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TENELIGLIPTIN: A LITERATURE REVIEW ON ANALYTICAL AND BIO-ANALYTICAL METHODS

Snigdha Rani Behera*, Abhishek Mohapatra, Priyanka Rani Sahu, Tejaswini Mishra, Ch. Gowri Sankar and Kirtimaya Mishra

Department of Pharmaceutical Analysis, Jeypore College of Pharmacy, Jeypore, Odisha.

***Corresponding Author: Snigdha Rani Behera**

Department of Pharmaceutical Analysis, Jeypore College of Pharmacy, Jeypore, Odisha.

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ABSTRACT

This study compiles information from previously published methods for analyzing Teneligliptin, either alone or in combination with other drugs. Many spectroscopic approaches, such as derivative techniques and chromogenic techniques, have been utilized for newly created and enhanced chromatographic procedures, which are also available by employing biological fluids and pharmaceutical formulations. Apart from these two approaches, there are several LC-MS/MS and HPTLC methods available. In today's analytical research scenario, the quality by design or design by expert methodology is utilized to improve method validation. This short review work can assist an analyst in selecting the most appropriate technique for developing and validating the best analytical procedure.

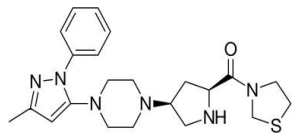
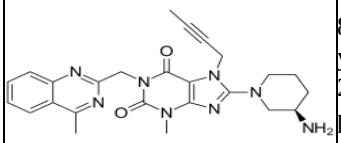
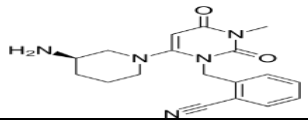
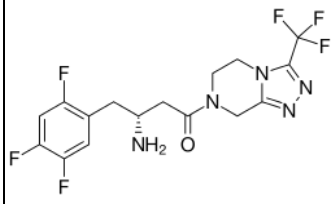
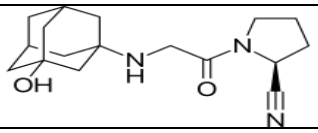
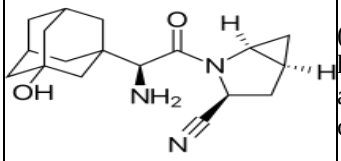
KEYWORDS: Chromogenic, LC-ms/ms, HPTLC, Teneligliptin.

INTRODUCTION

Every day, a revolution in human health is discovered as medications evolve. These medicines will have the optimum action if they are pure and devoid of contaminants. Regularly, different instrumental and chemical procedures for producing impurity-free drugs were developed. Impurities can appear at any phase of the process, from bulk medication production through final product packaging and storage (degradation). The two steps where contaminants are most likely to arise are storage and transportation. As a result, contaminants must be identified and quantified in these conditions. In order to identify and quantify the importance of analytical instruments and techniques cannot be overstated.[1]

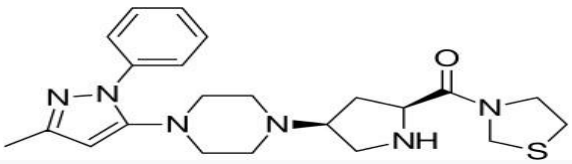
The intermediate pharmaceutical analysis becomes an essential tool for therapeutic process monitoring since it encompasses many phases such as testing of bulk medicines, intermediate products, finished goods, drug formulations, degradation products, chemical stability of drugs, and toxic contents of drug materials. Polypharmacy is now a valuable treatment for many diabetes patients. As a result, testing of combination formulations and analysis of biological samples are crucial for enhancing the quality of polypharmacy therapy. Diabetes is characterized by hyperglycemia due to defects in insulin production, insulin action, or both. Diabetes mellitus was largely acknowledged as IDDM or Type 1 and NIDDM or Type 2 was published by WHO in 1980.[2] DPP-4 inhibitors are the most recent medicines that operate by inhibiting the activity of DPP-4, an enzyme that degrades the hormone in cretin that helps the body generate more insulin only when required and reduces the amount of glucose produced by the liver when it is not needed.[3] The increase in glucagon corresponds linearly with an increase in glucose tolerance. Because these medicines enhance insulin production in response to an increase in blood glucose, it seems natural to combine them with treatments that work in a different way, such as insulin sensitizers or Metformin, it seems appropriate to pair them with drugs that have a different mechanism of action, such as insulin sensitizers or Metformin.[4] During short-term clinical studies, no higher incidence of acute pancreatitis was seen with Sitagliptin, Vildagliptin, Saxagliptin, Alogliptin, or Linagliptin.[5] Linagliptin (Trajenta) remains on the black triangle list, but Sitagliptin (Januvia), Saxagliptin (Onglyza), and Vildagliptin (Galvus) were eliminated in 2012.[6] Saxagliptin, Linagliptin, Alogliptin, Teneligliptin, and Vildagliptin are examples of DPPIV inhibitors (Gliptins). Detail about the gliptin derivatives are given in table no.1.

