



Short Communication

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ANALYTICAL METHOD DEVELOPMENT OF REPAGLINIDE IN BULK AND SINGLE COMPONENT FORMULATION

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ABSTRACT

Two simple, precise and economical UV methods have been developed for the estimation of Repaglinide in bulk and pharmaceutical formulation. Repaglinide absorbance maxima in the zero order derivative spectra was 293nm (Method A) and absorbance maxima in first order derivative spectra was 245nm (Method B). Drug followed the Beer-Lambert's law in the concentration range of 10-80µg/ml in method A and 10-70µg/ml for method B. Results of the analysis were validated statistically, by recovery studies and were found to be satisfactory.

KEYWORDS: Repaglinide tablets, UV-Visible Spectrophotometer, Zero order derivative, First order derivative, Methanol and distilled Water

INTRODUCTION

Repaglinide is an oral blood glucose-lowering drug of the meglitinide class used in the management of type 2 diabetes mellitus also known as non-insulin dependent diabetes mellitus or NIDDM. It is not official in any of the Pharmacopoeias except USP and BP and only listed in the The Merck Index¹, and Martindale², The Complete Drug Reference. Literature survey revealed that there are no analytical methods reported for estimation of Repaglinide as a single component by UV-Visible Spectrophotometry³. The methods reported are, UV colorimetric methods, RP-HPLC method⁴⁻⁹, Estimation of repaglinide in bulk and tablet dosage forms by HPTLC method¹⁰, Quantitative analysis of repaglinide in tablets by reversed-phase thin-layer chromatography with densitometric UV detection¹¹, A validated chiral LC method for the preparation of repaglinide on amylase based stationary phase¹². Hence, the present study deals with the development of simple, precise, accurate, sensitive, rapid and economical UV-Visible Spectrophotometric method for the estimation of Repaglinide in bulk and pharmaceutical formulations.

MATERIALS AND METHODS

Materials: A Shimadzu UV-1700 (Japan) was used with 1cm path length and spectral bandwidth of 2nm matched quartz cells. A Shimadzu electronic analytical balance was used for weighing the sample. An ultrasonic cleaner was used for sonicating the tablet powder. Analytical grade methanol (Qualigens) was used for making the solution. Repaglinide Tablets of 1mg strength were procured from local pharmacy i.e. Eureka (1mg) from Torrent pharmaceutical.

Method: Accurately about 10mg of Repaglinide was weighed and transferred to 100ml volumetric flask. To it 20 ml of methanol was added to dissolve the drug completely with vigorous shaking. Then the volume was made up with distilled water up to the mark to give the

drug stock solution of concentration 100µg/ml. Aliquots of standard stock solution were pipette out and suitably diluted with distilled water to get the final concentration of standard solutions. In the zero order derivative method at n=0 showed a sharp peak at 293nm (Figure 1). The absorbance difference at n=0 (dA/dλ) is calculated by the inbuilt software of the instrument which was directly proportional to the concentration of the standard solution. The standard drug solution was diluted so as to get the final concentration in the range of 10-80 µg/ml and scanned in the zero order derivative spectra. The calibration curve of dA/dλ against concentration of the drug showed linearity. Similarly, for first order derivative same method was employed at n=1 showed a sharp peak at 245nm (Figure 2). The standard drug solution was diluted so as to get the final concentration in the range of 10-70 µg/ml in first order derivative spectra. The calibration curve of dA/dλ against concentration of the drug showed linearity.

For estimation of Repaglinide in tablet formulation by the two methods, twenty tablets of the brand were weighed and triturated to fine powder. Tablet powder equivalent to 1mg of Repaglinide weighed and dissolve in 20ml of methanol. It was kept for ultrasonification for 45min, finally the volume was made up to the mark with distilled water, this was then filtered through Whatman filter paper no. 41 to get stock solution of concentration of 100µg/ml. Various dilution of the tablet solution were prepared and analyzed for six times and concentration was calculated by using the calibration curve for two methods.

