RESEARCH ARTICLE

Novel First-Order Derivative UV Spectrophotometric Method for the Determination of Acarbose in Solid Dosage Forms

Santosh Karajgi[2*], Gaviraj E. N.[1], Sunayana Mali[2], C. C. Patil[3], Shripad Potdar[2], Kotnal R. B.[2]

[1]*Department of Pharmacognosy, BLDEA's SSM College of Pharmacy and Research Centre, Vijayapur-586103, Karnataka, India*

[2]*Department of Quality Assurance, BLDEA's SSM College of Pharmacy and Research Centre, Vijayapur-586103, Karnataka, India*

[3]*Department of Pharmaceutics, BLDEA's SSM College of Pharmacy and Research Centre, Vijayapur-586103, Karnataka, India*

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ABSTRACT

An easy, perfect, specific, and accurate process has been studied for the estimation of acarbose pure drug form, as well as, tablet dosage forms. Using methanol as a solvent, acarbose has absorbance maxima at 206 nm, and this drug shows a linear response according to Beer's law in the concentration range of 24 to 40 µg/mL. The outcomes of the study were validated statistically, and recovery studies were satisfactory as per ICH guidelines. Thus, the projected method can be proficiently useful for the estimation of acarbose in regular analysis effort.

Keywords: Acarbose, First-order derivative method, UV spectrophotometric peak determination.

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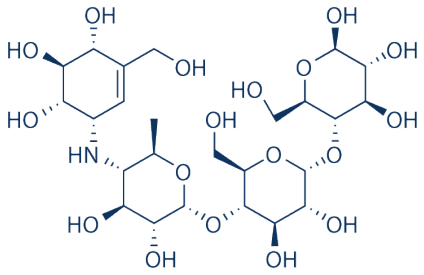
INTRODUCTION

(2R, 3R, 4R, 5S, 6R)-5-[(2R,3R,4R,5S,6R)-5-[(2R,3R,4S,5S,6R)-3,4-dihydroxy-6-methyl-5-[[(1S,4S,5S,6S)-4,5,6-trihydroxy-3-(hydroxymethyl)cyclohex-2-en-1-yl]amino]oxan-2-yl]oxy-3,4-dihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-6-(hydroxymethyl)oxane-2,3,4-triol.[1]

Acarbose is an alpha glycosidase inhibitor that decreases intestinal absorption of carbohydrates and is used as adjunctive therapy in the management of type 2 diabetes. Acarbose has been linked to rare instances of clinically apparent acute liver injury.[2]



Schema

REVIEW OF LITERATURE

Review literature reveals that a lot of work has been carried out for routine analysis of drugs in exiting formulation and bulk drugs. A number of references are available for the present study to develop an analytical method.

In the literature survey, it was found that different methods for the determination of acarbose have been reported, like visible spectrophotometric method,[3] liquid chromatography, and capillary electrophoresis of acarbose,[4] quantifications of acarbose by liquid chromatography-electrospray tandem mass spectrometry,[5] and analysis of acarbose by capillary electrophoresis.[6]

However, there is no first-order derivative UV spectrophotometric method found for the estimation of acarbose.

EXPERIMENTAL SECTION

Materials

Shimadzu 1800 spectronic UV spectrophotometer with 1 cm matched quartz cells was used for data collection and analysis. Methanol was used as a solvent for the drug substance.

*Author for Correspondence: santosh.karajgi@gmail.com

Methodology

Preparation of Standard Stock Solution

The standard stock solution was prepared by transferring 25 mg acarbose into a 25 mL volumetric flask, 25 mL methanol was placed into a volumetric flask and then shaken well and dissolved. Then, the volume was adjusted up to the mark with methanol to give a solution containing 1,000 µg/mL acarbose. From this solution, 10 mL was transferred to 100 mL volumetric flask, in addition, the volume was again diluted in another volumetric flask using methanol to give a solution containing 100 µg/mL of acarbose.