Table 1: Details of Gliptin Derivatives.

Drug	Structure	IUPAC Name	Molecular weight	Solubility
Teneligliptin		{(2s,4s)-4-[4-(3-Methyl-1-phenyl-1-H pyrazole-5-yl) piperazin-1-yl] pyrrolidin-2-yl} (1,3-thiazolidin-3-yl) methanone hemipentahydrobromide hydrate	426.58 g/mol	Soluble in DMSO, Methanol, Water
Linagliptin		8-[(3R)-3-aminopiperidin-1-yl]-7-(but-2-yn- 1-yl)-3-methyl-1-[(4-methylquinazolin-2-yl) methyl]-2, 3, 6, 7-tetrahydro-1H-purine-2,6-dione	472.54 g/mol	It is very slightly soluble in water, IPA, Acetone, soluble in methanol, sparingly soluble in ethanol
Alogliptin		2-((6-((3R)-3-aminopiperidin-1-yl)-3-methyl-2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)methyl) benzonitrile.	339.39 g/mol	Soluble in Methanol; Insoluble in Acetonitrile
Sitagliptin		(3R)-3-amino-1-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3- a]pyrazin-7(8H)-yl]-4-(2,4,5-trifluorophenyl)butan-1-one phos-phate hydrate	407.314 g/mol	It is soluble in water and N, N-dimethyl formamide; slightly soluble in methanol; very slightly soluble inethanol, acetone, and acetonitrile; and insoluble in isopropanol and isopropyl acetate
Vildagliptin		(2*S*)-1-{2-[(3-hydroxy-1-adamantyl)amino]acetyl}pyrrolidine-2-carbonitrile	303.399 g/mol	Slightly soluble in DMSO, Methanol
Saxagliptin		(1S, 3S, 5S)-2-[(2S)-2-Amino-2-(3-hydroxytricyclo [3.3.1.13, 7] dec-1-yl) acetyl]- 2-azabicyclo [3.1.0] hexane-3-carbonitrile	315.41 g/mol	It is sparingly soluble in water, slightly soluble in ethyl acetate,and soluble in methanol, ethanol, isopropyl alcohol, acetonitrile, acetone

Teneligliptin

From all these gliptin derivatives in this present journal about Teneligliptin is discussed briefly. DPP-4 inhibitors are categorized as peptidomimetic (i.e., Sitagliptin, Vildagliptin, Saxagliptin, and Anagliptin) or non-peptidomimetic (i.e., Alogliptin and Linagliptin). Teneligliptin, {(2S, 4S)-4-[4-(3-methyl-1-phenyl-1H-pyrazole-5-yl) piperazin-1-yl] pyrrolidin-2-yl} (1, 3-thiazolidine-3-yl) methanone hemipentahydrobromide hydrate is distinct, with five uninterrupted rings. (Fig.1). and is peptidomimetic. An X-ray co-crystal structure of Teneligliptin with DPP-4 shows that the main contact occurs between the pyrazole's phenyl ring and the DPP-4's S2 extensive subsite, which not only boosts the drug's potency but also its selectivity.[7] Teneligliptin has been authorized in Korea, Japan, Argentina, and India.



{(2*S*, 4S)-4-[4-(3-Methyl-1-phenyl-1*H*-pyrazol-5-yl)-1-piperazinyl]-2-pyrrolidinyl}(1, 3-thiazolidin-3-yl) methanone

Fig. 1: Chemical structure and IUPAC name of Teneligliptin.

