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REVIEW ARTICLE

A Comprehensive Review of Teneligliptin on its Pharmacological, Pharmaceutical, and Analytical Profile

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ABSTRACT

Teneligliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor that has gained prominence in the management of type 2 diabetes mellitus (T2DM). Pharmacologically, teneligliptin acts by inhibiting DPP-4, prolonging the action of incretin hormones, and promoting insulin secretion while reducing glucagon release. Clinical studies have established its efficacy in improving glycaemic control with a favorable safety profile. Pharmaceutically, teneligliptin is available in various dosage forms, including tablets and combination therapies, offering flexibility in treatment regimens. Its rapid absorption and relatively short half-life contribute to convenient dosing and patient adherence. Analytically, rigorous methods are employed to assess teneligliptin's purity, stability, and bioavailability, ensuring consistent and reliable dosing. Its pharmacological efficacy, diverse pharmaceutical formulations, and rigorous analytical assessment collectively make it a valuable option in the therapeutic armamentarium for managing T2DM. Staying informed about the latest developments in teneligliptin research is essential for optimizing its clinical use.

Keywords: Teneligliptin, Dipeptidyl peptidase-4 (DPP-4) inhibitor, Bioavailability, Chromatography, Spectroscopy

INTRODUCTION

Diabetes is a widespread noncommunicable ailment that has reached an epidemic level in numerous countries. On a global scale, there are 415 million individuals living with diabetes, making it a leading cause of mortality. Predictions indicate that this number will surge to 642 million by the year 2040, with a mortality toll of 5 million attributed to diabetes. Notably, the People's Republic of China, India, the United States, and the Russian Federation have reported the highest numbers of diabetes-related deaths.[1]

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Diabetes affects multiple organs, with complications arising from elevated blood glucose levels leading to disability, diminished quality of life, and premature death. In 2015, approximately 5 million people between the ages of 20 and 79 years lost their lives to diabetes worldwide, translating to one death every 6 s.

Managing diabetes is a long-term endeavor that necessitates constant medical care and a multifaceted approach to risk reduction and treatment, extending beyond mere glycemic control. The primary goal of treatment is to avert both short-term and long-term diabetes-related complications. Moreover, patient education and support play pivotal roles in enhancing patient outcomes, necessitating a multidisciplinary approach to diabetes management.[2,3]

Given the substantial epidemic of type 2 diabetes mellitus (T2DM), there is a continual demand for novel therapies that offer improved effectiveness, tolerability, and long-term adherence while also preventing T2DM-associated complications. Recently, a cost-effective dipeptidyl peptidase-4 (DPP-4) inhibitor known as teneligliptin has become available in several countries, including Japan (Teneria®), Argentina (Teneglucon®), and India (Tenepure; Teneza). This review aims to shed light on the role of teneligliptin in the management of T2DM.[4-7]

Drug profile

Teneligliptin is a DPP-4 inhibitor that has gained prominence in the management of type 2 diabetes mellitus. Pharmacologically, teneligliptin acts by inhibiting DPP-4, prolonging the action of incretin hormones, and promoting insulin secretion while reducing glucagon release. The chemical structure, the detailed drug Profile of Teneligliptin, Chemical Taxonomy and Predicted Properties were shown in Figure 1 and Tables 1-3 respectively.

PHARMACOLOGICAL PROPERTIES[10]

Pharmacodynamic (PD) data in T2DM

A pharmacokinetic (PK)/PD investigation was carried out among Japanese patients with T2DM. In this study, ninety-nine patients were subjected to a randomized, double-blind, placebo-controlled, parallel-group protocol, with some receiving either 10 or 20 mg of teneligliptin before breakfast for 4 weeks. Results revealed that both groups treated with teneligliptin experienced a significant reduction in postprandial glucose (PPG) levels after each meal, as well as a decrease in the 24-h average glucose and fasting plasma glucose values compared to the placebo group. Notably, when comparing the 20 mg teneligliptin group to the placebo group, the changes in 2-h PPG (expressed as LS means ± standard error) following each meal were substantial: −38.1 ± 7.8 mg/dl at breakfast, −28.6 ± 9.2 mg/dl at lunch, and −36.1 ± 7.5 mg/dl at dinner ($P < 0.001$, $P < 0.01$, and $P < 0.001$, respectively). Both dosages of teneligliptin also raised postprandial plasma active GLP-1 concentrations compared to the placebo group after each meal, with DPP-4 inhibition sustained over 24 h, with the 20 mg dosage demonstrating slightly stronger inhibition. The PK profile observed was similar to that seen in healthy individuals. These PK/PD findings offer the necessary support for prescribing a daily dose of teneligliptin at 20 mg.

