ejpmr, 2025, 12(3), 286-293

SJIF Impact Factor 7.065

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

A REVIEW ON VOGLIBOSE TESTING METHODOLOGIES

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Article Received on 15/01/2025 **Article Revised on 05/02/2025** **Article Accepted on 25/02/2025**

ABSTRACT

Voglibose may be a strong α-glucosidase inhibitor having anti-obesity and anti-diabetic action utilized within the treatment of hyperglycemia & type II diabetes mellitus. Much of the inquiry about work has been done on Voglibose concerning the union, pharmacology, and instrument of activity, and within the show article, the creators have centered on different expository strategies utilized for the estimation of Voglibose in pharmaceutical definitions. This audit covers all the explanatory methods like UV-visible spectroscopy, HPLC, UPLC, HPTLC, electrochemical techniques, and LC-MS for the examination of Voglibose either as a single or in combination.

KEYWORDS: Voglibose; UV-Visible; LC-MS; HPLC; UPLC; HPTLC; Electrochemical technique; Diabetes Mellitus.

INTRODUCTION

Individuals with diabetes mellitus use voglibose, an alpha-glucosidase inhibitor, to lower their blood glucose levels after meals.[1] Alpha-glucosidase inhibitor with antihyperglycemic properties, valiolamine derivative voglibose. Alpha-glucosidase is an enteric enzyme located in the brush border of the small intestines. It hydrolyzes oligosaccharides and disaccharides into glucose and other monosaccharides. Voglibose binds to this enzyme and inhibits it. As a result, the rise in postprandial blood glucose levels is reduced, and the breakdown of bigger carbs into glucose is prevented.[2]

Voglibose (VOG), chemically known as (1S, 2S, 3R, 4S, 5S)-5-[(1,3-dihydroxypropan-2-yl) amino]-1-(hydroxymethyl)Cyclohexane-1,2,3,4-tetrolb[3] is an alpha glucosidase inhibitor, which is prescribed for lowering post-prandial blood glucose levels in persons suffering from diabetes mellitus. It functions by postponing the intestinal absorption of glucose, preventing an abrupt spike in blood sugar levels following a meal, and mitigating the likelihood of microvascular problems. Additionally, given that first-phase insulin secretion is mostly responsible for postprandial hyperglycemia, it is advised for managing this condition. Carbohydrate digestion is slowed down when certain enzyme systems are inhibited. Voglibose is reported to have a pKa value of 7.66. Voglibose is available as a tablet with the brand name Advog (Enzo Biopharma), Asvogli (A S Pharmaceutical Pvt), Bogli (Sarian Healthcare), Bose (Three Dots Lifescience), PPG (AHPL), Prandial (Cipla Limited), etc., with a label claim of 0.2 or 0.3 mg in India.[4] Voglibose is available in combination with Metformin, Glimepiride, Pioglitazone, and Linagliptin. Individual determination of Voglibose is carried out by UV[5] HPLC[6][7] HPTLC[8] and LC-MS[9] A representative structure of Voglibose is shown in Figure 1.

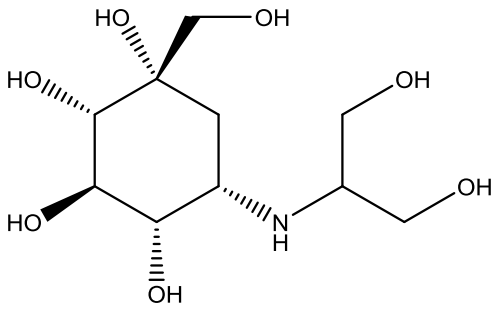

Figure 1: The structure of Voglibose.

Pharmacokinetic parameters are[10]

- **Absorption**: After oral administration, Voglibose is poorly absorbed. However, systematic unintended aspects have been observed.
- **Metabolism**: As a result, liver metabolism of Voglibose is negligible.
- **Excretion**: There is no renal excretion and no detectable plasma concentrations after oral administration.

