

Dapagliflozin Analysis: A Review on Chromatography and Spectroscopic Methods

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Abstract: Dapagliflozin is an anti-diabetic drug. Dapagliflozin comes under new class of SGLT-2 inhibitor. It is administered as tablets. This therapeutic agent used for type 2 diabetes mellitus. Dapagliflozin functions by inhibiting glucose reabsorption in the proximal tubules of the kidney's nephron, it efficiently lowers blood glucose levels and promotes glycosuria. In this review article we study about profile of Dapagliflozin which include mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects and drug interactions. Also reported analytical methods including UV, HPLC and HPTLC for assessment of Dapagliflozin single form and Dapagliflozin with other drugs are reviewed in this article.

Keywords: Diabetes Mellitus, Anti-diabetic, Dapagliflozin, SGLT-2 Inhibitor, UV, HPLC, HPTLC.

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I. INTRODUCTION

A. Introduction of Diabetes Mellitus

The term 'diabetes mellitus' means 'excessive discharge of sugary urine' [1]. Diabetes mellitus is a disorder of metabolism, primarily marked by increased blood glucose levels. It is often linked to factors such as physical inactivity, poor dietary habits, excess body weight, and other contributing elements. This condition significantly impacts on human health and quality of life [2].

Hyperglycemia arises when insulin is either inadequately produced or fails to efficiently activate its target cells.

B. Types of Diabetes Mellitus [3,4]

➤ Type-1 Diabetes Mellitus :

Insulin dependent diabetes mellitus often abbreviated as IDDM or type-1 diabetes. It has been observed that it can occur at any stage of life. In this type, the body's natural defense mechanism targets and destroys the pancreatic insulin producing cells, leading to an inability to produce insulin and causing insulin deficiency. Insulin is the key treatment for individuals with this type, which is typically injected subcutaneously.

➤ Type-2 Diabetes Mellitus:

Non insulin dependent diabetes mellitus often concise as NIDDM or type-2 diabetes. It is most commonly identified in individuals who are 45 years old or above.

In type-2 diabetes, issues arise in the receptors of target cells due to various aspects like genetics, excess weight, hypertension, and lack of physical activity. When target cells do not respond properly to insulin, it is known as "insulin resistance" which cause a rise in blood glucose level. Type-2 diabetes can be managed through anti-diabetic medications along with lifestyle modifications.

➤ Gestational diabetes:

Gestational diabetes is defined as hyperglycemia with first onset during pregnancy and is one of the common pregnancy complication [2]. Having a previous diagnosis of gestational diabetes mellitus refers to a significant contributing factor to developing the condition again. Treatment involves following specific dietary guidelines, engaging in regular physical activity, and using anti-diabetic medications help to regulate blood glucose levels.

C. Introduction of Anti-Diabetic Drugs

Anti-diabetic medications are used to regulate blood glucose levels in managing diabetes mellitus. While the majority of these medications are taken orally, a few, including insulin, exenatide, and pramlintide are administered through other methods [3].

Medications for diabetes that are consumed orally and are known as oral hypoglycemic or oral antihyperglycemic agents. The UK perspective on diabetes treatment indicates that insulin or its analogues serve as the conventional strategy for treating type-1, gestational, and specific occurrences of type 2 diabetes [1].

