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Forced Degradation and Solution Stability Studies of Pheniramine API Drug

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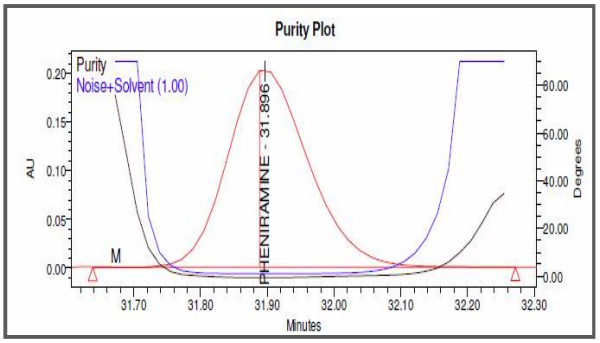
ABSTRACT

Pheniramine API drug were analyzed by forced degradation method using high performance liquid chromatography method was developed and validated. Two impurities in the Pheniramine API drug was identified. The separation was achieved on HPLC Columns (C-104) and (C-118) analytical column (250 mm × 4.6 mm i.d., 5.0 µm) using acetonitrile, methanol in the ratio 50:50 v/v as mobile phase and at a flow rate of 1.0 mL min^{-1}. Acid degradation (5N HCl) RT was 31.943, base degradation (5N NaOH) for impurity RT was 30.813 and for drug it was 31.911. Peroxide degradation (30% H_2O_2) RT was 31.896, reduction degradation (10% Sodium bisulphate) for impurity RT was 30.846 and for drug it was 31.878. Hydrolysis degradation for impurity RT was 30.856 and for drug it was 31.901. Thermal degradation (105°C/72 h) for impurity RT was 30.844 and for drug it was 31.969. Humidity degradation (25°C/92% RH for 72 h) for impurity RT was 30.611 and for drug it was 31.640. Photolytic degradation (1.2 Million lux hours) for impurity RT was 31.109 and for drug it was 32.262. The developed and validated method was successfully applied for the quantitative analysis Pheniramine API drug. The solution stability of spiked was studied.

Graphical Abstract



Chromatogram and Peak Purity of Peroxide degradation

Keywords: HPLC Techniques, Solubility Stability, Acid and Base Degradation, thermal, Peroxide Degradation.