- **Half-life**: 4.08 hours

Usage

- It is suggested that people with NIDDM take 0.2 mg tid before meals. Only in cases where a response to 0.2 mg tid of voglibose is not observed should dosage titration be advised. Voglibose should be taken in combination with diet or diet plus oral hypoglycemic medications.
- Visceral adipose tissue's response to subcutaneous adipose tissue is effectively reduced by the higher dose (0.3 mg three times daily), and glucose control was linked to alterations in VAT but not SATC.

Side effects are

Soft stools or diarrhea, flatulence, bloating, abdominal fullness, abdominal pain or discomfort, hepatitis with severe cholestasis, Metabolic hypoglycemicpisodes, nausea, vomiting, dizziness.

Methods of Analysis

In this study, we have only examined the analytical techniques created for voglibose measurement in biological samples and drug dosage forms. The current review article provides an overview of the analytical methods that have been developed thus far for the determination of voglibose. It also highlights some of the analytical parameters. These methods include spectrophotometry, high-performance liquid chromatography, ultra-performance liquid chromatography, and hyphenated techniques.[11]

UV spectroscopy

Voglibose cannot be detected with great sensitivity since it only absorbs UV light in the low wavelength range. Therefore, specific detection techniques are required for voglibose analysis. Voglibose has only demonstrated efficacious outcomes when combined with taurine and sodium periodate for a variety of analytical instruments.[12]

The JASCO V-630 double beam UV/visible spectrophotometer was utilized, along with a matched pair of quartz cells with a 1.0 cm path, to evaluate absorption. To achieve a concentration of 100 µg/ml, 10 mg of Voglibose was dissolved in 100 ml of methanol to create the standard drug solution. Both taurine and sodium periodate were used to derivatize the solution. Methanol was chosen as the solvent for additional research since it showed a unique λmax and the medication had a greater absorbance in this solvent. When the 10 µg/ml derivatized standard solution was scanned between 200 and 400 nm, the peak at 282 nm revealed maximum absorption.

Table 1: Comparative table for Voglibose (VGB) by using Spectrophotometric.

Solvent	LOD(µg/ml)	LOQ(µg/ml)	Linearity(µg/ml)	λmax	Reference
Mtethenol	----------	----------	10-80	282 nm 281nm	[5] [12]
Sodium Hydroxide Solution	0.24	0.73	5-25	214.5nm	[13]
Water	----------	----------	25-70	230nm	[14]

Table 2: Comparative table for Voglibose (VGB) in combination by using Spectrophotometric.

solvent	LOD(µg/ml)		LOQ(µg/ml)		Linearity(µg/ml)		λmax		reference
	VGB	MET	VGB	MET	VGB	MET	VGB	MET	
Sulphuric acid and methanol	0.62	0.86	1.87	2.60	2-10	10-50	220	242	[15]
Methanol	12.5	9.09	41.46	27.57	0.8-1.6	0.4-2	287	248	[16]
	VGB	NGL	VGB	NGL	VGB	NGL	VGB	NGL	
Methanol and dil hydrochloric acid	0.15	0.10	0.40	0.35	2-10	2-10	260	220	[17]

Hyphenated analytical technique

Two liquid chromatographic techniques are described by Raman et al.; the first uses post-column derivatization for fluorescence detection (LC-FD), while the other uses mass detection (LC-MS). The LC-FD approach used the post-column derivatization procedure because VB lacks chromophoric groups. However, this process elutes VB at a longer retention period and necessitates a high temperature. Because pre-column derivatization does not require specific equipment and does not impose any constraints on reaction parameters such as reaction duration, reaction temperature, amount of reagents, etc., we have chosen to adopt the pre-column derivatization approach with visual detection (LC-VD).[18][19]

The LC-MS methods reported, though validated and sensitive up to concentration levels of 5 ηg/mL12, are based on only a single ion recording of the parent ion [SIR, *m/z* 268.1] using electron spray ionization in positive mode. R. K. KHANDAL *et al* improved to take care of the deficiencies.

