



ESTIMATION OF SAXAGLIPTIN IN PHARMACEUTICALS-A REVIEW

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ABSTRACT

An oral diabetes medicine Saxagliptin helps to control blood sugar levels for the people suffering with type 2 diabetes mellitus alone or with combination. This review discusses the analytical methods documented so far in the literature for the estimation of Saxagliptin in bulk drug and in different formulations. The primary objective of this review is to provide a brief overview of Saxagliptin to researchers on solvents, mobile phases, stationary phases, linearity range, flow rates, retention times and retardation factor by various analytical methods such as spectrophotometric, chromatographic.

Keywords: Saxagliptin, Dapagliflozin, Metformin, chromatography, flow rate, retention time

INTRODUCTION:

Type 2 diabetes mellitus (T2DM) is a chronic progressive metabolic disorder characterized by absolute or relative insulin deficiency [1]. Saxagliptin (SAXA), chemically, known as (1s, 3s,5s)-2-[(2s)-2-amino-2-(3-hydroxy 1-tricyclo[3.3.1.1]dec-1-yl)acetyl]-2-azabicyclo[3.1.0] hexane-3-carbonitrile, is a potent, selective, long-acting, and reversible inhibitor of the enzyme dipeptidyl peptidase 4 (DPP-4) used for treatment of type 2 diabetes mellitus. It is used as monotherapy or in

combination with other drugs [2]. Chemical formula and molecular weight of Saxagliptin is $C_{18}H_{25}N_3O_2$, 315.41 g/mol (**Figure 1**). Saxagliptin is extensively metabolized by hydroxylation and oxidation via liver CYP₄₅₀ enzymatic system [3]. DPP-4 inhibitors enhance the body's own ability to control blood glucose by increasing the active levels of incretin hormones in the body. Their mechanism of action is distinct from any existing class of oral glucose-lowering agents. They control

elevated blood glucose by triggering pancreatic insulin secretion, suppressing pancreatic glucagon secretion, and signalling the liver to reduce glucose production [4]. Due to its therapeutic importance, quantitative determination of Saxagliptin in pharmaceuticals has considerable significance in quality control. Methods developed to determine Saxagliptin in active pharmaceutical ingredient, dosage forms are reviewed in the present article.

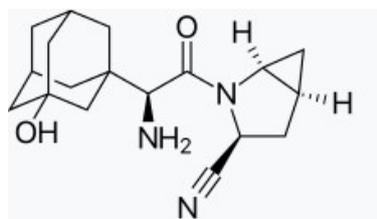


Figure 1:
Saxagliptin

METHODS FOR ESTIMATION

UV Spectrophotometric methods

Various UV spectrophotometric methods for Saxagliptin single and combination with other drugs are developed and are listed in the (Table 1).

Chromatographic methods:

Various chromatographic methods like HPLC, HPTLC, ion chromatography GC, UPLC, was developed for estimation of Saxagliptin in single and combination with other drugs. Methods for estimation of HPLC and HPTLC are listed in the (Table 2, 3).

Table 1: Methods for estimation of Saxagliptin single and combination with other drugs by UV Spectrophotometry

S. No.	Drugs	Application	Description	Reference
1.	Saxagliptin	In pure and from tablet formulation	Detection wave length: 208 nm Solvent: Methanol Linearity range: 5-40 µg/ml	[5]
2.	Saxagliptin	In bulk and pharmaceutical preparation	Reagents: DDQ, TCNQ DDQ: 2,3-dichloro-5,6-dicyano-1,4-benzoquinone TCNQ: 7,7,8,8-tetracyanoquinodimethane Wave length: DDQ: 461 nm TCNQ: 838 nm Solvent: Methanol Linearity range: DDQ: 50-300 µg/ml TCNQ: 10-110 µg/ml	[6]
3.	Saxagliptin hydrochloride and Metformin hydrochloride	Active pharmaceutical ingredient	Wavelength: Saxagliptin: 274 nm Metformin: 231 nm Solvent: Water Linearity range: Saxagliptin: 50-90 µg/ml Metformin: 02-10 µg/ml	[7]
4.	Saxagliptin and Methyldopa	API mixture	Wavelength: Saxagliptin: 211 nm Methyldopa: 280 nm Solvent: Water Linearity range: Saxagliptin: 05-30 µg/ml Methyldopa: 02-12 µg/ml	[8]
5.	Saxagliptin hydrochloride and Dapagliflozin propendiol	Combined dosage form	Wavelength: Saxagliptin: 214-220 nm Dapagliflozin: 208-209 nm Solvent: Methanol Linearity range: Saxagliptin: 4-16 µg/ml	[9]

