INTERNATIONAL JOURNAL OF PHARMACY AND ANALYTICAL RESEARCH

ISSN: 2320-2831

IJPAR |Vol.9 | Issue 4 | Oct - Dec-2020

Journal Home page: www.ijpar.com

Research Study Open Access

New spectrophotometric method development for the estimation of vildagliptin in bulk & Pharmaceutical dosage form

Gangadhari Harika, Dr.K.Rajeswar Dutt, Santhosh Illendula, K.N.V.Rao

Department of Pharmaceutical Analysis, Nalanda College of Pharmacy, Cherlapally, Nalgonda, Telangana-508001, India

***Corresponding Author: Gangadhari Harika**
Email: harikansm1999@gmail.com

ABSTRACT

A new simple, specific, rapid, reproducible and cost effective spectrophotometric method using Schiff's base reaction for the quantitative estimation of Vildagliptin in bulk and pharmaceutical dosage form. The developed UV spectrophotometric method for the quantitative estimation of Vildagliptin is based on the measurement of absorption at maximum wavelength 250nm using Vanillin Sulphuric acid as a reagent, ethanol as a solvent & methanol as a diluent. The stock solution of Vildagliptin was prepared and subsequently Vanillin sulphuric acid reagent was added. Finally, methanol was used to make up the volume in order to obtain the standard curve. The standard solution of Vildagliptin showed absorption maxima at 250nm. The drug obeyed Beer lambert's law in the concentration range of 100-1000µg/ml with λ_{max}at 250nm. The developed method can be adopted in routine analysis of Vildagliptin in bulk and tablet dosage form.

KEYWORDS: Vildagliptin, UV Spectrophotometry, Schiff's base reaction, Method development, Vanillin Sulphuric acid, Beer lambert's law.

INTRODUCTION

Vildagliptin is an Oral Anti-Hyperglycemic agent (Anti-Diabetic), Molecular Formula: $C_{17}H_{25}N_3O_2$. MolecularWeight:303.4gm/mole.IUPACName:(2S)-1-[2-[(3-hydroxy-1-adamantyl)amino]acetyl]pyrrolidine-2-carbo-nitrile,Mechanism of action of drug involves inhibition of dipeptidyl peptidase-4 [DPP-4]. This in turn inhibits the inactivation of GLP-1 (Glucagon-like peptide-1) by DPP-4, allowing GLP-1 to potentiate the secretion of insulin in the beta cells & supress the glucagon release by the alpha cells of the islets of langerhans in the pancreas.

Dipeptidyl peptidase-4's role in blood glucose regulation is thought to be through degradation of GIP (Gastric inhibitory polypeptide)&the degradation of GLP-1.

According to the literature survey (1-12) it was found that HPLC, RP-HPLC, HPLC-MS/MS, GC-MS, liquid chromatography, UV-visible spectrophotometric methods were reported for the estimation of Vildagliptin, whereas no UV spectrophotometric method was developed using a Schiff's base reaction. Hence, the main aim and objective of present work is to develop a new, simple, economical, straight forward, rapid, specific, sensitive, UV spectrophotometric method for the estimation of Vildagliptin in bulk and pharmaceutical dosage form using Schiff's base reactionfor routine internal control analysis.

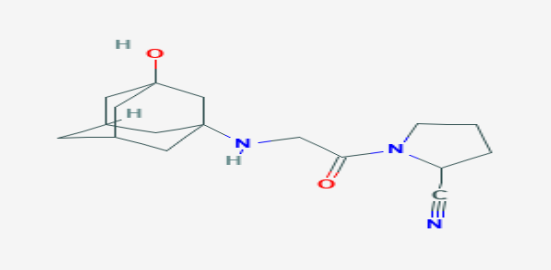

Fig-1 Structure of Vildagliptin

MATERIALS & METHODS

Chemicals& Reagents

Table-1 List of chemicals used for experimental work

S. No	Name of Chemical	Manufacturer
1	Ethyl alcohol	Premiere ethanols Pvt. Ltd.
2	Vanillin	Akshaya laboratories Pvt. Ltd
3	Conc.H_2SO_4	Elimchemicals
4	Methanol	Annexpharmaceuticals&chemicalsPvt.Ltd.
5	Distilled water	City distilled water & acid co.

