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Review Article

A Comprehensive Review on Dapagliflozin and Tadalafil: Role in Erectile Disfunction

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ABSTRACT

Erectile dysfunction (ED) is a common and distressing complication in men with type 2 diabetes mellitus (T2DM), primarily caused by endothelial dysfunction, impaired nitric oxide signaling, and metabolic abnormalities. Phosphodiesterase-5 inhibitors such as tadalafil are widely prescribed for ED; however, their effectiveness may be reduced in diabetic patients due to underlying vascular damage. Dapagliflozin, a sodium–glucose co-transporter-2 (SGLT2) inhibitor used for glycemic control, has demonstrated additional benefits including improvement in endothelial function, blood pressure reduction, and enhanced vascular health. These effects suggest a potential supportive role of dapagliflozin in improving erectile function and augmenting the therapeutic response to tadalafil in diabetic individuals. Alongside therapeutic considerations, accurate and reliable analytical methods are essential for quality control and regulatory compliance of these drugs. This review provides a comprehensive overview of the physicochemical properties, pharmacological significance, and reported analytical methods for dapagliflozin and tadalafil, with emphasis on reverse-phase high-performance liquid chromatography (RP-HPLC). Various chromatographic conditions, validation parameters, and official pharmacopoeia methods are discussed. Overall, this review serves as a valuable reference for pharmaceutical analysts and researchers involved in method development and quality assessment of these clinically important agents.

INTRODUCTION

Erectile dysfunction frequently endures despite proper glycaemic management, suggesting the necessity for treatment strategies that address the disease's vascular and metabolic components. The progressive metabolic disease known as type 2 diabetes mellitus (T2DM) has long-term consequences that seriously lower quality of life. Among these problems, endothelial dysfunction, reduced nitric oxide bioavailability, autonomic neuropathy, and vascular damage from long-term

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hyperglycaemia are the main causes of erectile dysfunction (ED), which is extremely common in male T2DM patients.

Dapagliflozin (DAPA)

By decreasing renal glucose reabsorption, dapagliflozin, a specific sodium–glucose cotransporter-2 (SGLT2) inhibitor, increases urine glucose excretion and improves glycaemic management without requiring insulin secretion. In addition to its antihyperglycemic actions, dapagliflozin has been shown to promote vascular health, reduce oxidative stress, and improve endothelial function. These pleiotropic effects raise the possibility that dapagliflozin may help reduce erectile dysfunction and other vascular problems associated with diabetes. Dapagliflozin may improve erectile function measures in men with type 2 diabetes, according to recent clinical evidence, potentially via increasing penile blood flow and endothelial reactivity.

Tadalafil (TADA)

One common first-line treatment for erectile dysfunction is tadalafil, a phosphodiesterase type-5 (PDE-5) inhibitor. It works by preventing the breakdown of cyclic guanosine monophosphate (cGMP), which improves erectile response and nitric oxide-mediated vasodilation in the corpus cavernosum. However, underlying endothelial dysfunction and decreased nitric oxide signalling may restrict the effectiveness of tadalafil as monotherapy in T2DM patients, requiring complementary therapeutic options to maximize clinical outcomes.

CAUSES OF ERECTILE DYSFUNCTION [2]

Erectile dysfunction is a multifactorial disorder resulting from disturbances in vascular, neurological, hormonal, psychological or endothelial function. The major causes include:

- **Vascular causes:** Atherosclerosis, cardiovascular disease and hypertension leading to reduced penile blood flow.
- **Metabolic disorders:** Diabetes mellitus and metabolic syndrome causing endothelial dysfunction, oxidative stress and neuropathy.
- **Endocrine causes**: Hypogonadism (low testosterone), thyroid disorders and other hormonal imbalances.
- **Neurological causes:** Stroke, spinal cord injury, multiple sclerosis and peripheral neuropathy affecting erectile nerve pathways.
- **Drug-induced causes:** Antihypertensives, antidepressants, antipsychotics, opioids and recreational drugs.
- **Psychological causes:** Depression, anxiety, stress and performance anxiety.
- **Lifestyle factors:** Smoking, obesity, alcohol abuse and sedentary lifestyle.

