EJPMR, 2026, 13(8), 26-40 **Review Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

A REVIEW ON ANALYTICAL METHOD DEVELOPMENT FOR DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE AND BISOPROLOL FUMARATE IN COMBINED PHARMACEUTICAL FORMULATIONS

S. Arunprasath[*1], T. Vetrichelvan Thangarasu[2], S. Murugan[3]

P.G. Scholar[1*], Dean Research[2], Professor[3]
Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy, Melmaruvathur-603319, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai 600032, Tamil Nadu, India.

***Corresponding Author: S. Arunprasath**

P.G. Scholar, Department of Pharmaceutical Analysis, Adhiparasakthi College of Pharmacy, Melmaruvathur-603 319, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai 600032, Tamil Nadu, India.

DOI: https://doi.org/10.5281/zenodo.21701774

How to cite this Article: S. Arunprasath[*1], T. Vetrichelvan Thangarasu[2], S. Murugan[3]. (2026). A Review on Analytical Method Development For Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate In Combined Pharmaceutical Formulations. European Journal of Pharmaceutical and Medical Research, 13(8), 26–40.

Article Received on 20/06/2026 **Article Revised on 10/07/2026** **Article Published on 01/08/2026**

ABSTRACT

This review analyse the analytical method associated with the co-administration of Dapagliflozin (an SGLT2 inhibitor) and Bisoprolol (a selective β1-blocker) in managing the heart failure and related metabolic comorbidities. By treating with Bisoprolol counteracts sympathetic overactivation and Dapagliflozin regulate cardiorenal pathways through osmotic diuresis and metabolic optimization, resulting in a complementary reduction in the cardiovascular mortality and hospitalization. This document evaluate analytical techniques developed for their simultaneous estimation in pharmaceutical formulations. We combined established methods covering UV-Vis Spectrophotometry, Reversed-Phase High-Performance Liquid Chromatography (RP-HPLC), High-Performance Thin-Layer Chromatography (HPTLC), and Liquid Chromatography-Mass Spectrometry (LC-MS/MS), highlighting method validation and emerging green analytical chemistry. As a result, this compilation serves as a dual-purpose reference for both the therapeutic purpose and the rigorous quality control work required for this vital cardiorenal and cardiovascular protection combination.

1. INTRODUCTION[1,2,3,4]

Dapagliflozin propanediol monohydrate (DAPA), a sodium-glucose co-transporter-2 (SGLT2) inhibitor, and bisoprolol fumarate (BISO), a β1-selective adrenergic blocker, represent a pharmacologically complementary fixed-dose combination (FDC). Clinical evidence shows SGLT2 inhibitors such as dapagliflozin in heart failure with reduced ejection fraction (HFrEF), where dapagliflozin 10 mg/day reduced the composite of cardiovascular death and worsening heart failure compared with placebo in the DAPA-HF trial.

This pharmacological synergic activity interest in DAPA-BISO FDCs for HFrEF management, particularly in patients with comorbid type 2 diabetes and hypertension, and the combination has been included in CDSCO approval correspondence (October 2024) for clinical trial conduct in India. Both the APIs are described in the most recent USPNF monographs (October 2024) The absence of an official compendial assay for this specific combination has driven a wave of analytical method-development papers across chromatographic, spectroscopic, and hyphenated methods. This review combined these efforts drawn from peer-reviewed journals to provide a comparative reference for analytical method simultaneous estimation of this FDC.

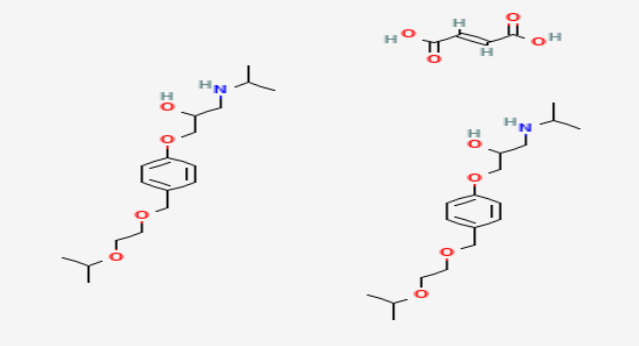
Available formulation of Dapaglifozin and Bisoprolol In market in India.

