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Analytical Method Development and Validation of Anti-Diabetic Drugs

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Abstract: *Sitagliptin, a vital pharmaceutical compound utilized in the management of type 2 diabetes, necessitates precise analytical methods for its determination. This structural abstract delineates two primary analytical techniques employed for Sitagliptin quantification: UV spectroscopy and RP-HPLC. In UV spectroscopy, a comprehensive scan ranging from 200 to 400 nm was conducted to ascertain the most efficacious detection wavelength, pinpointing 239 nm as optimal. Concurrently, a calibration curve was meticulously constructed by correlating concentration (µg/ml) with peak area, facilitating accurate Sitagliptin quantification. RP-HPLC methodology underwent rigorous development, meticulously optimizing chromatographic conditions encompassing column type, mobile phase composition, flow rate, and detection wavelength to achieve swift and efficient separation within a concise timeframe of 10 minutes. Subsequent validation encompassed accuracy, precision, and robustness through extensive recovery studies, % RSD values, and robustness assessments. Both UV spectroscopy and RP-HPLC methodologies demonstrated exceptional accuracy, precision, and reliability in Sitagliptin determination. UV spectroscopy identified 239 nm as the paramount wavelength for detection, while RP-HPLC exhibited sensitive and selective quantification capabilities across a concentration spectrum ranging from 50 to 250 µg/ml. The developed UV spectroscopy and RP-HPLC methodologies constitute indispensable tools for the precise determination of Sitagliptin within pharmaceutical formulations. These methodologies, validated for routine analysis and quality control, substantiate the potency and stability of Sitagliptin-containing products, thereby augmenting their therapeutic efficacy and ensuring regulatory compliance*

Keywords: Sitagliptin, UV spectroscopy, RP-HPLC, Pharmaceutical analysis, Quantification, Method development, Calibration curve, Validation