

## A REVIEW ON ANALYTICAL METHODS FOR ESTIMATION OF DAPAGLIFLOZIN AND SAXAGLIPTIN IN BULK AND IN PHARMACEUTICAL DOSAGE FORM BY HPLC METHODS

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### ABSTRACT

Dapagliflozin and Saxagliptin are very effectively used treatment for type II diabetes. They are very potent inhibitor of renal glucose reabsorption and dipeptidyl peptidase protein 4 and sodium glucose transport protein 2 and also they are called as DPP4 & SGLT2 inhibitors. They are generally administered as tablets. Determination of Dapagliflozin and Saxagliptin in pharmaceutical dosage form and bulk form, several analytical methods including UV, HPLC, LC-MS, HPTLC techniques has been developed. Method indicating human plasma stability and impurity profiling are also describe for both drugs. For qualitative and quantitative estimation of Dapagliflozin and Saxagliptin these analytical method can be used and it can also be used for its related degradants in bulk formulations and biological fluids.

**KEYWORDS:** Dapagliflozin, Saxagliptin, RP-HPLC.

### INTRODUCTION

Type two diabetes mellitus (T2DM) is a chronic progressive metabolic disorder characterized by absolute or relative insulin deficiency. Expected rise in prevalence of diabetes is mainly due to increased life span because of better healthcare facilities and increase in diabetes risk factors, especially physical inactivity and obesity due to sedentary life style. Blocking this transporter mechanism causes blood glucose to be eliminated through the urine leading to reduction of blood glucose level.

Dapagliflozin is chemically name as (1s)-1,5-anhydro-1-C-[4-chloro-3-[(4-ethoxy phenyl)methyl]phenyl]-D-glucitol. it has a molecular formula  $C_{24}H_{33}ClO_8$  with molecular

weight 408.98 g/mol<sup>3</sup>. Dapagliflozin is selective sodium Glucose Co Transporter 2 inhibitor (SGLT 2). It acts by reducing the re absorption of glucose by the kidney, leading to excretion of excess glucose in the urine and improving glycemic control in patients with type 2 diabetes mellitus. Saxagliptin is chemically name as (1S, 3S, 5S)-2[(2S)-2-amino-2-(3-hydroxy-1-adamantyl) acetyl]-2azabicyclo hexane-3-carbonitrile) with molecular formula of C<sub>18</sub>H<sub>25</sub>N<sub>3</sub>O<sub>2</sub> and molecular weight of 315.41 g/mol. Saxagliptin is selective and potent dipeptidyl peptidase (DPP)-4 inhibitor. In patients with T2DM, once daily administration of saxagliptin before breakfast in achieves sustained inhibition of plasma DPP-4 activity. Combination of Dapagliflozin and Saxagliptin is marketed as a Tablet (Qtern) containing 10 mg of Dapagliflozin and 5 mg of Saxagliptin. Combination of these two drug is indicated for the treatment of type-2 Diabetes.

Reported methods are categorized depending on the following consideration:

1. Methods for determination of Dapagliflozin Single and combination with other drug by HPLC techniques.
2. Methods for determination of Saxagliptin Single and combination with other drug by HPLC techniques.

**Table 1: Methods for determination of Dapagliflozin Single and combination with other drugs by HPLC techniques.**

Sr.No.	drugs	METHOD	DESCRIPTION	REF.NO.
1	Dapagliflozin API	RP-HPLC Method.	Wavelength: 203nm Mobile phase: Acetonitrile: Ortho Phosphoric acid (55:45%) Flow rate: 1.0ml/min Retention time: 2.8 min Linearity range: 25-150 µl/ml % Recovery: 99.8 % LOD: 0.60 µg/ml LOQ: 1.81 µg/ml	[4]
2	Dapagliflozin in bulk and Tablet dosage form	RP-HPLC Method	Wavelength: 246 nm Mobile phase: Methanol: Acetonitril: Ortho phosphoric acid (75:25:05 %) Flow rate: 1.0 ml/min Retention time: 2.79 min Linearity range: 0-70 µl/ml % Recovery: 100.29 % LOD: 0.04 µg/ml LOQ: 0.12 µg/ml	[5]