			Dapagliflozin: 10-22 µg/ml	
6.	Dapagliflozin and Saxagliptin	Synthetic mixture	Wavelength: Saxagliptin: 212 nm Dapagliflozin: 223 nm Solvent: Water: Methanol (80:20) Linearity range: Saxagliptin: 5-50 µg/ml Dapagliflozin: 4-24 µg/ml	[10]

Table 2: Methods for estimation of Saxagliptin single and combination with other drugs by HPLC

7.	Saxagliptin hydrochloride and Metformin hydrochloride	Active pharmaceutical ingredient	Detection wavelength: 240 nm Mobile phase: 0.02 M Potassium dihydrogen phosphate: Methanol: Acetonitrile = 50:25:25 v/v/v Column: Phenomenex C ₁₈ Flow rate: 1ml/min Linearity range: Saxagliptin: 10-50 µg/ml Metformin: 5-25 µg/ml Retention time: Saxagliptin: 4.85 min Metformin: 7.43 min	[11]
8.	Saxagliptin hydrochloride and Metformin hydrochloride	In bulk and pharmaceutical dosage form	Detection wavelength: 248 nm Mobile phase: Phosphate buffer: Acetonitrile = 94:6 v/v Column: Zodiac C ₁₈ Flow rate: 1.0 ml/min Linearity range: Saxagliptin: 0.125-0.75 µg/ml Metformin: 12.5-75 µg/ml Retention time: Saxagliptin: 4.1 min Metformin: 1.6 min	[12]
9.	Saxagliptin and Pioglitazone	Tablets	Detection wavelength: 260 nm Mobile phase: Acetonitrile: Phosphate buffer = 60:40 v/v Column: Inertsil C ₁₈ Flow rate: 0.8 ml/min Linearity range: Saxagliptin: 20-80 µg/ml Pioglitazone: 10-70 µg/ml Retention time: Saxagliptin: 2.48 Pioglitazone: 4.45 min	[13]
10.	Saxagliptin	Tablet dosage form	Detection wavelength: 220 nm Mobile phase: Acetonitrile: Potassium dihydrogen phosphate = 30:70 v/v Column: Hypersil C ₁₈ Flow rate: 1 ml/min Linearity range: 50-150 µg/ml Retention time: 3.487 min	[14]
11.	Saxagliptin and Metformin	Bulk	Detection wavelength: 225 nm Mobile phase: Methanol: Phosphate buffer = 50:50 v/v Column: Agilent C ₁₈ Flow rate: 1ml/min Linearity range: Saxagliptin: 5-125 µg/ml Metformin: 2.5-62.5 µg/ml Retention time: Saxagliptin: 5.83 Metformin: 3.47 min	[15]
12.	Saxagliptin	Bulk drug and pharmaceutical dosage form	Detection wavelength: 210 nm Mobile phase: Sodium dihydrogen phosphate: Acetonitrile Column: Inertsil C ₈ Flow rate: 1.2 ml/min Linearity range: 50-375 µg/ml Retention time: 7.68 min	[16]

