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REVIEW OF ANALYTICAL TECHNIQUES FOR THE ESTIMATION OF REPAGLINIDE AND VOGLIBOSE IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

Repaglinide is Chemically benzoic acid derivatives. It belongs to the class of antihyperglycemic medications. Repaglinide is an oral antihyperglycemic agent used for the treatment of non-insulin-dependent diabetic mellitus (NIDDM). It is a member of the meglitinide class of short-acting insulin secretagogues, which work by binding to β cells of the pancreas to stimulate insulin release. Repaglinide induces an early insulin response to meals decreasing postprandial blood glucose levels. Voglibose is an α -glucosidase inhibitor and it is chemically cyclohexane-1,2,3,4-tetrol) derivatives. It is used to lower postprandial blood glucose levels in people with diabetes mellitus. The fixed-dose combination of repaglinide and voglibose is an effective pharmacologic method for controlling both fasting (FHG) and after-meal hyperglycaemia (PPHG) with adequate tolerance and safety. The dosage ratio for the fixed-dose combination of repaglinide and voglibose is 0.5:0.2 mg. The present work highlights the analytical techniques that had been developed for the estimation of repaglinide and voglibose, either alone or in combination with other drugs. We have reviewed various analytical methods, such as HPLC-UV, Stability indicating RP-HPLC, TLC,

Spectrophotometric (UV-Vis), and other methods that have been developed for the combination of Repaglinide and Voglibose.

Keywords: Repaglinide, Voglibose, Analytical techniques, Antidiabetic, Stability indicating RP-HPLC, UV-visible Spectrophotometer, HPLC, TLC Method

INTRODUCTION:

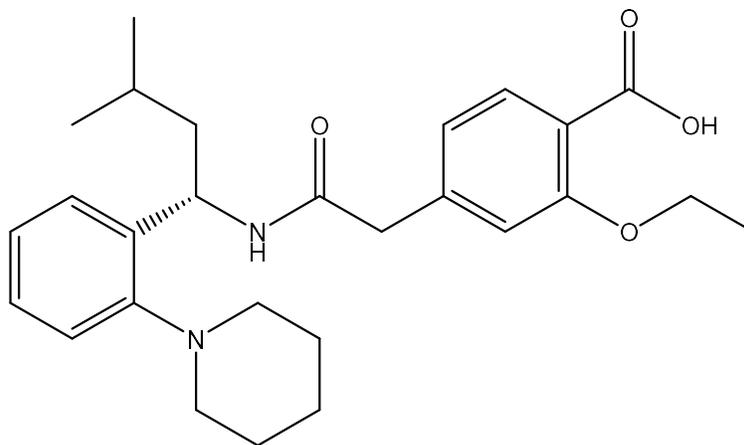
Repaglinide belongs to meglitinides, which is used in type 2 diabetes to help regulate blood sugar levels in addition to diet and exercise. “The repaglinide is an insulin secretagogue that binds to receptors on pancreatic β cells and stimulates insulin release” [1]. It also binds to an ATP-dependent potassium channel on β cells, known as SUR1, bringing about its closure, a main side effect concern is hypoglycemia [1].

In 1994, Voglibose made its debut in Japan. “Anti-hypoglycaemic action of voglibose results from a reversible inhibition of membrane-bound intestinal α -glycosidase enzyme which hydrolyzes oligosaccharides and disaccharides to glucose and other monosaccharides in the brush border of the

small intestine” [1]. Voglibose is an α -glucosidase inhibitor that helps persons with diabetes mellitus lower their postprandial blood glucose levels. “Voglibose delays the absorption of glucose thereby reducing the risk of macrovascular complications” [1].

Physicochemical properties:

“Repaglinide belongs to a class of antihyperglycemic agents known as meglitinides” [2]. The repaglinide has the following molecular formula and weight: $C_{27}H_{36}N_2O_4$ and 452.6 gm/mol, respectively. It has a half-life of 1 hour and it is majorly excreted in the feces (90%) and in urine (8%). Repaglinide has Log P value is 5.9. The melting point of repaglinide is 130-131°C. **Figure 1** displays the Repaglinide's chemical structure [2].