3	Dapagliflozin in bulk and tablet dosage form	RP-HPLC Method	Wavelength: 237 nm Mobile phase: Acetonitrile: Phosphate buffer (60:40%) Flow rate: 1.0 ml/min Retention time: 3.4 min Linearity range: 10-60 µl/ml % Recovery: 100.16 % LOD: 0.02 µg/ml LOQ: 0.06 µg/ml	[6]
4	Dapagliflozin in tablet form	RP-HPLC Method	Wavelength: 224 nm Mobile phase: Acetonitrile: Triethylamine (50:50%) Flow rate: 1.0 ml/min Retention time: 5.16 min Linearity range: 10-70 µl/ml % Recovery: 100.57 % LOD: 2.1 µg/ml LOQ: 6.3 µg/ml	[3]
5	Dapagliflozin in bulk and dosage form	Stability Indicating RP-HPLC Method	Wavelength: 222 nm Mobile phase: Acetonitrile: Dihydrogen potassium phosphate PH 6.5 with Ortho phosphoric acid (40:60%) Flow rate: 1.0 ml/min Retention time: 3.16 min Linearity range: 50-150 µl/ml % Recovery: 99.99 % LOD: 5.14 µg/ml LOQ: 15.6 µg/ml	[7]
6	Metformin Hydrochloride and Dapagliflozin in tablet dosage form	RP-HPLC Method	Wavelength: 266 nm Mobile phase: Buffer: Acetonitrile (60:40%) Flow rate: 1.0 ml/min Retention time: Metformin: 2.33 min Dapagliflozin: 3.09 min Linearity range: Metformin: 125-750 µl/min Dapagliflozin: 1.2-7.5 µl/ml % Recovery: Metformin: 99.59 % Dapagliflozin: 99.55% LOD: Metformin: 0.90 µg/ml Dapagliflozin: 0.02 µg/ml LOQ: Metformin: 2.73 µg/ml Dapagliflozin: 0.07 µl/ml	[8]
7	Metformin Hydrochloride and	RP-HPLC Method	Wavelength: 240 nm Mobile phase: Phosphate buffer PH 6.5: Methanol: Acetonitrile (50:30:20 %)	[9]

	Dapagliflozin in Tablet dosage form		Flow rate: 1.0 ml/min Retention time: Metformin: 2.47 min Dapagliflozin: 3.64 min Linearity range: Metformin: 85-510 µl/ml Dapagliflozin: 0.5-3 µl/ml % Recovery: Metformin: 100.67 % Dapagliflozin: 99.54 % LOD: Metformin: 2.40 µg/ml Dapagliflozin: 3.65 µg/ml LOQ: Metformin: 2.46 µg/ml Dapagliflozin: 3.64 µg/ml	
8	Dapagliflozin and Metformin Hydrochloride in synthetic Mixture	RP-HPLC Method	Wavelength: 285 nm Mobile phase: Acetonitrile: Water (75:25%) Flow rate: 1.0 ml/min Retention time: Dapagliflozin: 5.4 min Metformin: 3.2 min Linearity range: Dapagliflozin: 10-50 µl/ml Metformin: 20-100 µl/ml % Recovery: Dapagliflozin: 99.3% Metformin: 99.6% LOD: Dapagliflozin: 3.7 µg/ml Metformin: 5.0 µg/ml LOQ: Dapagliflozin: 11.4 µg/ml Metformin: 15.2 µg/ml	[10]
9	Metformin and Dapagliflozin in Pharmaceutical dosage forms	RP-HPLC Method	Wavelength: 240 nm Mobile phase: Acetonitrile: Phosphate buffer (70:30 %) Flow rate: 1.0 ml/min Retention time: Metformin: 2.46 min Dapagliflozin: 3.76 min Linearity range: Metformin: 50-250 µl/ml Dapagliflozin: 5-25 µl/ml % Recovery: Metformin: 97.0-98.0 % Dapagliflozin: 100-103 %	[11]
10	Dapagliflozin and Metformin	Stability Indicating	Wavelength: 227nm Mobile phase: 0.05M potassium Dihydrogen	[12]