Instruments

The Spectroscopic analysis was carried out using Double beam PG Instruments recording UV-Visible Spectrophotometer (SHIMADZU UV-1601**)** with 1mm path length matched quartz cells was used for analytical purpose.

Reagents and Solutions

Diluent: Methanol is used as a diluent.

Diluent preparation

Accurately measured 50ml of methanol was degassed in anultrasonic waterbath for 10 minutes & then filtered.

Preparation of standard stock solution of Vildagliptin

Accurately weighed 100mg of standard Vildagliptin was transferred into a clean and dry 10ml volumetric flask. Then, it was dissolved in the solvent system containing ethyl alcohol and finally the same solvent was used to make up the volume to 10ml. The final solution contained 10,000µg/ml ofVildagliptin solution.

Preparation of sample solution of Vildagliptin

Two Vildagliptin tablets of 50mg each were taken and then crushed using mortar & pestle. The powder obtained was transferred into a clean & dry 10ml volumetric flask and was dissolved in ethyl alcohol. The filtrate was obtained after filtering the dissolved
solution. The final solution contained 10,000µg/ml of Vildagliptin solution.

Preparation of Vanillin Sulphuric acid Reagent

Accurately weighed 100mg of vanillin was transferred into a clean and dry 10ml volumetric flask and dissolved in solvent system containing conc.Sulphuric acid. Finally, the same acid was used to make up the volume to 10ml.

Determination of wavelength of maximum absorbance for Vildagliptin

Standard Vildagliptin solution (1ml) was transferred into a separate 10ml volumetric flask and 4 drops (0.4ml) of Vanillin Sulphuric acid reagent was added to the above solution. The volume was adjusted to 10ml with methanol. After diluting with methanol the final solution contained 1000µg/ml. The absorbance of the final solution was scanned in the range 200 to 400nm against solvent mixture as blank.

Optimization of selection of Solvent/Diluent

It is well known that the solvents do exert a profound effect on the quality and shape of the peak. Thesolventsused for UV method development are: Methanol, Ethanol, DMF, Acetonitrile, Dimethyl Sulphoxide, Sodium citrate etc. First optimize the different solvents. From that solvents methanol has satisfied all the optimized conditions.

Optimization of the Reagent

Trials were done using other reagents like Benzaldehyde reagent (Benzaldehyde + Conc.HCL), Vanillin reagent (Vanillin + Glacial acetic acid) but, no colour was observed.

Wavelength Selection

The standard solutions were prepared by transferring the standard drug (Vildagliptin) in to a selected solvent (Ethyl alcohol), addition of a reagent **(**Vanillin Sulphuric acid)&

finally diluted with the diluent (Methanol). The prepared solution was scanned in the wavelength range of 200 to 400nm. This has been performed to know the absorption maxima of Vildagliptin. While scanning the Vildagliptin solution we observed the absorption maxima at 250nm. The UV spectrum has been recorded on(SHIMADZU UV-1601 make & model) UV – Visible spectrophotometer. The λ_{max} of Vildagliptin was found to be 250nm in diluent as solvent system.

Preparation of Calibration curve for Vildagliptin

Standard solutions of Vildagliptinin the concentration range of 100 to 1000µg/ml were obtained by transferring (1000, 2000, 3000……10,000µg/ml) ofVildagliptin stock solution to the series of clean and dry 10ml volumetric flasks. The volumes in each volumetric flask were made up to 10ml with the methanol (diluent) and mixed. The absorbancies of the solutions were measured at 250nm against the solvent system as blank and calibration curve was plotted. The Beer-lambert's Law was found to be linear in the concentration range of 100 to 1000µg/ml at 250nm for Vildagliptin.