PATHOPHYSIOLOGY

Combined Pathophysiology of Tadalafil and Dapagliflozin

In type 2 diabetes mellitus, chronic hyperglycaemia leads to oxidative stress, endothelial dysfunction and reduced nitric oxide (NO) availability, resulting in impaired cyclic guanosine monophosphate (cGMP) signalling and erectile dysfunction. Dapagliflozin improves glycaemic control by inhibiting renal sodium–glucose cotransporter-2, thereby reducing hyperglycaemia-induced oxidative stress and restoring endothelial function and NO

bioavailability. Tadalafil inhibits phosphodiesterase-5, preventing cGMP degradation and enhancing NO-mediated smooth muscle relaxation in the corpus cavernosum. The combined use of dapagliflozin and tadalafil therefore targets both the underlying metabolic abnormality and the impaired NO–cGMP pathway, producing a synergistic improvement in penile haemodynamic and erectile function in patients with type 2 diabetes mellitus.

MECHANISM OF ACTION (MOA) [3]

The management of erectile dysfunction (ED) aims to restore erectile function, improve sexual satisfaction and address underlying pathophysiological factors such as endothelial dysfunction, metabolic abnormalities and impaired nitric oxide signalling. Current treatment strategies include pharmacological therapy as the primary approach, along with lifestyle modification and management of comorbid conditions.

Role of Tadalafil in Erectile Dysfunction

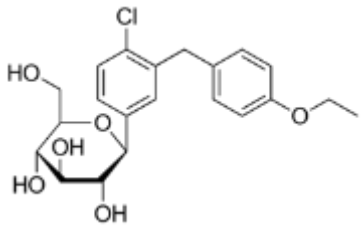
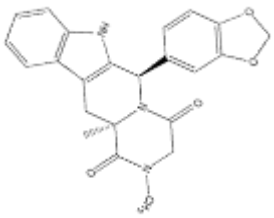
Phosphodiesterase type-5 inhibitors (PDE-5 inhibitors) represent the first-line pharmacological treatment for erectile dysfunction. Tadalafil is a long-acting PDE-5 inhibitor that enhances erectile function by inhibiting the degradation of cyclic guanosine monophosphate (cGMP), thereby potentiating nitric oxide–mediated smooth muscle relaxation in the corpus cavernosum. Compared to other PDE-5 inhibitors, tadalafil offers a prolonged duration of action, allowing flexible dosing regimens including on-demand and once-daily administration. Tadalafil is effective in a wide range of patients; however, its therapeutic response may be reduced in individuals with diabetes mellitus due to underlying endothelial dysfunction and impaired nitric oxide bioavailability.

Role of Dapagliflozin in Erectile Dysfunction

Dapagliflozin, a sodium-glucose cotransporter-2 (SGLT-2) inhibitor, is primarily indicated for the management of type 2 diabetes mellitus. Emerging evidence suggests that dapagliflozin may contribute to improvement in erectile dysfunction by targeting metabolic and vascular abnormalities associated with diabetes. By reducing hyperglycaemia, oxidative stress and inflammation, dapagliflozin improves endothelial function and enhances nitric oxide availability. Although not a conventional erectile dysfunction drug, dapagliflozin represents a novel adjunctive therapeutic option in diabetic patients with erectile dysfunction by addressing the underlying disease pathology rather than providing only symptomatic relief.