	Hydrochloride in bulk and dosage form	RP-HPLC Method	Ortho phosphate buffer PH 3.5: Acetonitrile (50:50 %) Flow rate: 1.0 ml/min Retention time: Metformin: 5.62 min Dapagliflozin: 2.63 min Linearity range: Metformin: 25-75 µl/ml Dapagliflozin: 5-15 µl/ml % Recovery: Metformin: 100.18 % Dapagliflozin: 100.40-101.2 % LOD: Metformin: 0.78 µg/ml Dapagliflozin: 0.28 µg/ml LOQ: Metformin: 2.37 µg/ml Dapagliflozin: 0.85 µg/ml	
11	Dapagliflozin and Metformin Hydrochloride in bulk and dosage form	Stability Indicating RP-HPLC Method	Wavelength: 236 nm Mobile phase: 0.05M Potassium Dihydrogen Phosphate buffer PH 4.6: Acetonitrile: Methanol (5:4:1 %) Flow rate: 0.5 ml/min Retention time: Metformin: 2.27 min Dapagliflozin: 8.31 min Linearity range: Metformin: 50-550 µl/ml Dapagliflozin: 0.5-25 µl/ml % Recovery: Metformin: 99.14 % Dapagliflozin: 100.15 % LOD: Metformin: 24.97 µg/ml Dapagliflozin: 0.25 µg/ml LOQ: Metformin: 48.99 µg/ml Dapagliflozin: 0.50 µg/ml	[13]
12	Metformin Hydrochloride and Dapagliflozin in bulk and tablet dosage form	Stability Indicating RP-HPLC Method	Wavelength: 260 nm Mobile phase: Acetonitrile: 0.1M Ortho phosphoric acid buffer (70:30 %) Flow rate: 1.0 ml/min Retention time: Metformin: 2.09 min Dapagliflozin: 3.69 min Linearity range: Metformin: 500-2500 µl/ml Dapagliflozin: 5-25 µl/ml % Recovery: Metformin: 100.58 %	[14]

			<p>Dapagliflozin: 100.54 %  LOD:  Metformin: 3.05 µg/ml  Dapagliflozin: 2.98 µg/ml  LOQ:  Metformin: 10.07 µg/ml  Dapagliflozin: 9.95 µg/ml</p>	
13	Metformin Hydrochloride and Dapagliflozin in bulk and Tablet dosage form	Stability Indicating RP-HPLC Method	<p>Wavelength: 240 nm  Mobile phase: buffer PH 6.8: Acetonitrile (50:50 %)  Flow rate: 1.0 ml/min  Retention time:  Metformin: 2.79 min  Dapagliflozin: 3.78 min  Linearity range:  Metformin: 85-510 µl/ml  Dapagliflozin: 0.5-3.0 µl/ml  % Recovery:  Metformin: 99.66-100.23 %  Dapagliflozin: 99.61-100.38 %  LOD:  Metformin: 1.32 µg/ml  Dapagliflozin: 0.43 µg/ml  LOQ:  Metformin: 3.95 µg/ml  Dapagliflozin: 1.43 µg/ml</p>	[15]
14	Dapagliflozin and Metformin Hydrochloride in bulk and dosage form	Stability Indicating RP-HPLC Method	<p>Wavelength: 285 nm  Mobile phase: 0.1M dihydrogen Phosphate: Acetonitrile: Methanol (60:30:10 %)  Flow rate: 1.2 ml/min  Retention time:  Metformin: 3.84 min  Dapagliflozin: 2.84 min  Linearity range:  Metformin: 200-600 µl/ml  Dapagliflozin: 2-6 µl/ml  % Recovery:  Metformin: 0.098-0.29 %  Dapagliflozin: 99.0-99.82 %  LOD:  Metformin: 0.27 µg/ml  Dapagliflozin: 0.004 µg/ml  LOQ:  Metformin: 0.90 µg/ml  Dapagliflozin: 0.014 µg/ml</p>	[16]

**Table No. 2 Method for determination of Saxagliptin Single and combination with other drug by HPLC techniques.**

Sr.No	DRUGS	METHOD	DESCRIPTION	REF.NO
1	Saxagliptin Hydrochloride in bulk and Tablet dosage form	RP-HPLC Method	Wavelength: 210 nm Mobile phase: Phosphate buffer: Acetonitrile (80:20 %) Flow rate: 1.0 ml/min Retention time: Saxagliptin: 5.43 min Linearity range: Saxagliptin: 0.10-0.30 µl/ml % Recovery: Saxagliptin: 100.28 % LOD: Saxagliptin: 9 µg/ml LOQ: Saxagliptin: 27 µg/ml	[17]
2	Saxagliptin In Tablet dosage form	RP-HPLC Method	Wavelength: 220 nm Mobile phase: Acetonitril: Potassium Dihydrogen Phosphate Buffer Flow rate: 1.0 ml/min Retention time: Saxagliptin: 3.48 min	[18]
3	Metformin Hydrochloride and Saxagliptin in Tablet dosage form	RP-HPLC Method	Wavelength: 248 nm Mobile phase: Phosphate buffer PH 6.8: Acetonitrile (94:6 %) Flow rate: 1.0 ml/min Retention time: Saxagliptin: 4.1 min Metformin: 1.6 min Linearity range: Saxagliptin: 0.12-0.75 µl/ml Metformin: 12.5-75 µl/ml % Recovery: Saxagliptin: 100.37 % Metformin: 100.61 % LOD: Saxagliptin: 0.01 µg/ml Metformin: 5.88 µg/ml LOQ: Saxagliptin: 0.03 µg/ml Metformin: 17.81 µg/ml	[19]
4	Dapagliflozin and Saxagliptin	Forced Degradation	Wavelength: 280 nm Mobile phase: Ammonium	[20]