13.	Saxagliptin and Metformin	Tablet dosage form	Detection wavelength: 242 nm Mobile phase: Phosphate buffer: Acetonitrile = 60:40 v/v Column: Phenomenex C ₁₈ Flow rate: 0.7 ml/min Linearity range: Saxagliptin: 1-6 µg/ml Metformin: 100-600 µg/ml Retention times: Saxagliptin: 2.9 Metformin: 1.7 min	[17]
14.	Saxagliptin and Metformin	In API and marketed formulation	Detection wavelength: 220 nm Mobile phase: 0.05 M Potassium dihydrogen phosphate: Methanol: Acetonitrile = 60:20:20 v/v/v Column: Enable C ₁₈ Flow rate: 0.6 ml/min Retention time: Saxagliptin: 6.92 Metformin: 4.38 min	[18]
15.	Saxagliptin	Pharmaceutical dosage form	Detection wavelength: 225 nm Mobile phase: 0.1% phosphoric acid: methanol = 70:30 v/v Column: Waters C ₁₈ Flow rate: 1 ml/min Linearity range: 15-100 µg/ml Retention time: 8 min	[19]
16.	Saxagliptin, Sitagliptin and Metformin	Pharmaceutical dosage form	Detection Wavelength: 215 nm Mobile phase: Potassium dihydrogen phosphate: Methanol: Acetonitrile = 70:10:20 v/v/v Column: Inertsil C ₁₈ Flow rate: 1 ml/min Retention time: 8 min	[20]
17.	Saxagliptin	Bulk and tablet dosage form	Detection wavelength: 210 nm Mobile phase: Phosphate buffer: Acetonitrile = 80:20 v/v Column: ODS C ₁₈ Flow rate: 1 ml/min Linearity range: 0.1-0.3 ng/ml Retention time: 5.43 min	[21]
18.	Saxagliptin, and Metformin	In bulk and Pharmaceutical dosage form	Detection wavelength: 242 nm Mobile phase: Sodium dihydrogen phosphate: Methanol = 80:20 v/v Column: Kromasil C ₁₈ Flow rate: 0.9 ml/min Linearity range: Saxagliptin: 0.5-3 µg/ml Metformin: 50-300 µg/ml Retention time: Saxagliptin: 2.25 Metformin: 3.157 min	[22]
19.	Saxagliptin	Formulated forms	Detection wavelength: 211 nm Mobile phase: Acetonitrile: Water = 20:80 v/v Column: Agilent C ₁₈ Column temperature: 18 ^o c Flow rate: 1 ml/min Linearity range: 10-90 µg/ml	[23]

20.	Saxagliptin hydrochloride and Metformin hydrochloride	Binary mixture	<p>Method 1 Detection wavelength: 220 nm Mobile phase: Phosphate buffer: Acetonitrile = 87:13 v/v Column: Kinetex C₁₈ Flow rate: 1.5 ml/min</p> <p>Method 2 Wavelength: 210 nm Mobile phase: Chloroform: Methanol: Formic acid = 80:20:0.3 Stationary phase: Silica gel aluminium plates</p>	[24]
21.	Saxagliptin hydrochloride and Dapagliflozin	Tablet dosage form	<p>Detection wavelength: 220 nm Mobile phase: Potassium dihydrogen phosphate: Acetonitrile = 45:55 v/v Column: Inertsil ODS C₁₈ Flow rate: 1.5 ml/min Retention time: Saxagliptin: 2.78 Dapagliflozin: 4.4 min</p>	[25]
22.	Saxagliptin and Pioglitazone	Tablet dosage form	<p>Detection wavelength: 272 nm Mobile phase: Potassium dihydrogen phosphate: Methanol = 80:20 v/v Column: Phenomenex C₁₈ Flow rate: 1 ml/min Linearity range: 40 µg/ml Retention time: Saxagliptin: 2.99 Pioglitazone: 4.31 min</p>	[26]
23.	Saxagliptin and Dapagliflozin	In bulk and combined tablet dosage forms	<p>Detection wavelength: 247 nm Mobile phase: Potassium dihydrogen phosphate: Acetonitrile = 45:55 v/v Column: Primesil ODS C₁₈ Flow rate: 1 ml/min Linearity range: Saxagliptin:5-30 Dapagliflozin:10-60 µg/ml Retention time: Saxagliptin: 2.3 Dapagliflozin: 3.2 min</p>	[27]
24.	Saxagliptin and Dapagliflozin	In bulk and Pharmaceutical dosage form	<p>Detection wavelength: 210 nm Mobile phase: Methanol: Potassium dihydrogen phosphate = 45:55 v/v Column: Inertsil ODS C₁₈ Flow rate: 1 ml/min Linearity range: 20-70 µg/ml Retention time: Saxagliptin: 6.68 Dapagliflozin: 4.70 min</p>	[28]
25.	Saxagliptin and Metformin hydrochloride	Bulk drug and Pharmaceutical formulations	<p>Detection wavelength: 228 nm Mobile phase: Methanol: phosphate buffer = 70:30 v/v Column: Waters C₈ Flow rate: 1 ml/min Retention time: Saxagliptin:4.9 Metformin: 2.8 min</p>	[29]
26.	Saxagliptin and Dapagliflozin	In tablet dosage form	<p>Detection wavelength: 210 nm Mobile phase: Potassium dihydrogen phosphate: Acetonitrile = 55:45 v/v Column: Standard BDS C₈ Flow rate: 1 ml/min Retention time: Saxagliptin: 2.8 Dapagliflozin: 2.2 min</p>	[30]
27.	Saxagliptin and Metformin	Pharmaceutical dosage form	<p>Detection wavelength: 256 nm Mobile phase: Potassium dihydrogen phosphate: Methanol = 65:35 v/v Column: Thermo C₁₈ Flow rate: 1 ml/min Linearity range: 50-150 µg/ml Retention time: Saxagliptin: 3.43 Metformin: 2.78 min</p>	[31]

