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Development and Validation of Stability-indicating HPLC-DAD method for simultaneous determination of Emtricitabine, Rilpivirine, and Tenofovir Alafenamide in bulk and their Pharmaceutical dosage forms

Saidulu.P*[1], Mastanamma.Sk[1], Suresh.P.V[2], A.Prameela Rani[1]

[1]Department of Pharmaceutical Analysis, University College of pharmaceutical science, AcharyaNagarjuna University, Nagarjunanagar, Guntur –522510.Andhra Pradesh (India).
[2]Department of Pharmaceutical Analysis, Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur –522510.Andhra Pradesh (India).

Abstract : A simple and rapid high performance liquid chromatographic method was developed and validated for simultaneous estimation of Emtricitabine(EMT), Rilpivirine (RPV), and Tenofovir alafenamide fumarate(TAF)in bulk active pharmaceutical ingredients & its tablet formulation. The method was established using Agilent C18 (250 × 4.6 mm, i.d., 5 µm) column, mobile phase consisting of 0.1%Formic acid: Acetonitrile (65:35%, v/v) at a flow rate of 1 mL/min with isocratic elution, injecting 20 µL sample into the chromatographic system. The eluted compounds were detected by using PDA detector at detection wavelength of 250 nm and temperature was maintained at 30 °C. Retention times of Reference Standard Emtricitabine, Rilpivirine, and Tenofovir alafenamide was found to be 2.90, 4.34, 6.58mins respectively. The calibration curve was plotted over the concentration range 4-20 μg/mL for EMT, 2-10 μg/mL of RPV and 1-5 μg/mL of TAF.The recoveries for EMT, RPV and TAF were found to be 99.12, 99.38, and 99.18%, respectively. All the validation parameters results were obtained with in acceptance limit.Developed method was subjected to forced degradation studies under specified conditions, which meets the required criteria. The present method was specific, sensitive, reproducible, precise, rapid and simple.

Keawords : RP-HPLC, Emtricitabine, Rilpivirine, and Tenofovir alafenamide, stability studies.

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