

RP-HPLC Method for the Simultaneous Analysis of Ambroxol Hydrochloride and Nitazoxanide in API and Tablet Dosage Form

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Abstract: Present work is aimed to develop a new simple, fast, rapid, accurate, efficient, and reproducible RP-HPLC method for the simultaneous analysis of Ambroxol Hydrochloride and Nitazoxanide in API & tablet dosage form. The chromatographic separation was performed using phenomenex C₁₈ Column having dimensions of 4.6x250mm having particle size of 5µm, with mobile phase consisting of Buffer P^H-3.5 and Acetonitrile (40:60% v/v), flow rate was adjusted to 1.0ml/min and detection wavelength at 235 nm. The proposed method has been validated for linearity, range, precision, accuracy and robustness were within the acceptance limit according to the ICH Q2B guidelines. The retention times of Ambroxol Hydrochloride and Nitazoxanide were 2.985 mins and 5.581 mins respectively. The linearity was performed in the concentration in the range of 7.5µg/ml to 45µg/ml and 25µg/ml to 150µg/ml and with a correlation coefficient of 0.999 and 0.999 respectively. % RSD for system precision was found to be 0.212 and 0.160; % RSD for repeatability 0.2 and 0.12, % RSD for intermediate precision was 0.06 and 0.06 respectively. The % percentage purity of Ambroxol Hydrochloride and Nitazoxanide was found to be 99.93% and 99.35% respectively. The method was found to be robust even by change in the mobile phase ±5% in less flow condition.