IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
October 2021 Vol.:22, Issue:3

A Novel Validated UV- Spectrophotometric Method Development for The Estimation of Acarbose in Bulk and Pharmaceutical Dosage Forms

IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

ANUSHREE K[1], DIVYA S[2], MONIKA M N[3], SANGEETHA S[4], SURAKSHA D J[5]. SURESHA D N*[6]

Department of Pharmaceutical Analysis,
Bharathi College of Pharmacy, Bharathinagara,
K.M.Doddi, Maddur Taluk, India.

Submitted: 20 September 2021
Accepted: 26 September 2021
Published: 30 October 2021

Keywords: Acarbose, Zero order UV- Spectroscopy, 0.1N NaOH, Accuracy

ABSTRACT

A Novel, specific, accurate, and precise Zero order derivative spectroscopy method was developed and validated for the estimation of Acarbose in Bulk and pharmaceutical dosage forms. The stock solution was prepared by weighing 100 mg of standard Acarbose in a 100 ml volumetric flask with 0.1 N NaOH. The stock solution was made to produce 1000 µg/ml with 0.1 N NaOH. Further dilutions were prepared as per the procedure. The drug solution showed the maximum absorbance at 222 nm. The linearity was found in the concentration range of 20-100 µg/ml. The correlation coefficient was found to be 0.9999. The regression equation was found to be Y=0.030x-0.000. The method was validated for linearity, accuracy, precision, the limit of detection, the limit of quantitation, and ruggedness. The limit of detection and limit of quantitation for estimation of Acarbose was found to be 0.649µg/ml and 6.495µg/ml respectively. Recovery of Acarbose was found to be in the range of 99.69-100.26 %. The proposed method was successfully applied for the quantitative determination of Acarbose in Bulk and pharmaceutical dosage forms.

INTRODUCTION: [1,2]

Acarbose is a *α-glucosidase* inhibitor that prevents absorption of sucrose and maltose. This compound has been found to delay digestion of complex disaccharides andcarbohydrate. It is an Antidiabetic drug. It has chemical name(3R,4R,5S,6R)-5-[(2R,3R,4R,5S,6R)-5-[(2R,3R,4S,5S,6R)-3,4-dihydroxy-6-methyl-5-[[(1S,4R,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.

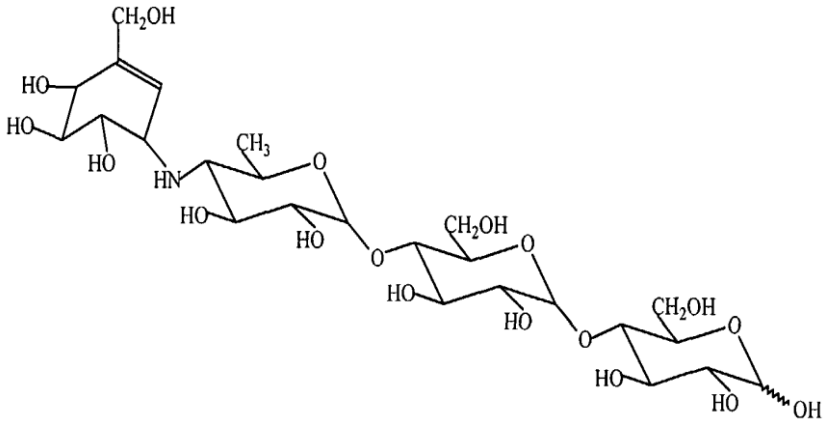

Figure no 1: Chemical structure of Acarbose

It has a molecular formula of $C_{25}H_{43}NO_{18}$ and a molecular weight of 645.6048g/mol. It has the structural formula (Fig.1).

Literature Survey revealed that the drug has been estimated by UV spectrophotometric [(3)] and Simultaneous RP- HPLC [(4-9)] method has been reported so far.