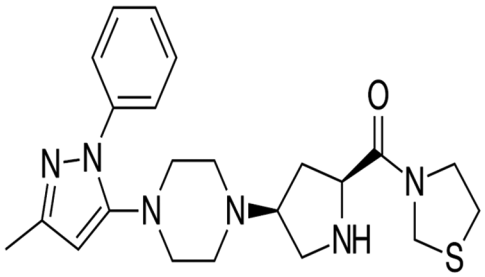

Figure 1: Chemical structure of teneligliptin[8]

In Vitro studies

Teneligliptin is a potent, selective, and long-lasting DPP-4 inhibitor that has approximately 700- to 1500-fold greater affinity for DPP-4 than other DPP enzymes, such as DPP-8 and DPP-9. Teneligliptin inhibits recombinant human DPP-4 and human plasma DPP-4 in a concentration-dependent manner: Concentrations producing half-maximal inhibition (IC_{50}) are 0.889 nmol/L and 1.75 nmol/L, respectively. In these respects, teneligliptin is more potent than sitagliptin (6.74 nmol/L and 4.88 nmol/L, respectively) and vildagliptin (10.5 nmol/L and 7.67 nmol/L, respectively), as demonstrated by lower IC_{50} values.

In Vivo studies

In rat models, a single oral dose of teneligliptin demonstrated a dose-dependent inhibition of plasma DPP-4, with a median effective dose of 0.41 mg/kg, in contrast to sitagliptin and vildagliptin, which required much higher doses of 27.3 and 12.8 mg/kg, respectively. The inhibition of DPP-4 by teneligliptin at a dosage of 10 mg/kg persisted for 24 h after administration, achieving over 50% inhibition. However, such persistence was not observed with sitagliptin or vildagliptin at doses of 100 mg/kg, with both yielding <3%

Table 1: Drug profile of teneligliptin[9]

DRUG	Teneligliptin
IUPAC name	{(2S,4S)-4-[4-(3-Methyl-1-phenyl-1H-pyrazol-5-yl)-1-piperazinyl]-2-pyrrolidinyl} (1,3-thiazolidin-3-yl) methanone
Chemical formula	$C_{22}H_3ON_6OS$
Molecular mass	426.58 g/mol
Melting point	>211°C
Physical state	Solid
Solubility	Soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide
pKa	7.55
t ½	20.8 and 18.9 h
Therapeutic use	They are used to reduce high blood sugar levels in patients with type 2 diabetes mellitus

DMSO: Dimethyl sulfoxide

Table 2: Chemical taxonomy[9]

Description	This compound belongs to the class of organic compounds known as alpha amino acid amides. These are amide derivatives of alpha amino acids.
Kingdom	Organic compounds
Superclass	Organic acids and derivatives
Class	Carboxylic acids and derivatives
Subclass	Amino acids, peptides, and analogs
Direct parent	Alpha-amino acid amides
Alternative parents	N- arylpiperazines/Phenylpyrazoles/ Dialkylarylamines/Pyrrolidinecarboxamides/ N-alkylpiperazines/Benzene and substituted derivatives/Heteroaromatic compounds/ Tertiary carboxylic acid amides/Thiazolidines/ Trialkylamines
Substituents	1,4-diazinane/Alpha-amino acid amide/Amine/ Aromatic heteromonocyclic compound/ Azacycle/Azole/Benzenoid/Carbonyl group/ Carboxamide group/Dialkylarylamine
Molecular framework	Aromatic heteromonocyclic compound
External descriptors	Not available

Table 3: Predicted properties[9]