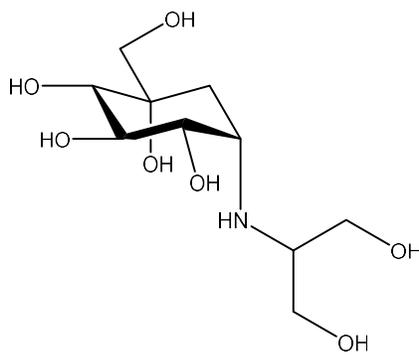


repaglinide

Figure 1: Chemical structure of Repaglinide

“Voglibose belongs to a class of competitive α -glucosidase inhibitors” [3]. The voglibose has the following molecular formula and weight: $C_{10}H_{21}NO_7$ and 267.3 gm/mol, respectively. It has a half-life of 4.08 hours

and it is majorly excreted in the feces (98%) and in urine (5%). Voglibose has Log P value is -2.33. The melting point of voglibose is 161-166°C. **Figure 2** displays the Voglibose's chemical structure [3].



Voglibose

Figure 2: Chemical structure of Voglibose

Table 1: Official techniques for estimation of Repaglinide

Sr. No.	Method	Description	Ref.
1	LC	Stationary phase: Silica gel AGP for chiral chromatography R (5 μ m) Column size: l= 0.1 m, \emptyset = 4.0 mm Mobile phase: A- 1.0 g/l Solution of potassium dihydrogen phosphate R (pH 4.7) with dilute sodium hydroxide solution R B- Acetonitrile R Flow Rate: 1.0 ml/min Detection: 240 nm Retention Time: (REPA)- About 3.3 min Injection volume: 10.0 μ l [4]	BP 2022 Volumn-2 P.P.- 806-808 [4]
2	LC	Stationary phase: Silica gel for chromatography R (5 μ m) Column size: l= 0.15 m, \emptyset = 4.6 mm Mobile phase: A- 4.0 g/l Solution of potassium dihydrogen phosphate R (pH 3.2) with dilute phosphoric acid R B- Mobile phase a: Acetonitrile R (300:700 v/v) Flow Rate: 1.5 ml/min Detection: 240 nm Retention Time: (REPA)- About 10 min Injection volume: 10.0 μ l [4]	BP 2022 Volumn-2 P.P.- 806-808 [4]
3	LC	Column size: 4.6 mm \times 12.5 cm; 5 μ m Mobile phase: Methanol: Buffer (8:2 v/v) Flow Rate: 1 ml/min Detection: 240 nm Injection volume: 10.0 μ l [5]	USP 2020 Volumn-2 P.P.- 3854-3857 [5]
4	LC	Column: size: 4.0 mm \times 6 cm; 5 μ m Mobile phase: Methanol: Buffer (pH 2.5) (7:3 v/v) Flow Rate: 1 ml/min Detection: 245 nm Injection volume: 20.0 μ l [5]	USP 2020 Volumn-2 P.P.- 3854-3857 [5]
5	LC	Column size: (12.5 cm \times 4 mm; 5 μ m) Mobile phase: Acetonitrile: Potassium phosphate (pH 2.3): Methanol Flow Rate: 1.0 ml/min Detection: excitation- 244 nm, emission- 348 nm Injection volume: 20.0 μ l [6]	IP 2018 Volume-3 P.P.- 3103-3104 [6]