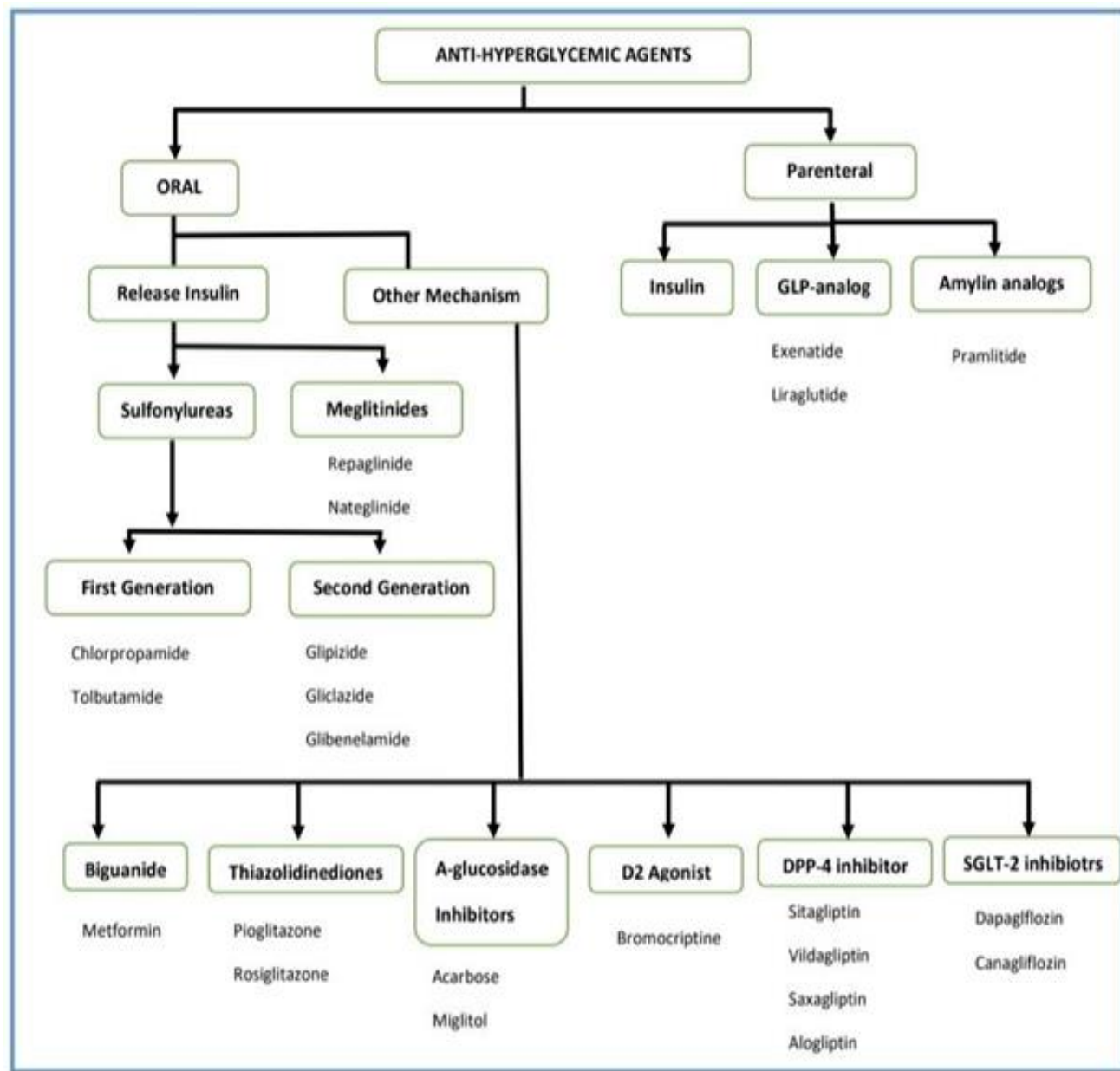


Fig 1: Classification of Anti-Diabetic Drugs

D. Introduction of SGLT-2 inhibitor

In the twenty-first century, several new classes of antidiabetic medications have emerged. One of which includes sodium-glucose cotransporter-2 (SGLT-2) inhibitors. Dapagliflozin was the initial drug introduced within this category of innovative treatments.^[5]

These inhibitors offer a novel and efficient treatment approach that works independently in insulin release or its function.^[6] These inhibitors are medications that act on SGLT-2 proteins in the proximal convoluted tubule to lower glucose. These drugs reduce glucose levels by blocking the reabsorption of glucose that has been filtered from the tubular lumen.^[7]

