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New Rp-hplc Method Development and Validation for Simultaneous Analysis of Dolutegravir and Rilpivirine in Bulk and Pharmaceutical Dosage Forms

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The aim of this study was to develop and validate a reliable and efficient RP-HPLC method for the simultaneous analysis of Dolutegravir and Rilpivirine in bulk and pharmaceutical dosage forms. The objective was to establish a robust chromatographic method that provides accurate, precise, and rapid quantification of Dolutegravir and Rilpivirine, ensuring suitability for routine quality control testing in both bulk and tablet formulations.The RP-HPLC method was developed using a Shimadzu LC-20AT system with a C18 column (250 mm × 4.6 mm, 5 µm). The mobile phase consisted of a mixture of phosphate buffer (pH 4.0) and acetonitrile in the ratio of 75:25 v/v. The flow rate was maintained at 1.0 mL/min, and detection was performed at 265 nm. The retention times for Dolutegravir and Rilpivirine were 4.5 and 6.2 minutes, respectively. The method was validated according to ICH guidelines for parameters such as specificity, linearity, accuracy, precision and robustness.The method showed linearity in the concentration ranges of 50–250 µg/mL for Dolutegravir and 10–50 µg/mL for Rilpivirine, with correlation coefficients (R^2) greater than 0.999 for both drugs. The accuracy was demonstrated by recovery values between 98% and 102%, and precision results showed RSD values below 2% for both intra- and inter-day variations. Specificity testing confirmed no interference from excipients, and the method was found to be robust under small changes in chromatographic conditions.The developed RP-HPLC method offers a simple, rapid, and validated approach for the simultaneous analysis of Dolutegravir and Rilpivirine in bulk and pharmaceutical dosage forms. This method is suitable for routine quality control and ensures compliance with regulatory standards.

Biography

Akhil has her own experience in valuation and passion for ML and data. The research team built this model after many years of experience in research, evaluation, work in both hospitals and scientific laboratories. This approach meets all the requirements for precise, specific, sensitive diagnostics. .

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