	Pharmaceutical dosage form	RP-HPLC Method	<p>dihydrogen Phosphate buffer PH 6.8: Methanol (65:35 %)</p> <p>Flow rate: 1.5 ml/min</p> <p>Retention time:</p> <p>Saxagliptin: 6.76 min</p> <p>Dapagliflozin: 4.67 min</p> <p>Linearity range:</p> <p>Saxagliptin: 1.25-20 µl/ml</p> <p>Dapagliflozin: 2.5-40 µl/ml</p> <p>% Recovery:</p> <p>Saxagliptin: 102 %</p> <p>Dapagliflozin: 98 %</p> <p>LOD:</p> <p>Saxagliptin: 0.078 µg/ml</p> <p>Dapagliflozin: 0.156 µg/ml</p> <p>LOQ:</p> <p>Saxagliptin: 0.156 µg/ml</p> <p>Dapagliflozin: 0.312 µg/ml</p>	
5	Saxagliptin Hydrochloride and Metformin Hydrochloride in API	RP-HPLC Method	<p>Wavelength: 240 nm</p> <p>Mobile phase: 0.02M Potassium Dihydrogen Phosphate: Acetonitrile: Methanol (50:25:25 %)</p> <p>Flow rate: 1.0 ml/min</p> <p>Retention time:</p> <p>Saxagliptin: 7.43 min</p> <p>Metformin: 4.85 min</p> <p>Linearity range:</p> <p>Saxagliptin: 10-50 µl/ml</p> <p>Metformin: 5-25 µl/ml</p> <p>% Recovery:</p> <p>Saxagliptin: 100.48 %</p> <p>Metformin: 101.1 %</p> <p>LOD:</p> <p>Saxagliptin: 1.91 µg/ml</p> <p>Metformin: 1.22 µg/ml</p> <p>LOQ:</p> <p>Saxagliptin: 5.78 µg/ml</p> <p>Metformin: 1.22 µg/ml</p>	[21]
6	Metformin and Saxagliptin in a Formulation	RP-HPLC Method	<p>Wavelength: 220 nm</p> <p>Mobile phase: 0.05 Potassium Phosphate buffer PH 4.5: Methanol: Acetonitrile (60:20:20 %)</p> <p>Flow rate: 1.0 ml/min</p> <p>Retention time:</p> <p>Saxagliptin: 6.92 min</p> <p>Metformin: 4.38 min</p> <p>Linearity range:</p>	[22]



			<p>Saxagliptin: 0.2-12 µl/ml  Metformin: 40-240 µl/ml  % Recovery:  Saxagliptin: 101.62 %  Metformin: 100.65 %  LOD:  Saxagliptin: 0.029 µg/ml  Metformin: 0.112 µg/ml  LOQ:  Saxagliptin: 0.096 µg/ml  Metformin: 0.373 µg/ml</p>	
7	Metformin Hydrochloride and Saxagliptin in bulk and Pharmaceutical dosage form	Stability Indicating RP-HPLC Method	<p>Wavelength: 229 nm  Mobile phase: Phosphate buffer PH 2.5: Acetonitrile (70:30 %)  Flow rate: 1.0 ml/min  Retention time:  Saxagliptin: 5.2 min  Metformin: 2.8 min  Linearity range:  Saxagliptin: 0.5-7.5 µl/ml  Metformin: 50-740 µl/ml  % Recovery:  Saxagliptin: 100.1 %  Metformin: 98.9 %</p>	[23]
8	Metformin Hydrochloride and Saxagliptin in bulk and combined tablet dosage form	Stability Indicating RP-HPLC Method	<p>Wavelength: 211 nm  Mobile phase: Phosphate buffer PH 5.0:  Acetonitrile: Methanol (25:50:25 %)  Flow rate: 1.0 ml/min  Retention time:  Saxagliptin: 4.516 min  Metformin: 2.246 min  Linearity range:  Saxagliptin: 1.25-7.5 µl/ml  Metformin: 125-725 µl/ml  % Recovery:  Saxagliptin: 99.66 %  Metformin: 99.93 %  LOD:  Saxagliptin: 0.17 µg/ml  Metformin: 1.25 µg/ml  LOQ:  Saxagliptin: 0.59 µg/ml  Metformin: 4.38 µg/ml</p>	[24]
9	Saxagliptin and Dapagliflozin	Stability Indicating RP-HPLC Method	<p>Wavelength: 210 nm  Mobile phase: Ortho Phosphoric acid PH 2.2:</p>	[25]

