ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF EZETIMIBE AND FENOFIBRATE IN BULK AND THEIR PHARMACEUTICAL DOSAGE FORM

Submitted By

PATEL KRUTIKA M.

(112140813033)

Supervised By

MR.VIRAG GOPHANE,

M.pharm,

Assistant professor,

Department of Quality Assurance

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 Ezetimibe and Fenofibrate in combined tablet dosage form and can be used in routine analysis. In Absorbance ratio method absorbance measured at Iso-absorptive point 253 nm (correlation coefficient was found to be 0.998 and 0.996 for Ezetimibe and Fenofibrate) and 286 nm (correlation coefficient was found to be 0.997 and 0.997 for Ezetimibe and Fenofibrate).The LOD was found to be 0.003355µg/mL and 0.076206 µg/mL for Ezetimibe and Fenofibrate respectively. The LOQ was found to be 0.010167µg/mL and 0.230927 µg/mL for Ezetimibe and Fenofibrate respectively.The methods were found to be linear in the concentration range of 2-12µg/mL and 2-12µg/mL for both the drugs.

In RP-HPLC, method was carried out by isocratic technique on a reversed-phase: phenomenex luna ODS C18 (250mm X 4.6 mm i.d.,5 µm particle size) and UV detection at 253 nm with mobile phase containing a mixture of Methanol: Water (90:10)at a flow rate of 1.0 mL/min. The average retention times for Ezetimibe

and Fenofibrate were 3.34 and 6.09 min respectively. The calibration curves were linear in the concentration range of 1-6µg/mL and 16-96µg/mL for Ezetimibe and Fenofibrate respectively. Correlation co efficient were found to be 0.999 and 0.997 for Ezetimibe and Fenofibrate respectively. The LOD was found to be 0.158612 µg/mL and 0.459654 µg/mL for Ezetimibe and Fenofibrate respectively. The LOQ was found to be 0.480643 µg/mL and 1.392891µg/mL for Ezetimibe and Fenofibrate respectively.

KEYWORDS: Ezetimibe and Fenofibrate, Absorption ratio, RP-HPLC