

**SIMULTANEOUS ESTIMATION OF VILDAGLIPTIN AND METFORMIN BY  
SIMULTANEOUSEQUATION METHOD IN BULK AND COMBINED TABLET  
FORMULATION USING SPECTROPHOTOMETRY**Khagga Bhavya Sri<sup>1\*</sup>, Saba Fatima<sup>2</sup>, B. Anila<sup>3</sup> and M. Sumakanth<sup>4</sup><sup>1,2,3</sup>Department of Pharmaceutical Analysis, RBVRR Women's College of Pharmacy.<sup>4</sup>Department of Pharmaceutical Chemistry, RBVRR Women's College of Pharmacy.**\*Corresponding Author: Dr. Khagga Bhavya Sri**

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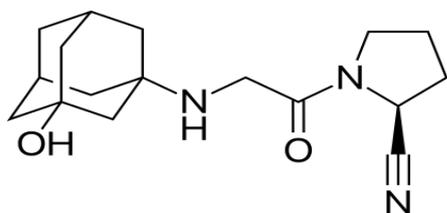
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**ABSTRACT**

A simple, rapid and economical UV-spectroscopic method was developed for the simultaneous estimation of Vildagliptin and Metformin in pure form and combined tablet dosage form. This method involved use of simultaneous equation, where the concentration of drugs was determined by using absorptivity values of pure drugs Metformin and Vildagliptin, along with the absorbance values of the combined tablet dosage form at selected wavelengths of 233nm and 266nm. Metformin is an anti-diabetic drug belonging to the class of biguanides and is used as the first-line medication. Vildagliptin is an oral anti-diabetic drug which belongs to class of drugs which inhibit dipeptidyl peptidase-4 (DPP-4) enzyme. The Vildagliptin and Metformin in combination has been used in diabetic patients to reduce the glycaemic index which has better results than the mono-drug therapy. The diluents distilled water and double distilled water were used for Metformin and Vildagliptin pure drugs respectively. For the analysis of drugs in combined tablet dosage form, double distilled water was used as a diluent. The method developed was easy to carry out and can be used as a routine quality control test for simultaneous estimation of combined tablet dosage form.

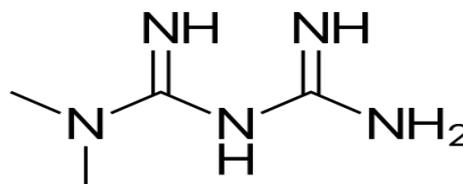
**KEYWORDS:-** Simultaneous equation, Vildagliptin, Metformin, combined tablet dosage form.**INTRODUCTION**

Vildagliptin (C<sub>17</sub>H<sub>25</sub>N<sub>3</sub>O<sub>2</sub>) chemically (S)-1-[N-(3-Hydroxy-1-adamantyl) glyceryl] pyrrolidine-2-carbonitrile, is an oral anti-diabetic drug belonging to class of inhibitor of dipeptidyl peptidase-4 (DPP-4) enzyme. Vildagliptin inhibits the inactivation of GLP-1<sup>[1][2]</sup> and GIP<sup>[2]</sup> by DPP-4, allowing GLP-1 and GIP to potentiate the secretion of insulin in the beta cells and suppress glucagon release by the alpha cells of the islets of Langerhans in the pancreas.

**Fig. 1: Structure of vildagliptin.**

Metformin (C<sub>4</sub>H<sub>11</sub>N<sub>5</sub>) chemically N, N-dimethyl biguanide, anti-hyperglycaemic drug which is the first-line medication used for the treatment of patients particularly who are overweight.<sup>[3-6]</sup> It is also used in the treatment of polycystic ovarian syndrome.<sup>[5]</sup> It acts by

the altering the energy metabolism of cell. Metformin exerts its effect by inhibiting the hepatic gluconeogenesis and opposing glucagon's action which results in reduced glucose levels in blood.<sup>[7]</sup>

**Fig. 2: Structure of metformin.**

In treatment-naive patients with type-2 diabetes mellitus, combination of Vildagliptin and Metformin of both high-dose and low-dose provides superior efficacy to monotherapy treatments.<sup>[8]</sup> While several analytical methods are available for the determination of Vildagliptin and Metformin as single ingredients,<sup>[9-16]</sup> HPLC methods for simultaneous estimation,<sup>[17-18]</sup> there is not one established method for the determination of Vildagliptin and Metformin when in combination using UV-Visible spectroscopy with double distilled water as diluent. Hence, this study was planned to develop a new

method for the estimation of Vildagliptin and Metformin simultaneously.

