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ADVANCES IN ANALYTICAL TECHNIQUES FOR VILDAGLIPTIN: A COMPREHENSIVE REVIEW

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ABSTRACT

The review article discusses vildagliptin, an antihyperglycemic medication targeting dipeptidyl peptidase-4 (DPP-4) to manage type 2 diabetes mellitus. This drug enhances pancreatic alpha- and beta-cell activity, improving glycaemic control as indicated by glycated haemoglobin and fasting plasma glucose (FPG) levels. Chemically identified as (s)-1-[(3-Hydroxy-1-adamantyl) glycyl] pyrrolidine-2-carbonitrile, vildagliptin's quantification in pharmaceutical formulations (tablets) and bulk is crucial. The review focuses on various analytical methods—UV spectroscopy, reversed phase high performance liquid chromatography (RP-HPLC), high performance liquid chromatography (HPLC), high performance thin layer chromatography (HPTLC), and ultra performance liquid chromatography (UPLC)—used to analyze vildagliptin alone or in combination forms, compiling recent advancements in analytical techniques.

KEYWORDS: Vildagliptin, UV spectroscopy, reversed phase high performance liquid chromatography (RP-HPLC), High performance thin layer chromatography (HPTLC) and Ultra performance liquid chromatography (UPLC).

INTRODUCTION

Vildagliptin regulates blood sugar levels by specifically inhibiting the body's dipeptidyl peptidase-4 (DPP-4). This medication is recommended for the treatment of type 2 diabetes mellitus due to its ability to decrease GLP-1 secretion and exert insulinotropic effects. Vildagliptin suppresses DPP-4, thereby preventing the degradation of the incretin hormone

glucose-dependent insulinotropic polypeptide (GIP). This action leads to increased insulin release and better control of blood sugar levels. Simultaneously, levels of GLP-1 and GIP rise, contributing to improved glycemic management. Clinical studies have shown that vildagliptin carries a relatively low risk of hypoglycemia.

In 2008, the European Medicines Agency approved oral vildagliptin for the treatment of adults with type 2 diabetes mellitus. It is prescribed for patients who have not achieved adequate glycemic control with monotherapy and may be used in combination with metformin, sulfonylureas, or thiazolidinediones. Marketed under the name Galvus, vildagliptin also comes in a fixed-dose combination called Eucreas for those whose glycemic control remains insufficient with vildagliptin alone. Clinical investigations on vildagliptin are currently ongoing in the United States.[1]

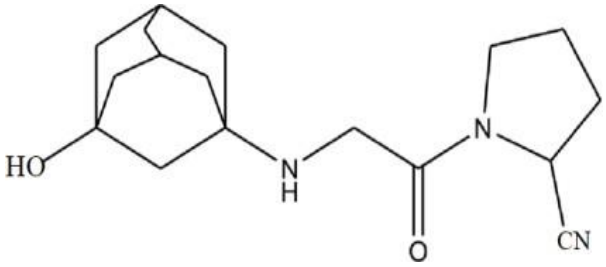

Fig. 1: Structure of vildagliptin.

Drug profile

DRUG	**Vildagliptin**
IUPACName	(2S)-1-{2-[(3-hydroxyadamantan-1-yl)amino]acetyl)pyrrolidine-2-carbonitrile
ChemicalFormula	$C_{17}H_{25}N_3O_2$
MolecularMass	303.3993g/mole
MeltingPoint	153— l55°C
PhysicalState	Solid
Solubility	SolubleinWaterandMethanol
pKa	14.71and9.03 Strongestacidicand basicrespectively
t1/2	90minutes
TherapeuticUse	Usedto reducehyperglycemiain type2 diabetesmellitus.

Analytical Methods for the Quantification of Vildagliptin in Pharmaceutical Formulations

Several analytical methods are employed to determine Vildagliptin in pharmaceutical preparations. UV spectroscopy, HPLC, HPTLC, UPLC, and RP-HPLC are among the

methods reported for its analysis. This review aims to compile key analytical techniques recently utilized for the assessment of Vildagliptin.

Literature Review of Vildagliptin

Several analytical methods have been developed for the estimation of vildagliptin in pharmaceutical formulations.

