ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF LOSARTAN POTASSIUM AND CHLORTHALIDONE IN BULK AND THEIR TABLET DOSAGE FORM

Submitted By

DESAI KETKI K.

112140813032

Supervised By

MR.VIRAG GOPHANE,

Assistant professor, M.pharm

Department of Pharmaceutical Quality Assurance

Mentor

MR.VIRENDRA BHATT

Head of F&D Bharat Parentrals Ltd., Vadodara

Parul Institute of Pharmacy and Research

Parul Institute, Limda, Ta. Waghodia, Dist. Vadodara

ABSTRACT

A simple, accurate, rapid, economical UV spectrophotometry methods namely Absorption ratio, and RP-HPLC methods have been developed and validated for estimation of Losartan Potassium and Chlorthalidone in combined tablet dosage form and can be used in routine analysis. In Absorbance ratio method absorbance measured at Iso-absorptive point 236 nm (correlation coefficient was found to be 0.998 and 0.9981 for Losartan Potassium and Chlorthalidone) and 284 nm (correlation coefficient was found to be 0.9984 and 0.9985 for Losartan Potassium and Chlorthalidone). Assay was found to be 99.26 % and 100.8% for Losartan Potassium and Chlorthalidone respectively. The methods were found to be linear in the concentration range of 1-6µg/ml and10-20µg/ml for both the drugs.

In RP-HPLC, method was carried out by isocratic technique on a reversed-phase: Thermoscientific ODS C18 (250mm X 4.6 mm i.d.,5 µm particle size) and UV detection at 234 nm with mobile phase containing a mixture of Buffer(disodium hydrogen phosphate) : ACN: Methanol andpH:4 (adjusted with orthophosphoric acid) at a flow rate

of 1.0 ml/min. The average retention times for Losartan Potassium and Chlorthalidone were 3.7 and 7.2 min respectively. The calibration curves were linear in the concentration range of 8-48µg/ml and 1-6µg/ml for Losartan Potassium and Chlorthalidone respectively. Correlation co efficient were found to be 0.9984 and 0.9987 for Losartan Potassium and Chlorthalidone respectively. Mean assay was found to be 98.07% and 101.07% for Losartan Potassium and Chlorthalidone respectively. The two methods were compared statistically using PAIRED T.TEST and it was found that they are not significantly differ indicating their suitability in routine analysis.

KEYWORDS: Losartan Potassium and Chlorthalidone , Q-Absorption ratio,

RP-HPLC