## MATERIALS AND METHODS

**Apparatus:** An UV visible spectrophotometer (ELICO-210) with  $\pm 0.5$  nm.

**Reagent and Chemicals:** Vildagliptin and Metformin pure drugs were a gift from pharmaceutical industry.

**Preparation of vildagliptin standard stock solution:** 10 mg of Vildagliptin pure drug was accurately weighed and transferred to a 10ml volumetric flask. It was dissolved in double distilled water and later filled up to the mark to obtain standard stock solution (1000  $\mu\text{g/ml}$ ).

**Preparation of metformin standard stock solution:** 10 mg of Metformin pure drug was accurately weighed and transferred to a 10ml volumetric flask. It was dissolved in distilled water and later filled up to the mark to obtain standard stock solution (1000  $\mu\text{g/ml}$ ).

**Selection of wavelengths:** The standard dilutions of Vildagliptin and Metformin (10  $\mu\text{g/ml}$ ) were scanned in the spectrum range of 200-400nm. The  $\lambda_{\text{max}}$  of Vildagliptin and Metformin were found to be 266nm and 233nm respectively.

**Analysis of formulation:** Twenty branded tablets of Vildader Met (50mg/500mg) were powdered and their average weight of each tablet was determined. The powdered tablet equivalent of 10 mg was taken in 10ml volumetric flask and completely dissolved in Double distilled water. This solution was further diluted to get the concentration 10  $\mu\text{g/ml}$ , and then the absorbance taken at 266 nm and 233 nm in photometric mode respectively.

**Simultaneous equation method:** This method is based on absorption of drugs (X and Y) at the maximum wavelength. Other quantification analyses of Vildagliptin & Metformin in binary mixture were performed with the following equations:

$$C_x = \frac{(A_{2\lambda_1} - A_{1\lambda_2})}{(a_{x2\lambda_1} - a_{x1\lambda_2})} \dots \text{Equation (1)}$$

$$C_y = \frac{(A_{1\lambda_2} - A_{2\lambda_1})}{(a_{y2\lambda_1} - a_{y1\lambda_2})} \dots \text{Equation (2)}$$

Where  $C_x$  and  $C_y$  are the concentrations of X and Y drugs respectively in the diluted sample;  $a_{x1}$  and  $a_{x2}$  are absorptivity of X at  $\lambda_1$  and  $\lambda_2$ ; and  $a_{y1}$  and  $a_{y2}$  are absorptivity of Y at  $\lambda_1$  and  $\lambda_2$ . The absorbance of the dilute samples at  $\lambda_1$  and  $\lambda_2$  are  $A_1$  ( $A_1 = a_{x1}bc_x + a_{y1}bc_y$ ) and  $A_2$  ( $A_2 = a_{x2}bc_x + a_{y2}bc_y$ ) respectively.<sup>[19]</sup>

## RESULTS AND DISCUSSION

The method of simultaneous equation is used for the simultaneous spectroscopic estimation of Vildagliptin and Metformin in the combined pharmaceutical dosage form, using Double distilled water as diluent. For the pure drugs Metformin and Vildagliptin, distilled water and double distilled water were used as diluents respectively. According to the equation 1 and 2, the concentration of Vildagliptin and Metformin was obtained, where  $A_1$  (0.8521) and  $A_2$  (0.0295) are the absorbance's of sample at 266 nm and 233 nm. The absorptivity values of X were  $a_{x1}$  (0.09583),  $a_{x2}$

(0.00231) and Y were  $a_{y1}$  (0.00493) and  $a_{y2}$  (0.00418). From the concentrations obtained the ratio of the concentrations calculated and compared to label claim of the Vildader Met (50mg/500mg) tablet. The literature review shows various methods for the simultaneous estimation of the Vildagliptin and Metformin in combined tablet dosage form using HPLC but no UV spectroscopic method was available. Hence this method was developed to provide an easy and effective method for analysis of the drugs.

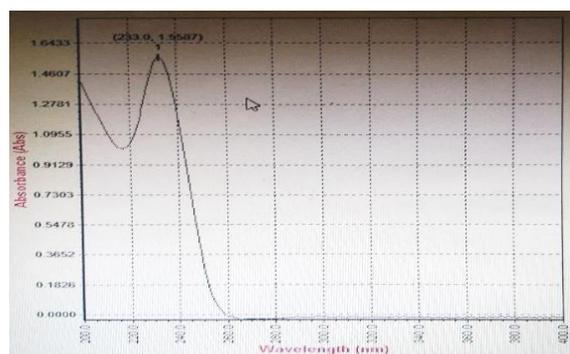


Fig. 3: UV spectra of metformin.

## CONCLUSION

The spectrophotometric method for the determination of Vildagliptin and Metformin from combination formulation is simple, selective, economic, rapid and easy. This method developed can be used for routine quality control analysis of Vildagliptin and Metformin simultaneously in a combined tablet dosage form.

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