Teneligliptin inhibits human plasma DPP-4 activity and recombinant human DPP-4 activity in a concentration-dependent manner, with half-maximal inhibitory concentrations (IC50) of 1.75 (95% CI, 1.62–1.89) nmol/L and 0.889 (95% CI, 0.812–0.973) nmol/L, respectively, according to the product information provided by the pharmaceutical company. Furthermore,

the IC50 values of teneligliptin for DPP-8, DPP-9, and fibroblast activation protein (FAP) are 0.189, 0.150, and >10 mol/L, respectively, more than 160 times higher than the value for recombinant human DPP-4. For the pharmacokinetic determination of Teneligliptin phosphate in plasma and urine of humans, rats, and dogs, several analytical methods based on RP-HPLC, LC-MS/MS, HPTLC, UV, and RP-UFLC have been reported.[8,9]

This review paper focuses on the analytical technique available for Teneligliptin estimate. The specifics of the previous studies are detailed in Tables II, III, IV, V, VI, and VII.

Table 2: Summary of methods related to HPLC technique.

S. No	Stationary Phase (Column)	Mobile Phase (with ratio)	pH	Wavelength	Flow rate	Reference
TENELIGLIPTIN with METFORMIN						
1	C8(250mm x4.6 mm)	Methanol : water 0.05 % OPA 50:50 (v/v)	=	235nm	0.7ml/min	[10]
2	C8(250mm x4.6 mm)	Methanol: Phosphate buffer 70:30 (v/v)	03	246nm	4.2ml/min	[11]
3	C8(250mm x4.6 mm)	Buffer: Acetonitrile: Methanol 65:25:10 (v/v/v)	=	254 nm	1 ml/min	[12]
4	C8(250mm x4.6 mm)	Water: Methanol 50:50 (v/v)	03	240 nm	1 ml/min	[13]
5	C8(250mm x4.6 mm)	Methanol: water 0.05 % OPA 50:50 (v/v)	=	241 nm	1 ml/min	[14]
6	C8(250mm x4.6 mm)	1% Orthophosphoric acid buffer: Acetonitrile 65:35 (v/v)	=	260 nm	1 ml/min	[15]
6	C8(250mm x4.6 mm)	Methanol: Water 50:50 (v/v)	3.5	242nm	0.7ml/min	[16]
7	C8(250mm x4.6 mm)	Methanol: Phosphate Buffer with NaOH 70:30 (v/v)	7.2	244 nm	1 ml/min	[17]
8	C8(250mm x4.6 mm)	Orthophosphoric acid:Methanol 60:40 (v/v)	4	236 nm	1 ml/min	[18]
Sl. No	**Stationary Phase (Column)**	**Mobile Phase (with ratio)**	**pH**	**Wave length**	**Flow rate**	**Reference**
TENELIGLIPTIN AS A SINGLE FORMULATION						
09	C8(250mm x4.6 mm)	Methanol : Phosphate Buffer 60:40 (v/v)	3.0	246nm	0.7ml/min	[19]
10	C8(250mm x4.6 mm)	Methanol : Phosphate Buffer 70:30 (v/v)	3.0	246nm	0.8ml/min	[20]
11	C18 (150 cm X 4.6 mm)	a) Acetonitrile: Water: Trifluoroacetic Acid 60: 1940: 2) v/v b) Acetonitrile: Trifluoroacetic Acid (2000: 2) v/v	=	245nm	1ml/min	[21]
12	C8(250mm x4.6 mm)	Acetonitrile:Methanol: Water (30:40: 30 v/v/v)	=	246nm	1ml/min	[22]
13	C8(250mm x4.6 mm)	Methanol: Buffer (72:28 v/v)	3.5	243.5 nm	1ml/min	[23]

Table 3: Summary of methods related to HPLC technique with plasma.

Sl. No	Stationary Phase (Column)	Mobile Phase (with ratio)	pH	Wavelength	Flow rate	Reference
TENELIGLIPTIN AS A SINGLE FORMULATION						
14	C8(250mm x4.6 mm)	Methanol and 5mm Potassium phosphate Buffer (60:40 v/v)	=	244 nm.	1ml/min	[24]

Table 4: Summary of methods related to LC-MS/MS technique with plasma

Sl. No	Stationary Phase (Column)	Mobile Phase (with ratio)	Detector	Flow rate	Reference
15	C 18 column (50mm×3.0 mm)	1. 0.1% Formic acid in Milli-Q water 2. 0.1% Formic acid in Acetonitrile	Electrospray ionization	0.5ml/min	[25]