Property	Value
Water solubility	1.4 mg/mL
logP	1.69
logP	1.42
logS	−2.5
pKa (strongest basic)	9.38
Physiological charge	1
Hydrogen acceptor count	5
Hydrogen donor count	1
Polar surface area	56.64 $Å^2$
Rotatable bond count	4
Refractivity	121.78 $m^3 \cdot mol^{-1}$
Polarizability	46.91 $Å^3$
Number of rings	5
Bioavailability	1
Rule of five	Yes
Ghose filter	Yes
Veber's rule	No
MDDR-like rule	No

and 15% inhibition, respectively. Teneligliptin's impact in an oral mixed meal tolerance test demonstrated that a dosage of 0.1 mg/kg produced near-maximum effects in reducing glucose excursion and increasing active GLP-1/insulin levels. Plasma DPP-4 inhibition remained above 40% throughout the entire duration of the oral mixed meal tolerance test, indicating that a 40% inhibition of DPP-4 was necessary for optimal efficacy. In the context of hyperglycemia and hypertriglyceridemia evaluation in Zucker fatty rats, a single dose of 1 mg/kg teneligliptin resulted in reduced PPG levels, as well as diminished excursions in free fatty acids and triglycerides following carbohydrate and fat intake. Following 2 weeks of repeated teneligliptin administration, glucose excursions after carbohydrate consumption were reduced, and non-fasting levels of free fatty acids and triglycerides showed a similar decrease.

PK PROPERTIES

The PKs of teneligliptin were examined across three sets of subjects, each consisting of eight individuals. These groups were categorized based on their level of hepatic impairment, with two groups having a chronic hepatic impairment (lasting over 6 months) characterized as either mild (Child–Pugh score 5–6) or moderate (Child–Pugh score 7–9), while the third group comprised of healthy subjects matched for

Table 4: Pharmacokinetic profile of teneligliptin in healthy Japanese subjects[10]

Category	Day	Dose (mg/day)	*n*	t_{max} (h)[a]	C_{max} (ng/mL)[b]	AUC_{∞} (ng·h/mL)[b]	$t_{½}$ (h)[b]
Single-dose	1	20	6	1.8 (1.0, 2.0)	187.20 (44.70)	2028.9 (459.5)	24.2 (5.0)
	1	40	6	1.0 (0.5, 3.0)	382.40 (89.83)	3705.1 (787.0)	20.8 (3.2)
Multiple-dose	1	20	7	1.0 (0.4, 2.0)	160.60 (47.26)	1627.9 (427.8)	25.8 (4.9)
	7	20	7	1.0 (1.0, 1.0)	220.14 (59.86)	2641.4 (594.7)	30.2 (6.9)

Table 5: Available marketed formulations of teneligliptin

S. No.	Name	Dosage form	Strength	Route	Manufacturer
1.	Victoza	Injection	6 mg/ml	Subcutaneous	Novo Nordisk
2.	Empagliflozin	Tablet	25 mg	Oral	Boehringer Ingelheim
3.	Lantus	Injection	100 IU/mL	Subcutaneous	Sanofi
4.	Humalog	Injection	100 U/mL	Subcutaneous	Lilly
5.	Janumet	Tablet	50 mg/500mg	Oral	MSD
6.	Forxiga	Tablet	10 mg	Oral	Astra Zeneca
7.	Januvia	Tablet	25 mg/50 mg/100 mg	Oral	Sun Pharma
8.	Levemir Flexpen	Injection	100 U/mL	Subcutaneous	Novo Nordisk
9.	Onglyza	Tablet	2.5 mg	Oral	Chemo Biological
10.	Amaryl	Tablet	4 mg	Oral	Sanofi
11.	Tradjenta	Tablet	5 mg	Oral	Lilly
12.	Glucotrol	Tablet	5 mg	Oral	USV Ltd
13.	Actos	Tablet	15 mg/30 mg	Oral	Mankind Pharma Ltd

comparison. The details of PK profile and Available marketed formulations of teneligliptin were shown in Tables 4 and 5.

Absorption

Oral administration of teneligliptin (0.1, 0.3, or 1.0 mg/kg) in rats showed rapid absorption, with mean peak plasma concentration (tmax) reached in 0.75–0.88 h.

