

Development and Validation of High-Performance Liquid Chromatographic Method for Analysis of Enrofloxacin

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Abstract: A rapid, sensitive, and reliable High-Performance Liquid Chromatographic (HPLC) method was developed and validated for the quantitative determination of Enrofloxacin (ENR), a widely used veterinary antibiotic. The chromatographic separation was achieved on a reversed-phase C18 column using an isocratic mobile phase consisting of 10mM Phosphate buffer (pH 3.5) and Acetonitrile (50:50 v/v) at a flow rate of 1.0 mL/min. UV detection was carried out at 277 nm. The method was validated according to USP guidelines for linearity, range, accuracy, precision (repeatability and intermediate precision), specificity (placebo interference), and robustness. The method exhibited good linearity over the concentration range of 40-90 µg/mL with a correlation coefficient (R^2) of 0.999. Accuracy, determined by recovery studies, was within the acceptable limits of 98-102%. Precision, expressed as the relative standard deviation (RSD), was less than 2.0% for both repeatability (0.02%) and intermediate precision (0.03%). The method was specific, with no interference from placebo. Robustness was demonstrated by evaluating the effect of small deliberate changes in flow rate, organic phase composition, and wavelength. The developed and validated HPLC method is suitable for routine quality control analysis of Enrofloxacin in pharmaceutical formulations

Keywords: Enrofloxacin, HPLC, Method Development, Validation, Pharmaceutical Analysis, Quality Control