Table 3: Comparative table for Voglibose (VGB) using Hyphenated Techniques.

Stationary phase		**Mobile phase**		**LOD (µg/ml)**		**LOQ (µg/ml)**		**Linearity (µg/ml)**		**RT**		**Ref**
Waters X Terra MS C-18, 100 mmx2.1 id, 5 µm column		1 mL of formic acid in 1000 mL of water and 1 mL of formic acid in 1000 mL of methanol (50:50)		1.5		3.0		25.0-1200		1.06		[9]
LC-MS	LC-VD	LC-MS	LC-VD	LC-MS	LC-VD	LC-MS	LC-VD	LC-MS	LC-VD	LC-MS	LC-VD	
Venusil XBPPH (150 × 4.6 mm, 5 m) column	Novapak C18 (300 × 3.9 mm, 4 m, Waters Corporation, Milford, USA) column	95:5 v/v mix ture of 0.01% formic acid and methanol	35:65 v/v mixture of buffer (0.01 M mixture of sodium di hydro gen orthophosphate and disodium hydrogen orthophosphate	--	--	--	--	4-6	20-30	--	6.4	[20]
LC-MS	**LC-FD**	**LC-MS**	**LC-FD**	**LC-MS**	**LC-FD**	**LC-MS**	**LC-FD**	**LC-MS**	**LC-FD**	**LC-MS**	**LC-FD**	
Cosmosil® 5NH2-MS column (150mm×4.6 mm, 5µm)	Cosmosil® 5NH2-MS column (150mm×4.6 mm, 5µm)	10mM aqueous NH4OAc and acetonitrile (3:7, v/v)	Acetonitrile and 30mM NaH2PO4 (pH 6.5) (2:1, v/v)	18	9.4	52	29	50-1000	50-1000	4.93	4.93	[21]

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY METHOD (HPLC)

For the quantitative determination of Voglibose**,** Kumar P. Jitendra et al. devised a high-pressure liquid chromatography technique. An isocratic PEAKHPLC equipment with a Zodiac C18 column (250 mm x 4.6 mm, 5 µ) was employed. The equipment has a variable-wavelength programmable LC 7000 UV detector and an LC 20AT pump for delivering solvent. The samples were injected using a 20 µL Rheodyne inject port. Software called PEAK was used to examine the data.

An HPLC analytical technique for voglibose was developed by Lakshmi Karunanidhi and Rajesh Tirumala**.** This HPLC system was comprised of a RID-10A refractive index detector linked to a Shimadzu CBM-20A Prominence communication bus module with a DGU-20A5 prominence degasser and SIL-10Advp auto-injector. The software used to collect and process the data was LC Solution version 1.22 SP1. The Waters C18 analytical column has a 4.6 x 250 mm size and a 5 µm particle size. The isocratic mobile phase was a 50:50 v:v combination of acetonitrile and water that was pumped at a rate of 0.5 mL/min. At 40°C, the cell temperature was kept constant.

A high-pressure liquid chromatography technique was developed by Daswadkar Shubhangi C. et al**.** for the quantitative measurement of Voglibose. The Agilent 1120 small HPLC system, which has a manual Rheodyne injector facility and a 20 µL capacity per injection, was utilized. Agilent TC C18 (250 x 4.6 mm) 5 µm was the column that was employed, and the UV/VIS detector performed at 272 nm. EZChrom Elite Compact software was used to control the equipment.

Table 4: Comparative table for Voglibose (VGB) using HPLC.