Present work aimed to develop and validate a novel, rapid, simple, precise, and specific Zero order derivative UV-Spectrophotometric method for estimation of Acarbose in its bulk and pharmaceutical dosage form.

MATERIALS AND METHOD:

Instrument:

UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on an analytical balance.

Chemicals:

Acarbose was given as a gift sample by Zydus Pharma Limited, Hyderabad. Tablets of Acarbose were procured from the local market.

Solvent:

0.1 N NaOH

Selection of analytical wavelength:

Appropriate dilutions were prepared for the drug from the standard stock solution and the solution was scanned in the wavelength range of 200-400 nm. The absorption spectra thus obtained were derivatized from the Zero order method. It shows maximum absorbance at 222 nm were shown in Fig.2.

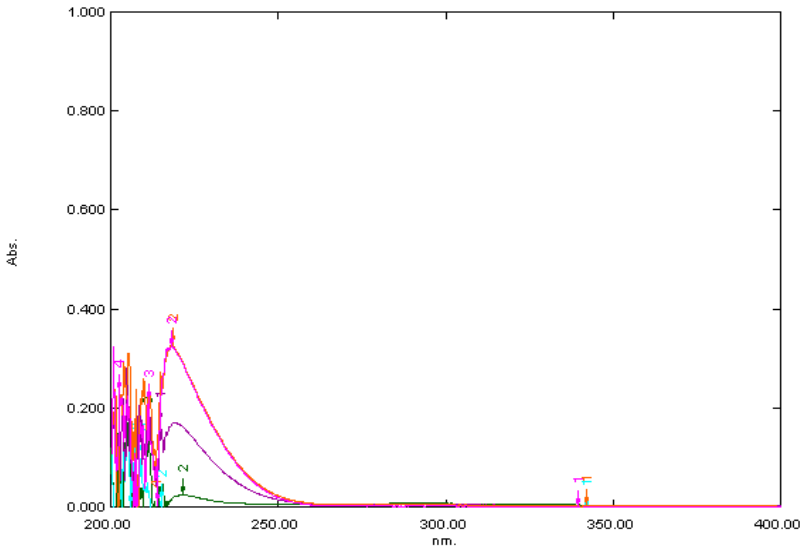

Figure no.2: Zero-order spectra of Acarbose showing absorbance at 222 nm

Preparation of Standard stock solution:

Accurately weigh100mg of Acarbose was transferred into 100ml volumetric flask and diluted with 0.1N NaOH up to the mark. From this pipette out 10ml into 100ml volumetric flask and diluted with 0.1N NaOH up to the mark, from this solution pipette out 2, 4, 6, 8, 10ml in 10 ml individual volumetric flask and add 0.1 N NaOH up to the mark, this gives 20, 40, 60, 80, 100 µg/ml concentrations.

Preparation of Sample solution:

The commercially available GLUCOBAY50 contains 50 mg of Acarbose. From this twenty Tablets were weighed and powdered. The Tablet powder equivalent to100 mg of Acarbose was transferred into a 100 ml volumetric flask then it was diluted with the 0.1N NaOH solution and made up to the mark and the solution was filtered through Whatman filter paper NO. 41. From the above solution, 10 ml was pipetted out into a 100 ml volumetric flask and the volume was made up to the mark with 0.1N NaOH. The final concentration of Acarbose was brought to 60µg/ml.

Method validation:

The method is validated according to the ICH guidelines[10- 12].

RESULTS AND DISCUSSION:

Method: Zero-order derivative spectroscopy

Linearity:

The working standard solution was diluted serially with 0.1N NaOH to obtain the range of 20-100µg/ml. a calibration curve for Acarbose was obtained by measuring the absorbance at the λmax of 222nm and absorbance values are shown in Table.1 and the Calibration graph were presented in Fig.3. Statistical parameters like slope, intercept, coefficient of correlation, and Sandel's sensitivity was determined and presented in Table.2.

Table no.1: Results of calibration curve for Acarbose at 222 nm by zero-order Spectroscopy.