Safila Naveed et al. (2014) proposed a UV spectrophotometric method utilizing water as a solvent, with vildagliptin demonstrating a linear calibration curve (R^2 = 0.985) over the concentration range of 12.5-200 µg/ml. The method was validated for accuracy and precision.[2]

Sheetal Vishnudas Mane et al. (2022) developed a UV spectrophotometric method where vildagliptin exhibited maximum absorbance at 210 nm in water, 0.1 N HCl, and phosphate buffer pH 7.4. The method showed excellent linearity (R^2 = 0.9991–0.9998) over the concentration range of 2–12 µg/ml.[3]

Samer Housheh et al. (2019) reported a UV spectrophotometric method with vildagliptin showing maximal absorbance at 202.5 nm in 0.5 M HCl. The method demonstrated high accuracy (100.17%) and precision (%RSD < 2%) over the range of 10–40 µg/ml, with LOD and LOQ levels of 0.055 µg/ml and 0.166 µg/ml, respectively.[4]

Ravishankar Chadchankar et al. (2002) also developed a UV spectrophotometric method, showing good linearity (R^2 = 0.9995) over the concentration range of 10–50 µg/ml, meeting the accuracy and precision criteria set by ICH guidelines.[5]

Ramakrishna et al. (2024) proposed a UV spectrophotometric method with vildagliptin demonstrating a linear calibration curve (R^2 = 0.9995) in the concentration range of 5–30 µg/ml. However, the precision (%RSD) did not meet the ICH limit of 2.0%.[6]

Prasad et al. (2017) developed a UV spectrophotometric method using 0.1% NaOH as a solvent, with vildagliptin exhibiting maximum absorption at 216.00 nm. The method showed good linearity (R^2 = 0.997) over the concentration range of 10–100 µg/ml.[7]

Gayatri Gaikwad et al. (2022) utilized 0.1% NaOH as a diluent in their UV spectrophotometric method, with vildagliptin showing maximum absorption at 227 nm. The

method demonstrated a linear relationship between 10 and 90 µg/ml, with excellent precision (%RSD 0.33%) and recovery rates ranging from 98.33% to 101%.[8]

HPLC methods have also been explored for vildagliptin estimation. Hanumantha Rao et al. (2014) used an isocratic mode with acetonitrile and phosphate buffer as the mobile phase, demonstrating good recovery rates (99.73%) for vildagliptin tablets.[9]

Thangabalan Boovizhikannan et al. (2013) developed an RP-HPLC method using a 0.1 M phosphate buffer and acetonitrile mobile phase, showing linear calibration over the range of 10–150 mg/ml.[10]

Ahire Sujeet Kumar et al. (2023) utilized RP-HPLC with a mobile phase of 80:19:1 and buffer pH 3.0, achieving accurate detection at 210 nm.[11]

Other methods include HPTLC by Amruta Khurd et al. (2020) and UPLC by Camila Ferrazza Alves Giordani et al. (2020), showing promising results in terms of precision, accuracy, and sensitivity.[12,13]

These methods collectively demonstrate diverse approaches to accurately and precisely estimate vildagliptin in pharmaceutical formulations, catering to various analytical needs and requirements**.**

CONCLUSION

In conclusion, this literature review underscores the variety and efficacy of analytical methods developed for the estimation of vildagliptin in pharmaceutical formulations. UV spectrophotometric methods, prominently featured in the reviewed studies, consistently demonstrate robustness with linear calibration curves and precise quantification capabilities across different solvent systems and concentration ranges. HPLC, HPTLC, and UPLC methods also play significant roles, offering enhanced sensitivity and specificity suitable for different analytical needs. Each method showcased adherence to international guidelines for accuracy, precision, and validation, affirming their reliability in pharmaceutical analysis. Researchers have continuously refined these techniques, optimizing conditions to achieve high recovery rates and minimal variability, thus ensuring consistent and reproducible results. Moving forward, continued advancements in analytical methodologies will further enhance the field's capabilities, potentially expanding applications beyond routine pharmaceutical analysis to include research and development contexts. These efforts underscore the critical

role of analytical chemistry in pharmaceutical sciences, ensuring the quality and safety of vildagliptin-containing products for clinical use.

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