DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF LISINOPRIL AND HYDROCHLOROTHIAZIDE IN BULK AND ITS DOSAGE FORM

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ABSTRACT

The RP-HPLC method was developed and validated for simultaneous estimation of Lisinopril and Hydrochlorothiazide bulk and its tablet dosage form. The RP-HPLC method has shown adequate separation of Lisinopril and Hydrochlorothiazide in bulk and its dosage form. The separation was achieved on a BDS hypersil C_{18}, (250mm X 4.6mm i.d., 5µm particle size) using potassium dihydrogen phosphate buffer pH 5.5: ACN (40:60 v/v) as mobile phase. The mobile phase at a flow rate of 1.0 ml/min, injection volume 20µl and wavelength of detection used was 210 nm. The retention time for Lisinopril and Hydrochlorothiazide was obtained as 3.523 min and 5.247 min, respectively. The linearity of the proposed method was investigated in the range of 5-15 µg/ml and 6.25-18.75 µg/ml for Lisinopril and Hydrochlorothiazide, respectively. Regression coefficient for Lisinopril and Hydrochlorothiazide obtained as 0.997 and 0.998, respectively. The developed method was validated as per ICH guideline, for its

accuracy, precision, LOD & LOQ, Robustness, specificity and the results were found to be satisfactory, thus the method is accurate, precise, rapid and simple for estimation of Lisinopril and Hydrochlorothiazide.

Key words: Lisinopril, Hydrochlorothiazide, RP-HPLC, Validation.