			<p>Acetonitrile (55:45 %)  Flow rate: 1.0 ml/min  Retention time:  Saxagliptin: 3.601 min  Dapagliflozin: 2.785 min  Linearity range:  Saxagliptin: 0-75 µl/ml  Metformin: 0-150 µl/ml  % Recovery:  Saxagliptin: 99.91 %  Metformin: 101 %  LOD:  Saxagliptin: 0.13 µg/ml  Metformin: 0.09 µg/ml  LOQ:  Saxagliptin: 0.39 µg/ml  Metformin: 0.27 µg/ml</p>	
10	Dapagliflozin and Saxagliptin in bulk and tablet dosage form	Stability Indicating RP-HPLC Method	<p>Wavelength: 248 nm  Mobile phase: Acetonitrile: Water (60:40 %)  Flow rate: 1.0 ml/min  Retention time:  Saxagliptin: 3.24 min  Dapagliflozin: 2.091 min  Linearity range:  Saxagliptin: 50-250 µl/ml  Dapagliflozin: 100-500 µl/ml  % Recovery:  Saxagliptin: 99.88 %  Dapagliflozin: 100.78 %  LOD:  Saxagliptin: 3.02 µg/ml  Dapagliflozin: 3.00 µg/ml  LOQ:  Saxagliptin: 10.01 µg/ml  Metformin: 9.98 µg/ml</p>	[26]
11	Saxagliptin and Dapagliflozin	Stability Indicating RP-HPLC Method	<p>Wavelength: 225 nm  Mobile phase: Phosphate buffer PH 4.0: Acetonitrile (50:50%)  Flow rate: 1.0 ml/min  Retention time:  Saxagliptin: 2.1 min  Dapagliflozin: 2.8 min  Linearity range:  Saxagliptin: 20-60 µl/ml  Dapagliflozin: 40-120 µl/ml  % Recovery:</p>	[27]

			Saxagliptin: 99.99 % Dapagliflozin: 100.50 % LOD: Saxagliptin: 1.63 µg/ml Dapagliflozin: 1.94 µg/ml LOQ: Saxagliptin: 5.39 µg/ml Dapagliflozin: 6.50 µg/ml	
12	Saxagliptin and Metformin in Tablet Dosage form	RP-HPLC Method	Wavelength: 242 nm Mobile phase: Phosphate Buffer: Acetonitrile (60:40 %) Flow rate: 1.0 ml/min Retention time: Saxagliptin: 2.9 min Metformin: 1.7 min Linearity range: Saxagliptin: 1-6 µl/ml Metformin: 100-600 µl/ml % Recovery: Saxagliptin: 100.6 % Metformin: 99.9 % LOD Saxagliptin: 0.0042 µg/ml Metformin: 0.0148 µg/ml LOQ Saxagliptin: 0.212 µg/ml Metformin: 0.662 µg/ml	[28]

## CONCLUSION

This review depicts the reported chromatographic method developed and validated for estimation of Dapagliflozin and Saxagliptin. Different chromatographic methods are available for single and combination. It was found that the mobile phase containing phosphate buffer, Acetonitrile and Water were common for most of the chromatographic methods to provide more resolution. It was observed that the most common combination of Dapagliflozin and Saxagliptin were with Metformin. For chromatographic method, flow rate is observed in the range 1.0-1.5 ml/min to get good resolution time. Hence, this method is found to be simple, accurate, economic, precise and reproducible in nature.

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