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Development and Validation of Analytical method for Estimation of Antiviral Drug in Solid Dosage Form by HPLC

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Abstract: *The present work aimed to develop a new simple, accurate and reproducible RP- HPLC method for the analysis of Zanamivir. The method was validated according to ICH (Q2R1) guidelines. The chromatographic conditions were effectively monitored for the elution of analyte utilizing Thermo Hypersil Gold C18 (250mm×4.6mm),5µm; water: methanol (80:20 % v/v) as a solvent system with a 1.0 mL/min of flow at detection wavelength of 233 nm. The retention of analyte was achieved at 3.290 minutes. The tablet sample was assayed with 99.44 %±0.16 purity. The system suitability parameters such as theoretical plates and retention time were found to be 7582 and 3.292, respectively. The linearity of the method achieved at the concentration range of 50-150 µg/mL with a correlation coefficient (R2) of 0.9818. The accuracy study showed 99.83%±0.28 of recovery of analyte. Precision in terms of repeatability was found within the limit (% RSD-1.21), while intermediate precision was shown % RSD of 0.23. In addition, the method found robust at a deliberate change of flow rate and solvent composition. Therefore, the results confirmed the suitability of the method for quantifying Zanamivir in their formulations.*

Keywords: Zanamivir, Method development and Validation

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