Determination of λ_{max}

Accurate volume 6 mL of stock solution of acarbose was shifted to 25 mL volumetric flask, and the volume was adjusted to the mark with the same solvent to get the solution of concentration 24 µg/mL. After that, the prepared solution was scanned in the UV range of 200 to 230 nm. The λ_{max} was found to be 206 nm. The spectrum of acarbose was recorded (Figure 1).

Stability of Drug in Selected Solvent

The stability of the drugs in the selected solvent was found by evaluating the absorbance of the drug solutions (24 µg/mL) at different time intervals. After 15 minutes, the absorbance was calculated. For acarbose, the stability data is given in the Table 1 below:

Selection of Analytical Wavelength Range

By the use of Shimadzu 1800 spectronic UV-visible spectrophotometer, the derivative spectra of acarbose were taken at n = 9, and the standard solutions of acarbose in methanol subjected to a scan 200 to 230 nm. The λ_{max} was found to be at 206 nm. The first-order derivative of the spectras with n = 9 was proposed to proceed for the selection of analytical wavelength.

Linearity

From the standard stock solution of acarbose, appropriate aliquots were pipette out into 25 mL of the volumetric flask, and dilutions were made with methanol for working standard solution of acarbose 24, 28, 32, 36, and 40 µg/mL. The difference in amplitude of acarbose was measured in the first derivative mode with n = 9 of the instrument at UV scan range, at 200 to 230 nm. The calibration curve of the drug acarbose was plotted (Figure 2). The concentration range, over which the drug followed linearity was chosen as an analytical concentration range, i.e., 24 to 40 µg/mL for acarbose (Table 2;

