ChemTech

International Journal of ChemTech Research
CODEN(USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.10 No.5,pp731-739,2017

Development and Validation of RP-HPLC Method for the Simultaneous Estimation of TenofovirAlafenamide and Emtricitabine in Bulk and Tablet Dosage Form

Bhushan P. Badgujar*, MoreshwarP.Mahajan, Sanjay D. Sawant.

Department of Quality Assurance Technique, Smt. KashibaiNavale College of Pharmacy Kondhwa (Bk.) Pune-411048, India.

Abstract:A simple, precise, reliable, rapid and reproducible reversed-phase high performance liquid chromatographic (RP-HPLC) method has been developed and validated for the simultaneous estimation of Emtricitabine and Tenofoviralafenamide. Chromatography was carried out Younglin (S.K) Gradient System UV DetectoronC18(4.6X250 mm, 5µ) column with a mobile phase composed of Methanol: Distill water (60:40 v/v) at a flow rate of 1 ml/min. The pH of mobile was adjusted by 0.05% ortho phosphoric acid (pH-3). Detection was carried out using a UV detector at 260 nm.Parameters such as linearity, precision, accuracy, ruggedness, LOD and LOQ were studied as per the ICH Q2(R1) guidelines. The retention times of Emtricitabine and Tenofovir were 3.10 min and 7.38 min respectively. The linearity range for Tenofoviralafenamideand Emtricitabine were 5-30µg/ml, 40-240µg/ml respectively. The correlation coefficients of Emtricitabine and Tenofovir were found to be 0.999. Developed method was found to be accurate, precise, selective and rapid for simultaneous estimation of Emtricitabine and Tenofoviralafenamide in pharmaceutical dosage forms. The proposed method can be useful in quality control of bulk manufacturing and pharmaceutical dosage forms.

Keywords: Emtricitabine, Tenofoviralafenamide, HPLC,Development, Validation.

*****