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# RP-HPLC DETERMINATION OF VILDAGLIPTIN IN PURE AND IN FORMULATION

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## ABSTRACT

The purpose of this study is to develop a simple, quick, and reproducible reverse phase high performance liquid chromatography (RP-HPLC) technique for estimating Vildagliptin in both pure and tablet dose form utilizing an Agilent Eclipse XDB-C18, 4.6 x 150 mm, 5 µm column. The mobile phase is made up of mixture of phosphate buffer and acetonitrile in the ratio of 85:15% v/v. The detection was performed at 210 nm, and the calibration curve was linear in the concentration range of 10-150 µg/mL. The approach was statistically verified in terms of linearity, precision, accuracy, stability, specificity, LOD, and LOQ. The suggested RP-HPLC technique may be utilized to determine Vildagliptin in pure form because of its simplicity, speed, high precision, and accuracy.

**Keywords: Vildagliptin, RP-HPLC, mobile phase, flow rate, linearity, validation**

## INTRODUCTION

Vildagliptin is a potent dipeptidyl peptidase IV (DPP IV) inhibitor used for treating type 2 diabetes. It improves fasting and postprandial glycemic control without hypoglycemia or weight gain. Vildagliptin inhibits the inactivation of GLP-1 and GIP by DPP IV,

allowing them to increase insulin secretion in beta cells and suppress glucagon release in alpha cells of the islets of Langerhans.

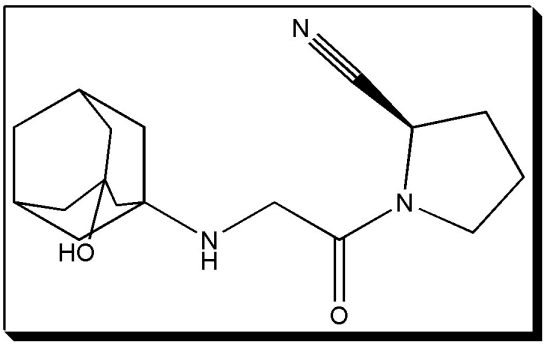


**Figure 1: Chemical structure of vildagliptin**

**[1-4]** Literature survey reveals that vildagliptin can be estimated by UV spectroscopic method, **[5]** RP-HPLC method, which is a time consuming method being the retention time is more than 10 min,**[6]** RP-LC/MS method, requires mass spectroscopy detection and the LOD and LOQ are more than the present method, and has a narrow linearity range, **[7]** HPLC method, which requires a solid-phase extraction and determination by high-performance liquid chromatography quadrupole time-of-flight mass spectrometry which requires a special attention throughout the study but the present work is a simple method **[8]**. So based on the above mentioned reasons the authors aim to develop a simple, sensitive and accurate RP-HPLC method for the estimation of vildagliptin in pure form and tablet dosage form.

## Experimental

### Instrumentation

Waters 2695 HPLC system equipped with Agilent zorbax eclipse XDB-C18, 4.6 x 150 mm, 5 µm column, Rheodyne injector with 25 mL loop, 2996 PDA detector and Empower-2 software was used.

### Reagents and chemicals

Potassium dihydrogen orthophosphate of analytical quality, HPLC grade Milli-Q water, and acetonitrile were utilized. Micro labs, India, sent a complimentary sample of Vildagliptin. The vildagliptin pills were bought from a nearby drugstore.

### Preparation of buffer solution

A 0.1M phosphate buffer was created by dissolving 13.6 g of potassium dihydrogen orthophosphate in 1000 mL of HPLC grade water.

### Chromatographic condition

Vildagliptin was eluted on an Agilent XDB C18 column using a mobile phase mixture of phosphate buffer and acetonitrile, with a lambda max of 210 nm and a 25 mL injection volume with an 8-minute runtime.

### Procedure for standard solution preparation

A 100 mL flask was filled with 100 milligrams of pure vildagliptin, dissolved in HPLC grade water, and adjusted to 1000 mg/mL for accurate measurement.

**Construction of calibration curve**

The standard vildagliptin solution was diluted to various concentrations (10 to 150 µg/mL) using mobile phase. Each calibration standard solution was injected into a HPLC system, and chromatograms were recorded. The concentration of vildagliptin in µg/mL was taken in the X axis, and the peak area of individual concentrations was taken in the Y axis. The calibration graph was plotted for tablet estimation.

