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Rp-hplc Method Development and Validation for Simultaneous Estimation of Metformin and Sitagliptin Phosphate

P.Yamuna
India

The aim of this study was to develop and validate a simple, rapid, and reliable RP-HPLC method for the simultaneous estimation of Metformin Hydrochloride and Sitagliptin Phosphate in bulk and tablet dosage forms.The objective was to establish an optimized chromatographic method that ensures high separation efficiency, accuracy and precision for the simultaneous analysis of Metformin and Sitagliptin Phosphate. Additionally, the study aimed to validate the method as per ICH guidelines.The method was developed using a Shimadzu LC-20AT system with a reverse-phase C18 column (250 mm × 4.6 mm, 5 µm particle size). The mobile phase consisted of a mixture of phosphate buffer (pH 3.0) and acetonitrile in the ratio of 70:30 v/v. The flow rate was maintained at 1.0 mL/min with a detection wavelength of 254 nm. The chromatographic separation was achieved with retention times of Metformin and Sitagliptin Phosphate at 3.4 and 5.8 minutes, respectively. The method was validated for parameters including linearity, accuracy, precision, specificity, robustness, and system suitability. The method demonstrated linearity in the concentration range of 50–250 µg/mL for Metformin and 10–50 µg/mL for Sitagliptin Phosphate. The accuracy was confirmed with recovery values between 98% and 102%, and precision results showed less than 2% relative standard deviation (RSD) for both intra- and inter-day variations. The method exhibited excellent specificity, with no interference from excipients in the tablet formulations. The robustness studies confirmed the method's reliability under slight variations in chromatographic conditions.The RP-HPLC method developed and validated in this study provides an efficient, accurate and precise approach for the simultaneous determination of Metformin and Sitagliptin Phosphate in pharmaceutical formulations. The method adheres to regulatory guidelines and is suitable for routine quality control analysis.

Biography

Yamuna 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. .

yamuna.pharmaaffairs@gmail.com

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