RESULTS & DISCUSSION

The standard solutions of Vildagliptin in ethyl alcohol with Vanillin Sulphuric acid reagent, using methanol as diluent were subjected to a scan individually at the series of wavelengths of 200 to 400nm. Absorption maximum of Vildagliptin was found to be at 250nm. Therefore, 250nm was selected as λ_{max} of Vildagliptin for the present study. The calibration curve of Vildagliptin was found to be linear in the concentration range of 100-1000µg/ml at λ_{max} 250nm. Therefore, it was clear that Vildagliptin can be determined without interference of any irrelevant substance in single component pharmaceutical products. The used technique was initially attempted on bulk drugs in their synthetic sample and concentrations were estimated

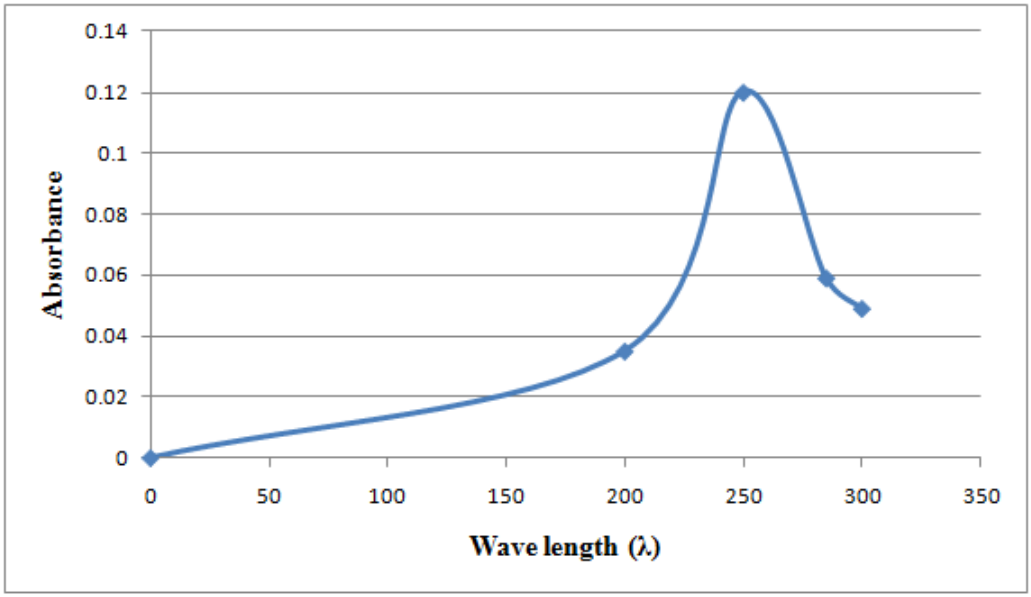

Figure-2 Absorption maxima/ λ_{max}curve of Vildagliptinat 250 nm.

Table-2 Results of Calibration curve

Concentration(µg/ml)	Absorbance
100	0.03
200	0.059
300	0.087
400	0.116
500	0.15
600	0.175
700	0.21
800	0.235
900	0.268
1000	0.30
1100	0.24