Distribution

After oral administration of [14C] teneligliptin to Sprague–Dawley rats, teneligliptin was predominantly distributed in the kidney and liver, followed by the lung, spleen, and pituitary gland. It was reported that tissue DPP-4 activity was greatest in the kidney, followed by the lung, adrenal gland, jejunum, and liver.

Metabolism

The mass balance study conducted using teneligliptin revealed that this compound undergoes both metabolism and renal excretion, collectively accounting for its total body clearance. Metabolism and renal excretion contributed to 65.6% and 34.4%, respectively, of the overall clearance of teneligliptin. Notably, in plasma, teneligliptin emerged as the predominant radioactive component, comprising 71.1% of the total, while the most abundant metabolite detected in plasma was a thiazolidine-1-oxide derivative, designated as M1, constituting 14.7% of the components. The principal enzymes responsible for the metabolism of teneligliptin are cytochrome P450 (CYP) 3A4 and flavin-containing monooxygenase 3, with both enzymes making equal contributions to the process.

Elimination

The elimination of [14C] teneligliptin from tissues with high DPP-4 activity (kidney, liver, and lung) was slower in wild-type fisher rats than in DPP-4-deficient rats, although there was no marked difference in low DPP-4 activity tissues (the heart and pancreas).

Table 6: List of analytical methods available for teneligliptin estimation[13-41]

S. No.	Parameters		Results	
		Method: UV		
1.	System	A double-beam UV spectrophotometer (UV-1800, Shimadzu, Japan)	Linearity	1–30 µg/mL
			Wavelength	245 nm
			%RSD	1.10
2.	System	Shimadzu UV 1800, Corporation Japan	Linearity	2–12 µg/mL
			R^2	0.9992
			λmax	248 nm
	Mobile phase	Methanol: Water	LOD	5.88 µg/mL
			LOQ	17.29 µg/mL
			%RSD	0.986
3.	System	UV-Visible spectrophotometer (Shimadzu UV-1700)	Linearity	5-25 µg/mL
			R^2	0.9929
	Solvent	Methanol	%RSD	100.55
4.	System	Shimadzu 1800 double beam UV-VIS spectrophotometer (Japan)	Linearity	I. 5–70 µg/mL II. 5–80 µg/mL III. 5–70 µg/mL
			Wavelength	I. 244 nm II. 266.4 nm III. 238.6–247.8 nm
	Solvent	Distilled water	R^2	0.999
			%RSD	≤2
		HPTLC		
1.	Stationary phase	Pre-coated silica gel G60 F254 aluminum sheets 10×10 cm^2 thickness of 0.2 mm	Linearity	4–28 µg/mL
	Mobile phase	Methanol: ammonium sulfate (0.5%w/v):triethylamine (9:2.7:0.5v/v/v)	R^2	0.993
	Detection wavelength	237 nm	LOD	0.3
			LOQ	3
			%RSD	<2%
			Rf	0.63
2.	Stationary phase	Precoated silica gel aluminum plate 60F254 (20 cm×10 cm with 0.2 mm thickness)	Linearity	500–3000 ng/band
	Mobile phase	Methanol: toluene: trimethylamine (1:3:1% v/v)	R^2	0.998
	Detection wavelength	245 nm	LOD	67.46 ng/band
	Rf	0.63	LOQ	204.42 ng/band
			%RSD	<2%
3.	System	HPTLC system (Camag, Switzerland)	Linearity	250–1250 ng/band
	Stationary phase	Pre-coated with silica gel 60 F254 aluminum plate	R^2	0.998
	Mobile phase	Butanol: water: glacial acetic acid (6:2:2 v/v/v)	LOD	60.50 ng/band
	Detection wavelength	245 nm	LOQ	183.36 ng/band
	Rf	0.65	%RSD	0.65–1.72%
		Method: HPLC		
1.	System	Shimadzu LC-20AT system	Linearity	16–64 µg/mL
	Column	C18 Inertsil ODS (150×4.6) mm, 5µ	R^2	1
	Mobile phase	Buffer: CAN (85:15% v/v) and methanol: CAN (50:50% v/v) gradient	Theoretical plates	2020
	Flow rate	0.8 ml/min	%RSD	<2%
	Injection volume	10 µl	LOD	1.95 µg/mL
	Detection wavelength	249 nm	LOQ	6.4 µg/mL
	Detector	PDA detector		

(Contd...)