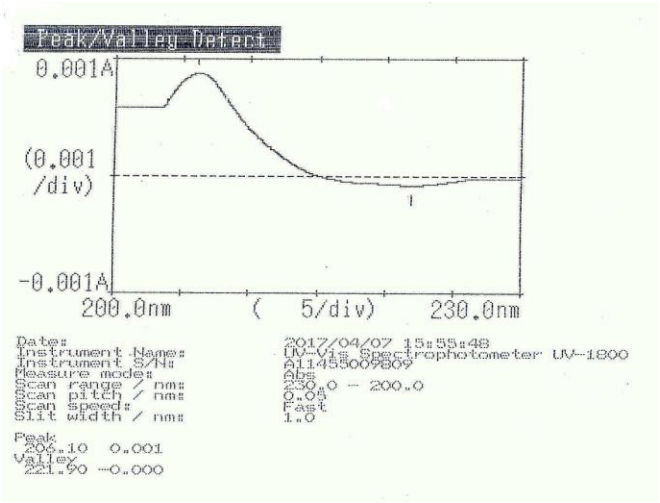


Figure 1: Spectrum of λ_{max} of acarbose

Table 1: Stability data for acarbose

S. No.	*Time (min)*	*Absorbance*
1	0	0.001
2	15	0.005
3	30	0.004
4	45	0.003

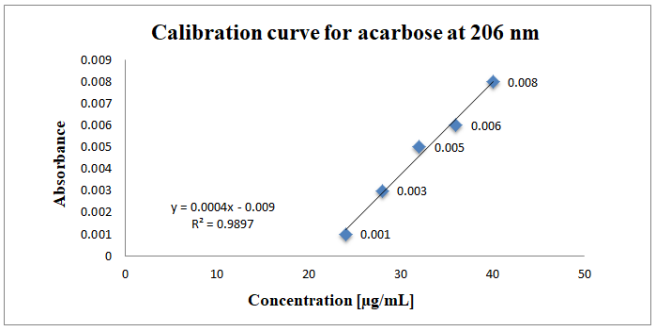


Figure 2: Standard calibration curve for acarbose at 206 nm

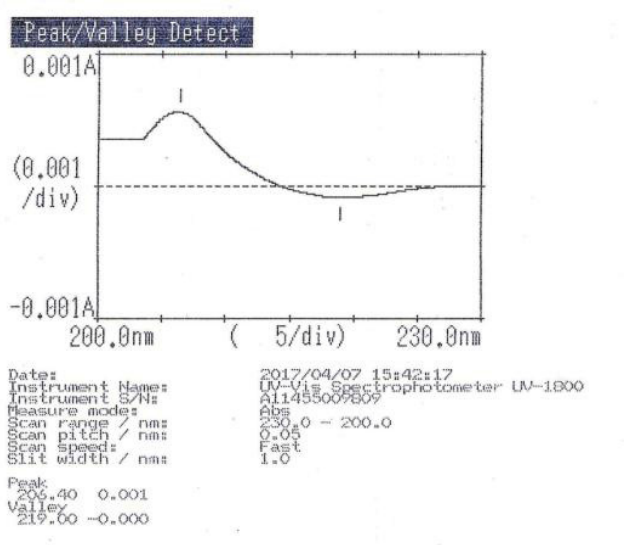


Figure 3: First derivative spectrum of acarbose concentration 24 µg/mL

Table 2: Standard calibration table for acarbose at 206 nm

S. No.	*Concentration of acarbose (µg/mL)*	*Absorbance at 206 nm*
1	24	0.001
2	28	0.003
3	32	0.005
4	36	0.006
5	40	0.008

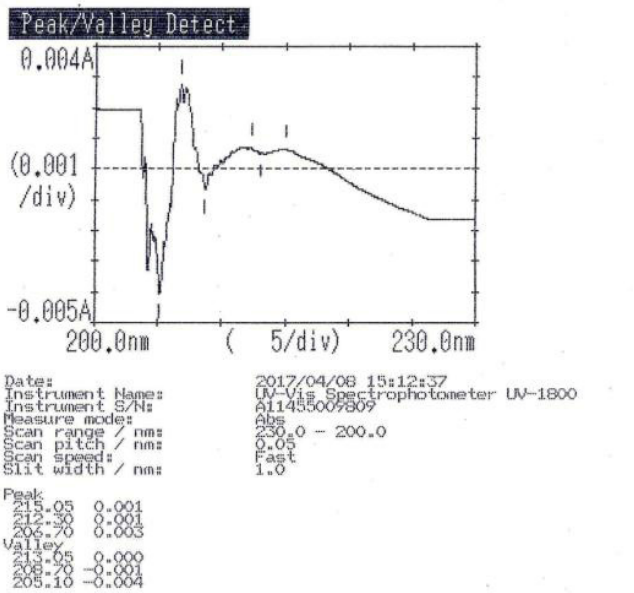


Figure 4: First derivative spectrum of acarbose concentration 28 µg/mL

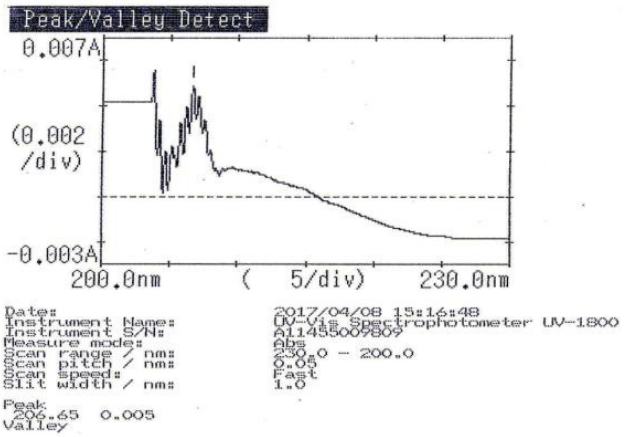


Figure 5: First derivative spectrum of acarbose concentration 32 µg/mL

Figures 3 to 7).

The following figures represent the linearity of acarbose at 206 nm.