E. Introduction of Dapagliflozin

Dapagliflozin is an SGLT2 inhibitor employed in the care of diabetes mellitus of type-2. Dapagliflozin was first SGLT2 inhibitor to receive approval for modulating diabetes mellitus of type-2. When used in combination with nutritional management and physical activity in adults, it enhances regulation of blood glucose through disrupting glucose reabsorption in the nephron's proximal tubule, consequent upon increased glucose excretion. By inhibiting glucose reabsorption in the renal organs, dapagliflozin increases urinary glucose loss, which helps lower glucose levels in the bloodstream while safeguarding against severe low blood sugar events. Dapagliflozin has been studied both as a standalone treatment and alongside insulin or other oral antidiabetic medications.^[8]

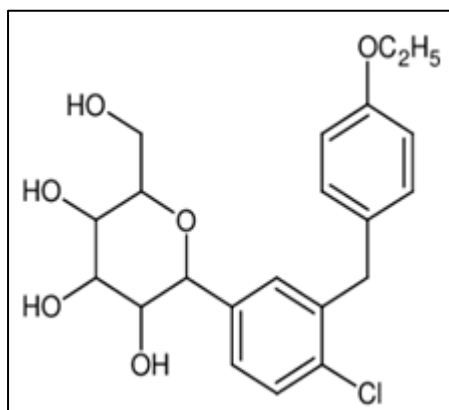


Fig 2 : Chemical Structure of Dapagliflozin

F. Mechanism of Action of Dapagliflozin

Dapagliflozin works by inhibiting sodium-glucose cotransporter 2 (SGLT2), which predominantly resides in the proximal section of the nephron. Since SGLT2 is responsible for nearly 90% of glucose is returned to the bloodstream by the kidneys, blocking it promotes glucose expulsion through urine. This mechanism aids in improved glucose balance and could also support body mass reduction among individuals with diabetes mellitus of second type.^[8]

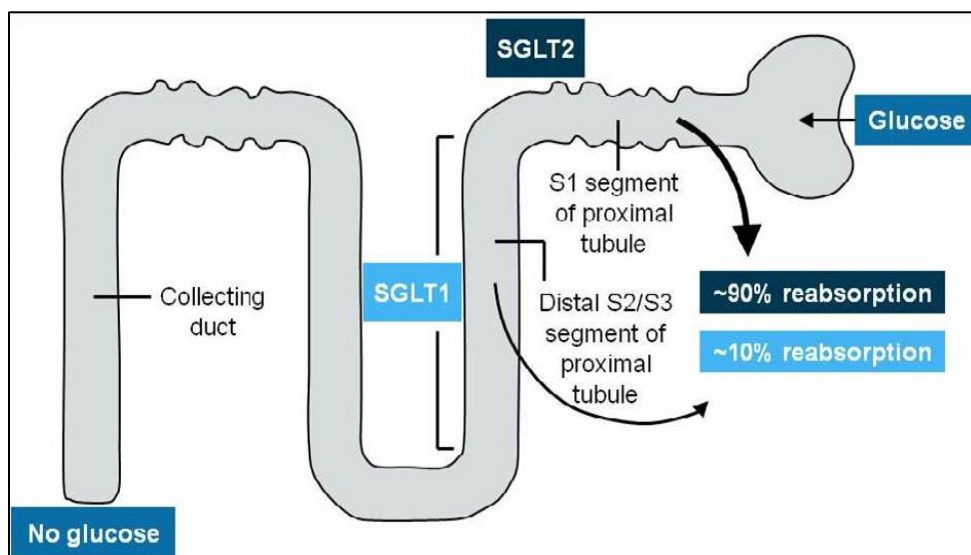


Fig 3: Mechanism of Action Dapagliflozin

G. History of Dapagliflozin

The FDA granted initial approval for dapagliflozin on January 8, 2014, to aid in glycemic regulation in individuals experiencing type 2 diabetes during adulthood when combined along by managing food consumption and physical activity. In April 2021, It's approval was expanded to include reducing the odds of worsening renal efficiency, kidney failure, cardiovascular mortality, and hospital care necessitated by heart failure in those with chronic kidney disease.^[8]

H. Chemistry of Dapagliflozin

Dapagliflozin is a medication applied in the care of diabetes. its molecular formula having $C_{21}H_{25}ClO_6$ and molecular weight is 408.88 g/mol. IUPAC name of Dapagliflozin is 2-{4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl}-6-(hydroxymethyl)oxane-3,4,5-triol. It is solid in nature and the melting range is 55-58 °C. Dapagliflozin dissolves in DMSO, methanol and

ethanol, and has minimal solubility in toluene and tetrahydrofuran.