Brand name	Manufacturer	Strength Profile (Dapagliflozin + Bisoprolol) Brand
Corbis D 1.25	Torrent Pharmaceuticals Ltd	Dapagliflozin 10 mg + Bisoprolol 1.25 mg
Gluxit Beta 1.25	Eris Lifesciences Pvt Ltd	
DapaBiso 10/1.25	Zydus Lifesciences Ltd	
Bisolong-D 1.25	Micro Labs Ltd	

Corbis D 2.5	Torrent Pharmaceuticals Ltd	Dapagliflozin 10 mg + Bisoprolol 2.5 mg
Gluxit Beta 2.5	Eris Lifesciences Pvt Ltd	
DapaBiso 10/2.5	Zydus Lifesciences Ltd	
Daplo-BIS 2.5	Dr. Reddy's Laboratories Ltd	
Justoza B 2.5	Mankind Pharma Ltd	
Corbis D 10/5	Torrent Pharmaceuticals Ltd	Dapagliflozin 10 mg + Bisoprolol 5 mg
Gluxit Beta 5	Eris Lifesciences Pvt Ltd	
Oxra Biso 10/5	Sun Pharmaceutical Industries Ltd	
DapaBiso 10/5	Zydus Lifesciences Ltd	
Bisofig D 5	Cipla Ltd	
Justoza B 5	Mankind Pharma Ltd	
Bisolong D 5	Micro Labs Ltd	
Daplo-BIS 5	Dr. Reddy's Laboratories Ltd	
Bisoheart D 5	Mankind Pharma Ltd	
Dapoflit B 5	Cafoli Lifecare Pvt Ltd	
Bisocor Dapa 5/10	Healing Pharma / Lancer	
Glidapa Biso 10/5	Steris Healthcare Pvt Ltd	
Glidapa Biso 10/10	Steris Healthcare Pvt Ltd	Dapagliflozin 10 mg + Bisoprolol 10 mg
Dapoflit B 10	Cafoli Lifecare Pvt Ltd	

1.2DRUG PROFILE

1.2 a) BISOPROLOL FUMARATE[2,4]



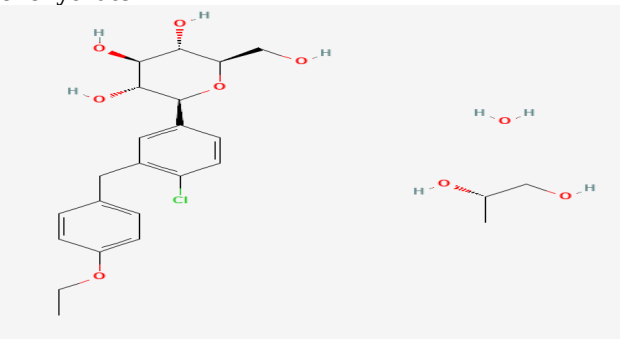
- MOLECULAR FORMULA: C40H66N2O12
- MOLECULAR WEIGHT: 766.97 g/mol
- IUPAC NAME: (2E)-but-2-enedioic acid; bis(1-[(propan-2-yl)amino]-3-(4-{[2-(propan-2-yloxy)ethoxy]methyl}phenoxy)propan-2-ol)
- BIOAVAILABLITY: 90%

MECHANISM OF ACTION: Bisoprolol is used for prevention of cardiovascular events following a heart attack in patients with risk factors for disease progression, in the management of congestive heart failure with reduced ejection fraction, and as a second-line agent for hypertension.