Validation of the Proposed Method

Estimation of Drug (Acarbose) from Dosage Form: Tablet Assay Study

Brand Name: Glucobay ® 25

Standard: From the standard stock solution of acarbose, appropriate aliquots were pipette out into 25 mL of the volumetric flask, and methanol is used for dilutions to obtain the standard solution of acarbose 24 µg/mL. This concentration was scanned at the wavelength of 200 to 230 nm in derivative mode with n = 9.

Sample: For analysis of tablet formulation, marketed brands' tablet strips of acarbose were obtained. The total weight of all tablets was recorded. Crushed tablets were powdered, and a section of tablet powder was weighed equivalent to

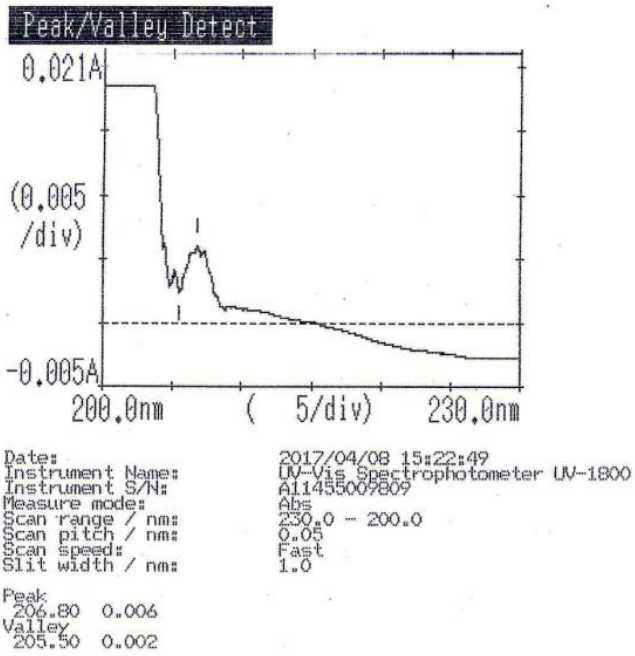


Figure 6: First derivative spectrum of acarbose concentration 36 µg/mL

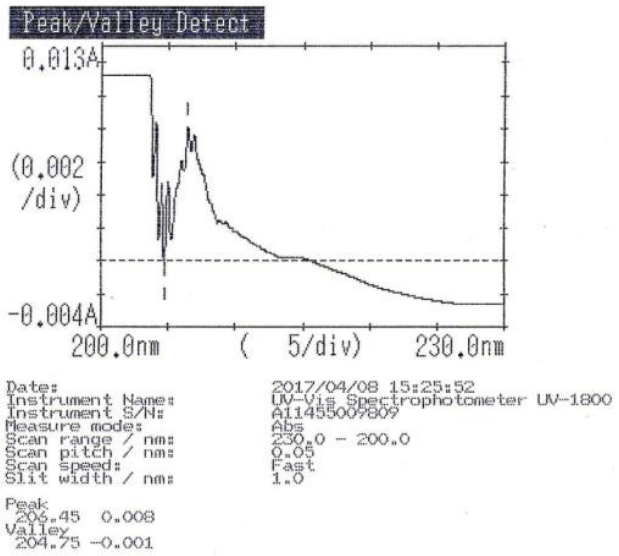


Figure 7: First derivative spectrum of acarbose concentration 40 µg/mL

100 ma to prepare the 100 µg/mL stock solution. Then, a series of solutions of concentration 24, 28, 32, 36, and 40 µg/mL prepared, and the absorbance measured at 206 nm derivative mode with n = 9. The results are shown in Table 3.

