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A Validated RP-HPLC Method for Simultaneous Determination of Pregabalin and Duloxetine in Pharmaceutical Dosage Forms

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Abstract: ***Background:*** *A simple, rapid, and reliable reverse-phase high-performance liquid chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation of Pregabalin and Duloxetine in bulk drug and pharmaceutical dosage forms. Chromatographic separation was achieved using a C18 column (4.6 × 100 mm, 2.5 µm particle size) with a mobile phase consisting of methanol and 0.1% orthophosphoric acid buffer (75:25 v/v). The flow rate was maintained at 0.8 mL/min, and detection was carried out at 215 nm using a UV detector. Under optimized chromatographic conditions, the retention times of Pregabalin and Duloxetine were found to be 3.02 min and 6.50 min, respectively, with good peak resolution and symmetrical peak shapes. The developed method was validated according to the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use with respect to system suitability, accuracy, precision, and robustness. The percentage assay for Pregabalin and Duloxetine in bulk drugs was found to be 99.97% and 100.86%, respectively, indicating excellent agreement with the labeled claim. Recovery studies at different concentration levels showed percentage recoveries close to 100%, confirming the accuracy of the method. Precision studies revealed low %RSD values, demonstrating good reproducibility. The robustness study indicated that small variations in chromatographic conditions did not significantly affect the analytical results. The developed RP-HPLC method was found to be accurate, precise, and reliable and can be successfully applied for routine quality control analysis of Pregabalin and Duloxetine in pharmaceutical formulations.*

Keywords: Pregabalin, Duloxetine, RP-HPLC, Method Development, Method Validation, Simultaneous Estimation, Pharmaceutical Analysis, ICH Guidelines

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