DRUG PROFILE [4,5,6]

Tab.1 Drug profile of Dapagliflozin and Tadalafil

Drug	Dapagliflozin	Tadalafil
Chemical Structure		
IUPAC Name	2-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol	(6R,12aR)-2,3,6,7,12,12a-Hexahydro-2-methyl-6-(3,4-methylene dioxyphenyl)

		pyrazino (1′,2′:1,6) pyrido (3,4-b) indole-1,4-dione
Molecular Formula	$C_{21}H_{25}ClO_6$	$C_{22}H_{19}N_3O_4$
Molecular Weight	408.88 g/mol	389.404 g/mol
Solubility	DMSO, dimethyl formamide and ethanol, methanol	Very low soluble in Water Very slightly Soluble in Methanol
pKa	13.23	13.1
Log p	2.7	2.36
Melting Point	65-70°C	301- 302°C
Therapeutic Uses	Oral Hypoglycaemic Agent	To treat Erectile Dysfunction (ED)

LITERATURE REVIEW OF DAPAGLIFLOZIN

There are no official methods available for Dapagliflozin in Pharmacopoeia

Tab. 2 UV spectrophotometric method of Dapagliflozin

Sr. No.	Matrix	Solvent	Detection Wavelength (nm)	Ref. No.
1	Bulk	Ethanol	278	07
2	Tablet	Methanol	224	08
3	Bulk & Tablet	Methanol	220	09
4	Bulk & Tablet	Methanol	228	10
5	API	Ethanol	237	11
6	Bulk & Tablet	Methanol	225	12

Reported HPLC method of Dapagliflozin

Tab. 3. HPLC method of Dapagliflozin

Sr. No.	Matrix	S.P.	Solvent System	Detection Wavelength (nm)	Flow Rate (mL/min)	Retention Time (min)	LOD (µg/mL)	LOQ (µg/mL)	Ref. No.
1	Tablet	Zorobax Eclipse Plus Phenyl Hexyl (25×0.46cm, 5µm)	Buffer: Methanol: ACN (40:35:25 % Vol/Vol)	267	1.0	8.99	-	-	13
2	Synthetic Mixture	$C1_8$ (25×0.46cm, 5µm)	ACN: Methanol: $NH_4CH_3CO_2$ Buffer (pH-5.5) (60:20:20 %Vol/Vol/Vol)	268	1	8.328	0.78	2.36	14
3	Tablet	Shimadzu C_{18} (15×0.46cm, 5 µm)	Buffer: ACN (65:35 % Vol/Vol)	205	0.8	6.986	-	-	15
4	Tablet	Princeton C_{18}	ACN: 0.1%TEA	254.6	1	-	-	-	16

		(25×0.46cm, 5µm)	(50:50 Vol/Vol)						
5	Tablet	C_{18} (15×0.46cm, 2.5 µm)	ACN: 0.05% H_3PO_4 (80:20 % Vol/Vol) pH 6.5 With 0.1% TEA	286	1	3.044	2.11	6.40	17
6	Tablet	Cosmosil C_{18} (25×0.46cm, 5 µm)	Methanol: Buffer (85:15 Vol/Vol) With Adjusted pH 3 By KH_2PO_4	224	0.9	4.365	0.8076	0.2447	18
7	Tablet	Princeton C_{18} (25×0.46cm, 5 µm)	ACN: 0.1% TEA (pH-5.0) (50:50 Vol/Vol)	224	1	5.163	2.1	6.39	19
8	Bulk & Tablet	Phenomenex C_{18} (25×0.46cm, 5 µm)	Water: Methanol (50:50 Vol/Vol)	230	1	3.338	263000 ppb	324000 ppb	20
9	Tablet	Hypersil BDS C_{18} (25×0.46cm, 5 µm)	ACN: Water (90:10 Vol/Vol)	245	1	7.82	0.065	0.196	21
10	Tablet	Agilent Poroshell 120 EC- C_{18} (25×0.46cm, 5 µm)	Water: ACN (30:70 Vol/Vol)	225	0.9	10.020	0.25	1.6	22
11	Synthetic Mixture	Shimadzu C_{18}, (25×0.46cm, 5 µm)	ACN: Methanol: Buffer (pH 4) (35:35:30 Vol/Vol/Vol)	236	1	4.0	0.288	0.951	23
12	Tablet	Zorbax Eclipse Plus, Agilent Technology (15×0.46cm, 5µm)	Water: Methanol (25:75 Vol/Vol)	230	1	3.1	2.5	10.00	24
13	Tablet	C_{18} Column (25×0.46cm, 5 µm)	ACN:0.1% H_3PO_4 (50:50 Vol/Vol)	210	0.98	3.45	0.09	0.27	25
14	Tablet	Hypersil BDS C_{18} (25×0.46cm, 5 µm)	Methanol: ACN (60:40 Vol/Vol)	215	1.5	-	-	-	26
15	Tablet	Phenomenex C_{18} (15×0.46cm, 5µm)	Buffer: ACN: Methanol (30:5:65 Vol/Vol/Vol) (pH 3.5)	249	1.2	3.238	0.084	0.254	27