Bisoprolol may be beneficial in the treatment of high blood pressure, but it is not recommended as a first-line antihypertensive agent. It can be an adjunct to first-line antihypertensive agents in patients with accompanying comorbidities, for example, congestive heart failure, where selected beta blockers can be added in patients who remain mildly to moderately symptomatic despite appropriate doses of an angiotensin-converting-enzyme inhibitor.

In cardiac ischemia, the drug is used to reduce the activity of the heart muscle, thereby reducing its oxygen and nutrient demands and allowing its reduced blood supply to still transport sufficient amounts of oxygen and nutrients to meet its needs.

Dapagliflozin Propanediol Monohydrate[2,3]



- MOLECULAR FORMULA: $C_{24}H_{35}ClO_9$
- MOLECULAR WEIGHT: 502.99 g/mol
- IUPAC NAME: (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
- BIOAVAILABLITY: 78%

MECHANISM OF ACTION

- Dapagliflozin inhibits subtype 2 of the sodium-glucose transport proteins (SGLT2), which are responsible for at least 90% of the glucose reabsorption in the kidney. Blocking this transporter mechanism causes blood glucose to be eliminated through the urine.
- In combination with metformin, dapagliflozin at standard treatment dose of 10 mg daily lowered HbA1c by 0.54-0.84% (5.9-9.3 mmol/mol) when compared to metformin monotherapy in patients with inadequately controlled type 2 diabetes and normal renal function.
- Its protective effects in heart failure are attributed primarily to haemodynamic effects, where SGLT2 inhibitors potently reduce intravascular volume through osmotic diuresis and natriuresis. This consequently may lead to a reduction in preload and afterload, thereby alleviating cardiac workload and improving left ventricular function.

Physicochemical properties of Dapagliflozin and Bisoprolol[5,6]

Parameters	Description	
Drug Name	**Dapagliflozin Propanediol Monohydrate**	**Bisoprolol fumarate**
CAS Number	960404-48-2	104344-23-2
Category	Anti diabetic agent SGL2 inhibitor	β1-blocker
Chemical Formula	$C_{24}H_{35}ClO_9$	$C_{40}H_{66}N_2O_{12}$
Molecular Weight	502.99 g/mol	766.97 g/mol
Physical State and Appearance	White to Pale Yellow Solid	White to off- White crystalline powder or solid
Melting Point	74-78℃	100℃ - 105 ℃
Solubility	Methanol, Ethanol, Dimethyl formamide	Very soluble in water, methanol freely soluble in chloroform glacial acetic acid and alcohol. Slightly soluble in acetone and ethyl acetate.
Pka value	12.6	9.5
Drug Approved by CDSCO	29 November 2022	13 May 1999

Contemporary Trends in Analytical Method Development for Dapagliflozin and Bisoprolol: A Critical Review of Spectroscopic and Chromatographic Approaches

2. Comparative Summary of Reported Methods

Summarizes representative chromatographic and spectroscopic methods reported for the simultaneous estimation of DAPA and BISO, either in synthetic mixtures, marketed tablet formulations, or biological matrices. Methods are grouped by underlying technique (RP-HPLC variants A-D, planar chromatography, UV spectrophotometry, and LC-(MS/MS).

Reported method of Bisoprolol Fumarate.

Title	*Name of Journal with year of Publication*	Summary	Ref. No.
Development and Validation of Bisoprolol Fumarate In Bulk and Tablets	World journal of pharmaceutical research, **2026**	**UV** **Solvent :** Ethanol **Lamda max λ 273nm.**	7
Single-Run RP-HPLC Method for Comprehensive Separation of Nine Bisoprolol Fumarate Impurities Aligned with USP and EP	Research Square, **2026**	**Shimadzu Prominence-1 and LC-2010 CHT (Shimadzu Incorporation) HPLC 119** system equipped with an **LC-2010 CHT quaternary pump, SPD-M30A photodiode array (PDA) detector**	8
Advances in quality control through the development of a more sustainable and eco-friendly direct spectrophotometric method than pharmacopoeial methods for the determination of bisoprolol fumarate	Drug Analytical Research **2025**	**UV** **SOLVENT :**0.10 N NaOH **DETETCION** : 273 nm by zero-order spectrophotometric method	9

