

[QbD-Enhanced HPLC Method Development for Vildagliptin and Metformin HCl Formulations.](#)

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Description

Objectives: This research employs the Quality by Design strategy to design an optimized High-Performance Liquid Chromatography method aimed at analyzing vildagliptin and metformin hydrochloride in pharmaceutical dosage forms. Materials and Methods: The mobile phases A and B comprised a buffer-acetonitrile mixture in ratios of 950: 50 v/v and 600: 400 v/v, respectively. Chromatographic separation was achieved using an YMC Triart C-18 column, with Vildagliptin detection conducted at 210 nm via UV absorbance. Various independent parameters were selected for investigation and risk assessment was employed to evaluate their impact on the analytical responses. Results: QbD prioritizes product understanding, risk management and process control to enhance quality assurance and regulatory tractability. Analytical Quality by Design principles ensure robust and flexible methods throughout the product ...

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