Table 2: Reported techniques for estimation of Repaglinide

Sr. No.	Author	Method	Description	Ref. No.
1	Mohite M <i>et al.</i> 2013 [7]	UV-Visible	Linearity Range: Method A- 10-80 µg/ml Method B- 10-70 µg/ml R ² : Method A- 0.9995 Method B- 0.9996 Zero order Derivative spectra: 293 nm First-order Derivative spectra: 245 nm [7]	[7]
2	Begum AK <i>et al.</i> 2014 [8]	HPLC	Column: ACE- C ₁₈ (250 x 4.0; 5 microns) Mobile phase: Potassium dihydrogen phosphate: Methanol (80:20 v/v) Flow rate: 1 ml/min Wavelength: 285 nm R ² : 0.99 Retention time: 3.016 min [8]	[8]
3	Mishra J <i>et al.</i> 2016 [9]	UV-Visible	Linearity Range: 10µg/ml to 90µg/ml R ² : 0.999 Wavelength: 237nm Solvent: Methanol [9]	[9]
4	Jain PS <i>et al.</i> 2013 [10]	HPTLC	Stationary phase: Aluminum plates precoated with silica gel 60 RP-18 F254 Mobile phase: Chloroform: Methanol: Ammonia (4.5:0.8:0.05 v/v) Linearity Range: 600–1600 ng/spot R ² : 0.998 R _f value: 0.55 ± 0.03 [10]	[10]
5	Pingale PL <i>et al.</i> 2012 [11]	RP-HPLC	Column: C ₁₈ column (100×4.6) mm×5µ Kromasil ODS Mobile phase: Methanol: Phosphate buffer (pH 3) (70:30 v/v) Flow rate: 1 ml/min Linearity Range: 1-5 µg/ml Wavelength: 242 nm R ² : 0.999 Retention time: 3.81 min [11]	[11]
6	Pattanaik P <i>et al.</i> 2013 [12]	RP-HPLC	Column: HSF5 C ₁₈ (4.6mm x 250 mm; 5 µm) Mobile phase: Methanol: Ammonium acetate buffer (pH 4) (80:20 v/v) Flow rate: 1 ml/min Linearity Range: 0.5-200 µg/ml Wavelength: 240 nm R ² : 0.9996 Retention time: 6.2 min Injection volume: 20µl Column temperature: 23 ± 0.2 °C [12]	[12]

Official technique for estimation of Voglibose
Voglibose does not have an official method in any pharmacopeia.

Table 3: Reported techniques for estimation of Voglibose

Sr. No.	Author	Method	Description	Ref. No.
1	Nagasrapu MR <i>et al.</i> 2020 [13]	HPTLC	Stationary phase: Silica gel 60 F254 TLC plates (20×10 cm & 10×10 cm, layer thickness 0.2 mm, Merck, Germany) Mobile phase: Acetonitrile: Methanol: Ammonia (15:4:0.1 v/v/v) Linearity Range: 100 to 450 ng/spot R ² : 0.9995 R _f value: 0.66 ± 0.03 [13]	[13]
2	Rao NM <i>et al.</i> 2010 [14]	UV-Visible	Linearity Range: 10-80 µg/ml R ² : 0.997 Wavelength: 282 nm Solvent: Methanol [14]	[14]
3	Daswadkar SC <i>et al.</i> 2013 [15]	RP-HPLC	Column: TC C ₁₈ (250 × 4.6 mm; 5µm) Mobile phase: Acetonitrile: Water (20:80 v/v) Flow rate: 1 ml/min Linearity Range: 10–70 µg/ml Wavelength: 272 nm R ² : 0.9992 Retention time: 3.17 ± 0.01 min Injection volume: 20µl Temp.: Ambient 25 °C [15]	[15]

Table 4: Reported techniques for estimation of Repaglinide & Voglibose

Sr. No.	Author	Method	Description	Ref. No.
1	Hadad GM <i>et al.</i> 2009 [16]	HPLC	Column: C ₁₈ (25 cm × 0.46 cm) Hypersil BDS Mobile Phase: Buffer (pH 3.5): Methanol (30:70 v/v) Flow Rate: 1.0 ml/min Linearity Range: (REPA) 7.5-22.5 µg/ml (VOG) 4.5-13.5 µg/ml Wavelength: 240 nm R ² : (VOG)- 0.9992 (REPA)- 0.9994 Retention time: Repaglinide: 3.670 min Voglibose: 5.333 min Injection volume: 20.0µl Run time: 20 min [16]	[16]
2	Konatham TK <i>et al.</i> 2020 [17]	RP-HPLC	Column: Symmetry C ₁₈ (150 cm × 4.6 mm; 5 µm) Mobile phase: Methanol: Dihydrogen phosphate buffer (pH 5.0) (60:40 v/v) Flow rate: 1.5 ml/min Linearity Range: (REPA) 2-18 µg/ml (VOG) 2-18 µg/ml Wavelength: 255 nm R ² : (VOG)- 0.9989 (REPA)- 0.9868 Retention time: Repaglinide: 5.8 min Voglibose: 3.1 min Injection volume: 20.0µl [17]	[17]