Accuracy (Recovery Study)

The accuracy of the method was studied by using recovery experiments. The recovery study was carried out by adding a known amount of powder sample from the capsule. Recovery was performed at three levels, 80, 100, and 120% of acarbose standard concentration. The recovery samples were prepared before the mentioned procedure. Three samples were prepared

Table 3: Assay of acarbose in tablet form by first-order derivative method

Amount taken (mg/tablet)	*Amount found (mg/tablet)*	*Amount found (%)*
25	24.99	98.90
25	25.03	100.13
25	25.05	100.40
25	24.98	99.87
25	26.01	100.65
	Mean	99.99
	SD	0.6756
	CV	0.0067

Table 4: Accuracy parameters of acarbose for first derivative method

Level of % recovery	*Amount present (mg)*	*Amount of standard added (mg)*	*Total amount recovered (mg)*	*% recovery*	*% mean recovery*	*SD*	*CV*
80	25	20	19.98	99.9			
80	25	20	20.03	100.15	100	0.1322	0.0013
80	25	20	19.99	99.95			
100	25	25	24.97	99.88			
100	25	25	25.04	100.16	100	0.1442	0.0014
100	25	25	24.99	99.96			
120	25	30	29.99	99.96			
120	25	30	28.89	96.3	99.73	2.1044	0.0212
120	25	30	29.98	99.93			

Table 5: Determination of precision of acarbose first-order derivative method

	Assay of acarbose as % of labeled amount			
Sample number	*Analyst-1*	*Analyst-2*	*Analyst-3*	*Analyst-4*
1	99.88	100.12	99.79	100.24
2	99.54	99.30	100.32	100.10
3	100.34	99.45	99.96	99.98
4	99.98	99.76	99.97	99.45
5	99.67	100.17	99.95	99.98
Mean	99.88	99.76	99.99	99.95
SD	0.3087	0.3890	0.1946	0.2993
CV	0.0030	0.0038	0.0019	0.0029

for each recovery level. The solutions were analyzed. Percentage recoveries were calculated by using the following formula:

$$\% \text{ recovery} = \frac{\text{Observed amount of compound in sample}}{\text{Amount of all compound present in sample}} \times 100$$

The recovery values are summarized in the following Table 4:

Precision

The precision (inter-day) was evaluated by using four independent samples of acarbose. Intermediate precision (inter-day precision) of the process was also performed by using four different analysts in the same laboratory. The values obtained by four analysts were summarized in Table 5.

RESULTS AND DISCUSSION

The standard solutions of acarbose in methanol subjected to a scan at the series of wavelengths of 200 to 230 nm at first-order and the derivative spectra were taken at n = 9 using Shimadzu 1800 spectronic UV-visible spectrophotometer and λ_{max} found to be 206 nm. The calibration curve of acarbose was found to be linear at a concentration range 24 to 40 µg/mL at 206 nm.

Therefore, it was clear that acarbose can be determined in the presence of methanol with no intervention of any irrelevant substance in pharmaceutical products. To determine the practicability of the developed technique for the assessment of commercially available brand (Glucobay® 25) of medicinal formulations, the technique was initially attempted on bulk drugs in their synthetic mixture sample, as well as,

concentrations were estimated. Then, the technique was subjected to the assay of in marketed dosage forms, and satisfactory results were attained within the appropriate limits, as per the content of the label claim for acarbose.

The newly developed method was validated as per the international guidelines and parameters. The novel method for the quantitative investigation of acarbose was subjected to different validation parameters, like specificity and selectivity in the presence of formulation additives and excipients, studied for linearity and range, at different levels of concentrations and calibration standards, where the determination range was optimized, recovery studies proved accuracy at different concentration levels, precision was established through inter-day precision studies, where the samples were subjected to changed conditions other than optimized parameters.

CONCLUSION

From the above experimental studies, it is concluded that the first order derivative peak detect method developed for estimation of acarbose was suitable for the routine determination of acarbose. The proposed method for the selected drug acarbose was found to be precise and accurate. The most important striking features of spectrophotometric methods are their rapidity and simplicity. The newly developed method is alternative to High-performance liquid chromatography (HPLC) methods and better than zero order UV Spectrophotometric methods. Results of validation parameters demonstrate that these performed analytical procedures are suitable for its intended purpose and meet the criteria defined in ICHQ2A/B guidelines.

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