DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF VALSARTAN AND CILNIDIPINE IN COMBINATION

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ABSTRACT

A simple, accurate and precise UV spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Valsartan and Cilnidipine in combination. First order derivative method was developed using methanol as a solvent. At ZCP of valsartan (248nm) cilnidipine showed a measurable derivative absorbance where as at zero crossing point of cilnidipine (240) valsartan showed an appreciable derivative absorbance value. The calibration curve were linear in a concentration range of 8-48 μg/ml for Valsartan and 1-6 μg/ml for Cilnidipine at their respective wavelength. In combination both the drugs were estimated in the range 98.50-101.33%. The RP-HPLC method has shown adequate separation of Valsartan and Cilnidipine in combination. The separation was achieved on a Enable C18 (250mm X 4.6 mm i.d., 5 μm particle size) with an Isocratic system of Acetonitrile :

Water (pH 4.4) in the ratio of 80:20 v/v. The mobile phase at a flow rate of 1.0 ml/min, injection volume 20µl and wavelength of detection used was 227nm. The retention time for Valsartan and Cilnidipine was obtained as 3.711± 0.1min and 7.882± 0.05min respectively. The linearity of the proposed method was investigated in the range of 8-56µg/ml and 1-7µg/ml for Valsartan and Cilnidipine 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 Valsartan and Cilnidipine.

Conclusion: The above methods ware cost-effective quality-control tool for routine analysis of Valsartan and Cilnidipine in Combination.

Keywords: Valsartan (VAL), Cilnidipine (CIL), UV Spectrophotometry, First order derivative Spectrophotometry, RP HPLC.