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Analytical Method Development and Validation by using RP- HPLC of Pharmaceutical Dosage Form

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Abstract: *A simple, precise, and accurate Reverse Phase High-Performance Liquid Chromatographic (RP-HPLC) method was developed and validated for the quantitative estimation of* ***Paracetamol*** *in its* ***tablet dosage form****. Chromatographic separation was achieved on a* ***C18 column (250 × 4.6 mm, 5 µm)*** *using a mobile phase composed of* ***Acetonitrile:Water (40:60 v/v)****, delivered at a flow rate of* ***1.0 mL/min****. The detection wavelength was set at* ***254 nm****, and the retention time of Paracetamol was found to be approximately* ***4.8 minutes****. The method was validated according to ICH Q2(R1) guidelines and showed excellent linearity in the range of* ***10–100 µg/mL****, with a correlation coefficient (r^2) of* ***0.9994****. The percentage recovery was between* ***98.7% and 101.3%****, confirming the accuracy of the method. Precision studies showed relative standard deviation (RSD) values of less than* ***1.5%****. The method was found to be robust and specific, with no interference from excipients. Hence, the developed RP-HPLC method is suitable for routine analysis of Paracetamol in bulk and pharmaceutical dosage forms.*

Keywords: RP-HPLC, Method Development, Method Validation, Paracetamol, Pharmaceutical Dosage Form, Linearity, Accuracy, Precision, ICH Guidelines, Reverse Phase Chromatography Quality Control, Analytical Method, Tablet Analysis

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