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Critical Review of Analytical Estimation Methods for Metformin Hydrochloride, Dapagliflozin Propanediol Monohydrate, and Glimepiride

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Abstract: Diabetes mellitus (DM) is a chronic metabolic disorder characterized by elevated blood glucose levels resulting from defects in insulin secretion, insulin action, or both. Persistent hyperglycemia in diabetes leads to disturbances in carbohydrate, fat, and protein metabolism. It is mainly classified into type I and type II DM. Type I Diabetes Mellitus (DM) is primarily managed through insulin replacement therapy, as pancreatic β-cell destruction results in absolute insulin deficiency. In contrast, Type II DM is typically treated with oral hypoglycaemic agents and, when necessary, insulin therapy. Combination therapy is often employed to achieve optimal glycaemic control and minimize complications. Globally, Diabetes Mellitus represents a major public health challenge, with an estimated 589 million adults projected to be affected by 2025, reflecting the increasing prevalence linked to sedentary lifestyles, obesity, and aging populations.

Keywords: *Molnupiravir, Diabetes Mellitus, Development and Validation, RP-HPLC.*

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I. INTRODUCTION

➢ *Introduction of Diabetes Mellitus*

Diabetes Mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from impaired insulin secretion, insulin action, or both. The deficiency or ineffectiveness of insulin disrupts normal glucose homeostasis, leading to alterations in carbohydrate, lipid, and protein metabolism. As the disease progresses, patients commonly develop microvascular (nephropathy, retinopathy, neuropathy) and macrovascular (cardiovascular) complications, which significantly increase morbidity and mortality rates. [1–2]

DM is broadly classified into Type I and Type II forms. Type I DM arises from autoimmune destruction of pancreatic β-cells, leading to absolute insulin deficiency and necessitating insulin replacement therapy. In contrast, Type II DM is associated with insulin resistance and relative insulin deficiency, typically managed using oral hypoglycaemic agents. [3-4]

In the year 2025, it is estimated that approximately 589 million adults aged 20–79 years worldwide are living with diabetes mellitus, reflecting a significant global health burden and a steady increase in prevalence over recent decades, which is about 1 in 9 adults worldwide. More than 40% of individuals living with diabetes remain undiagnosed, highlighting a substantial gap in early detection and disease management worldwide. [5-6]

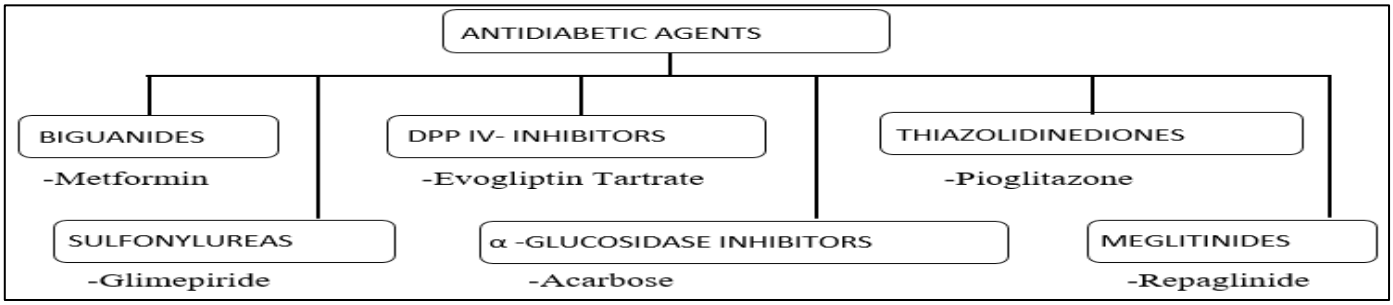

Fig 1 Classification of Anti Diabetic Drugs

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➢ *Introduction of Metformin Hydrochloride*

Unlike many other antidiabetic agents, metformin does not stimulate insulin secretion, which minimizes the risk of hypoglycaemia.

Beyond its established role in diabetes management, metformin has also attracted attention for its potential therapeutic applications in oncology, where it is being investigated for its anticancer effects due to its influence on cellular metabolism and AMP-activated protein kinase (AMPK) activation. The active component, metformin, is marketed in various formulations, with Glucophage being one of the most common trade names.

