desloratadine in commercially available tablet dosage form and results were found to be satisfactory.

So the method can be used for estimation of combination of these drugs in tablet dosage form.

Key words: Ambroxol Hydrochloride, Desloratadine, Reverse phase high pressure liquid chromatography.