Development and Validation of Analytical Methods for Simultaneous Estimation of Ramipril and Chlorthalidone in Bulk and in Tablet dosage form

Submitted By

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ABSTRACT

A Solvent extraction method and RP-HPLC methods were developed and validated for simultaneous estimation of Ramipril and Chlorthalidone in bulk and in tablet dosage form. A simple, Rapid and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of Ramipril and Chlorthalidone. The method employed solvent extraction method based on the measurement of absorbance at two wavelengths 210 nm and 275 nm Ramipril and Chlorthalidone. The calibration curve was linear in a concentration range of 5-30µg/ml for Ramipril and 12.5-75 µg/ml for Chlorthalidone. The RP-HPLC method has shown adequate separation of Ramipril and Chlorthalidone in bulk and in tablet dosage form. The separation was achieved on a C18 (250mm X 4.6 mm i.d., 5 µm particle size) with a gradient system of Acetonitrile: Water in the ratio of 40:60 v/v. The mobile phase at a flow rate of 1.0 ml/min,

Injection volume 20 µl and wavelength of detection used was 218 nm. The retention time for Ramipril and Chlorthalidone was obtained as 2.433±0.1min and 3.721±0.1min. The linearity of the method was investigated in the range of 2-10 µg/ml and 5-25µg/ml for Ramipril and Chlorthalidone. Correlation coefficient was 0.997 and 0.998 for Ramipril and Chlorthalidone. 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 for estimation of Ramipril and Chlorthalidone. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in formulation.

Key words: Ramipril, Chlorthalidone, Solvent Extraction method, RP-HPLC, Validation.