It was first synthesized and described in the scientific literature in 1922 by Emil Werner and James Bell. [7]

- *Mechanism of Action:*

Metformin exerts its antihyperglycemic effect through mechanisms distinct from other oral antidiabetic agents. It primarily reduces hepatic glucose production (gluconeogenesis), enhances peripheral glucose uptake and utilization, and decreases intestinal glucose absorption.

After oral administration, metformin enters hepatocytes via the organic cation transporter-1 (OCT1) and accumulates within cells due to its positive charge. It inhibits mitochondrial complex I, resulting in reduced ATP production and increased AMP:ATP ratios, which activate AMP-activated protein kinase (AMPK)- a key regulator of energy metabolism.

Activation of AMPK leads to the suppression of gluconeogenic enzymes, reduction of lipid synthesis, and enhanced fatty acid oxidation, thereby improving insulin sensitivity and glycemic control.

Recent studies also highlight the gastrointestinal tract as an important site of metformin action, where it may enhance GLP-1 secretion, increase glucose metabolism in enterocytes, and contribute to its overall glucose-lowering effect. [8-9]

- *Drug Profile of Metformin Hydrochloride:*

Metformin hydrochloride (Fig. 2) is chemically known as 1-carbamimidamido-N,N-dimethylmethanimidamide hydrochloride, with the molecular formula $C_4H_{11}N_5 \cdot HCl$ and a molecular weight of 165.62 g/mol. It is a white to off-white crystalline compound with a melting point ranging from 223°C to 226°C. The compound exhibits a partition coefficient (log P) of 0.062, indicating its hydrophilic nature, and a dissociation constant (pKa) of 12.4, consistent with its basic character.

Metformin hydrochloride is freely soluble in water, soluble in methanol, and slightly soluble in acetonitrile, reflecting its high polarity and limited lipid solubility. The drug is typically administered orally at a dose of 500 mg twice daily for the management of Type II diabetes mellitus. [10]

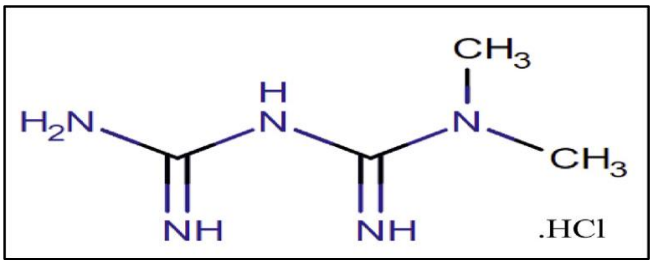

Fig 2 Structure of Metformin Hydrochloride

➢ *Introduction of Dapagliflozin Propanediol Monohydrate*

Dapagliflozin is a novel oral antidiabetic agent that lowers blood glucose levels by inhibiting sodium-glucose co-transporter-2 (SGLT2) in the renal proximal tubules, thereby preventing glucose reabsorption and promoting its excretion through urine (glucosuria)**.** This insulin-independent mechanism aids in reducing plasma glucose without contributing to insulin resistance. Dapagliflozin is effective as monotherapy, or as part of combination or add-on therapy, to help achieve and maintain optimal glycemic control in patients with type II diabetes mellitus**.**

Dapagliflozin propanediol monohydrate, marketed under the trade name Farxiga, is a selective sodium-glucose co-transporter-2 (SGLT2) inhibitor. It was first approved by the European Medicines Agency (EMA) on November 12, 2012, for the management of type 2 diabetes mellitus. [11]

- *Mechanism of Action:*

Dapagliflozin is a potent and highly selective SGLT2 (sodium-glucose co-transporter-2) inhibitor that acts by blocking renal glucose reabsorption in the proximal convoluted tubule, thereby promoting urinary glucose excretion (glucosuria) and effectively lowering blood glucose levels in patients with type 2 diabetes mellitus**.**

SGLT2 is predominantly expressed in the kidneys and minimally in other tissues such as the liver, muscle, or brain, ensuring its selective renal action. Unlike other antidiabetic agents, dapagliflozin acts independently of insulin secretion or sensitivity, reducing the risk of hypoglycemia. The inhibition of glucose reabsorption helps maintain both fasting and postprandial glucose levels and encourages the utilization of fat as an alternative energy source. Clinical studies have also shown that long-term use of dapagliflozin may contribute to improved β-cell function. [12]

- *Drug Profile of Dapagliflozin Propanediol Monohydrate:*

Dapagliflozin propanediol monohydrate (Fig.3) is chemically designated as (2S)-propane-1,2-diol (2S,3R,4R,5S,6R)-2-{4-chloro-3-[(4-ethoxyphenyl) methyl] phenyl}-6-(hydroxymethyl) oxane-3,4,5-triol hydrate**.** It has the molecular formula $C_{24}H_{35}ClO_9$ and a molecular weight of 502.99 g/mol.