Stationary phase	Mobile phase	Linearity (µg/ml)	LOD (µg/ml)	LOQ (µg/ml)	Pump mode	RT (min)	Reference
Zodiac C18 column (250 X 4.6 mm, 5µ)	Methanol : ACN (75:25) (v/v/)	60-200	0.2	0.65	Isocratic	6.84	[6]
Waters C18, with 4.6 x 250 mm, 5 µm	acetonitrile and water mixture (50:50, v:v)	10-100	2.91	9.70	Isocratic	3.264	[22]
Agilent TC C18 (250 X 4.6 mm) 5µm	water and acetonitrile (80: 20)	10-70	0.037	0.114	gradient	3.17	[7]
Hibar RT column (250 × 4.6 mm)	0.025M potassium dihydrogen phosphate pH 2.5: 100 – 500 acetonitrile: methanol (40: 55: 5 % v/v/v)	100- 500	30	100	isocratic	2.6	[23]

Table 5 Comparative table for Voglibose (VGB) in combination by using HPLC.

Stationary phase	Mobile phase	Linearity (µg/ml)		LOD (µg/ml)		LOQ (µg/ml)		Pump mode	RT (min)		Reference
C18 (25 cm × 0.46 cm) Hypersil BDS	KH2PO4 Buffer, pH 3.5: Methanol (30:70%v/v)	**VGB**	**RPG**	**VGB**	**RPG**	**VGB**	**RPG**		**VGB**	**RPG**	[24]
		4.5-13.5	7.5-22.5	0.386	0.541	1.171	1.639	Isocratic	5.333	3.670	
		VGB	**MET**	**VGB**	**MET**	**VGB**	**MET**		**VGB**	**MET**	
Hypersil ODS 18(250×4.6, 5 mm) column	phosphate buffer: acetonitrile (50:50)	0.3-0.18mcg/ml	50-300mcg/ml	--	--	--	--	--	3.177	1.960	[25]
n Waters ODS (C18) RP Column, 250 mm x 4.6 mm. 5µm	Phosphate Buffer (pH- 6.5): Acetonitrile = (65: 35)	10 µg/ml–60 µg/ml	05 µg/ml–40 µg/ml	0.06 µg/ml	0.08µg/ml	0.18µg/ml	0.24µg/ml	isocratic	--	--	[26]

Table 6: Comparative table for Voglibose (VGB) in combination by using HPLC.

Stationary phase	Mobile phase	Linearity (µg/ml)			LOD (µg/ml)			LOQ (µg/ml)			Pump mode	RT (min)			Reference
Jasco 2075 HPLC systems with Fine pack ODS C18 column (250mm)	acetonitrile: phosphate buffer in the ratio of 85:15 (pH 4)	**VGB**	**MET**	**GLM**	**VGB**	**MET**	**GLM**	**VGB**	**MET**	**GLM**	**VGB MET GLM**	**VGB**	**MET**	**GLM**	(27)
		1-6	10-60	2-12	0.5854	0.6447	0.0637	0.7176	0.8100	0.1931	- - -	2.3	3.8	5.1	
Inertsil ODS 3V	0.02 M Phosphate buffer	0.08 -	200-600	0.8-2.4	0.004	0.05	0.002	0.012	1.5	0.006	gradient	8.191	2.423	11.708	(28)

(150 × 4.6 mm, i.e. 5 µm) column	adjusted to pH 2.5 using dilute orthophosphoric acid	0.24													
cosmosil C18 column (250mm x 4.6Id, particle size: 5µ)	Methanol: water (65:35v/v)	**VGB**	**MET**	**TEN**	**VGB**	**MET**	**TEN**	**VGB**	**MET**	**TEN**	**VGB MET TEN**	**VGB**	**MET**	**TEN**	
		250-1250	250-1250	0.1-0.5	0.001	0.99	0.10	0.0042	2.87	0.332	--	--	--	--	(29)
Cosmosil C18 (250 x 4.6 mm, 5µm) column	acetonitrile: triethylamine (30:70, v/v)	**VGB**	**MET**	**PIO**	**VGB**	**MET**	**PIO**	**VGB**	**MET**	**PIO**	**VGB MET PIO**	**VGB**	**MET**	**PIO**	(30)
		0.08-0.24	200-600	30-90	0.0032	5.45	0.93	0.0097	16.52	2.83	**gradient**	10.10	2.74	4.82	

Ultra pressure liquid chromatography (UPLC)

In order to estimate Glimepiride + Metformin + Voglibose in bulk medication and market dosage form, Ahmed Mohd. Kareem et al. used ultra pressure liquid chromatography (UPLC). With Hypersil C18 (100 mm x 2.1 mm, 1.7 µm) and a mobile phase consisting of 68:32% v/v acetonitrile and methanol, the method employed a gradient mode. At 260 nm, the effluent's flow rate was measured to be 1.0 ml/min. The approach was verified in terms of linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), etc., in accordance with ICH criteria.