16	Tablet	C_{18} (15×0.46cm, 5µm)	2% GAA: ACN (85:15 Vol/Vol)	230	1	1.979	0.18	-	28
17	Synthetic Mixture	Gemini, C_{18}, (25×0.46cm, 5µm)	Methanol: 20 mM CH_5NO_2 (70:30 Vol/Vol)	225	1	4.20	0.947	2.869	29
18	Bulk	ODS C_{18} (25×0.46cm, 5µm)	ACN: HPLC Water (30:70 Vol/Vol)	230	1	-	0.138	0.417	30
19	Bulk Drug	Inertsil C_{18} (15×0.46cm, 5 µm)	ACN: 10 mM KH_2PO_4 pH 6.5 By TEA (75:25 %Vol/Vol)	214	1	11.411	0.35	1.06	31
20	Bulk & Tablet	Agilent 5 TC C_{18} (15×0.46cm, 4µm)	Water: Methanol (30:70 Vol/Vol).	224	1.2	6.5	-	-	32
21	Bulk & Tablet	Phenomenex Luna® LC C_{18} (15×0.46cm, 5µm)	ACN: Water (65:35 Vol/Vol)	225	1.0	2.2	0.306	0.929	33
22	Bulk & Tablet	Zorbax Eclipse Plus C_8 (15×0.46cm, 5µm)	Buffer (pH 7.6) Tris: Methanol (60:40 Vol/Vol)	224	1	1.467	0.207	0.693	34
23	Tablet	Inertsil ODS-3V (15×0.46cm, 5µm)	50% ACN :50% Water (50:50 Vol/Vol.)	223	1.00	8	0.257	0.778	35
24	Bulk & Tablet	Agilent C_{18} (15×0.46cm, 5 µm)	ACN: K_2HPO_4 With pH-6.5 By H_3PO_4 (40:60 %Vol/Vol)	222	1.00	3.067	5.14	15.6	36
25	Tablet	ZORBAX (C_{18}) (25×0.46cm, 5 µm)	Phosphate Buffer: ACN: Methanol (55:40:05 Vol/Vol/Vol)	225	1.00	2.12	-	-	37
26	Tablet	C_{18} Column (25×0.46cm, 5 µm)	Methanol: Water (75:25 % Vol/Vol) pH-3 Adjusted With 0.05 % H_3PO_4	233	1.00	5.099	0.06	0.1855	38
27	Tablet	X-Bridge C_{18}, (25×0.46cm, 5µm)	Mobile Phase A: Phosphate Buffer: ACN (900:100 Vol/Vol)	230	1.00	15.639	-	-	39

