

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

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Publication date

2025/4/2

Journal

Indian Journal of Pharmaceutical Education & Research

Volume

59

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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