DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF INDAPAMIDE AND NEBIVOLOL IN BULK AND ITS TABLET DOSAGE FORM

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Abstract

A Simultaneous equation and RP-HPLC methods were developed and validated for simultaneous estimation of Indapamide (IND) and Nebivolol (NEB) in Tablet dosage form. Accurate and precised UV spectrophotometric method with good sensitivity has been developed for simultaneous estimation of IND and NEB. The employed simultaneous equation method based on the measurement of absorbance maxima of IND at 241 nm and NEB at 282 nm. The calibration curve was linear in a concentration range of 1-5 µg/ml for IND and 5-30 µg/ml for NEB. The RP-HPLC method has shown adequate separation of IND and NEB in tablet dosage form. The separation was achieved

on an ODS HYPERSIL (100 mm 4.6 mm, 5 µm particle size) with an isocratic system of Buffer:ACN in the ratio of 72:28 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 220nm. The retention time for IND and NEB was obtained as 3.71±0.1 min and 2.97±0.2 min respectively. The linearity of the proposed method was investigated in the range of 2.5-15 µg/ml and 10-60 µg/ml for IND and NEB respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory. Thus the method is specific, rapid and simple with good sensitivity for estimation of IND and NEB in marketed dosage Form.

Key words: Indapamide, Nebivolol , Simultaneous equation method, RP-HPLC, validation.