I. Pharmacokinetics of Dapagliflozin

➤ Absorption

Dapagliflozin is quickly and efficiently absorbed following oral intake, attaining its maximum plasma concentration within 2 hours. Its bioavailability is 78% with a once-daily 10 mg dose. Dapagliflozin can be taken with or without food.^[11]

➤ Metabolism

Dapagliflozin undergoes metabolism within hepatic and renal systems through uridine diphosphate glucuronosyltransferase-1A9 (UGT1A9). By blocking SGLT2 in the proximal convoluted tubule (PCT), it promotes glucose excretion through urine, thereby reducing blood glucose level.^[12]

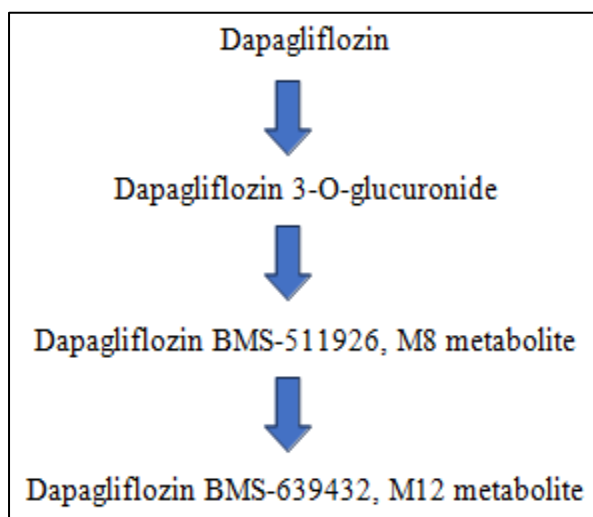


Fig 4: Metabolism of Dapagliflozin

➤ *Distribution*

The volume of distribution is approximately 118L, with 91% of dapagliflozin bound to protein. This protein binding remains unaffected by hepatic or renal disease.

➤ *Excretion*

The primary clearance route for dapagliflozin as well as its metabolites is through urinary output. Healthy individuals were given one time 50 mg dose of [U-14C] dapagliflozin, 75% of the aggregate radioactivity was detected through the urinary excretion, while 21% was found in the feces. Of this, 2% was eliminated in the urine without any change and 15% was eliminated in the feces in its unchanged form.

J. Pharmacodynamics of Dapagliflozin

Dapagliflozin acts as a selective and reversible inhibitor of the SGLT2 transporter. Its effects are dose-dependent, leading to glycosuria and an average increase in diuresis of approximately 375 mL/day. Dapagliflozin decreases sodium reabsorption and enhances sodium delivery to the distal tubule, potentially affecting various physiological processes. In hyperglycemia, as seen in type 2 diabetes mellitus (T2DM), SGLT2 is upregulated, promoting increased glucose reabsorption. However, this mechanism eventually becomes overwhelmed, leading to glycosuria. In individuals with T2DM, daily administration of dapagliflozin at 5 or 10 mg for 12 weeks has been shown to result in the urinary expulsion of approximately a daily amount of 70 gm glucose by end of the 12 week treatment. 20 mg dapagliflozin administered once daily resulted in the maximum rate of glucose discharge. This increased glucose removal in urine also leads to rise urinary volume. Upon stopping dapagliflozin, the elevated urinary glucose levels typically return to baseline. It takes roughly 3 days for the 10 mg dose.

