

DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF DOXOPHYLLINE AND AMBROXOL HYDROCHLORIDE AS API AND ITS FORMULATION

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ABSTRACT

A simple, accurate and precise UV Spectrophotometric methods and RP-HPLC method was developed and validated for simultaneous estimation of Doxophylline and Ambroxol Hydrochloride As API and its formulation. Two UV spectrophotometric methods were developed. Simultaneous Equation Method was carried out at 274nm and 247nm λ_{\max} of Doxophylline and Ambroxol Hydrochloride respectively. Both the drugs were show absorbance of λ_{\max} of another drug. Calibration curves were linear with correlation coefficient between 0.999 over the concentration range of 8-32 $\mu\text{g/ml}$ and 0.6-2.4 $\mu\text{g/ml}$ and in the formulation both the drug were estimated as 99.68% and 98.67%, Doxophylline and Ambroxol Hydrochloride respectively. While in another Q-absorption ratio method determination was carried out at 247 nm λ_{\max} of Ambroxol Hydrochloride and 254 nm an Iso-absorptive point of both the drug. The linearity range lies between 8-32 $\mu\text{g/ml}$ and 0.6-2.4 $\mu\text{g/ml}$ for Doxophylline and Ambroxol Hydrochloride at their respective wavelengths and

Iso-absorptive point. Both the drugs were found in good agreement with the label claimed in the marketed formulation. In the tablets both the drugs were estimated as 100.22% and 98.33% Doxophylline and Ambroxol Hydrochloride respectively. A simple, accurate, precise RP-HPLC method was developed and validated for simultaneous estimation of Doxophylline and Ambroxol Hydrochloride As API and its formulation. The separation was achieved on a Phenomenex luna ODS C₁₈ (250mm X 4.6 mm i.d., 5 µm particle size) with an isocratic mixture of 50mM monobasic Pottasium Phosphate : methanol in the ratio of 50 : 50 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection was kept at 254 nm. The retention time Doxophylline and Ambroxol Hydrochloride was 3.11±0.1min and 8.33±0.1min, respectively. The method was investigated in the range of 40-175 µg/ml and 3-13 µg/ml for Doxophylline and Ambroxol Hydrochloride, respectively. Correlation coefficient was 0.9996 and 0.9995, limit of detection was 0.0397µg/ml and 0.0310µg/ml and limit of quantification was 0.1203µg/ml and 0.0940µg/ml for Doxophylline and Ambroxol Hydrochloride, respectively.

Keywords: Doxophylline , Ambroxol Hydrochloride, UV Spectroscopic method, Simultaneous Eqation method, Q-Absorption Ratio method and RP-HPLC