The compound appears as a white to off-white crystalline powder with a melting point range of 74°C to 78°C. It exhibits a partition coefficient (log P) of 2.45, indicating moderate lipophilicity, and a dissociation constant (pKa) of 12.6. Dapagliflozin propanediol monohydrate is

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freely soluble in methanol and water and soluble in acetonitrile. [12]

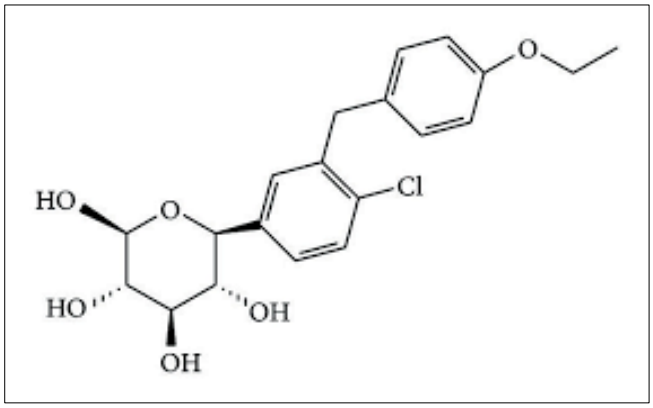

Fig 3 Structure of Dapagliflozin Propanediol Monohydrate

➢ *Introduction of Glimepiride*

Glimepiride is a second-generation sulfonylurea antidiabetic agent. Similar to other sulfonylurea derivatives, Glimepiride exerts its antihyperglycemic effect by blocking ATP-sensitive potassium (K^+ATP) channels in the pancreatic β-cells. This inhibition causes membrane depolarization, leading to the opening of voltage-gated calcium channels and subsequent insulin release.

Glimepiride was patented in 1979 and introduced to the market with the brand name Amaryl in 1995, developed by Sanofi. [13]

- *Mechanism of Action:*

Glimepiride is an insulin secretagogue belonging to the sulfonylurea class of oral hypoglycemic agents. Its glucose-lowering effect depends on the presence of functional pancreatic β-cells. Glimepiride binds to and inhibits ATP-sensitive potassium (K^+ATP) channels on the β-cell membrane, preventing potassium efflux and causing membrane depolarization. This depolarization activates voltage-gated calcium channels, resulting in an increase in intracellular calcium concentration, which triggers the exocytosis of insulin granules.

The released insulin binds to its receptors on peripheral tissues, stimulating GLUT-4 translocation and promoting cellular glucose uptake, thereby reducing blood glucose levels. In addition to this classical mechanism, studies suggest that glimepiride may also interact with Epac2 (also referred to as Epac3), a cyclic AMP-dependent guanine nucleotide exchanger involved in insulin granule exocytosis. Clinical investigations have demonstrated a dose-dependent relationship between serum glimepiride levels and insulin secretion under both euglycemic and hyperglycemic conditions. [14]

- *Drug Profile of Glimepiride:*

Glimepiride (Fig. 4) is chemically described as 3-ethyl-4-methyl-N- {2-[4-({[(4-methylcyclohexyl) carbamoyl] amino} sulfonyl) phenyl] ethyl} -2-oxo-2, 5-dihydro-1H-pyrrole-1-carboxamide. It has the molecular formula $C_{24}H_{34}N_4O_5S$ and a molecular weight of 490.62 g/mol. The compound appears as a white to yellowish-white crystalline powder with a melting point of 207–209°C. Its partition coefficient (log P) of 3.5 indicates moderate lipophilicity, and the dissociation constant (pKa) is 6.2, reflecting its weakly acidic character. Glimepiride is soluble in methanol and acetonitrile, but insoluble in water**.** **[15]**

