

Research Paper

VALIDATION AND ANALYTICAL METHOD FOR THE SIMULTANEOUS DETERMINATION OF ALBUTEROL SULPHATE AND IPRATROPIUM BROMIDE

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A simple, sensitive and specific RP-HPLC method was developed for the quantification of related impurities of albuterol sulfate (AS) and ipratropium bromide (IB) in liquid pharmaceutical dosage form. The chromatographic separation employs gradient elution using an Peerless basic C8 (150 X 4.6 mm, 5 μ m) columns. Mobile phase consisting of mobile phase A (Mixture of anhydrous potassium dihydrogen orthophosphate and 1-pentane sulphonic acid sodium salt monohydrate, pH 4.0 $\pm$ 0.05 (Sol. A), acetonitrile (95:5 v/v)) and mobile phase B (Mixture of anhydrous potassium dihydrogen orthophosphate and 1-pentane sulphonic acid sodium salt monohydrate, pH 4.0 $\pm$ 0.05 (Sol. B), acetonitrile (70:30 v/v)) delivered at a flow rate of 1.0 ml min⁻¹. The analytes were detected and quantified at 276 nm and 220 nm using photodiode array (PDA) detector. The method was validated as per ICH guidelines, demonstrating to be accurate and precise (repeatability and intermediate precision level) within the corresponding linear range of known impurities of AS and IB. All these results provide the stability indicating capability of the method.

Keywords: albuterol sulfate, ipratropium bromide High Performance Liquid Chromatography, Validation

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