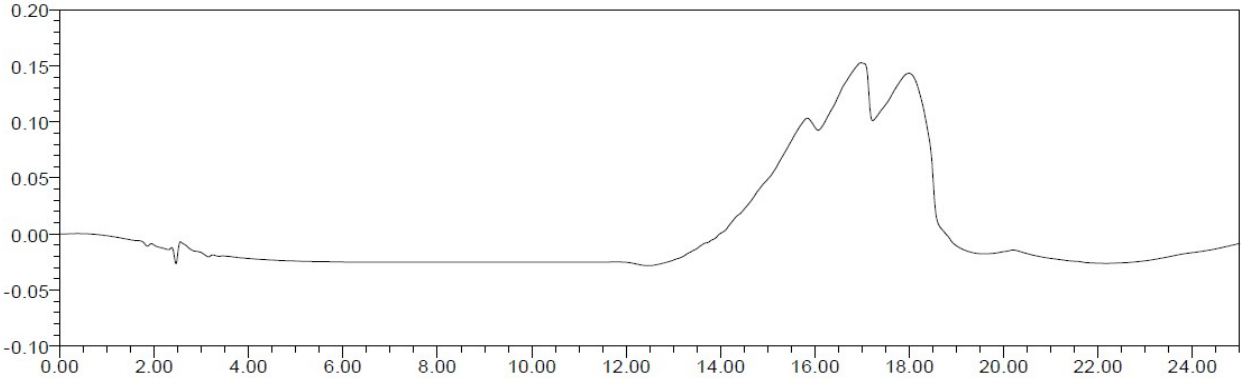


**Figure 2: Chromatogram of blank**

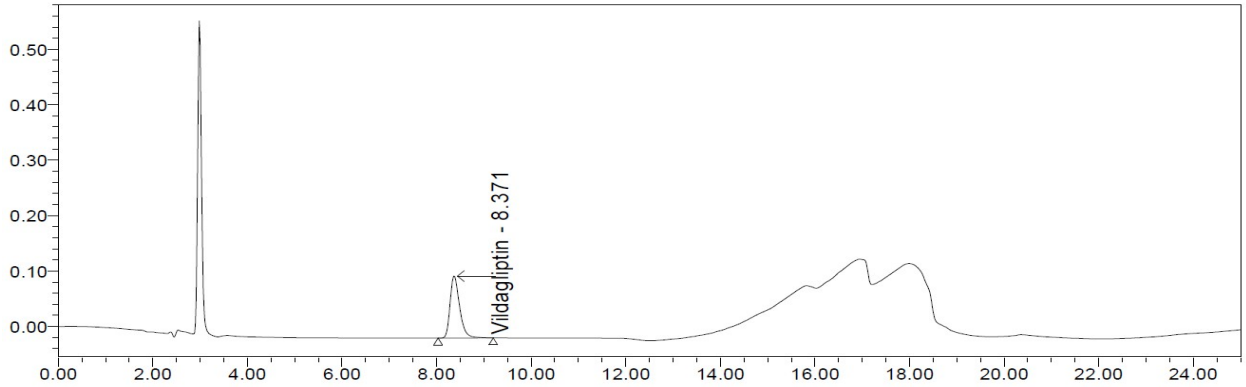


**Figure 3: Chromatogram of standard at 210nm for Vildagliptin**

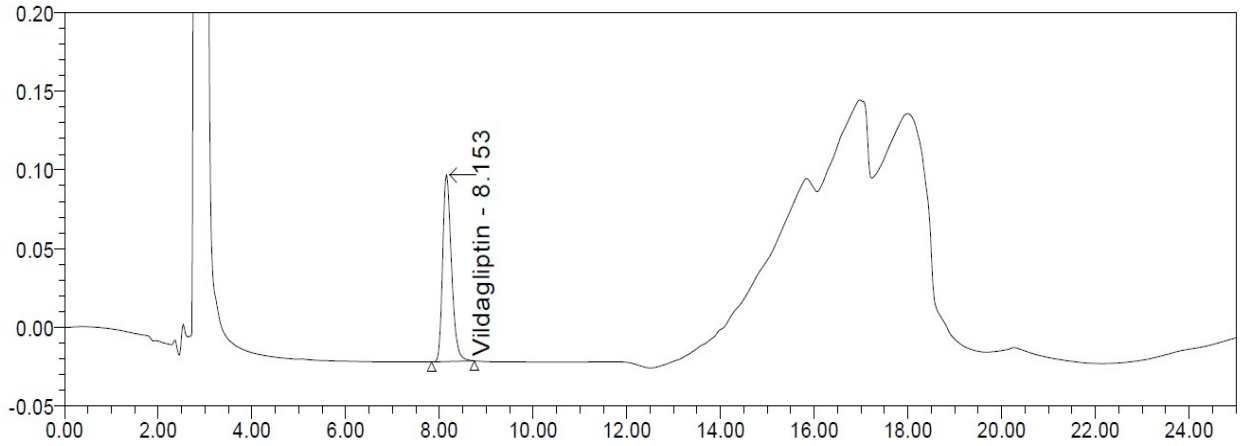


**Figure 4: Chromatogram of sample at 225nm for Vildagliptin**

**Estimation of vildagliptin**

The study involved weighing and powdering twenty tablets of vildagliptin, transferring the equivalent to 100 mg powder to a calibrated standard flask, adding 70 mL of HPLC grade water, sonicating for 15 minutes, and filtering the mixture. The solution was diluted with mobile phase to 50 µg/mL, and then injected six times into the HPLC system. The mean value of peak areas was calculated, and the drug content in the tablet was quantified.

