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Rapid and Reliable: UV-Spectrophotometric Determination of Vildagliptin in Bulk and Solid Dosage Forms

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Abstract*—A simple, precise, and reliable UV spectrophotometric method was developed for the quantitative estimation of vildagliptin in bulk and tablet dosage forms. The drug exhibited maximum absorbance at 215 nm in a methanol-water mixture (60:40 v/v). The method was validated in accordance with ICH guidelines, addressing parameters such as linearity, accuracy, precision, limit of detection (LOD), and limit of quantification (LOQ). Vildagliptin obeyed Beer's law in the concentration range of 10–50 µg/mL, with a regression equation of Y = 0.00457x + 0.0021 and a correlation coefficient of 0.9998. The percent recovery ranged between 98.5% and 101%, while the %RSD was below 2%. The LOD and LOQ were determined to be 0.39 µg/mL and 1.19 µg/mL, respectively. These findings confirm that the proposed method is suitable for routine analysis of vildagliptin in both bulk and tablet forms*.

***Keywords*—** *Vildagliptin, UV spectroscopy, international conference on harmonization*.

I. INTRODUCTION

Vildagliptin is a selective inhibitor of dipeptidyl peptidase-4 (DPP-4), which enhances glycemic control by increasing incretin levels, thereby promoting insulin secretion and suppressing glucagon release in type 2 diabetes mellitus (T2DM) patients[1]. The drug demonstrates rapid and near-complete inhibition of DPP-4 following administration, while showing minimal inhibition of DPP-8 and DPP-9 due to rapid dissociation[2].

Structurally, vildagliptin contains an adamantane ring system and a nitrogenous heterocyclic moiety[3]. It is orally bioavailable, rapidly absorbed, and shows minimal pharmacokinetic variability across different populations[4–5]. Approximately 85% of the administered dose is excreted renally, with 23% eliminated unchanged and the rest metabolized by hydrolysis[6]. The drug is not influenced by food intake and does not significantly interact with cytochrome P450 enzymes[7]. Vildagliptin is also free from clinically significant interactions with commonly co-administered drugs such as simvastatin, ramipril, amlodipine, warfarin, and metformin[8].

While various HPLC methods have been developed to estimate vildagliptin alone or in combination with metformin[9–12], these methods can be expensive, labor-intensive, or lack sensitivity. Therefore, there is a need for a simpler, economical, and reliable analytical method such as UV spectrophotometry, which offers practical utility for routine pharmaceutical analysis[13–14].

II. MATERIALS AND METHODS

2.1 Chemicals and Instrumentation

Methanol, water, and orthophosphoric acid were procured from Research Lab. Vildagliptin tablets (Debiglip® and Vimed®) were purchased from a local pharmacy. A PG Instruments T60 UV double-beam spectrophotometer was used for analysis. Additional equipment included a Wensar PGB 200 electronic balance, an Ultrasonic DP 120 cleaner, and a Global DPH 500 digital pH meter.

2.2 Methodology Overview

The method was developed and validated as per ICH Q2(R1) guidelines[15], involving preparation of standard solutions, determination of λmax, and evaluation of linearity, precision, accuracy, LOD, LOQ, robustness, solution stability, and assay.

III. RESULTS AND DISCUSSION

3.1 Linearity

A series of solutions (10–50 µg/mL) were analyzed, and the calibration curve showed good linearity ($R^2 = 0.9998$).

TABLE 1. Linearity Data of Vildagliptin

S. No	Concentration (µg/mL)	Absorbance
1	10	0.047
2	20	0.093
3	30	0.141
4	40	0.186
5	50	0.229

TABLE 2. Linearity Parameters of Vildagliptin

Parameter	Result
Λmax	215 nm
Slope	0.00457
Intercept	0.0021
Linearity Range	10–50 µg/mL
Correlation Coefficient (R^2)	0.9998

3.2 Precision

Results demonstrated excellent precision for both intraday and interday measurements.

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TABLE 3. Intraday Precision of Vildagliptin (30 µg/mL)

Replicate	Absorbance
1	0.247
2	0.247
3	0.246
4	0.247
5	0.246
Mean	0.246
SD	0.000548
%RSD	0.12%

TABLE 4. Interday Precision of Vildagliptin (30 µg/mL)

Replicate	Absorbance
1	0.167
2	0.167
3	0.168
4	0.167
5	0.168
Mean	0.168
SD	0.001
%RSD	0.5%

3.3 Accuracy (Recovery Studies)

Recovery was within the accepted ICH range (98–102%).

TABLE 5. Accuracy Data of Vildagliptin

Level (%)	Spiked Conc. (µg/mL)	Amount Added (µg/mL)	% Recovery
50	30	10	98.7
			99.0
			98.0
Average			**98.5%**
100	30	30	99.0
			100.5
			99.7
Average			**99.7%**
150	30	50	100.5
			101.0
			101.7
Average			**101%**

3.4 LOD and LOQ

TABLE 6. LOD and LOQ of Vildagliptin

Parameter	Value (µg/mL)
LOD	0.39
LOQ	1.19

3.5 Robustness

No significant deviation was observed with slight changes in wavelength.

TABLE 7. Robustness Data of Vildagliptin (30 µg/mL)

Wavelength (nm)	Absorbance
210	0.139
215	0.141
220	0.143

3.6 Solution Stability

Samples were stable after 24 hours.

TABLE 8. Stability of Debiglip® (30 µg/mL)

Time	Absorbance
Initial	0.62
24 hours	0.59

TABLE 9. Stability of Vimed® (30 µg/mL)

Time	Absorbance
Initial	0.58
24 hours	0.56

3.7 Assay

The assay values were within the standard range (98–102%).

TABLE 10. Assay of Debiglip®-50 mg (n = 6)

Label Claim	Amount Found	% Assay
50 mg	49.25 mg	98.5%

TABLE 11. Assay of Vimed®-50 mg (n = 6)

Label Claim	Amount Found	% Assay
50 mg	49.85 mg	99.2%

IV. CONCLUSION

The UV spectrophotometric method developed is simple, accurate, robust, and cost-effective. It meets all validation criteria for the estimation of vildagliptin in both bulk and tablet dosage forms, offering a reliable alternative to complex chromatographic techniques for routine quality control.

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Conflict of Interest

The authors declare no conflict of interest.

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