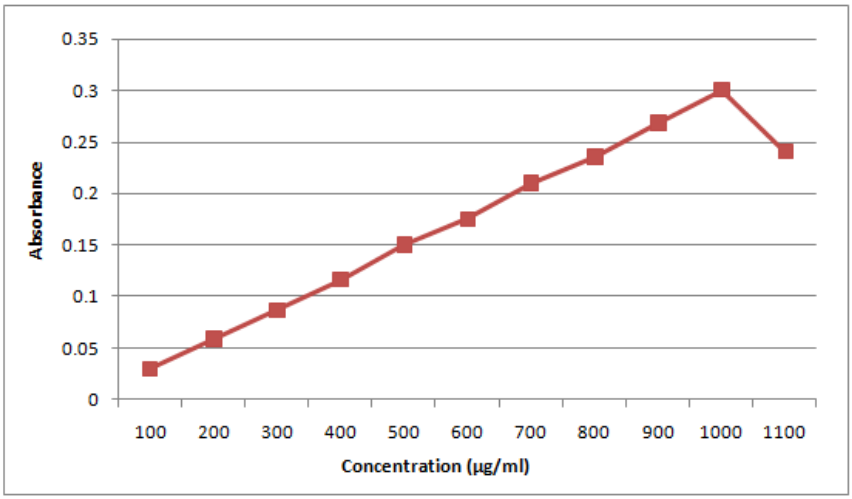

Figure-3 Calibration curve of Vildagliptin at λ_{max} 250 nm

For Vildagliptinthe Beer- Lambert's law was obeyed in the concentration range of 100 to 1000µg/ml at 250nm. From the above calibration curve Beer-Lambert's law was found to be linear.Same procedure was repeated for the sample solution of Vildagliptin (Pharmaceutical dosage form).

CONCLUSION

Literature survey reveals that several spectrophotometric methods were reported for the estimation of Vildagliptin. In the view of need of a suitable UV spectroscopic method using Schiff's base reaction for routine analysis of Vildagliptin formulation, attempts were made to develop simple, analytical method for estimation of Vildagliptin and extended it for their determination in bulk and dosage formulation.

From the experimental studies, it can be concluded that best UV spectroscopic method was developed for Vildagliptin in bulk and marketed pharmaceutical dosage form. We hope that the developed method is simple, economical and this method is not suffered from any interference such as degradants/impurities due to common excipients. So the above work performed gives documental evidence that the analytical method for the Vildagliptin by UV spectroscopy in tablet dosage forms will consistently analyze these drugs quantitatively and could be used for the routine drug analysis.

ACKNOWLEDGEMENT

The authors are grateful to the management of Nalanda College of Pharmacy, Nalgonda for providing the facilities to carry out the present research work.

REFERENCES

1. General Introduction to Schiff bases http://shodhganga.inflibnet.ac.in/jspui/bitstream/10603/8812/6/06_chapter 1.pdf
2. Ashraf M. A. Mahmood K. Wajid A: Synthesis, Characterization and Biological Activityof Schiff Bases, IPCBEE, 2011, 10, 1–7
3. ABUDABA JamiaMiliaIslamia, https://www.slideshare.net/abudardazilli/schiff-base-ligand (2017)
4. Katarzyna Brodowska, Schiff bases - Interesting range of applications in various fields of science (2014)
5. Vildagliptin drug bank. URL:http://www.drugbank.ca/drugs/DB06594.
6. Vildagliptin-PubChem–NIH https://pubchem.ncbi.nlm.nih.gov/compound/Vildagliptin
7. Vildaglyptininformation from drugs update http://www.drugsupdate.com/generic/view/919
8. AparajitaMalakar*, BishwajitBokshi, DilrubaNasrin, Development and Validation of RP-HPLC method for estimation of Vildagliptin tablet dosage form (2012).
9. P.V.Prasad*, K.Divya, M.V.Ramana, A. Krishnaveni, J.Vinay, M.Mahadeswar, Analytical Method Development and Validation for the estimation of Vildagliptin in bulk and its dosage form using UV spectrophotometer (2017).
10. JagdaleRamkrishnaRaosaheb*, DabhadeM.P.KokateShekharVikram, ShindeVikas Sanjay and Shaikh Wasim Chand, RP-HPLC Method Development & Validation of Vildagliptin in bulk and dosage form (2017).
11. Tekkeli, SerifeEvrimKepekci&Bahadori, Fatemeh, Development &Valildation of Spectrophotometric Methods for the Determination & Spectroscopic Characterization of Vildagliptin using II-acceptors in Pharmaceutical preparations (2014).
12. MarwaS.Moneeb, Spectrophotometric & Spectrofluorimetric methods for determination of Saxagliptin & Vildagliptin in bulk and Pharmaceutical preparations (2013).