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● *RESEARCH NOTE* ●

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Method development and validation for simulataneous estimation of emtricitabine and tenofovir disoproxil fumerate in pharmaceutical dosage form

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ABSTRACT

A rapid, sensitive and specific RP-HPLC method involving UV detection was developed and validated for determination and quantification of Emtricitabine and Tenofovir disoproxil fumerate in tablet dosage form. Chromatography was carried out on a pre-packed zorbax SB - phenyl, 250 x 4.6 mm, 5 m column using filtered and degassed Buffer:Methanol as mobile phase at a flow rate of 1.0 ml/min in gradient method and effluent was monitored at 265 nm. The method was validated in terms of linearity, precision, accuracy, and specificity, limit of quantification and limit of detection. The assay was linear over the concentration range of Emtricitabine and Tenofovir disoproxil fumerate was 20 mcg-60 mcg/ml and 30 mcg/ml to 90 mcg/ml, respectively. Accuracy of the method was determined through recovery studies by adding known quantities of standard drug to the pre analyzed test solution and was found to be 98.49 % - 98.9 % and 98.6 % - 99.6 % within precision RSD of 0.54 and 0.55 for Emtricitabine and Tenofovir disoproxil fumerate, respectively. The system suitability parameters such as retention time, theoretical plates and tailing factors were found to be 4.86, 12081, 1.08 and 7.84, 31182, 0.99, respectively for Emtricitabine and Tenofovir disoproxil fumerate. The method required only 12 mins as run time for analysis which prove the adoptability of the method for the routine quality control of the drug.

Key words : Emtricitabine, Tenofovir disoproxil fumerate, Gradient, Method development, Validation

Emtricitabine[1-3] is chemically 5-fluoro-1-(2R,5S)-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl] cytosine and used for treating HIV infection in adults in combination with other antiretroviral agents. Emtricitabine enters cells by passive diffusion and is phosphorylated by deoxycytidine kinase and cellular kinases to its active metabolite, emtricitabine triphosphate. The intracellular triphosphate acts as a competitive inhibitor of reverse transcriptase and is incorporated into HIV DNA to cause chain termination. Tenofovir disoproxil fumerate[1-3] is chemically 9 [(R) 2 [[bis[[(isopropoxycarbonyl)oxy]methoxy]phoshinyl]-Methoxy] propyl] adenine fumarate (1:1) and used for treating HIV infection in adults in combination with other antiretroviral agents. Tenofovir disoproxil fumarate is hydrolyzed rapidly to tenofovir and then is phosphorylated by cellular kinases to its active metabolite, tenofovir diphosphate. The active moiety is, in fact, a triphosphate compound because the parent drug starts out as the monophosphate. The intracellular diphosphate is a competitive inhibitor of viral reverse transcriptases and is incorporated into HIV DNA to cause chain termination because it has an incomplete ribose ring. There is a plethora of analysis of such formulations without prior separation. For the estimation of multi-component formulation, the instrumental techniques, which are commonly employed, are spectrophotometry, GLC, high performance thin layer chromatography (HPTLC), HPLC etc. These methods are based upon the measurement of specific and nonspecific physical properties of the substances. The literature survey reveals that there is no methods have been reported. This present study is to develop[4] an accurate and reliable HPLC method for simultaneous estimation of Emtricitabine and Tenofovir disoproxil fumerate in solid dosage form.

In this paper we describe a simple, inexpensive, sensitive and validated HPLC method[5-9] for the simultaneous determination of Emtricitabine and Tenofovir disoproxil fumerate in pharmaceutical formulation.

Working standards of Emtricitabine and Tenofovir disoproxil fumerate were obtained from well reputed

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