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Development and Validation of First Order Derivative Method for Tenofovir alafenamide in Bulk using UV Visible Spectroscopy

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Abstract : A simple, rapid, accurate, and economical UV-spectrophotometric method has been developed for the estimation of tenofoviralafenamide from bulk drug. The developed method is validated as per ICH guidelines. The method uses a shimadzu UV-Visible with matched quartz cells (1 cm) for the estimation of drug from bulk. The λmax of tenofoviralafenamide in methanol was found to be 259 nm. The drug follows linearity in the concentration range 5-35µg/mL with a correlation coefficient value of 0.9968. Themethod applied was area under curve (AUC) in which area was integrated in the wavelength of range250.12- 261.26 nm.The proposed method was found to be precise as % RSD values for intraday aswell as interday precision was satisfactory. The drug at each of the 80 %, 100 % and 120 % levels showed goodrecoveries that is in the range of 98.00 to 99.00%, hence itcould be said that the method was accurate.The LODand LOQ were calculated as 0.3819 µg/ml and 1.5917µg/ml.Thus, the developed method is found to be robust and rugged which can be applied as a rapid tool for routine analysis of tenofoviralafenamide in the bulk and in the pharmaceutical dosage form.

Keywords : UV, validation, Assay, Precision, % Recovery, Tenofoviralafenamide, area under curve.

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