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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF LAMUVIDINE AND ZIDOVUDINE IN SOLID DOSAGE FORM BY RP-HPLC METHOD

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Abstract:

A simple rapid, accurate, precise and reproducible validated reverse phase HPLC method was developed for the determination of Lamivudine, Zidovudine in bulk and pharmaceutical dosage forms. The quantification was carried out using Hypersil C18 (150X4.6mm, 5µm) column running isocratic way using mobile phase comprising of Buffer:Methanol:Ammonium acetate buffer (40:60 v/v) pH 3.8 as mobile phase at a flow rate of 1.0 ml/min and wavelength at 260nm., and injection volume of 20µL, with a flow rate of 1.0mL/min. The retention times of Lamivudine, Zidovudine was found to be 3.465, 8.510. The method was validated intermsoflinearity, precision, accuracy, LOD, LOQ and robustness in accordance with ICH guidelines. The linearity ranges of the proposed method lies between 0.075mg/mL to 0.125mg/mL, with correlation coefficient of r2=0.9999, 0.9998 for Lamivudine, Zidovudine. The assay of the proposed method was found to be 99.98%, 99.96%. The recovery studies were also carried out and mean% Recovery was found to be 100.7%, 100.28%,. The %RSD from reproducibility was found to be <2%. The proposed method was statistically evaluated and can be applied for routine quality control analysis of Lamivudine, Zidovudine in bulk and in Pharmaceutical dosage form.

Keywords: Lamivudine, Zidovudine, RP-HPLC, Symmetry C18, Tablets, Validation.