Both the methods were validated according to ICH guidelines^{11,12} by carrying out analysis of six replicate samples of the tablets (Table 1). Recovery studies were carried out at three different levels i.e. 80%, 100% and 120% by adding the pure drug (8, 10 and 12mg respectively) to previously analyzed tablet powder sample. From the amount drug found, percentage recovery was calculated (Table 2).

Table 1: Optical characteristics and other parameters for Repaglinide

Parameters	Method A	Method B
λ_{Max} (nm)/wavelength range (nm)	293	245
Beer's – Lambert's range ($\mu\text{g/ml}$)	10-80	10-70
Coefficient of correlation (r^2)	0.9995	0.9996
Regression Equation $y = mx + c$		
a. Slope (m)	0.0195	-0.1158
b. Intercept (c)	0.0124	0.1947
LOD	0.00772	-0.00864
LOQ	0.0316	-0.02618

A is zero order derivative spectrum method with $n=0$, B first order derivative spectrum method with $n=1$, T₁ is the brand of tablet formulation

Table 2: Analysis of standard Repaglinide

7	Tablet Formulation	Label claim (mg)	Conc. Obtained	% Mean	S.D.	R.S.D.	S.E.
A	T ₁	1	1.006	100.6	0.2597	0.2595	0.1060
B	T ₁	1	0.9979	99.79	0.4527	0.4536	0.1848

A is zero order derivative spectrum method with $n=0$, B first order derivative spectrum method with $n=1$, T₁ is the brand of tablet formulation i.e. Eureka (Torrent pharmaceutical), *The results are the mean of six readings ($n=6$)

Table 3: Recovery studies

Method	Tablet Formulation	Level of recovery	Label claim (mg)	Conc. Obtained	% Mean	S.D.	R.S.D.	S.E.
A	T ₁	80	1	0.9990	99.90	0.4053	0.4058	0.2341
		100	1	1.0043	100.43	0.1323	0.1317	0.0763
		120	1	1.0029	100.29	0.2946	0.2937	0.1701
B	T ₁	80	1	0.9971	99.71	0.6971	0.6990	0.4025
		100	1	0.9978	99.78	0.2611	0.2616	0.1508
		120	1	0.9993	99.93	0.6312	0.6315	0.3644

A is zero order derivative spectrum method with $n=0$, B first order derivative spectrum method with $n=1$, T₁ is the brand of tablet formulation i.e. Eureka (Torrent pharmaceutical), *The results are the mean of six readings ($n=6$)

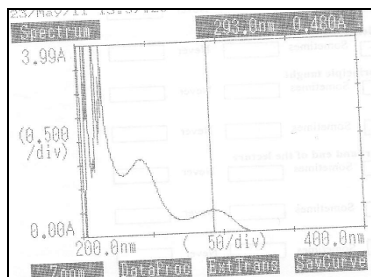


Figure 1: Zero order derivative spectrum of Repaglinide

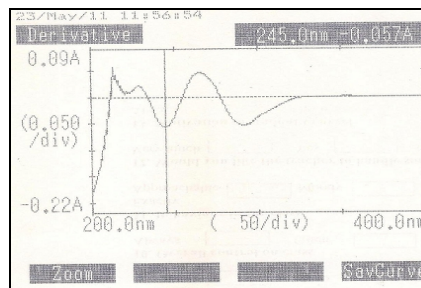


Figure 2: First order derivative spectrum of Repaglinide

RESULT AND DISCUSSION

Both the methods A and B for the estimation of Repaglinide in tablets dosage form were found to be simple accurate and reproducible. Beer- Lambert's law was obeyed in the concentration range of 10-80 $\mu\text{g/ml}$ in method A and 10-70 $\mu\text{g/ml}$ in method B. The value of standard deviation was satisfactory and the recovery studies were close to 100%.

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