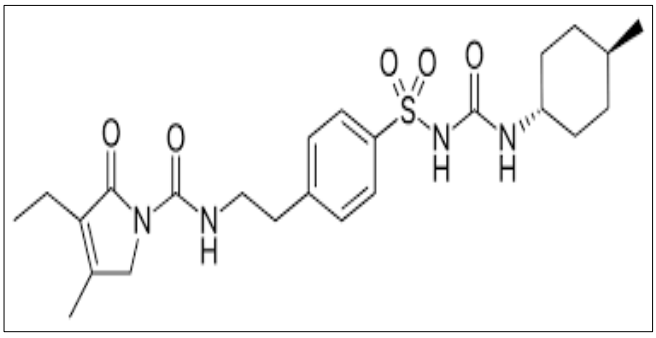

Fig 4 Structure of Glimepiride

II. REVIEW OF LITERATURE

➢ *Official Reported Methods*

Table 1 Official Reported Methods for Assessment of Metformin Hydrochloride, Dapagliflozin Propanediol Monohydrate and Glimepiride [16-19]

Sr. No.	Official	Method	Description
METFORMIN HYDROCHLORIDE [16, 17]			
1	Indian Pharmacopoeia (2022)	Chromatographic system for API and TABLET	Stationary phase: A stainless steel column, packed with Octadecylsilane bonded to porous silica (300 × 4 mm, 10 µm) Mobile phase: A solution containing 0.087% w/v of Sodium Pentanesulphonate and 0.12% w/v of Sodium Chloride, adjusted to pH 3.5 using 1% v/v solution of Orthophosphoric acid. Flow rate: 1 mL/min Wavelength: 218 nm Injection volume: 20 µL
GLIMEPIRIDE [18, 19]			

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2	Indian Pharmacopoeia (2022)	Chromatographic system for API and TABLET	Stationary phase: A stainless steel column, packed with endcapped Octadecylsilane bonded to porous silica (250 × 4 mm, 4 µm) Mobile phase: A mixture of 50 volumes of a solution prepared by dissolving 0.5 g of Sodium Dihydrogen Orthophosphate in 500 mL of Water, adjusted to pH 2.5 with Orthophosphoric acid and 50 volumes of Acetonitrile Flow rate: 1 mL/min Wavelength: 228 nm Injection volume: 20 µL

- *Dapagliflozin Propanediol Monohydrate*
  Official method is Not Reported for Dapagliflozin Propanediol Monohydrate as per any Pharmacopeia.

➢ *Reported Methods*

Table 2 Reported Methods for Assessment of Metformin Hydrochloride [15-20]

Sr. No.	Title	Description	Ref. No.
1	Development and Validation of UV-Spectrophotometric Method for Estimation of Metformin in Bulk and Tablet Dosage Form	Solvent: Water Linearity: 10-50 µg/mL Wavelength: 234 nm	20
2	Estimation of Metformin Hydrochloride by UV Spectrophotometric Method in Pharmaceutical Formulation	Solvent: Water Linearity: 2-10 µg/mL Wavelength: 232 nm	21
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY			
3	HPLC Method for Estimation of Metformin Hydrochloride in Formulated Microspheres and Tablet Dosage Form	Stationary Phase: C_{18} ODS column (250 × 4.60 mm, 5 µm) Mobile Phase: Acetonitrile: Phosphate buffer (pH 5.75) (65:35 % v/v) Flow rate: 1 mL/min Wavelength: 230 nm	22
4	Implementation of QbD Approach to the Analytical Method Development and Validation for the Estimation of Metformin Hydrochloride in Tablet Dosage Form by HPLC	Stationary Phase: Thermo scientific ODS Hypersyl™ chromatographic column (250 × 4.6 mm, 5 µm) Mobile Phase: Methanol: Acetate buffer (pH 3.0) (30:70 % v/v) Flow rate: 0.5 mL/min Wavelength: 235 nm	23
HIGH PERFORMANCE THIN LIQUID CHROMATOGRAPHY			
5	HPTLC Method for Estimation of Metformin Hydrochloride	Stationary Phase: Camag microlitre syringe on precoated silica gel aluminium plate 60 F_{254} (10 × 10 cm, 250 µm) Mobile Phase: Methanol: Chloroform: Ammonium acetate (6:3:1 % v/v/v) Wavelength: 236 nm	24
6	Stability- Indicating HPTLC Densitometric Method for Determination of Metformin Hydrochloride in Tablet Formulation	Stationary Phase: Camag microliter syringe on precoated silica gel aluminium Plate 60 F_{254} (20 × 10 cm, 0.2 mm) Mobile Phase: Water: Methanol: Triethylamine (1:3.5:0.2 % v/v) Wavelength: 247 nm	25

