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DEVELOPMENT OF UV-SPECTROPHOTOMETRIC METHOD FOR SITAGLIPTIN IN BULK AND PHARMACEUTICAL FORMULATION

[1]J. ANUDEEPA, [2]R.MANAVALAN, [3]R.VENKATANARAYANAN

R.V.S College of Pharmaceutical Sciences, Sulur, Coimbatore, INDIA

E mail: anudeeparagav@gmail.com

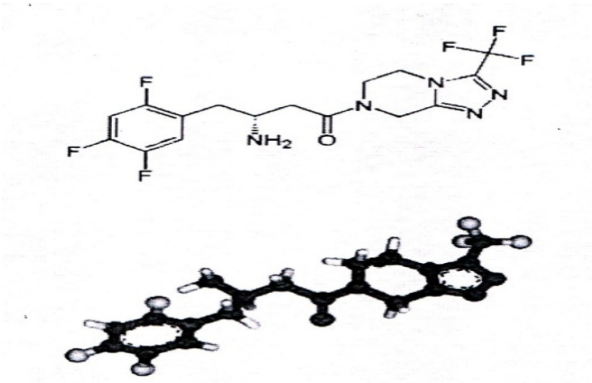
ABSTRACT

The newer analytical method developed for drugs must specific, accurate, sensitive, precise, reliable and reproducible. UV/Vis spectroscopy is routinely used in analytical chemistry for the quantitative determination of different analytes, such as transition metal ions, highly conjugatedorganic compounds, and biological macromolecules. Sitagliptin previously identified as MK-0431 and marketed as the phosphate salt under the trade name (Januvia®) is an oral antihyperglycemic drug of the dipeptidyl peptidase-4 (DPP-4) inhibitor class. This study aim to perform UV spectrophotometric analysis of Sitagliptinin bulk and pharmaceutical formulations. UV spectrophotometric analysis of analysis of Sitagliptinin tablet (25mg) and pharmaceutical formulation (Januvia®) was performed using a Lab India UV spectrophotometer 3000+ double beam by using 1 cm quartz cells. The significant spectra for Sitagliptin appeared in 0.1N Hcl and this solvent was selected for determining Sitagliptin content in formulations by UV spectroscopic method. Stock solutions of Sitagliptin were prepared by dissolving 100 mg of drug in 100 ml of 0.1N Hcl, to obtain the concentration of 1000 µg of drug / ml. It was further diluted to obtain concentration ranging from 20-100 µg / ml. Sitagliptin exhibited maximum absorbance at about 267 nm. The measured absorbance was plotted against concentration. From the optical characteristics of the proposed method it was found that the absorbance of Sitagliptin is267nm. The drug obeys linearity with in the concentration 20-100µg/ml. The linearity was shown by calibration curve and the correlation co-efficient 0.998. The percentage recovery of the pure drug is between 96-99% indicating that the proposed method is simple, accurate, sensitive, reliable and reproducible.

Keywords: *Sitagliptin, oralhyperglycemic, Januvia, stock solution*

1. INTRODUCTION

Drug Analysis and Assay play an important role in the development, manufacture and therapeutic uses of drugs. Many new drugs are introduced in the market nowadays and to develop an analytical method in essential. The newers analytical method developed for drugs must be specific, accurate, sensitive, precise, reliable and reproducible. UV/Vis spectroscopy is routinely used in analytical chemistry for the quantitative determination of different analytes, such as transition metal ions, highly conjugatedorganic compounds, and biological macromolecules. [1] Spectroscopic analysis is commonly carried out in solutions but solids and gases may also be studied. A complete spectrum of the absorption at all wavelengths of interest can often be produced directly by a more sophisticated spectrophotometer. In simpler instruments the absorption is determined one wavelength at a time and then compiled into a spectrum by the operator.[2] By removing the concentration dependence, the extinction coefficient (ε) can be determined as a function of wavelength. Sitagliptin previously identified as MK-0431 and marketed asthe phosphate salt under the trade name (Januvia) is an oral antihyperglycemic (antidiabetic) of the dipeptidyl peptidase-4 (DPP-4) inhibitor class. [3] It was developed, and is marketed, by Merck & Co. This enzyme-inhibiting drug is used either alone or in combination with other oral antihyperglycemic agents (such as metformin or a thiazolidinedione) for treatment of diabetes mellitus.[4]



(R)-4-OXO-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3,a]pyrazine-7-(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine

Sitagliptin works to competitively inhibit the enzyme dipeptidyl peptidase 4 (DPP-4). This enzyme breaks down the incretins GLP-land GIP, gastrointestinal hormones released in response to a meal.[5] R 121 By preventing GLP-1 and GIP inactivation, they are able to increase the secretion of insulin and suppress the release of glucagon by the alpha cells of the pancreas. This drives blood glucose levels towards normal. As the blood glucose level approaches normal, the amounts of insulin released and glucagon suppressed diminishes, thus tending to prevent an "overshoot" and subsequent low blood sugar (hypoglycemia) which is seen with some other oral hypoglycemic agents. It is slightly less effective than metformin when used as a monotherapy. It does not cause weight gain and has less hypoglycemia compared to sulfonvlureas. Sitagliptin is recommended as a second line drug (in combination with other drugs)

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after the combination of diet/exercise and metformin fails.