K. Adverse Effect of Dapagliflozin

Dapagliflozin may cause following side effects such as frequent urination including during the night, nasal congestion or runny nose, sore throat, and pain in the legs or arms, urine with a pungent odor, dry mouth, dark-colored

urine, low perspiration, dry skin, and additional signs of dehydration, rash, itching, trouble in breathing, swelling of the face, mouth, tongue or eyes, tiredness. ^[13]

L. Toxicity

An antidote for SGLT-2 inhibitors is not available, and dialysis does not eliminate them. An analysis of previous overdose cases involving SGLT-2 inhibitors reported to 13 U.S. toxicology centers found that hypoglycemia did not occur in most cases of mild exposure, with the exception of pediatric patients. An overdose of SGLT2 inhibitors, when done intentionally can cause symptoms may include hypoglycemia, vomiting, confusion, high blood pressure, rapid heart rate, and loss of bladder control. According to standard hypoglycemia protocols, treatment involves instantly in a conscious patient, administering oral glucose can help to raise low blood glucose levels, or other interventions for those with impaired consciousness. To treat hypoglycemia, IV dextrose (25 g) should be administered. If IV access is not available, glucagon (0.5 to 1 mg by subcutaneous or intramuscular injection) should be given immediately. In cases of refractory hypoglycemia, subcutaneous or intravenous octreotide may be used. For complicated overdoses, it is essential to contact the poison control center.

M. Drug interaction

- **Loop diuretics:** It is recommended not to combine Dapagliflozin with Loop diuretics to prevent the risk of hypertension and dehydration.
- **Abaloparatide:** Combining Abaloparatide with Dapagliflozin may increase the risk of adverse effects.
- **Acetylsalicylic acid:** Combining Acetylsalicylic acid with Dapagliflozin may raise the risk of hypoglycemia.

Sulphonyl urea and Insulin: Research on Dapagliflozin used with Sulfonylurea and Insulin has shown for it to produce effective results, offering the advantage of losing weight. When Insulin is used together with Dapagliflozin, the daily insulin requirement can be reduced for patients.

II. LITRATURE REVIEW

Table 1: Reported Methods for Assessment of Dapagliflozin Single form

Sr. no.	Title	Description	Ref. no.
1	Analytical Method Development and Validation of Dapagliflozin by UV-Spectroscopy	Solvent : Nitric Acid Linearity : 10-60 µg/mL Wavelength : 232 nm R² : 0.9947	14
2	Unique UV-Spectrophotometric Method for Reckoning of Dapagliflozin in Bulk and Pharmaceutical Dosage Forms	Solvent : Ethanol : Phosphate Buffer Solution Linearity : 10-35 µg/mL Wavelength : 233.65 nm R² : 0.9998	15
3	Estimation of Dapagliflozin from its Tablet Formulation by UV- Spectrophotometry	Solvent : methanol Wavelength : 224 nm Linearity : 5-40 µg/mL R² : 0.998	16
4	Development and Validation of UV- Spectroscopy Method for the Determination of Dapagliflozin	Solvent : Distilled water Wavelength : 278 nm Linearity : 5-10 µg/mL R² : 0.9992	17
5	Method Development and Validation of Dapagliflozin API by UV-Spectroscopy	Solvent : Ethanol Wavelength : 237 nm Linearity : 0.5-0.9 µg/mL R² : 0.994	18
6	Development and Validation of Dapagliflozin by RP-HPLC Method and it's Forced Degradation Studies	Mobile Phase : Orthophosphoric acid buffer : Acetonitrile (60 : 40 % v/v) Stationary Phase : Hypersil BDS column (250 mm × 4.6 mm, 5 µ) Wavelength : 245 nm Flow Rate : 1 mL/min Injection Volume : 10 µL Retention Time : 2.789 min	19
7	RP-HPLC Method for Estimation of Dapagliflozin from its Tablet	Mobile Phase : Acetonitrile : 0.1% Triethylamine (pH-5.0) (50 : 50 % v/v) Stationary Phase : Princeton C18 column Wavelength : 224 nm Flow Rate : 1 mL/min Injection Volume : 20 µL Retention Time : 5.163 min	20
8	Development and Stability Indicating HPLC Method for Dapagliflozin in API and Pharmaceutical Dosage Form	Mobile Phase : Dipotassium hydrogen phosphate : Acetonitrile (60 : 40 % v/v) Stationary Phase : Agilent C18 column (4.6 mm × 150, 5 µm) Wavelength : 222 nm Flow Rate : 1 mL/min Run	21