Development and Validation of RP-HPLC Method for Estimation of Bisoprolol Fumarate In Bulk and Tablets	*Journal for Pharmaceutical, Chemical Sciences and Ayurveda,* **2024**	**RP-HPLC** **Column:** Fortis RP C18 column (250 mm ×4.6 mm) 5µm **M. P.:** Methanol: Water (80:20) pH adjusted to 8 with triethylamine **Mode:** Gradient **Detection wavelength:** 230 nm **Flow Rate:** 1.0 ml/min **RT BSL:** 6.312 min	76
Development and Validation of Analytical Method for Estimation of Bisoprolol Fumarate in Bulk and Solid Dosage Form by RP HPLC	*International Journal of Pharmaceutical Research and Applications*, **2023**	**RP-HPLC** **Column:** Shimadzu make RP 18 analytical column (250 mm × 4.6 mm i.d., 5.0 µm) **M. P.:** Acetonitrile: Water with pH 3.0 (70:30 %v/v)	31.
Design of Optimized RP-HPLC Method for Quantitative Analysis of Bisoprolol Fumarate in Bulk and Pharmaceutical Dosage Form	*Scholars International Journal of Chemistry and Material Sciences*, **2023**	**RP-HPLC** **Column:** Reprosil pure basic C18 **M. P.:** Acetonitrile : Potassium dihydrogen phosphate buffer (0.050 mol/L) (30:70 %V/V), pH 3.5 (adjusted with phosphoric acid **Mode:** Isocratic **Detection wavelength:** 233 nm **Flow Rate:** 1.0 ml/min **RT BSL:** 5.7 min **RT Telmisartan:** 7.6 min	32
An Insight on Analytical Profile on Bisoprolol Fumarate – A Selective Beta-1 Adrenoreceptor Blocker	*Journal of Pharmaceutical Technology, Research and Management*, **2017**	Analytical methods which include capillary electrophoresis, HPLC, HPTLC, UV-Spectroscopy, UPLC, impurity profiling and electrochemical methods implemented for estimation of BF as a single component as well as in multicomponent	33
Quantitative Determination of Bisoprolol Fumarate by HPLC	*Revista de Chimie,* **2016**	**Column:** Eclipse XDB C18 (150 mm x 4.6 mm, 5 m) **M. P.:** Water: Methanol: Acetonitrile (50:30:20 %v/v) **Mode:** Isocratic **Detection wavelength:** 225 nm **Flow Rate:** 1.0 ml/min	34
Development And Validation of Rp-Hplc Method for The Determination of Bisoprolol Fumarate Tablets	*International Journal of Research in Pharmaceutical and Nano Sciences*, **2013**	**RP-HPLC** **Column:** prontosil, chromo bond, C18, (250X4.6) mm, 5µ **M. P.:** buffer (pH 5.6): Acetonitrile (75:25 %v/v) **Mode:** Isocratic **Detection wavelength:** 226 nm PDA detector **Flow Rate:** 1.0 ml/min **RT BSL:** 9.15 min	35

Reported methods of Bisoprolol Fumarate in combination with other drugs.