Table 3 Reported Methods for Assessment of Dapagliflozin Propanediol Monohydrate [21-27]

Sr. No.	Title	Description	Ref. No.
UV-VISIBLE SPECTROSCOPY			
1	Estimation of Dapagliflozin from its Tablet Formulation by UV-Spectrophotometry	Solvent: Methanol Linearity: 5-40 µg/mL Wavelength: 224 nm	26
2	Estimation Method for Dapagliflozin in Bulk and Marketed Dosage Form: Development and Validation by UV-	Solvent: Methanol Linearity: 5-30 µg/mL Wavelength: 220 nm	27

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	Spectroscopy		
3	A Novel UV Spectrophotometric Method Development and Validation of Dapagliflozin in Bulk and Pharmaceutical Dosage Form	Solvent: Acetonitrile and Ethanol (70:30) Linearity: 3-18 µg/mL Wavelength: 224 nm	28
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY			
4	Development and Stability Indicating HPLC Method for Dapagliflozin in API and Pharmaceutical Dosage Form	Stationary Phase: Agilent C_{18} column (150 × 4.6 mm, 5 µm) Mobile Phase: Acetonitrile: Di-potassium hydrogen phosphate (40:60 % v/v) Flow rate: 1 mL/min Wavelength: 222 nm	29
5	Generation of Predictive Models for Oxidative Degradation Kinetics of Dapagliflozin with the Applications of DOE and Stability Indicating HPLC Method	Stationary Phase: C_{18} column (150 × 4.6 mm, 5 µm) Mobile Phase: Acetonitrile: 0.1% Triethylamine (70:30 % v/v) Flow rate: 1 mL/min Wavelength: 270 nm	30
6	A New RP-HPLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form	Stationary Phase: C_{18} column (250 × 4.6 mm, 5 µm) Mobile Phase: Phosphate buffer (pH 3.0): Acetonitrile (60:40 % v/v) Flow rate: 1 mL/min Wavelength: 237 nm	31
HIGH PERFORMANCE THIN LIQUID CHROMATOGRAPHY			
7	A New High-Performance Thin Layer Chromatographic Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form	Stationary Phase: Merck precoated silica gel aluminum plate 60 F_{254} (10 x 10 Cm, 0.2 mm) Mobile Phase: Chloroform: Methanol (9:1 % v/v) Wavelength: 223 nm	32

Table 4 Reported Methods for Assessment of Glimepiride [28-33]

Sr. No.	Title	Description	Ref. No.
UV-VISIBLE SPECTROSCOPY			
1	UV Spectrophotometric Method for Determination of Glimepiride in Pharmaceutical Dosage Forms	Solvent: Chloroform Linearity: 5-30 µg/mL Wavelength: 249 nm	33
2	Development and Validation of an UV-Derivative Spectrophotometric Method for Determination of Glimepiride in Tablets	Solvent: NaOH Linearity: 2-40 µg/mL Wavelength: 228 nm	34
3	Simple UV Spectrophotometric Assay of Glimepiride	Solvent: Water Linearity: 6.25-50 µg/mL Wavelength: 200 nm	35
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY			
4	Determination of Glimepiride in Pharmaceutical Formulations using HPLC and First- Derivative Spectrophotometric Methods	Stationary Phase: C_{18} column (250 × 4.6 mm, 5 µm) Mobile Phase: Acetonitrile: 2% Formic acid solution (80:20 % v/v) Flow rate: 1 mL/min Wavelength: 228 nm	36
5	Development of a Quality by Design Based Hybrid RP-HPLC Method for Glimepiride: Bioanalytical and Industrial Applications	Stationary Phase: Phenomenex C_{18} column (150 × 4.6 mm, 4 µm) Mobile Phase: Ammonium Acetate buffer (pH 4.0): Acetonitrile (40:60 % v/v) Flow rate: 0.8 mL/min Wavelength: 228 nm	37
HIGH PERFORMANCE THIN LIQUID CHROMATOGRAPHY			
6	Stress Stability Study Showing Effect of Acid, Base, H_2O_2 and Dry Heat on Glimepiride by HPTLC Method	Stationary Phase: TLC aluminium sheets Silica gel 60 F_{254} (20 × 10 cm, 250 µm) Mobile Phase: Toluene: Chloroform: Ethanol (4:4:1 % v/v/v) Wavelength: 234 nm	38