Table 5: Summary of methods related to HPTLC technique

Sl. No	Stationary Phase (Column)	Mobile Phase (with ratio)	Wavelength	Development chamber	Reference
16	Aluminum plate precoated with silica gel 60 f 254	Toluene: Methanol: GAA: TEA (5:4:0.5:0.5, v/v/v)	257 nm	Twin trough chamber with stain- steel lid	[26]
17	silica gel G60 F254 aluminum sheets 10×10 cm 2	Methanol: Ammonium sulfate : Triethylamine (9: 2.7: 0.5 v/v/v).	237 nm	Camang Twin Trough chamber	[27]
18	Aluminum plate precoated with silica gel 60 f 254	Methanol: Toluene: Triethylamine (1:3:1, v/v)	245 nm	Twin through glass chamber with steel lid	[28]

Table 6: Summary of Analysis of Teneligliptin by UV-Spectroscopic method.

Sl. No	Drug	Method	Description	Reference
19	Estimation of Teneligliptin	UV-VIS spectroscopic Method	Detection wavelength: 244nm nm Linearity range: 5-70 µg/ml Co-relation Co-efficient: 0.999 Recovery range: 99.45- 100.26% % RSD: ≤ 2%	[29]
20	Estimation of Teneligliptin	UV-VIS spectroscopic Method	Detection wavelength: 243.6nm Linearity range: 10- 50µg/ml Co-relation Co-efficient: 0.9991 Recovery range: 99-102% RSD: ≤ 2%	[30]
21	Estimation of Teneligliptin hydrobromide hydrate and Metformin hydrochloride	UV spectroscopic methods by simultaneous equation	Detection wavelength: 237nm for Teneligliptin and 246 nm for Metformin Linearity range: 1-20 µg/m for Teneligliptin & Metformin Co-relation Co-efficient: 0.9996 for Teneligliptin and 0.9993 for Metformin Recovery range: 98.75 % - 98.96% RSD: ≤ 2%	[31]
22	Estimation of Teneligliptin	UV-VIS spectroscopic Method	Detection wavelength:267.2nm Linearity range: 20-100µg/ml Co-relation Co-efficient: 0.999 Recovery range: 102-104%% % RSD: ≤ 2%	[32]
23	Estimation of Teneligliptin	UV-VIS spectroscopic Method	Detection wavelength: 242nm Linearity range: 05-25µg/ml Co-relation Co-efficient: 0.999 Recovery range: 98.2-102%% % RSD: ≤ 2%	[33]

Table 7: Summary of Analysis of Teneligliptin by RP-UFLC method.

S. No	Stationary Phase (Column)	Mobile Phase (with ratio)	pH	Wavelength	Flow rate	Reference
TENELIGLIPTIN						
24	C8(250mm x4.6 mm)	Methanol : Acetonitrile (60:40 v/v)	=	246 nm	1mL/min	[34]
25	C18 (250 mm × 4.6 mm)	Methanol: acetonitrile: potassium dihydrogen orthophosphate (40:20:40 v/v/v)	4.6	246 nm	1.0 ml/min	[35]

Quality By Design

Currently, the Quality by Design methodology is frequently utilized to improve analytical methods. Quality by design (QBD) which is discussed in ICH Q8, Q9, and Q2 is well established for the development and manufacture of pharmaceuticals.[36]

Benefits Of Quality By Design Method

It assists in the development of a robust technique. Sources of variability can be better managed according to the design configuration. Method transfer success is increased when a method is moved from the research level to the quality control department. This approach

allows for the development of new procedures through continual improvement throughout the lifespan.[37]

CONCLUSION

This review summarizes the known Spectrophotometric and Chromatographic techniques for Teneligliptin estimation that have been developed and verified. According to this review, it was concluded that for Teneligliptin different Spectroscopic & Chromatographic methods are available for a single component as well as for combination and It was also discovered that the mobile phase containing phosphate buffer, methanol, and acetonitrile were common for most of the chromatographic method to provide more resolution. It was observed that the most common combination of Teneligliptin with Metformin (ex. TOTAGLIPT M, TENEBITE-M). For the chromatographic method, the flow rate is observed in the range of 0.5- 4.2 ml/min to get a good retention time. For most of the Spectroscopic methods, the common solventis Methanol. Hence this all methods were found to be simple, accurate, economic, precise, and reproducible in nature. However, it is evident from this analysis that existing approaches may be enhanced by employing the Design of Expert (DOE) process, which produces more accurate and unambiguous results.

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Data Availability

Not declared.

Conflict of Interest

The authors affirm that they have no conflict of interest.

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