Table 5: Reported techniques for estimation of Repaglinide & and other drugs

Sr. No.	Author	Method	Description	Ref. No.
1	Kamal AH <i>et al.</i> 2022 [18]	HPLC/UV	Column: Termo Hypersil® ODS C ₁₈ column (150 mm × 4.6 mm; 5 µm) Mobile phase: Phosphate buffer (10 mm, pH 2.5): Acetonitrile (45:55 v/v) Flow rate: 1 ml/min Linearity Range: 1-100 ng/ml [18]	[18]
2	Kumar HK <i>et al.</i> 2021 [19]	UPLC	Column: DIKMA Endoversil (2.1 x 50 mm; 1.7µm) Mobile phase: Phosphate buffer (pH 4.2): Methanol (38:62 v/v) Flow rate: 0.3 ml/min Linearity Range: 1-50 µg/ml Wavelength: 241 nm R ² : (MET)- 0.997 (REPA)- 0.999 Retention time: (REPA) 1.152 min (MET) 0.516 min Injection volume: 10.0µl [19]	[19]
3	Han DG <i>et al.</i> 2019 [20]	HPLC	Column: C ₁₈ column (250 × 4.6 mm; 5 µm, 100 Å) Mobile phase: ACN: (pH 6.0) Phosphate buffer (53.6:46.4 v/v) Flow rate: 1 ml/min Linearity Range: 10-2000 ng/ml Wavelength: (REP) 240 nm (CEL) 380 nm Injection volume: 20 µl Run time: 23 min [20]	[20]
4	M Fouad M <i>et al.</i> 2014 [21]	HPLC	Column: C ₁₈ column (250 x 4.6; 5µ particle size) Mobile phase: Methanol: 0.2% Heptane sulphonate sodium (70:30 v/v) Flow rate: 1 ml/min Linearity Range: (REPA) 5- 40 µg/ml (MET) 2-12 µg/ml	[21]

			Wavelength: 240 nm R ² : (MET)- 0.9982 (REPA)- 0.9903 Retention time (min): (REPA) 14.21 (MET) 3.42 [21]	
5	Tatiparthi R <i>et al.</i> 2010 [22]	RP-HPLC	Column: BDS Hypersil® column C ₁₈ (150mm × 4.6mm; 5µm) Mobile phase: Acetonitrile: Phosphate buffer (pH 4.0) (60:40 v/v) with 1% triethylamine Flow rate: 0.8 ml/min Linearity Range: (REPA) 55-550 ng/ml (MET) 420-4200 ng/ml Wavelength: 254 nm R ² : (MET)- 0.997 (REPA)- 0.9995 Retention time (min): (REPA) 7.4 (MET) 5.1 [22]	[22]
6	Joshi SS <i>et al.</i> 2012 [23]	RP-HPLC	Column: YMC-pack AM-ODS column (5 µm; 250 mm × 4.6 mm) Mobile phase: (70:30 v/v) Methanol: 10 mm Potassium dihydrogen phosphate buffer (pH adjusted to 2.5 with 10% ortho-phosphoric acid) Flow rate: 1 ml/min Linearity Range: (REPA) 1-200 µg/ml (MET) 5-200 µg/ml Wavelength: 210 nm R ² : (MET)- 0.9997 (REPA)- 0.9998 Retention times: (MET) 2.6 min (REPA) 11.3 min [23]	[23]
7	Aslan SS <i>et al.</i> 2017 [24]	HPLC - UV	Mobile phase: Acetonitrile: Phosphoric acid pH adjusted to 3 with 1 N NaOH (40:60 v/v) Flow rate: 1 ml/min Linearity Range: 5.0 - 50.0 µg/ml UV R ² : (MET)- 0.9999 (REPA)- 0.9950 HPLC R ² : (MET)- 0.9999 (REPA)- 1.0000 Retention times: (MET) 4.25 min (REPA) 6.28 min [24]	[24]