Title	***Name of Journal with year of Publication***	**Summary**	**Ref. No.**
Sustainable green spectrophotometric determination of bisoprolol and amlodipine via diazotization–coupling approach in pharmaceutical and biological matrice	*Science direct* **2026**	**Uv** **Solvent:** ethanol–water medium (50/50 *v*/v), **Detector:** 545.5 nm for BIS and 550 nm for AML.	77
Development of stability indicating greener rp-hplc method for the analysis of drugs used for combined hypertension therapy in pharmaceutical preparations using analytical quality by design	*World Journal of Pharmaceutical Science and Research,* **2026**	**Column:** Hypersil ODS C18 column **Mobile phase:** acetonitrile-water (70:30 v/v) **Detection** - 225 nm. **Flow rate** – 1.0 ml/min **Mode:** Gradient	78
A Novel Analytical Method for	*Biomedical and*	**Column:** Waters X Terra	36

Simultaneous Quantification of Bisoprolol and Cilnidipine by Reversed-Phase HPLC in Pure and Tablet Dosage Form	*Pharmacology Journal*, **2025**	(150x4.6mm; 3.5µm) **M. P.:** Acetonitrile: 0.1% trifluoroacetic acid (60:40%v/v) **Mode:** Isocratic **Detection wavelength:** 225 nm **Flow Rate:** 1.0 ml/min **RT BSL:** 3.129min **RT Cilnidipine:** 6.925min	
Development and validation of RP-HPLC method for simultaneous estimation of rosuvastatin and Bisoprolol fumarate in bulk and formulations.	*International Journal of Health Sciences*, **2022**	**Column:** C18 column **M. P.:** Methanol: Phosphate buffer (pH 3.5) 45:55% V/V **Mode:** Isocratic **Detection wavelength:** 220 nm **Flow Rate:** 1.0 ml/min **RT Rosuvastatin:** 3.624 min **RT Bisoprolol fumarate :** 5.178 min	37
Stability-indicating RP- HPLC method development and validation for simultaneous estimation of bisoprolol fumarate and amlodipine besylate in bulk and in tablet dosage form.	*Journal of Applied Pharmaceutical Science*, **2021**	**RP-HPLC** **Column:** Oyster ODS3 (150 × 4.6 mm, 5 µm) **M. P.:** Phosphate buffer with pH 2.5 (adjusted by 5% orthophosphoric acid): Methanol :Acetonitrile (42:29:29 %v/v/v) **Mode:** Isocratic **Detection wavelength:** 230nm **Flow Rate:** 1.0 ml/min **RT BSL:** 2.543 nm **RT Amlodipine:** 4.883 nm	38
Development and validation of a fast and simple HPLC method for the simultaneous determination of bisoprolol and enalapril in dosage Form.	*Pharmacia, **2021***	**RP-HPLC** **Column:** Zorbax Rx C8 250x4.6mm, 5um **M. P.:** Water: Methanol: 0.07% perchloric acid (55:45 %v/v) **Mode:** Isocratic **Detection wavelength:** 214 nm **Flow Rate:** 1.0 ml/min **RT BSL:** 4.7 min **RT Enalapril:** 5.2 min	39
RP-HPLC Method Development and Validation for Simultaneous Estimation of Bisoprolol Fumarate and Cilnidipine in Pharmaceutical Dosage Form	*Journal of Pharmaceutical Science and Bioscientific Research*, **2020**	**RP-HPLC** **Column:** (C18) Inertsil ODS 3V column (150*4.6mm,5µm) **M. P.:** Buffer (0.1% Formic acid in water): Methanol (20:80 %v/v) **Mode:** Isocratic **Detection wavelength:** 231nm **Flow Rate:** 1.0 ml/min **RT BSL:** 2.84min **RT Cilnidipine:** 1.518min	40
HPLC method development for the analysis of bisoprolol in combined dosage form containing bisoprolol and enalapril and in vitro dissolution studied	*International Journal of Applied Pharmaceutics*, **2019**	**Column:** Hi Qsil C18 (5 µm, 4.6x250 mm) **M. P.:** Methanol: phosphate buffer solution (65:35, v/v) **Mode:** Isocratic **Detection wavelength:** 225 nm **Flow Rate:** 1.0 ml/min **RT BSL:** 4.75 min **RT Enalapril:** 5.329min	41
RP-HPLC Method Development and	*International Journal of*	**RP-HPLC**	42

