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RP-HPLC dissolution method development and validation for emtricitabine and tenofovir alafenamide in tablet dosage form

Abstract:

Reversed Phase-High Performance Liquid Chromatography (RP-HPLC) is an isocratic method that is simple, specific, accurate, fast, and inexpensive. It was developed and validated for the quantitative determination of emtricitabine and tenofovir alafenamide in pharmaceutical tablet dosage forms. The HPLC method was used for an in vitro dissolution study of tablets containing the aforementioned drugs. Phenomenex C18 (250 mm X 4.6 mm, 5 µm) was used in the development of the RP-HPLC technique. The mobile phase consisted of Methanol: Water (70: 30 % v/v). The UV-Vis detector was used to monitor the responses at 216 nm while the flow rate was set to 1.0 mL/min. With a USP Apparatus II at 37°C and 500 mL of 50 mM Sodium Citrate buffer (pH 5.50) as the dissolution medium, the dissolution test was carried out at 75 rpm. It was discovered that the retention periods for EMT and TNF were 4.13 and 5.82 minutes, respectively. EMT (correlation coefficient 0.99998) in the 10–150 µg/mL range and TNF (correlation coefficient 0.99994) in the 1.25–18.75 µg/ml range were found to be linear. The developed method's specificity, linearity, precision, accuracy, robustness, limit of detection, and limit of quantitation were all validated. The developed method can be applied to regular quality control examinations of EMT and TNF in tablet dosage form.

Biography

Shankar Sahebrao Yelmame holds a Master of Pharmacy (M. Pharm) and is currently pursuing a Ph.D. at SNJB's Shriman Sureshdada Jain College of Pharmacy, located in Neminagar, Chandwad, Nashik-423101. With a strong academic background and a keen interest in pharmaceutical research, Shankar is dedicated to advancing his knowledge and contributing to the field of pharmacy. His work aims to address important challenges in drug development and formulation, reflecting his commitment to enhancing healthcare outcomes.