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Table 5 Reported Methods for Combination of Drugs [34-38]

Sr. No.	Title	Description	Ref. No.
Metformin and Dapagliflozin			
1	Stability indicating HPLC Method Development and Validation for Simultaneous Estimation of Dapagliflozin and Metformin Tablet Dosage Form	Stationary phase: C_{18} column (250 × 4.6 mm and 5 µm) Mobile phase: Methanol: Water (75:25 % v/v) Flow rate: 1 mL/min. Wavelength: 233 nm	39
2	Method Development and Validation of Metformin HCl and Dapagliflozin by using RP-HPLC	Stationary phase: Unisol C_{18} column (150 × 4.6 mm, 3 µm) Mobile phase: Phosphate buffer (pH 6.8): Acetonitrile (45:55 % v/v) Flow rate: 1 mL/min. Wavelength: 233 nm	40
3	An Improved Validated RP-HPLC Method for the Simultaneous Estimation of Metformin and Dapagliflozin	Stationary phase: Unisol C_{18} column (150 × 4.6 mm, 3 µm) Mobile phase: Buffer (pH 3.7): Methanol: Acetonitrile (40:35:25 % v/v) Flow rate: 0.8 mL/min. Wavelength: 232 nm	41
Metformin and Glimepiride			
4	RP-HPLC Method Development and Validation of Metformin Hydrochloride & Glimepiride in Fixed Dose Combination and Evaluation of 5 Marketed Formulations by Quality by Design	Stationary phase: Symmetry C_{18} (150 x 4.6mm, 5µm) Mobile phase: Potassium Dihydrogen Phosphate: Acetonitrile (40:60 % v/v) Flow rate: 1 mL/min. Wavelength: 230 nm	42
5	Validated RP-HPLC Method Development for the Simultaneous Estimation of Metformin and Glimepiride in Combine Tablet Dosage Form	Stationary phase: Grace RP- C_{18} column (150 x 4.6 mm, 5 µm) Mobile phase: Acetonitrile: Dihydrogen Potassium Phosphate (60:40 % v/v) Flow rate: 0.7 mL/min. Wavelength: 242 nm	43

III. CONCLUSION

Diabetes mellitus is a chronic metabolic disorder with a rapidly enlarge global generality and is correlated with serious long-term difficulty such as nephropathy, retinopathy, and cardiovascular diseases. Effective glycemic control is therefore essential to prevent disease progression and improve patient outcomes. Type 2 diabetes mellitus (T2DM), the most prevalent form, often requires pharmacological intervention beyond lifestyle modification, and combination therapy has become a cornerstone in achieving and maintaining optimal glycemic targets.

Metformin Hydrochloride remains the first-line drug for T2DM due to its proven efficacy, safety profile, and ability to reduce hepatic glucose production while improving insulin sensitivity without causing significant hypoglycemia. Dapagliflozin Propanediol Monohydrate, a selective SGLT2 inhibitor, offers an insulin-independent mechanism by enhancing urinary glucose excretion, with additional benefits on body weight, cardiovascular outcomes, and renal protection. Glimepiride, a second-generation sulfonylurea, effectively lowers blood glucose by stimulating insulin secretion from functional pancreatic β-cells, making it useful in patients requiring enhanced insulin release.

The distinct and complementary mechanisms of action of metformin, dapagliflozin, and glimepiride support their use either as monotherapy or in combination therapy for T2DM. Such combination approaches target multiple pathophysiological defects of diabetes, improve glycemic control, reduce the risk of complications, and enhance overall therapeutic efficacy. Hence, rational selection and combination of these antidiabetic agents play a vital role in the comprehensive management of type 2 diabetes mellitus.

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