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To Develop, Validate and Apply a HPLC Method for the Analysis of Sodium Diclofenac

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Abstract: *HPLC is the predominant separation technique in contemporary pharmaceutical and biomedical analysis. A new reverse phase high performance liquid chromatographic method has been developed for the estimation of diclofenac sodium in pharmaceutical dosage forms using RPC-18 column. The mobile phase consisted of methanol and water in the ratio of 50: 50. Losartan potassium was used as internal standard. The detection was carried at 230 nm and the linearity was found to be in the range of 0.1-30 µg. The method was found to be simple, precise and reproducible.*

The objective of this project was to develop and validate a robust, accurate, and precise High-Performance Liquid Chromatography (HPLC) method for the quantitative analysis of [Drug Name or Compound] in [formulation matrix, e.g., pharmaceutical dosage form, biological matrix]. The method was designed to ensure reliable separation and quantification, in accordance with ICH Q2(R1) guidelines for analytical method validation.

The chromatographic separation was achieved using a [Column Type, e.g., C18 reversed-phase column] with a mobile phase consisting of [describe mobile phase composition, e.g., acetonitrile and phosphate buffer] in isocratic/gradient mode. The flow rate was maintained at [e.g., 1.0 mL/min], and detection was carried out at [e.g., 254 nm] using a UV detector.

Method validation parameters including specificity, linearity, accuracy, precision (intra-day and inter-day), limit of detection (LOD), limit of quantification (LOQ), robustness, and system suitability were evaluated. The method demonstrated good linearity over the concentration range of [range], with correlation coefficients (R^2) greater than [value, e.g., 0.999]. Recovery studies confirmed the method's accuracy, and %RSD values for precision studies were within acceptable limits, indicating high reproducibility.

This validated HPLC method is suitable for routine quality control analysis and can be applied for the assay and stability testing of [Drug Name or Compound] in bulk and finished dosage forms.

Keywords: Estimation, Diclofenac sodium, Losartan potassium and HPLC

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