Table 7: Comparative table for Voglibose (VGB) in combination by using UPLC.

Stationary phase	Mobile phase	Linearity			LOD			LOQ			Pump mode	Retention time			Reference
Hypersil C18 (100 mm x 2.1 mm, 1.7 µm)	Acetonitrile and Methanol(68:32%v/v)	**VGB**	**MET**	**GLM**	**VGB**	**MET**	**GLM**	**VGB**	**MET**	**GLM**	**gradient**	**VGB**	**MET**	**GLM**	(31)
		20- 100 µg/ml			0.2099 (µg/ml)			0.6362 (µg/ml)				2.176 ± 0.12	3.587 ± 0.12	8.846 ± 0.12	
Inertsil ODS column	Buffer (PH=30 and methanol (70:30 v/v)	---			---			---			---	3.181	0.903	2.619	(32)

High Performance Thin Layer Chromatographic Method

Since most carbohydrates don't include chromophore or fluorophore groups, derivatization processes are frequently needed in order to analyze them using liquid chromatography (LC). Voglibose cannot be directly and highly sensitively detected since it only absorbs UV light in the low-wavelength area.[34]

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A straightforward, quick, accurate, cost-effective, and repeatable approach was created by **Kumar K. Ravi et al.** to determine the amount of voglibose in bulk and tablet dosage forms using HPTLC and to confirm the results in accordance with ICH recommendations.

Table 8: Comparative table for Voglibose (VGB) using HPTLC.

Stationary phase	Mobile phase	Linearity	LOD	LOQ	Rf value	Reference
Silica gel 60F254 TLC plates (20×10 cm & 10×10 cm, layer thickness 0.2 mm, Merck, Germany)	acetonitrile: methanol: ammonia (15:4:0.1% V/V/V)	100 to 450 ng/spot	40ng/spot	100 ng/spot	0.66±0.03.	[8]

Novel spectrophotometric method by using potassium ferricyanide-Fe (III) as chromogenic agent

The electrochemical features of electroactive materials, such as the reversible process of electrode reactions, the absorption surface of an electrode area, and the chemical reaction process, were studied using an electrochemical K3 [Fe (CN) 6] (potassium ferricyanide) as a probe reagent. Potassium ferricyanide plays a very important role in chemiluminescence due to its oxidation.

Cheepurupalli Prasad et al. offered a unique technique for estimating voglibose levels utilizing a system to detect potassium ferricyanide-Fe (III) in pharmaceuticals using spectrophotometry (Guoa et al., 2009; Litao et al., 2011; Rao et al., 2015). It was found that voglibose was used to reduce Fe (III) to Fe (II), and that potassium ferricyanide was present in the form of K-Fe-III [Fe (II) (CN)6], which is created when Fe (II) reacts with potassium ferricyanide in situ to form soluble Prussian blue. The approach shown here is less expensive, more sensitive, easier to use, and has fewer detection constraints.

Chromogenic agent	λmax	Linearity	LOD (µg/ mL)	LOQ (µg/ mL)	Reference
potassium ferricyanide-Fe(III)	775 nm	1-5 µg/mL	0.27	0.81	[33]

CONCLUSION

There have been reports on the estimation of Voglibose in bulk and pharmaceutical formulations using UV, HPLC, UPLC, HPTLC, electrochemical and Hyphenated techniques. Readers will have a greater comprehension of the analytical methods used to measure Voglibose after reading this article.

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