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R E S E A R C H A R T I C L E

Method Development and Validation of Voglibose in Tablet Formulation by using UV Double Beam Spectrophotometer

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A B S T R A C T

The present work was aimed to develop and validate UV spectrophotometric method for the quantification of Voglibose in tablet formulation. Distilled water used as a solvent. The absorption maxima was measured at 245 nm. This method shows linearity in the range of 5-30 µg/ml with correlation coefficient was found to be 0.999. The proposed methods were found to be precise, reproducible and accurate and can be employed for routine quality control analysis of Voglibose in bulk drug as well as dosage forms.

Keywords: Voglibose, UV Spectrophotometry, Distilled water, Linearity, Validation

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

Voglibose is an Alpha-glucosidase inhibitor, it is used treatment of diabetes mellitus in adults. Alpha-glucosidase inhibitors are saccharides that act as competitive inhibitors of enzymes needed to digest carbohydrates: specifically alpha-glucosidase enzymes in the brush border of the small intestines. The membrane-bound intestinal alpha-glucosidases hydrolyze oligosaccharides, trisaccharides, and disaccharides to glucose and other monosaccharides in the small intestine. Acarbose also blocks pancreatic alpha-amylase in addition to inhibiting membrane-bound alpha-glucosidases. Pancreatic alpha-amylase hydrolyzes complex starches to oligosaccharides in the lumen of the

small intestine. Inhibition of these enzyme systems reduces the rate of digestion of complex carbohydrates. Less glucose is absorbed because the carbohydrates are not broken down into glucose molecules. In diabetic patients, the short-term effect of these drugs therapies is to decrease current blood glucose levels.

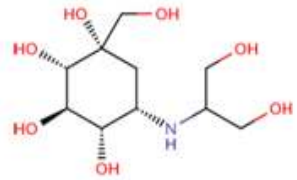

Fig 1: Chemical structure of Voglibose

Literature review reveals that there is no analytical method reported for the analysis of Voglibose by estimation by Uv–Visible Spectrophotometer. Spectrophotometer and Spectroscopy are the reported analytical methods for compounds either individually or in combination with other dosage form. Hence, it was felt that, there is a need of new Spectrophotometer method development for the estimation of Voglibose in pharmaceutical dosage form.

2. Materials and Methods

Materials: Voglibose was a gift sample from Dr. Reddys Lab, Hyderabad. All chemicals (distilled water, methanol) and reagents used were of analytical grade and purchased from Qualigens Fine Chemicals, Mumbai, India.

Apparatus:

A Labindia UV–visible spectrophotometer (UV-T60-India) was used for all absorbance measurements with matched quartz cells.

Method Development

Preparation of standard stock solution:

Accurately weighed 10 mg of Voglibose was transferred to a 100 ml volumetric flask, dissolved in 20 ml distilled water by shaking manually for 10 min. The volume was adjusted with the same up to the mark to give the final strength, i.e. 100 µg/ml.

Selection of wavelength for analysis of Voglibose:

Appropriate volume 1 ml of standard stock solution of Voglibose was transferred into a 10 ml volumetric flask, diluted to a mark with distilled water to give concentration of 10 µg/ml(and also 20, 30µg/ml). The resulting solution was scanned in the UV range (200–400 nm). In spectrum Voglibose showed absorbance maximum at 245 nm

Validation of the method

The method was validated in terms of linearity, accuracy, precision, and ruggedness. The developed method was statically validated accordance with ICH guidelines $Q_2(R_1)$.

Linearity study:

Different aliquots of Voglibose in the range 0.5–3 ml were transferred into series of 10 ml volumetric flasks, and the volume was made up to the mark with distilled water to get concentrations 5, 10, 15, 20, 25, and 30 µg/ml, respectively. The solutions were scanned on a spectrophotometer in the UV range 200–400 nm. The spectrum was recorded at 245 nm. The calibration plot was constructed as concentration vs. absorbance

Accuracy:

To the preanalysed sample solutions, a known amount of standard stock solution was added at different levels, i.e. 50%, 100%, and 150%. The solutions were reanalyzed by the proposed method.

Precision:

Precision of the method was studied as intraday and interday variations. Intraday precision was determined by analyzing the 10, 15 and 20 µg/ml of Voglibose solutions for three times in the same day. Interday precision was determined by analyzing the 10, 15, and 20 µg/ml of Voglibose solutions daily for 3 days over the period of week.

Sensitivity:

The sensitivity of measurements of Voglibose by the use of the proposed method was estimated in terms of the limit of quantification (LOQ) and limit of detection (LOD). The LOQ and LOD were calculated using equation LOD = 3 × N/B and LOQ = 10 × N/B, where 'N' is standard deviation of the peak areas of the drugs (n = 3), taken as a measure of noise, and 'B' is the slope of the corresponding calibration curve.