28.	Saxagliptin and Dapagliflozin	In tablet dosage form	Detection wavelength: 210 nm Mobile phase: Acetonitrile: Ortho phosphoric acid = 50:50 v/v Column: Discovery C ₁₈ Flow rate: 0.98 ml/min Run time: 6 min	[2]
29.	Saxagliptin and Glimepiride	In bulk mixture and tablets	Detection wavelength: 230 nm Mobile phase: Acetonitrile: Sodium dihydrogen ortho phosphate Column: ODS C ₁₈ Flow rate: 0.75 ml/min Retention time: Saxagliptin: 3.28 Glimepiride: 26.12 min	[32]
30.	Saxagliptin and Dapagliflozin	In tablet dosage form	Detection wavelength: 215 nm Mobile phase: Methanol: Potassium phosphate buffer = 80:20 v/v Column: Cosmosil C ₁₈ Flow rate: 0.8 ml/min Linearity range: 5-10 µg/ml Retention time: Saxagliptin: 4.96 Dapagliflozin: 6.15 min	[33]

Table 3: Methods for estimation of Saxagliptin single and combination with other drugs by HPTLC

31.	Saxagliptin	In API and pharmaceutical dosage form	Detection wavelength: 222 nm Mobile phase: Methanol: Chloroform = 6:4 v/v Stationary phase: HPTLC aluminium sheets of silica gel Retardation factor: 0.50 Linearity range 400-1200 ng/spot	[34]
32.	Saxagliptin	In bulk and tablet formulation	Detection wavelength: 215 nm Mobile phase: Methanolic ammonium acetate: Toluene = 5:5 v/v Stationary phase: HPTLC aluminium sheets of silica gel Linearity range: 300-1100 ng/band Retardation factor: 0.48	[35]
33.	Saxagliptin, Sofosbuvir, Ribavarin	In pure and pharmaceutical dosage form	Detection wavelength: 228 nm Mobile phase: Acetonitrile: Water = 80:20 v/v Stationary phase: HPTLC aluminium sheets of silica gel Linearity range: 400-10000 ng/band Retardation factor: Saxagliptin: 0.21 Sofosbuvir: 0.71, Ribavarin: 0.36	[36]

CONCLUSION

A broad range of techniques are available in estimation of Saxagliptin in bulk drug and in different pharmaceutical dosage forms. From the analysis of documented data out of all these techniques HPLC with UV detection was extensively used with mobile phases Methanol, Acetonitrile and

Potassium dihydrogen phosphate with a flow rate of 0.6-1.5 ml/min and retention time < 8 min because this approach offers reliable and low cost in comparison with more advanced technology. This review was carried out on the summary of the current state of the art of analytical

methods for the determination of Saxagliptin.

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