2. AIM & OBJECTIVES

To perform UV spectrophotometric analysis of Sitagliptinin bulk and pharmaceutical formulations.

- Location of λ max of Sitagliptin
- Optimisation of Analytical Parameters
- Study of Beer-Lambert's Law
- Application of proposed method for estimation in marketed formulation
- Recovery studies

3. MATERIALS AND METHODS

UV spectrophotometric analysis of analysis of Sitagliptinin tablet (25mg) and pharmaceutical formulation(Januvia®)was performed using a Lab India UV spectrophotometer 3000+ doublebeam by using 1 cm quartz cells.The significant spectra for Sitagliptin appeared in 0.1N Hcland this solvent was selected for determining Sitagliptin content in formulations by UV spectroscopic method . A stock solution of Sitagliptin was prepared by dissolving 100 mg of drug in 100 ml of 0.1N Hcl, to obtain the concentration of 1000 µg of drug / ml. It was further diluted to obtain concentration ranging from 20-100 µg / ml. Sitagliptin exhibited maximum absorbance at about 267 nm. The measured absorbance was plotted against concentration. From the graph it was found that the Beer's law concentration for Sitagliptinbetween 20-100 µg / ml.

4. RESULTS AND DISCUSSION

The proposed UV Analytical method for the quantification of Sitagliptinin tablets formulation is simple, accurate, rapid and can be employed for the substances which obey Beer's law. The low standard deviation and good percentage recovery indicated the reproducibility and accuracy of the method. From the optical characteristics of the proposed method it was found that the absorbance of Sitagliptin is267nm. The drug obeys linearity with in the concentration 20-100µg/ml. The linearity was shown by calibration curve and the correlation co-efficient 0.998. The percentage recovery of the pure drug is between 96-99% indicating that the proposed method is simple, accurate, sensitive, reliable and reproducible.

5. CONCLUSION

Simple precise and accurate methods were developed for the quantification of Sitagliptinin tablet formulation. In UV spectroscopic method, the wavelength 267 nm was fixed for the quantification. Different concentrations of Sitagliptin were prepared from the stock solution and their absorbances were measured at the selected wavelength. Calibration curves were obtained in the range of 20-100 µg / ml for Sitagliptin with the correlation co-efficient of 0.998. The sample solution was prepared by dissolving 100 mg of Sitagliptinin 0.1N Hcl and made upto 100 ml in a standard flask and filtered. The above solution was diluted to get a concentration ranging from 20-100 µg / ml. Spectrum was recorded and the absorbances were measured at the selected wavelength. The recovery studies were carried out by adding known amount of standard drug to the pre-analysed formulation and analysed as per formulation procedure.The proposed methods were found to be accurate, simple and rapid. The low standard deviation value and good percentage recovery indicate the reproducibility and accuracy of the newly developed method. In this UV spectroscopic method requires simple instrument consuming less time for analysis.

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TABLE 1: Analysis of Sitagliptin Formulation

Drug	Amount mg/tab		% Recovery	SD*
	Label	Found*		
JANUVIA®	25 mg	24.07mg	96.3%	± 0.128

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TABLE 2: Absorbance of sitagliptin

(Pure drug)

Sl.No.	Concentration mcg / ml	At 267 nm
1	20	0.104
2	40	0.19
3	60	0.271
4	80	0.35
5	100	0.431

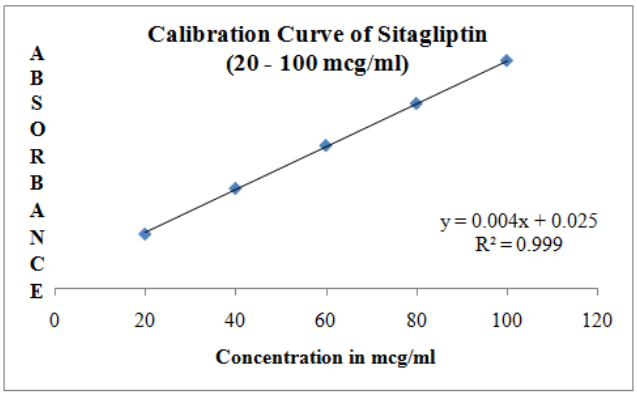

FIGURE 1: Caliberation curve