		Time : 6 min Injection Volume : 20 µL Retention Time : DAPA API = 3.160 min DAPA TABLET = 3.067 min	
9	Method Development and Validation of Dapagliflozin by RP-HPLC	Mobile Phase : Methanol : Water (80 : 20 % v/v) Stationary Phase : Shim-pack GIST C18 column (250mm × 4.6mm, 5µm) Wavelength : 235 nm Flow Rate : 1 mL/min Retention Time : 4.422 min	22
10	A New RP-HPLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form	Mobile Phase : Phosphate buffer : Acetonitrile (60 : 40 % v/v) Stationary Phase : Waters C18 column (25 cm × 4.6 mm, 5 µm) Wavelength : 237 nm Flow Rate : 1 mL/min Run Time : 6 min Retention Time : 3.461 min	23
11	Analytical Method Development and Validation of Dapagliflozin by RP- HPLC Method in Tablet Dosage Form	Mobile Phase : Acetonitrile : Water (50 : 50 % v/v) Stationary Phase : Inertsil ODS-3V (150 mm × 4.6 mm, 5 µm) Wavelength : 223 nm Flow Rate : 1 mL/min Injection Volume : 20 µL Run Time : 8 min	24
12	RP-HPLC Method Development and Validation on Dapagliflozin	Mobile Phase : Methanol : Water (70 : 30 % v/v) Stationary Phase : Agilent 5 TC CT8 column (150mm × 4.6 mm, 4µm) Wavelength : 224 nm Flow Rate : 1.4 mL/min Run Time : 10 min Injection Volume : 50 µL Retention Time : 6.5 min	25
13	Development and Validation of Stability-Indicating RP-HPLC Method for Determination of Dapagliflozin	Mobile Phase : Acetonitrile : Ortho phosphoric acid (55 : 45 % v/v) Stationary Phase : BDS column Wavelength : 245 nm Flow Rate : 1 mL/min Injection Volume : 10 µL Retention Time : 2.873 min	26
14	A New HPTLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form	Mobile Phase : Chloroform : Methanol (9 : 1 % v/v) Stationary Phase : Precoated silica gel 60 F254 aluminium plate	27

		Wavelength : 223 nm Saturation Time : 30 min	
15	A Validated Stability Indicating HPTLC Method for the Analysis of Dapagliflozin in Bulk Drug and Marketed Tablet Formulation	Mobile Phase : Methanol : Toluene : Ammonium acetate (6.9 : 3 : 0.1 % v/v/v) Stationary Phase : Aluminium plates coated with silica gel 60 F254 Wavelength : 250 nm Saturation Time : 15 min	28