**Table 1: System suitability data**

| Drug | Theoretical plates (N) | Tailing factor (T) | Retention time (min) (n=6) | | Peak area (n=6) | |
|---|---|---|---|---|---|---|
| | | | Mean± S.D | % RSD | Mean ±S.D | % RSD |
| Vildagliptin | 3311 | 1.13 | 3.04 _ 0.0117 | 0.3837 | 486592 _ 216.6 | 0.0445 |

**Table 2: Linear regression data for calibration curve**

| Parameters | Values |
|---|---|
| Concentration range, µg/mL | 10-150 |
| Slope | 9944 |
| Intercept | 5738.83 |
| Correlation coefficient | 0.999 |

**Table 3: Assay, Recovery results and Precision studies**

| Formulation | Labeled amount (mg/tablet) | (%) Label claim [a]± S.D. | % Recovery | Precision (% RSD) | |
|---|---|---|---|---|---|
| | | | | Inter-day (n= 24) | Intra-day (n = 6) |
| Vildagliptin tablets | 50 | 99.92±0.2125 | 99.47-100.83% | 0.1668 | 0.1497 |

[a] Average of six determinations

## RESULTS AND DISCUSSION

The study weighed twenty tablets of vildagliptin, which is soluble in water and acetonitrile. Different mobile phase compositions were tried to elute the drug from the column, and the most suitable solvent system was found to be phosphate buffer and acetonitrile in a ratio of 85:15% v/v with an Agilent Eclipse XDB C18 column. The maximum absorbance of vildagliptin was found at 210 nm in the mobile phase, indicating the column outlet was detected at 210 nm in the proposed method. The system suitability tests were carried out on freshly prepared standard stock solution and summery, indicating good sensitivity and selectivity of the developed method.

The HPLC method involved a simple and rapid extraction procedure, requiring less time. A good linear relationship was obtained in the concentration range of 10-150 µg/mL. The proposed method was used to estimate the amount of vildagliptin in tablets, with precision determined by repeatability and intermediate precision. The accuracy of the developed method was tested by adding the known amount of vildagliptin pure drug to a

placebo solution and subjecting it to the proposed method. The limit of detection (LOD) and limit of quantification (LOQ) for vildagliptin were found to be 0.0329 and 0.0998, respectively.

## CONCLUSION

The proposed method for determining vildagliptin from pure form and tablet dosage form is simple, precise, accurate, and rapid. It uses a simple mobile phase and has a runtime of 8 minutes, making it less time-consuming. The recovery study shows no additive interference, making it suitable for routine quality control and dissolution studies.

### List of Abbreviations

RP-HPLC: Reverse phase high performance liquid chromatographic

LOD: limit of detection

LOQ: limit of quantification

### Human and Animal Rights

This study employed no animals or people.

### Consent for publication

Not relevant.

### The availability of data and materials

The authors affirm that the data supporting the study's conclusions are available in the journal.

### Conflict of interest

The author discloses no conflicts of interest, either financial or otherwise.

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## REFERENCE

**[1]** McIntosh CH, Demuth HU, Pospisilik JA, Pederson R. Dipeptidyl peptidase IV inhibitors. How do they work as new antidiabetic agents. Regul Pept. 2005;128:159-165.

**[2]** Weber AE. Dipeptidyl peptidase IV inhibitors for the treatment of diabetes. J Med Chem. 2004;47:4135-4141.

**[3]** Lauster CD, McKaveney TP, Muench SV. Vildagliptin: a novel oral therapy for type 2 diabetes mellitus. Am J Health Syst Pharm. 2007;64:1265-1273.

**[4]** He H, Tran P, Yin H, et al. Absorption, metabolism, and excretion of [14C]vildagliptin, a novel dipeptidyl peptidase 4 inhibitor, in humans. Drug Metab Dispos. 2009;37:536-544.

**[5]** Thangabalan Boovizhikannan, Vijayaraj Kumar Palanirajan. RP-HPLC determination of vildagliptin in pure and in tablet formulation. J. Pharm. Res, 2013,7,113-116.

**[6]** El-Bagary RI, Elkady EF, Ayoub BM. Spectrophotometric methods for the determination of sitagliptin and vildagliptin in bulk and dosage forms. Intern J Biomed Sci. 2011;7:55-61.

**[7]** Pharne AB, Santhakumari B, Ghemud AS, Jain HK, Kulkarni MJ. Bioanalytical method development and validation of vildagliptin a novel dipeptidyl peptidase iv inhibitor by RP-HPLC method. Intern J Pharm Pharm Sci. 2012;4:119-123.

**[8]** Kedar A. Jagtap, Vasudha S. Bavadekar, Pravin D. Chaudhari, Geeta A. Anawade, Akshata B. Birajdar. RP-HPLC Method Development and Validation of Metformin, Vildagliptin and Remogliflozin in Bulk and Pharmaceutical Dosage form, Eur. Chem. Bull. 2023, 12 (s3), 6526 – 6540.