Table 6: *(Continued)*

S. No.	Parameters		Results	
2.	System	Waters HPLC 2695 system equipped with quaternary pumps	Linearity	1.25–7.5 µg/mL
	Column	Kromasil C18 (4.6×150 mm, 5 µm)	R^2	0.99
			Retention time	2.994 min
	Mobile phase	Acetonitrile: KH2PO4 (65:35)	LOD	0.03
	Flow rate	1 mL/min		
	Column temperature	30°C	LOQ	0.09
	Detector wavelength	228 nm		
	Injection volume	10 µL	%RSD	<2%
	Run time	6.0 min		
3.	System	UV-VIS detector Shimadzu SPD-20A VP	Linearity	1.25–7.5 g/mL
	Column	C18 (250 mm×4.6 mm, 5 µm)	R^2	0.9998
	Mobile phase	Methanol: Phosphate buffer (pH 3) (70:30)	Retention time	3.4 min
	Flow rate	1 ml/min	LOD	0.34
	Detection wavelength	235 nm	LOQ	1.04
			%RSD	1.653389
4.	System	Agilent high-performance liquid chromatographic system (1200 series, Agilent Technologies, Waldbronn, Germany)	Linearity	2–60 µg/mL
	Column	C18 HPLC Column, Zorbax C18 (100mm×4.6 mm, i.d., particle size 5 µm)	R^2	0.9989
	Mobile phase	58%:42% (v/v) acetonitrile: 20 mM phosphate buffer	Retention time	1.65 min
	Flow rate	1.2 mL/min	Theoretical plates	5855.7
	Detector wavelength	Diode array detector 210 nm	LOD	0.56
	Injection volume	20 µL	LOQ	1.64
	Temperature	25°C	%RSD	1.15
5.	System	Young Lin HPLC system	Linearity	500–3000 µg/mL
	Column	Grace Smart C18 (250×4.6 mm, 5 µm)	R^2	0.9942
	Mobile phase	0.05 M Potassium dihydrogen phosphate PH 4.0 and Acetonitrile (80:20% v/v)	Theoretical plates	7701
	Detector wavelength	PDA detector 242	LOD	9.539 µg/mL
	Flow rate	1.0 mL/min	LOQ	59.210 µg/mL
	Injection volume	20 µl	%RSD	0.2852
6.	Stationary phase	C8 (250 mm×4.6 mm)		
	Mobile phase	Methanol and 5 mm potassium phosphate buffer (60:40 v/v)		
	Wavelength	244 nm		
	Flow rate	1 ml/min		
7.	System	Shimadzu LC2010	Linearity	10–50 µg/mL
	Column	Inersil C18 (250 mm×4.61D, 5 µm)		
	Mobile phase	Methanol: Water (90:10)	R^2	0.999
	PH	03		
	Detection wavelength	248 nm	LOD	0.956
	Flow rate	0.8 ml/min	LOQ	0.171
	Temperature	Room temperature	%RSD	<2%
	Run time	30 min		

(Contd...)