Table 2: Reported methods for Assessment of Dapagliflozin with other Drug

Sr. no.	Title	Description	Ref. no.
1	Development And Validation Of UV-Spectrophotometric Method For Estimation Of Saxagliptin And Dapagliflozin In Bulk And Dosage Form	Solvent: Methanol: Water Wavelength: Saxagliptin:224 nm Dapagliflozin:274 nm Linearity : Saxagliptin:2-10 µg/mL Dapagliflozin:4-20 µg/mL R² : 0.999	29
2	Method Development, Validation and Stress Studies of Dapagliflozin and Metformin Hydrochloride Using UV- Spectroscopy in Bulk and Combined Pharmaceutical Formulations	Solvent : Water Wavelength : Dapagliflozin:222 nm Metformin HCL:232 nm Linearity : Dapagliflozin:2-32 µg/mL Metformin HCL:1-20 µg/mL R² : 0.999	30
3	Development and Validation of UV Spectroscopic First Derivative Method for Simultaneous Estimation of Dapagliflozin and Metformin Hydrochloride in Synthetic Mixture	Solvent : Methanol Wavelength : Dapagliflozin:235 nm Metformin HCL:272 nm Linearity : Dapagliflozin:0.5-2.5 µg/mL Metformin HCL:25-125 µg/mL R² : Dapagliflozin:0.98 Metformin HCL:0.9826	31
4	New Eco-friendly UV-spectroscopic Methods for Simultaneous Assessment of Dapagliflozin, Saxagliptin and Metformin in Ternary Mixture	For Simultaneous Equation Method Solvent : Water Wavelength : Dapagliflozin:223 nm Saxagliptin:212 nm Metformin HCL:232.6 nm Linearity : 2-10 µg/mL (For All) R² : Dapagliflozin:0.9975 Saxagliptin:0.9975 Metformin HCL:0.9995	32
5	Various Innovative UV-spectroscopic Methodologies for Concurrent Estimation of Dapagliflozin and Vildagliptin in Combined Tablet	For Simultaneous Equation Method Solvent : Water Wavelength : Dapagliflozin:223 nm Vildagliptin:210 nm Linearity : Dapagliflozin:0.5-10 µg/mL Vildagliptin:5-100	33

		<p>$\mu\text{g/mL } R^2 :$ Dapagliflozin:0.9997 Vildagliptin:0.9999</p>	
6	Development and Validation of UV- Spectroscopic Method for Simultaneous Estimation of Dapagliflozin and Saxagliptin in Marketed Formulation	<p>Solvent : Phosphate buffer pH 6.8 Wavelength : Dapagliflozin:276 nm Saxagliptin:222 nm Linearity : 5-25 $\mu\text{g/mL}$ (For Both) R^2 : 0.999 (For Both)</p>	34
7	Development of a Validated Highly Sensitive and Eco Friendly Approach for the Simultaneous Determination of Dapagliflozin and Gliclazide in Bulk and Tablet Formulation by RP-HPLC Method	<p>Mobile Phase : 0.01% Formic acid (pH-2.7) : Acetonitrile (30 : 70 % v/v) Stationary Phase : Lichrospher 100 RP-18e (250 mm \times 4 mm, 5μ) Wavelength : 219 nm Flow Rate : 0.8 mL/min Run Time : 5 min Retention Time : Dapagliflozin:3.1 min Gliclazide:4.7 min</p>	35
8	Stability Indicating HPLC Method Development and Validation for Simultaneous Estimation of Dapagliflozin and Metformin Tablet Dosage Form	<p>Mobile Phase : Methanol : Water (75 : 25 % v/v) Stationary Phase : Agilent C18 column (250 mm \times 4.6 mm, 5 μm) Wavelength : 233 nm Flow Rate : 1 mL/min Retention Time : Dapagliflozin:5.099 min Metformin:2.165 min</p>	36
9	Stability Indicating HPLC Method Development and Validation for Simultaneous Estimation of Metformin, Dapagliflozin and Saxagliptin in Bulk Drug and Pharmaceutical Dosage Form	<p>Mobile Phase : Phosphate buffer (pH = 3) : Acetonitrile (60 : 40 % v/v) Stationary Phase : Kromasil C18 column (150 \times 4.6 mm, 5 μm) Wavelength : 230 nm Flow Rate : 1 mL/min Run Time : 4 min Injection Volume : 10 μL</p>	37
10	RP-HPLC Method for Dapagliflozin and Metformin HCL in Bulk and Combined Formulation	<p>Mobile Phase : Water : Methanol (50 : 50 % v/v) Stationary Phase : Phenomenex C18 (250 mm \times 4.6 mm, 5 μ) Wavelength : 230 nm Flow Rate : 1 mL/min Retention Time : Dapagliflozin:2.178 min Metformin HCL:3.338 min</p>	38

