

The intraday and interday precision studies (intermediate precision) were carried out by estimating the corresponding responses 3 times on the same day and on 3 different days for three different concentrations of CPM (0.5, 1.5, and 2.5 µg/mL), IBU (25, 75, and 125 µg/mL), and the results were reported in terms of relative standard deviation.

Linearity: Appropriate aliquots of CPM and IBU working standard solutions were taken in different 10 mL volumetric flasks and diluted up to the mark with mobile phase to obtain final concentrations of 0.5, 1.0, 1.5, 2.0, and 2.5 µg/mL of CPM, 25, 50, 75, 100, and 125 µg/mL of IBU, and 1.25, 2.50, 3.75, 5.00 respectively.

Part of the method development to verify that the system is adequate for the analysis of CPM, IBU, (RT), tailing factor, asymmetry factor, and theoretical plates for the five suitability injections were determined.

Preparation of Standard Stock Solutions: separate 10 mL volumetric flasks and volumes were made up to the mark with mobile phase to yield a solution containing 1000 µg/mL of CPM and IBU respectively.

Method Validation: The proposed method was subjected to validation for various parameters like linearity and range, precision, accuracy, and robustness in accordance with International Conference on Harmonization Guidelines.

Appropriate volume of the aliquot was transferred to a 10 mL volumetric flask and the volume was made up to the mark with the mobile phase to obtain a solution containing 1.0 µg/mL of CPM, 50 µg/mL of IBU, The solution was sonicated for 10 min.

Apparatus: The liquid chromatographic system consists of Waters series equipped with a series PDA detector, series 515 quaternary pump, and manual injector rheodyne valve with fixed loop.

Chromatographic Conditions: The C 18 column equilibrated with mobile phase acetonitrile : methanol : phosphate buffer (50 : 20 : 30, v/v/v; pH 5.6) and adjusted with 0.01% O-phosphoric acid was used.

Calibration curves were constructed by plotting average peak area versus concentrations and regression equations were computed for two drugs.

Precision: The repeatability studies were carried out by estimating response of CPM (2 µg/mL) and IBU (100 µg/mL) six times and results were reported in terms of relative standard deviation.

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