Table 6: *(Continued)*

S. No.	Parameters		Results	
8.	Column	Grace C18 (250 mm×4.6ID, Particle size: 5micron)	Linearity	10–50 µg/mL
	Mobile phase	Methanol: 0.05%OPA (20:80)		
	Flow rate	0.8 ml/min	R^2	0.999
	Injection volume	20 µl	LOD	0.616 µg/mL
	Pump mode	Isocratic	LOQ	1.866 µg/mL
	Detector	UV VIS		
	Wavelength	249 nm	% RSD	<2.0%
	Column temperature	25°C		
	Run time	10 min	Retention time	5.255 min
9.	System	HPLC system	Linearity	80–120 µg/mL
	Column	Kromasil 100-5-C18	R^2	0.9972
	Mobile phase	Ph 5.5 phosphate buffer and methanol (75:25 v/v)	Retention time	2.51 min
	Flow rate	1.2 mL/min	%RSD	≤2%
	Run time	11.5 min		
	Injection volume	20 µL		
	Detection wavelength	270 nm		
10.	System	Waters HPLC 2695	Linearity range	5–30 µg/mL
	Column	Kromasil C18 column (250×4.6 mm, 5 µm)	Retention time	2.842 min
	Column temperature	30°C	Run time	6 min
	Mobile phase	Buffer: acetonitrile: methanol (65:25:10, v/v/v)	LOD	0.02 µg/mL
	Flow rate	1 mL/min	LOQ	0.07 µg/mL
	Detection wavelength	254 nm	%RSD	≤2
	Inj. volume	10 µL		
11.	System	HPLC system (cyberlab LC-UV 100)	Linearity range	50–150 µg/mL
	Column	Kromasil C18 column (150 mm×4.6 mm, 5µ)		
	Column temperature	40°C	Retention time	11.2 min
	Mobile phase	A) acetonitrile, water, and trifluoroacetic acid B) acetonitrile and trifluoroacetic acid		
	Flow rate	1.0 mL/min		
	Detection wavelength	245 nm	Run time	55 min
	Detector	UV	%RSD	0.42%
	Injection volume	10 µl		
12.	System	HPLC-DAD system (Shimadzu corporation, prominence Modular UFLC, Kyoto, Japan)	Linearity range	50–350 µg/mL
	Column	Waters Reliant (250 mm×4.6 mm, 5 µm particle size)		
	Column temperature	25°C	R^2	0.9996
	Mobile phase	Acetonitrile and water (6:4, v/v)		
	Flow rate		LOD	7.7953 µg/mL
	Detection wavelength	230 nm		
	Detector	Photo-diode array	LOQ	23.6222 µg/mL
	Inj. volume	20 µl		
13.	System	HPLC-3000 series compact liquid chromatographic system	Linearity range	10–50 µg/mL
	Column	Cosmosil C18 (250 mm×4.6ID. Particle size: 5 µm)	R^2	0.9968
	Mobile phase	70:30 (Methanol: Phosphate buffer pH-3)	LOD	0.109 µg/mL
	Flow rate	0.8 mL/min	LOQ	0.3305 µg/mL
	Wavelength	246 nm	No. of Theoretical plates	9520
	Inj. volume	20 µL	Tailing factor	1.15
	Detector	UV-3000-M		

(Contd...)