			Mobile Phase B: Phosphate Buffer: ACN (300:700 Vol/Vol)						
28	Tablet	Develosil ODS HG-5 C_{18} (15×0.46cm, 5µm)	Phosphate Buffer: ACN (80:20 Vol/Vol)	292	1.00	3.545	0.09	0.27	40
29	Tablet	C_{18} Inertsil ODS (15×0.46cm, 5µm)	Phosphate Buffer: ACN (55:45 Vol/Vol), pH 4.0 Adjusted By GAA	220	0.8	3.15µ6	-	-	41
30	Tablet	C_{18} Thermoquest , Hypersil (25×0.46 cm, 5 µm)	10 mM $NH_4CH_3CO_2$ Buffer pH 4: Methanol: ACN (30:65:05 Vol/Vol/Vol)	227	0.8	5.988	1.121	3.396	42
31	Tablet	Inertsil ODS 3V (25×0.46cm, 5µm)	ACN: H_3PO_4 (0.1%) (50:50 Vol/Vol)	235	1.2	4.683	-	-	43
32	Tablet	Shim-Pack C_{18} RP (25×0.46cm, 5 µm)	Water: Ethanol (40 :60, % Vol/Vol) pH 3.0.	212	1.00	3.85	0.0223	0.06693	44
33	Tablet	Agilent Zorbax SB-Aq (25×0.46cm, 5 µm)	Water: ACN (50:50 % Vol/Vol)	258	1	6.45	23.44	2.62	45
34	Drug	YMC Pack Pro C_{18}, (25×0.46cm, 5 µm)	ACN: H_3PO_4 (50:50 Vol/Vol)	225	0.8	21	1.9	0.8	46
35	Bulk And Tablet	Hypersil C_{18} (25×0.46cm, 5 µm)	ACN: Water (90:10 Vol/Vol) Adjusting pH 3 Using $NH_4CH_3CO_2$	244	1	3.01	0.052	0.15	47
36	Tablet	Cosmosil C_{18} (25×0.46cm, 5 µm)	Methanol: KH_2PO_4 Buffer With pH 3.0 (80:20 %Vol/Vol)	228	0.9	3.6	0.052	0.158	48

37	Bulk & Tablet	Develosil ODS HG-5 RP C_{18}, (15×0.46cm, 5µm)	Methanol: Phosphate Buffer (0.02M, pH-3.6) (45:55 % Vol/Vol)	255	1.0	3.29	5.004	15.164	49
38	Bulk & Tablet	Symmetry C_{18}, (25×0.46cm, 5 µm)	Methanol: ACN: H_3PO_4 (75:25:05 Vol/Vol/Vol)	246	1.0	2.797	0.04	0.12	50
39	Bulk & Tablet	Sunsil C_{18} (15×0.45cm, 5µm)	Methanol: Water (85:15 Vol/Vol)	225	1.0	2.47	0.011	0.034	51
40	Bulk & Tablet	Lichrospher 100 RP-18e (25×0.46cm, 5 µm)	0.01% Formic Acid: ACN (30:70 Vol/Vol)	219	0.8	3.1	0.06	0.21	52
41	Bulk & Tablet	Prontosil C_{18} (25×0.46cm, 5 µm)	20mM KH_2PO_4: ACN (pH 3.5 With H_3PO_4) (30:70 Vol/Vol)	275	1	-	0.018	0.050	53
42	API & Impurities	X-Bridge Phenyl C_{18}, (25×0.46cm, 5 µm)	Aq. Trifluoracetic Acid: ACN (80:20 % Vol/Vol)	210	1	7.389	0.0000627 ppm	0.000619 ppm	54
43	Bulk & Tablet	Agilent C_{18} (25×0.46cm, 5 µm)	Methanol: 0.05 % H_3PO_4 Buffer (70:30 Vol/Vol)	233	1.00	5.576	1.1942	3.617	55
44	Tablet	Zorbax Eclipse Plus C_{18} (25×0.46cm, 5 µm)	10 mM $NH_4CH_3CO_2$ Buffer: Water: Methanol: ACN (40:50:10 Vol/Vol/Vol)	224	0.6	12.7	0.50	1.56	56
45	Bulk & Synthetic Mixture	Phenomenex Luna C_{18} (25×0.46cm, 5 µm)	ACN: Water (75:25 % Vol/Vol)	285	1.00	5.4	3.7	11.4	57
46	Bulk & Tablet	C_{18} Thermo (25×0.46cm, 5 µm)	Methanol: 0.1 % H_3PO_4 (60:40 Vol/Vol)	220	1.00	7.30	-	-	58
47	Tablet	Zorbax Eclips XDB C_{18} (15x 0.46cm, 5µm)	Buffer: ACN: Methanol (60:37:03 % Vol/Vol).	220	1	5.99	-	-	59