Table 6: Reported techniques for estimation of Voglibose & other drugs

Sr. No.	Author	Method	Description	Ref. No.
1	Mamatha B <i>et al.</i> 2019 [25]	HPLC	Column: Waters ODS C ₁₈ RP Column Mobile phase: Phosphate Buffer (pH - 6.5): Acetonitrile (65:35 v/v) Flow rate: 1.0 ml/ min Linearity Range: (VOG) 10–60 µg/ml (MET) 05–40 µg/ml Wavelength: 251 nm R ² : (MET)- 0.9998 (VOG)- 0.9991 Injection Volume: 10µl Run time: 6 min [25]	[25]
2	Neelima K <i>et al.</i> 2014 [26]	RP-HPLC	Column: Inertsil ODS 3V (150 × 4.6 mm; 5 µm) Mobile phase: 0.02 M Phosphate buffer adjusted to pH 2.5 using dilute orthophosphoric acid: Acetonitrile (50:50 v/v) Flow rate: 1 ml/min Linearity Range: (VOG) 0.08-0.24 µg/ml (MET) 200-600 µg/ml (GLI) 0.8-2.4 µg/ml Wavelength: 230 nm R ² : 0.999 Retention times: (MET) 2.423 min (VOG) 8.191 min (GLI) 11.708 min Injection volume: 20 µl [26]	[26]
3	Devi MG <i>et al.</i> 2018 [27]	RP-HPLC	Column: Hypersil BDS C ₁₈ column (250 × 4.6; 5 µm) Mobile phase: 0.02M KH ₂ PO ₄ : Acetonitrile (50:50 v/v)	[27]

			Flow rate: 1 ml/min Linearity Range: (VOG) 0.3-0.18 µg/ml (MET) 50-300 µg/ml Wavelength: 236 nm R ² : (MET)- 0.997 (VOG)- 0.998 [27]	
4	Dholakia SP <i>et al.</i> 2022 [28]	RP-HPLC	Column: Cosmosil BDS C ₁₈ (15 cm × 0.46 cm; 5µm) Mobile phase: Phosphate buffer (pH 4.0): Methanol (30:70 v/v) Flow rate: 1 ml/min Linearity Range: (VOG) 0.5-1.50 µg/ml (MITI) 25-75 µg/ml Wavelength: 233 nm R ² : (MITI)- 0.999 (VOG)- 0.998 Injection volume: 20µl Run time: 8 min [28]	[28]
5	Shende MA <i>et al.</i> 2019 [29]	RP-HPLC	Column: Cosmosil C ₁₈ (250 x 4.6 mm; 5µm) Mobile phase: 0.1% v/v Acetonitrile: Triethylamine (30:70 v/v) pH 2.5 Flow rate: 0.8 ml/min Linearity Range: (VOG) 0.08-0.24 µg/ml (MET) 200-600 µg/ml (PIO) 30-90 µg/ml Wavelength: 232 nm R ² : (MET)- 0.998, (PIO)- 0.999, (VOG)- 0.999 Injection volume: 20µl [29]	[29]

CONCLUSION:

The present work highlights the analytical techniques that have been developed for the estimation of repaglinide and voglibose, either alone or in combination with other drugs. We have reviewed various analytical methods, such as HPLC-UV, Stability indicating RP-HPLC, TLC, Spectrophotometric (UV-Vis), and other methods that have been developed for the combination of Repaglinide and Voglibose. An overview of the latest progressive analytical techniques for determining repaglinide and voglibose is provided in this paper, which will be helpful for future studies on this combination. This review will help the reader to get acquainted with the various solvents & laboratory equipment, which are useful for the analysis of repaglinide and voglibose.

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