DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF CHLORTHALIDONE AND OLMESARTAN MEDOXOMIL IN TABLET DOSAGE FORM

Submitted By

Ketankumar G Bhanderi

Supervised By

Ms. Bhumika Patel

M.pharm, Assistant professor,

Department of Quality Assurance.

Abstract

A First order derivative spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Chlorthalidone(CHT) and Olmesartan Medoxomil(OLM) in Tablet dosage form. Accurate and precised UV spectrophotometric method with good sensitivity has been developed for simultaneous estimation of CHT and OLM. The method employed First order derivative method based on the measurement of absorbance of CHT at ZCP 239.40 nm and OLM at ZCP 275.60 nm. The calibration curve was linear in a concentration range of 5-25 µg/ml for CHT and 10-50 µg/ml for OLM. The RP-HPLC method has shown adequate separation of CHT and OLM in Tablet dosage form. The separation was achieved on a Enable C18 (250 mm - 4.6 mm, 5 µm particle size) with an isocratic system of Methanol:Acetonitrile:Water in the ratio of 60:20:20 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 OLM and CHT

was obtained as 1.89±0.1 min and 2.98±0.2 min respectively. The linearity of the proposed method was investigated in the range of 6.25-37.50 μg/ml and 10-60 μg/ml for CHT and OLM 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 CHT and OLM In Marketed dosage Form.

Key words: Chlorthalidone, Olmesartan Medoxomil, First order derivative method, RP HPLC,Validation.