LITERATURE REVIEW OF TADALAFIL

Tab. 4 Official Method of Tadalafil

Sr. No.	Official Method	Matrix	S.P.	Solvent System	Detection Wavelength (nm)	Flow Rate (mL/min)	Ref. No.
1.	IP 2018, Volume 2	Bulk	A stainless-steel column 25 cm x 4.6 mm packed with Silica gel AD for chiral separation.	Equal volumes of hexane and isopropyl alcohol	222	0.75	60
2.	IP 2018, Volume 2	Tablet	A stainless-steel column 5 cm x 4.6 mm packed octadecylsilane bonded to porous silica (3.5 µm)	A mixture of equal volumes of methanol and water	225	2	61
3.	USP 2019, Volume 2	Bulk	4.6 mm × 25 cm; 5 µm packing L7	Acetonitrile: solution (Add 1 ml of trifluoroacetic acid to 1L of water (45:55)	285	1.5	62
4.	USP 2019, Volume 2	Tablet	4.6 mm × 25 cm; 3.5 µm packing L7	Methanol: Water (50:50 v/v)	285	2	63

Tab. 5 UV spectrophotometric method of Tadalafil

Sr. No.	Matrix	Solvent	Detection Wavelength (nm)	Ref. No.
1	Bulk & Tablet	Methanol	284	64
2	Bulk & Tablet	Methanol: Water (80:20)	284.5	65
3	Bulk & Tablet	DMSO	285.6	66
4	Bulk	Methanol	284.40	67
5	Bulk & Tablet	Methanol	235	68
6	Bulk & Tablet	Methanol	284	69

Reported HPLC method of Tadalafil

Tab. 6 HPLC method of Tadalafil

Sr. No.	Matrix	S.P.	Solvent System	Detection Wavelength (nm)	Flow Rate (mL/ min)	Retention Time (min)	LOD (µg/ mL)	LOQ (µg/ mL)	Ref. No.
1.	Tablet	Supelco C_{18} column (25cm x 4.6 mm; 5 µm)	Methanol: Water: Triethylamine (60:38:2 v/v/v) pH adjusted to 4.0 with dilute phosphoric acid	220	1.3	3.6	0.02811	0.09345	70

2.	Bulk and Tablet	Agilent Eclipse XDB C_{18} column (150 mm × 4.6 mm, 5 µ)	Buffer (potassium dihydrogen orthophosphate) and acetonitrile in the ration of 50:50 v/v	285	1.2	3.181	0.03	0.09	71
3.	Tablet	Agilent Zorbax SB C_8 column (50 ×4.6 mm, 1.8 µm)	0.030M of ammonium formate (adjusted to pH 3.0 with formic acid) and acetonitrile in the ratio 70:30, v/v	230	1.3	5.067	0.1	-	72
4.	Tablet	Agilent eclipse C_{18} column (4.6 x 250mm, 5um)	Phosphate buffer pH 4.0: Acetonitrile (50:50 v/v)	284	1.0	6	-	-	73
5.	Tablet	Hypersil GOLD C_{18} column (150 mm × 4.6 mm internal diameter, 5 µm particle size)	Methanol: Water: Acetonitrile (40:40:20 v/v/v)	260	0.5	7.10	0.12	0.36	74
6.	Tablet	Water Symmetry C_{18} (150 x 4.6 mm)	50mM Phosphate buffer (pH 6.0) : Acetonitrile (65:35 v/v)	285	1.0	10.08	0.039	0.129	75
7.	Tablet	Phenomexgemini C_{18} (150 mm, 4.6 mm, 5µm)	Methanol: 10 mM ammonium formate (74.1: 25.9, v/v)	260	0.94	4	-	-	76

CONCLUSION

Dapagliflozin and tadalafil represent an effective therapeutic approach for managing erectile dysfunction in patients with type 2 diabetes mellitus by improving metabolic and vascular function. This review summarizes the pharmacological relevance and the wide range of reported RP-HPLC methods for their estimation in bulk and pharmaceutical dosage forms. The compiled analytical information provides a useful reference for method selection and future analytical method development.

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