DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF OLOPATADINE HYDROCHLORIDE AND AMBROXOL HYDROCHLORIDE IN BULK AND IT'S DOSAGE FORM

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ABSTRACT

First order derivative spectroscopy, Dual Wavelength Spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Olopatadine Hydrochloride and Ambroxol Hydrochloride in bulk and It's Dosage form. Simple and easy UV spectrophotometric methods with good sensitivity have been developed for simultaneous quantification of Olopatadine Hydrochloride and Ambroxol Hydrochloride. The method employed First order derivative method based on the measurement of absorbance at two wavelengths, 302.6 and 248.34 nm, ZCP of Olopatadine Hydrochloride and Ambroxol Hydrochloride, respectively. The calibration curve was linear in a concentration range of 5-15 µg/ml for Olopatadine Hydrochloride and 30-90 µg/ml for Ambroxol Hydrochloride. The % recoveries of the both the drugs were found to be 99.37- 100.53 % and 98.95– 100.11%. The Dual Wavelength Spectroscopy Method based on measurement of the absorbance difference between two wavelengths, for Dual Wavelength method linearity was obtained in the concentration range 5-15µg/ml for Olopatadine Hydrochloride and 30-90 µg/ml for Ambroxol Hydrochloride at absorbance difference between 242.9nm and

252.06nm, 295.5nm and 309.5nm, respectively. The %recoveries for both drugs were found to be 99.88- 100.04% and 99.7-100.42%, respectively. The RP-HPLC method has shown adequate separation of Olopatadine Hydrochloride and Ambroxol 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 Isocratic system of Methanol: 0.05M Phosphate buffer (pH 7) in the ratio of 80:20 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20 µl and wavelength of detection used was 302nm. The retention time for Olopatadine Hydrochloride and Ambroxol Hydrochloride was obtained as 2.51 ± 0.1 min and 5.1 ± 0.1min, respectively. The linearity of the proposed method was investigated in the range of 10-60 µg/ml and 60-360 µg/ml for Olopatadine Hydrochloride and Ambroxol Hydrochloride respectively. Correlation coefficient was 0.9988 and 0.9994 for Olopatadine Hydrochloride and Ambroxol 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 Olopatadine Hydrochloride and Ambroxol Hydrochloride. It can also be adopted for quality control tests for these drugs in tablets.

Key words: Olopatadine Hydrochloride, Ambroxol Hydrochloride, First order derivative method, Dual Wavelength method, RP-HPLC, Validation.