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Stability Indicating Method Development and Validation for Estimation of Antiasthmatic Drug in Combined Dosages Formed by RP-HPLC

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Abstract : A simple stability indicating high performance liquid chromatographic method has been developed for the simultaneous determination of Levosalbutamol Sulphate and Ipratropium Bromide in bulk and pharmaceutical dosage form using reverse phase Zorbax Eclipse Plus C8 column (250mm×4.6mm), with mobile phase phosphate buffer (0.05M KH2PO4): acetonitrile (55:45v/v) pH 3.5 adjusted with ortho-phosphoric acid, the flow rate was 1.0 mL/min and the detection was carried at 212 nm. The retention times of Levosalbutamol Sulphate and Ipratropium Bromide were 2.2007 and 2.6611 min respectively. The correlation coefficient of Levosalbutamol Sulphate and Ipratropium Bromide was found to be 0.997 and 0.998.Calibration plots were linear over the concentration ranges 10-100µg/mL for both Levosalbutamol Sulphate and Ipratropium Bromide. The LOD and LOQ of Levosalbutamol Sulphate were 2.520µg/mL and 7.638µg/mL while for Ipratropium Bromide was 1.201µg/mL and 3.640 µg/mL. The accuracy of the proposed method was determined by recovery studies and found to be 100.15% for Levosalbutamol Sulphate and 100.19% for Ipratropium Bromide respectively. The method was validated for accuracy, linearity, sensitivity, precision, robustness, system suitability. The proposed method could be utilized for routine analysis of Levosalbutamol Sulphate and Ipratropium Bromide in bulk and pharmaceutical capsule dosage form.

Keywords : levosalbutamol sulphate, ipratropium bromide, RP-HPLC, phosphate buffer, acetonitrile
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