SL. NO	Concentration inµg/ml.	Mean Absorbance±Standard deviation
1.	20	0.06±0.001
2.	40	0.122±0.0005
3.	60	0.181±0.0025
4.	80	0.241±0.0015
5.	100	0.304±0.0015

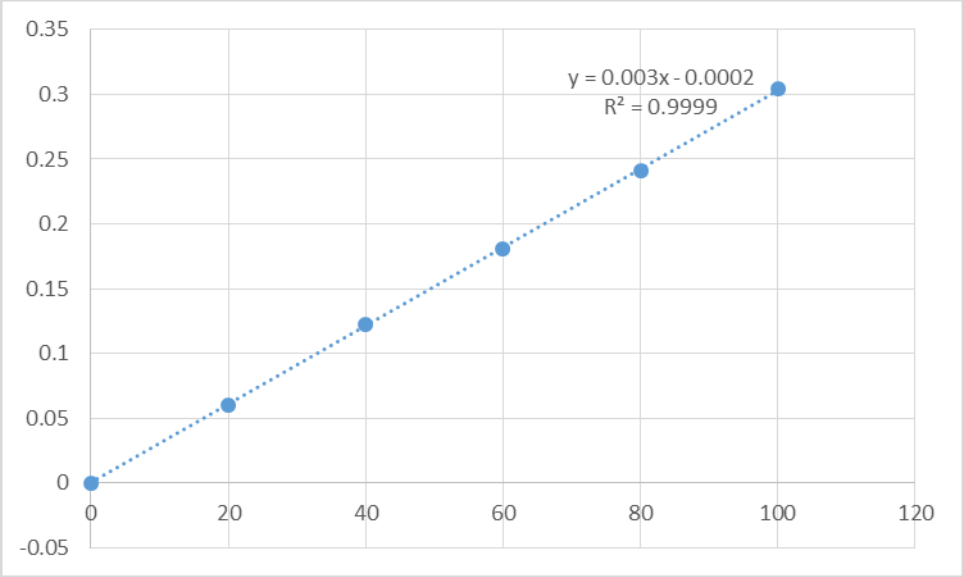

Figure no.3: Calibration curve for Acarbose at 222 nm by Zero-order Spectroscopy

Table no.2: Regression parameters for Acarbose by zero-order spectroscopy

Regression Parameters	**Acarbose**
Range	20-100µg/ml
Max	222nm
Regression Equation	Y=0.030x-0.000
Slope (b)	0.030
Intercept(a)	-0.000
Correlation coefficient (r2)	0.999
Sandell's Sensitivity	0.331

Precision:

The precision of the method was studied as intra-day and inter-day precision. Intra-day precision was determined by analyzing the 20, 40, 60, 80, and 100 µg/ml concentrations three times in the same day. Inter-day precision was determined by analyzing the same concentration of solution daily for three days. Precision results are shown in Table.3.

Table no.3: Determination of precision results for Acarbose at 222 nm by Zero order derivative spectroscopy.

Concentration (µg/ml)	Intra-day Absorbance ±SD**	%RSD	Inter-day Absorbance ±SD**	%RSD
20	0.06±0.001	1.66	0.059±0.00057	0.96
40	0.122±0.0005	0.40	0.121±0.001	0.82
60	0.181±0.0025	1.38	0.180±0.001	0.41
80	0.241±0.0015	0.62	0.240±0.001	0.41
100	0.304±0.0015	0.49	0.304±0.0026	0.85

Accuracy:

To assess the accuracy of the proposed method, recovery studies were carried out at three different levels i. e, 50%, 100%, and 150%. In which the formulation concentration was kept constant and varied pure drug concentration. Accuracy results were shown in Table.4.

Table no.4: Determination of accuracy results for Acarbose by Zero order derivative spectroscopy.

