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Stability Indicating RP-HPLC Method Development and Validation for the Quantification of Tenofovir Disoproxil Fumarate in Bulk and its Dosage form

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Abstract : A simple, selective and sensitive reverse phase high performance liquid chromatography (RP-HPLC) method has been proposed for the estimation of Tenofovir Disoproxil Fumarate in pure form as well as in its pharmaceutical formulation. The chromatography was carried on Phenomenex Luna C18 (250 x 4.6 mm x 5 µm) column, with mobile phase Orthophosphoric Acid: Acetonitrile: Methanol in the ratio of (40:50:10% v/v) and pH adjusted to 3.0. The flow rate was 0.9 ml/min with detection at 254 nm. The retention time was found to be 2.21 min. The proposed method was validated in accordance with ICH guidelines. The linearity was found in the range of 10-60 µg/mL respectively. All validation parameters were within the acceptable range. From the recovery studies, non interference of excipients with the drug was identified and % recovery was found to be 100.19. The drug was subjected to stress studies by subjecting to various conditions like acid, base, oxidative, thermal and photolytic from which sensitivity of drug can be determined. The developed method was successfully applied to estimate the amount of drug in tablet dosage form and to study the stability of the product in various stress conditions as per ICH guidelines.

Keywords: Tenofovir disoproxil fumarate, RP-HPLC Method development, Validation, Stress studies.

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