Repeatability:

Repeatability was determined by analyzing 20 µg/ml concentration of Voglibose solution for six times.

Ruggedness:

Ruggedness of the proposed method is determined for 20 µg/ml concentration of Voglibose by analysis of aliquots from a homogenous slot by two analysts using same operational and environmental conditions.

3. Results and Discussion

Selection of wavelength for analysis of Voglibose:

During the development phase, the use of ethanol as the diluent resulted in preferable outcome in UV analysis. The pre-determined wavelength of maximum absorption (λmax) was 245 nm.

Linearity: Linearity can be assessed by performing single measurements at 5-30 µg/ml concentrations. To plotting the calibration curve absorbance Vs concentration. The correlation coefficient was found to be 0.999.The results were tabulated in table 2.

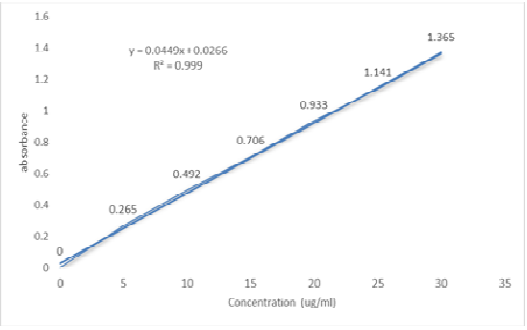

Fig 2: Calibration curve for Voglibose

Accuracy: Accuracy was tested (%Recovery and %RSD of individual measurements) by analyzing samples at least in triplicate, at each level 50%, 100% and 150% of label claim. For each determination fresh samples were prepared and

assay value is calculated. The mean percent recovery for this method was calculated and shown in table 3.

Precision: Both intraday and inter day precision was performed by three different concentrations of voglibose standard solutions. The % RSD was found to be less than 2. The results were shown in table 4.

Sensitivity: The linearity equation was found to be y=0.0449x + 0.0266. The LOQ and LOD for Voglibose were found to be 1.54 µg and 0.541 µg, respectively.

Repeatability:

Repeatability was determined by analyzing 20 µg/ml concentration of Voglibose solution for six times and the % amount found was 99.74 % RSD < 2. The results were shown in table 5.

Ruggedness:

The peak area was measured for same concentration solutions, six times. The results are in the acceptable range for both the drugs. The result showed that the % RSD was less than 2%. The results were given in table 6.

Assay of tablet formulation:

Two tablets are powdered and the average weight was calculated. A quantity equivalent to 40 mg of drug was dissolved in Methanol. Finally the volume was made up to get a working concentration of 10µg/ml each of Voglibose and absorbances were noted at 245nm respectively. An assay of Voglibose was found to be 98.66%.

Table 1: Results for selection of wavelength

Stocks	Wavelength of stocks	Absorbance
5 µg/ml	245	0.301
10 µg/ml	245	0.514
15 µg/ml	245	0.715

Table 2: Linearity Results

Concentration (ug/ml)	Absorbance (nm)
0	0
5	0.265
10	0.492
15	0.706
20	0.933
25	1.141
30	1.365

Table 3: Accuracy results

%Concentration (at specification Level) N=3	absorbance	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	0.354	5.0	4.995	99.9	99.92
100%	0.601	10	9.992	99.92	
150%	0.695	15	14.991	99.94	

Table 4: Intra-day and inter-day precision determined for three different concentrations of Voglibose (n=3)

Concentration (µg/mL)	Intra-day precision			Inter-day precision		
	Absorbance measured	RSD (%)	Average (%)	Absorbance measured	RSD (%)	Average (%)
5	0.357±0.12	1.33	99.15	0.364±0.17	1.21	99.10
10	0.605±0.21	0.91	98.75	0.615±0.25	1.24	99.14
15	0.699±0.25	1.01	99.14	0.684±0.20	1.19	98.95

Table 5: Repeatability results

Concentration (µg/mL)	Absorbance measured (Mean ± SD)	Amount Found (%)	RSD (%)
20	0.7154±0.024	99.74	0.05

Table 6: Results for Ruggedness

Analyst	Concentration (µg/mL)	Absorbance measured (Mean ± SD)	Amount Found (%)	RSD (%)
I	20	0.7114±0.0241	98.94	0.04
II	20	0.7215±0.0154	99.16	0.02

Table 7: Assay Results

Drug	Amount (mg/tab)		% label claim	% RSD*
	Labeled	Found		
Voglibose	200mg	123.5	98.66%	0.95%

4. Conclusion

This UV-spectrophotometric technique is quite simple, accurate, precise, reproducible, and sensitive. The UV method has been developed for quantification of Voglibose in tablet formulation. The validation procedure confirms that this is an appropriate method for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound.

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