Spiked Levels	Amount of sample (µg/ml)	Amount of standard (µg/ml)	Amount Recovered (µg/ml)	%Recovery ±SD**	%RSD
50	40	20	59.83	99.69±0.0052	0.0052
100	40	40	80.10	100.13±0.0086	0.0085
150	40	60	100.26	100.26±0.0067	0.0066

**Average of six determinations

Ruggedness:

Ruggedness was determined between different analysts. The value of %RSD was found to be less than 2 were shown in Table.5.

Table no.5: Determination of Ruggedness results for Acarbose at 222 nm by Zero-order Spectroscopy

Analysts	Analyst-1	Analyst-2
Mean absorbance	0.181	0.180
Standard deviation	0.0025	0.001
%RSD	1.38	0.55

Limit of detection and Limit of Quantitation:

The LOD and LOQ of the present method were calculated based on a standard deviation of the Response and slope of the linearity curve. LOD and LOQ values of Acarbose were found to be 0.649µg/ml and 6.495µg/ml.

CONCLUSION:

In the present investigation, we have developed novel, simple, accurate, and precise UV-spectrophotometric methods like Zero order derivative spectroscopy for the routine estimation of Acarbose in Bulk and pharmaceutical dosage form, and the methods were validated in terms of linearity, accuracy, precision, ruggedness, and robustness.

ACKNOWLEDGEMENT:

We like to thank the Management, Director, Principal, Project Guide, and non-teaching staff of Bharathi college of pharmacy for their continued co-operation and support.

REFERENCES:

1. http://www.wikipedia.org/wiki/acarbose
2. http://www.pubchem.com/acarbose.html.
3. Kumar, Juyal G, Badoni V, Kumar P Rawat S M S M. Spectrophotometric Method Development of Acarbose from Bulk and In Its Tablet Dosage Form, Journal of PharmacyResearch, 2(10), 2009, 1595.
4.Ashutosh, Manidipa and SeshagiriRao. Development of stability indicating RP-HPLC method for simultaneous estimation of metformin hydrochloride and Acarbose phosphate monohydrate in bulk as well as in pharmaceutical formulation, Pelagia ResearchLibrary, Der Pharmacia Sinica, 4(4), 2013, 47-61.

5. Karimulla, Vasanth, Ramesh, Ramesh. Method development and validation of Acarbose and metformin using reverse phase HPLC method in bulk and tablet dosage form, Pelagia Research Library, Der PharmaciaLetter, 5(5), 2013, 168-174.
6. Raja, Lakshmana. Validated RP-HPLC method for simultaneous estimation of Metformin hydrochloride and Acarbose phosphate in Bulk drug and pharmaceutical formulation, International Journal of pharmaceutical, Chemical and Biological Sciences, 2(4), 2012, 696-702.
7. Ramanjaneyulu, Nagarjuna, Dhanalakshmi, Ramesh. A new analytical method development and Validation for simultaneous estimation of Acarbose And metformin hydrochloride in tablet dosage form by RPHPLC**.** Indian Journal of PharmaceuticalSciences, 3(5), 2013, 360-364.
8. Sumithra, Shanmugasudaram, Sankar, Niharika. Development of RP-HPLC method and it's validation for simultaneous estimation of Acarbose and metformin, InternationalJournal of Pharmaceutical and ChemicalSciences, 1(1), 2012, 360-364.
9. Alagar Raja. M, Dhanalaxmi. J, David Banji, Rao K N V, Selva Kumar. D. Stability Indicating RP-HPLC Method Development And Validation Of Simultaneous Estimation Of Metformin And Acarbose In Bulk And pharmaceutical Formulation.Asian journal of research and Biological and Pharmaceutical sciences. 3(2), 2015, 66 - 77.
10. ICH, Q2A Text on Validation of Analytical Procedures; 1994.
11. ICH, Q2B Validation of Analytical Methodology; 1996.
12. ICH, Q2 (R1) Validation of Analytical Procedures: text and methodology; 2005.