Table 6: *(Continued)*

S. No.	Parameters		Results	
14.	System	Shimadzu HPLC system	Linearity	10-50 µg/mL
	Column	ACE C_{18} (150×4.6 µ)	R^2	0.9993
	Mobile phase	Methanol: Phosphate buffer (70:30)	Retention time	5.7 min
	Flow rate	1.0 mL/min	Theoretical plates	26486
	Injection volume	20 µL	%RSD	0.49
	Detection wavelength	245 nm		
15.	System	WATERS HPLC system	Linearity	7.20–490 ng/mL
	Column	Thermo C18 column (250×4.6 mm, 5 µm)	R^2	0.999
	Mobile phase	Methanol and 5 mm potassium hydrogen phosphate 60:40 v/v	Retention time	3.9 min
	Run time	7 min	LLOQ	7.200 ng/mL
	Flow rate	1 mL/min	LQC	18.000 ng/mL
	Injection volume	20 µl	MQC	211.680 ng/mL
	Column temperature	25°C	HQC	376.000 ng/mL
	Detector	PDA detector		
16.	Column	Protecol C18 ENDURO 250 mm×4.6 mm ID5 µm 120A	Linearity	10–90 µg/mL
	Mobile phase	Methanol: Buffer (72:28) v/v		
	Pump mode	Isocratic	R^2	0.998
	pH of water	pH 3.5		
	Diluent	0.1 N HCL	Retention time	5.8 min
	Temp	Ambient	LOD	0.023 µg/mL
	Wavelength	243.5nm	LOQ	0.071 µg/mL
	Injection volume	20 µL		
	Flow rate	1.0 mL/min	%RSD	<2%
	Run time	12 min		
17.	System	Shimadzu HPLC system	Linearity	2.5-7.5 µg/mL
	Column	C18 column (Hypersil BDS C18 column, 250 mm×4.6 mm)	R^2	0.998
	Mobile phase	Water: Acetonitrile (90:105V/V)	Retention time	3.010 min
	Flow rate	1 ml/min	LOD	0.206 µg/mL
	Injection volume	20 µL	LOQ	0.627 µg/mL
	Detection wavelength	UV detection 247.5 nm	%RSD	<2%
18.	System	WATERS alliance 2695 separation module	Linearity	5–25 mg/mL
	Colum	X – Terra C18 (4.6×150 mm, 5 µm)	R^2	
	Mobile phase	Methanol: TEA Buffer pH 4.5:Acetonitrile (65:15:20)	Retention time	2.090 min
	Flow rate	1.0 ml/min	Theoretical plates	5463
	Wavelength	243 nm	LOD	0.9 µg/mL
	Detector	996 PDA detector	LOQ	2.0 µg/mL
			%RSD	<2.0%
19.	System	Shimadzu UV-1800	Linearity	5–15 µg/mL
	Column	Phenomenex luna ODS C18 (250×4.6 mm, 5 µm)	R^2	0.9972
	Mobile phase	0.025M K2HPO4 buffer (pH-3.0)(OPA):CAN (75:25 v/v)	Retention time	6.033 min
	Flow rate	1 mL/min	Theoretical plates	8398
	Column temperature	25°C	LOD	0.771 µg/mL
	Detection wavelength	238 nm	LOQ	2.336 µg/mL
	Injection volume	20 µL	%RSD	<2%
	Run time	10 min		

(Contd...)

Table 6: *(Continued)*

S. No.	Parameters		Results	
20.	System	Waters HPLC 2695	Linearity	5–30 µg/mL
	Column	Discovery (250 mm×4.6 mm, 5 µm is particle size)	R^2	0.9991
	Mobile phase	0.1% orthophosphoric acid buffer: acetonitrile (65:35 v/v)	Retention time	3.687 min
	Diluent	Water: Acetonitrile	Theoretical plates	6734
	Detector	PDA	LOD	0.19 µg/mL
	Column temperature	30°A	LOQ	0.56 µg/mL
	Detection wavelength	260 nm	%RSD	<2%
	Injection volume	10 µl		
	Flow rate	1 ml/min		
	Run time	6 min		
21.	System	HPLC system	Linearity	100–500 µg/mL
	Column	Kromasil 100-5C18 (250×4.6 mm, 5 µm)	R^2	0.99
	Mobile phase	pH 6.0 phosphoric buffer and acetonitrile (60:40 v/v)	LOD	4.04 µg/mL
	Flow rate	1.0 mL/min	LOQ	12.259 µg/mL
	Injection volume	20 µL	%RSD	<2%
	Detection wavelength	246 nm		
		Method: UPLC		
1.	System	Agilent 1290 series	Linearity	20–100 µg/mL
	Column	Zorbax eclipse plus C18 (150×4.6 mm, 5 µm)	R^2	0.999
	Mobile phase	Buffer and acetonitrile (65:35 v/v)	Retention time	2.81
	Flow rate	0.7 mL/min	Theoretical plates	6949
	Injection volume	5 µL	LOD	1.29 µg/mL
	Column temperature	30°C	LOQ	3.93 µg/mL
	Detector wavelength	DAD detector 233 nm	%RSD	<2%
2.	System	Acquity UPLC system	Linearity	100–500 µg/mL
	Column	BEH C18 1.7 µm, 2.1×50 mm	R^2	0.99
	Mobile phase	A. (10% acetonitrile in water with 0.1% formic acid) B. (90% acetonitrile with 0.1% formic acid)	LOD	4.04 µg/mL
	Flow rate	0.3 mL/min	LOQ	12.259 µg/mL
	Column temp.	25°C	%RSD	<2%
	Detector	Photodiode array detector 200-400 nm		
		Method: UFLC		
1.	System	UFLC system	Linearity	1–100 µg/mL
	Column	C8 (Phenomenex) column (250 mm×4.6 mm i.d., 5 µm particle size)		
	Mobile phase	Formic acid: methanol: acetic acid (25:75:0.1, v/v)	R^2	0.9999
	Flow rate	0.4 mL/min	Retention time	4.982±0.02 min
	Detection range	245 nm	LOD	0.2598 µg/mL
	Column temp.	25°± 2°C		
	Injection volume	20 µL	LOQ	0.8134 µg/mL
	Detector	SPD M20A prominence photodiode array detector		
	Elution	Isocratic mode	% RSD	0.89–1.06
	Total run time	10 min		

