

A VALIDATED STABILITY INDICATING RP-HPLC METHOD FOR THE DETERMINATION OF EMTRICITABINE IN BULK AND CAPSULES

PRADEEP KUMAR*¹, S.C.DWIVEDI¹, ASHOK KUSHNOOR²

¹*School of Pharmacy, Suresh Gyan Vihar University, Jaipur, Rajasthan, India*

²*Shri Gopichand College of Pharmacy, Baghpat, Uttar Pradesh, India*

*corresponding author: pradeep_alpine@yahoo.co.in

Abstract

A rapid, precise, accurate, specific and simple RP-HPLC (reversed phase – high performance liquid chromatography) method was developed for the assay of Emtricitabine from tablets. A High performance liquid chromatograph 10AT SHIMADZU- SPD10A, using Phenomenex - Luna RP-18(2),250X4.6mm, 5 μm column, with a mobile phase composition of buffer : acetonitrile [85:15 % (v/v)] was used. The flow rate of 1.0 mL min⁻¹ and the effluent was detected at 280 nm. The retention time of Emtricitabine was 9.341 minutes. Linearity was observed over the concentration range of 20-600 $\mu\text{g mL}^{-1}$. The limit of detection was found to be 5.539 $\mu\text{g mL}^{-1}$ while the quantification limit was 16.786 $\mu\text{g mL}^{-1}$. The accuracy of the proposed method was determined by recovery studies and was found to be 99.468% to 101.110 %. The commercial tablet formulation was successfully analyzed using the developed method and the proposed method is applicable to stability studies and routine analysis of Emtricitabine in bulk and pharmaceutical formulations.

The proposed method was validated for various ICH (International Conference on Harmonization) parameters like linearity, limit of detection, limits of quantification, accuracy, precision, range and specificity.

Rezumat

Lucrarea prezintă etapele de elaborare și validare a unei metode RP-HPLC (*reversed phase – high performance liquid chromatography*) rapidă, specifică și simplă, pentru determinarea cantitativă a Emtricitabinei din tablete. S-a utilizat un sistem cromatografic de tip 10AT SHIMADZU- SPD10A, dotat cu o coloană Phenomenex - Luna RP-18(2),250X4.6mm, 5 mm. Detectia s-a realizat la 280nm, timpul de retenție al Emtricitabinei a fost de 9.341 minute. Domeniul de linearitate s-a înregistrat pe domeniul de concentrații 20-600 $\mu\text{g mL}^{-1}$, limita de detecție s-a înregistrat la 5.539 $\mu\text{g mL}^{-1}$, limita de cuantificare a fost 16.786 $\mu\text{g mL}^{-1}$, iar coeficientul de regăsire 99.468%-101.110 %. Metoda a fost validată conform ICH (*International Conference on Harmonization*)

Keywords: Emtricitabine, RP-HPLC, Stability studies, ICH guidelines

Introduction

Emtricitabine is chemically 4-amino-5-fluoro-1-[(2R, 5S)-2-(hydroxymethyl)-1, 3-oxathiolan-5-yl] pyrimidin-2-one (Fig. 1). It is a white