11	Simultaneous Estimation of Saxagliptin and Dapagliflozin in Human Plasma by Validated High Performance Liquid Chromatography - Ultraviolet Method	Mobile Phase : 0.1% Orthophosphoric acid (pH-4.5) : Acetonitrile (50 : 50 % v/v) Stationary Phase : Eclipse XDB C18 column (150 mm × 4.6 mm, 5 µm) Wavelength : 254 nm Flow Rate : 1 mL/min Run Time : 10 min Retention Time : Internal Std:2.746 min Saxagliptin:5.173 min Dapagliflozin:7.218 min	39
12	Stability Indicating HPLC Method for the Simultaneous Determination of Dapagliflozin and Saxagliptin in Bulk and Tablet Dosage Form	Mobile Phase : Acetonitrile : Water (60 : 40 % v/v) Stationary Phase : Xterra RP18 (4.6 mm × 150 mm, 5 µm) Wavelength : 248 nm Flow Rate : 1 mL/min Run Time : 10 min Injection Volume : 20 µL Retention Time : Dapagliflozin:2.089 min Saxagliptin:3.253 min	40
13	Development and Validation of RP- HPLC Method for Simultaneous Estimation of Dapagliflozin and Metformin in Bulk and in Synthetic Mixture	Mobile Phase : Acetonitrile : Water (75 : 25 % v/v) Stationary Phase : Phenomenex Luna C18 column (4.6 mm I.D. × 250 mm, 5 µm) Wavelength : 285 nm Flow Rate : 1 mL/min Injection Volume : 10 µL Retention Time : Dapagliflozin:5.4 min Metformin:3.2 min	41
14	HPTLC Method for the Determination of Metformin Hydrochloride, Saxagliptin Hydrochloride, and Dapagliflozin in Pharmaceuticals	Mobile Phase : Acetonitrile : Ammonium acetate (9 : 1 % v/v) Stationary Phase : Aluminium HPTLC sheets coated with silica gel 60 F254 Wavelength : 210 nm	42
15	Development and Validation of HPTLC Method for Simultaneous Quantification of Dapagliflozin and Vildagliptin in Tablet Dosage Form	Mobile Phase : Toluene : Ethyl Acetate : Methanol : Ammonia (6.0 : 2.0 : 2.0 : 0.1 % v/v/v/v) Stationary Phase : Aluminum plates coated with silica gel 60 F254 Wavelength : 217 nm Saturation Time : 15 min	43

16	Development and Validation of Stability Indicating HPTLC Method for Simultaneous Estimation of Dapagliflozin and Linagliptin	Mobile Phase : Toluene : Chloroform : Methanol : Triethylamine (7 : 2 : 1 : 0.2 % v/v/v/v) Stationary Phase : Pre- coated HPTLC silica gel aluminum plate 60 F254 Wavelength : 224 nm Saturation Time : 40 min	44
17	Development and Validation of Stability-Indicating HPTLC Method for Simultaneous Estimation of Metformin, Saxagliptin and Dapagliflozin in their Combined Matrix Using AQbD	Mobile Phase : Methanol : 0.5 % Aqueous ammonium sulphate (8 : 2 % v/v) Stationary Phase : Pre- coated silica gel 60 F254 HPTLC aluminum plates Wavelength : 222 nm Saturation Time : 20 min	45
18	Stability-Indicating HPTLC Method Development and Validation for Dapagliflozin Propanediol Monohydrate, Vildagliptin, and Metformin Hydrochloride in Active Pharmaceutical Ingredient and its Tablet Dosage Form	Mobile Phase : Acetonitrile : Formic acid : Water (9 : 1 : 0.5 % v/v/v) Stationary Phase : Silica gel 60 F254 plates Wavelength : 215 nm	46

III. CONCLUSION

Dapagliflozin plays an essential part in controlling type-2 diabetes mellitus. Its benefits extend to weight loss, cardiovascular protection and kidney health improvement, making it a many-sided therapeutic option. There have been several reported methods for assessment of Dapagliflozin. This review concluded that a single form of Dapagliflozin and combination with other drugs different spectroscopic and chromatographic methods are available. Analytical methods including UV, HPLC and HPTLC. It was found that these methods were simple, precise, economic and accurate.

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