HPLC: High-performance liquid chromatography

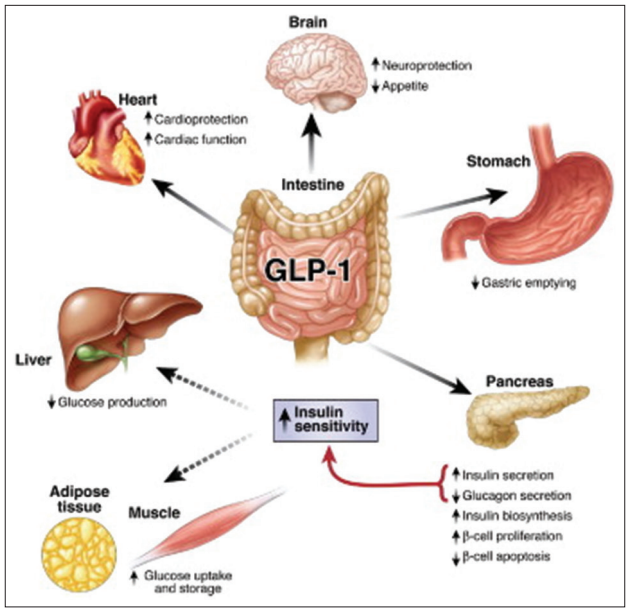

Figure 2: Mechanism of action of teneligliptin[12]

Mechanism of action[11]

Teneligliptin is a third-generation DPP-4 inhibitor approved for treatment of type 2 diabetes. The mechanism of teneligliptin is to increase incretin levels (GLP-1 and GIP), which inhibit glucagon release, which in turn increases secretion, decreases gastric emptying, and decreases blood glucose levels. The mechanism of action of teneligliptin is shown in Figure 2. Based on thorough literature search we have found different analytical methods like UV, HPTLC, HPLC, UPLC, UFLC[13-41] available for the estimation of Teneligliptin in bulk and its pharmaceutical formulations, the study parameters were shown in Table 6.

CONCLUSION

The pharmacological, pharmaceutical, and analytical profile of teneligliptin presents a comprehensive understanding of this important medication in the management of T2DM. From a pharmacological perspective, teneligliptin has shown its efficacy as a DPP-4 inhibitor by effectively improving glycemic control in diabetic patients. Its mechanism of action, which involves increasing the levels of active incretin hormones, leads to enhanced insulin secretion and reduced glucagon release, ultimately resulting in lowered blood glucose levels. Moreover, teneligliptin has demonstrated a favorable safety and tolerability profile in clinical trials, making it a valuable option for patients who require antidiabetic therapy. In the pharmaceutical context, the development and formulation of teneligliptin have evolved to meet various patient needs. Available in different dosage forms, including tablets and combinations with other antidiabetic agents, teneligliptin offers flexibility in treatment regimens. In addition, its PK properties, such as rapid absorption and a relatively short half-life, allow for convenient dosing and improved patient adherence. Analytically, the accurate quantification and quality control of teneligliptin are essential for ensuring its therapeutic effectiveness and safety. Analytical methods, including high-performance liquid chromatography (HPLC) and mass spectrometry, have been developed to assess the drug's purity, stability, and bioavailability. These analytical techniques play a pivotal role in maintaining the high standards of pharmaceutical manufacturing and ensuring that patients receive reliable and consistent dosages of teneligliptin.

CONFLICT OF INTEREST

All the authors have no conflict of interest.

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