Validation for Simultaneous Estimation of Cilnidipine and Bisoprolol Fumarate in Tablet Dosage Form	*Chem Tech Research*, **2019**	**Column:** Shiseido – C18 (250×4.6mm, 5 µm) **M. P.:** Phosphate buffer (pH-3.5) : Methanol (60 : 40) **Mode:** Isocratic **Detection wavelength:** 225nm **Flow Rate:** 1.0 ml/min **RT BSL:** 5.730min **RT Cilnidipine:** 4.073min	
Simultaneous estimation of bisoprolol fumarate and cilnidipine in tablet dosage form using rp-hplc method	International Journal of Pharma and bio sciences 2018	**RP-HPLC** **Column:** (C18) Inertsil ODS 3V column (150*4.6mm,5µm) **M. P.:** Buffer (0.1% Formic acid in water): Methanol (20:80 %v/v) **Mode:** Isocratic **Detection wavelength:** 231nm **Flow Rate:** 1.0 ml/min **RT BSL:** 2.84min **RT Cilnidipine:** 1.518min	43
Development and Validation of Analytical Method for Simultaneous Estimation of Bisoprolol Fumarate and Telmisartan by Using RPHPLC Method	International Journal of Pharmaceutical and Clinical Research, *2018*	**RP-HPLC** **Column:** Waters X Bridge RP C18 (4.6 x 250 mm) **M. P.:** Methanol and water (75:25 v/v) **Mode:** Isocratic **Detection wavelength:** 231nm **Flow Rate:** 1.0 ml/min **RT BSL:** 5.730min **RT Telmisartan:** 7.3 min	44
Validated and Stability Indicating Liquid Chromatography Method for Quantification of Bisoprolol Fumarate in Tablet Dosage Form	International Journal of Pharmacy, 2012	**RP-HPLC** **Column:** C18 **M. P.:** orthophosphoric acid buffer/acetonitrile (75:25, v/v, pH 5.6) **Mode:** Isocratic **Detection wavelength:** 226nm **Flow Rate:** 1.0 ml/min **RT BSL:** 9.50 min	45
Simultaneous estimation of bisoprolol fumarate and hydrochlorothiazide in tablet dosage form by RP-HPLC method	Indian journal of pharmaceutical science, 2006	**RP-HPLC** **Column:** Lichrospher 100 C-18, 5 µm column 20 cm × 4.6 mm **M. P.:** Acetonitrile and tetrahydrofuran of (80:20:5 v/v/v) **Mode:** Isocratic **Detection wavelength:** 225nm **Flow Rate:** 1.0 ml/min **RT BSL: 1.7min** **RT Hydrochlorthiazide: 4.72 min**	46

Official Methods of Dapagliflozin.

United States Pharmacopoeia (USP) **2024**[47]	**RP-HPLC** **Column:** Octadecylsilanized silica gel (C18) (250 mm ×4.6 mm) 3.5µm **M.P.:** Acetonitrile and Water 60:40 %v/v **Detection wavelength:** 245nm **Flow Rate:** 1.0 ml/min

PUBLISHED METHOD FOR DAPGLIFOZIN

A novel uv spectrophotometric method development and validation of dapagliflozin in bulk and pharmaceutical dosage form	*World Journal of Pharmaceutical Research,* **2025**	**UV** **M.P-**acetonitrile and ethanol (70:30) **Detection wavelength:** 224nm Zero order derivative	69
Development and Validation of stability-Indicating RP-HPLC method for determination of Dapagliflozin	*Journal of Advanced Pharmacy Education & Research,* **2024**	**RP-HPLC** **Column:** BDS column **M. P.:** Acetonitrile and Ortho phosphoric acid (55:45%v/v) **Mode:** Gradient **Detection wavelength:** 245nm **Flow Rate:** 1ml/min **RT DGZ:** 2.873 min	48
Analytical Method Development, Validation and Forced Degradation Study of Dapagliflozin by RP-HPLC	*Drug Metabolism and Bioanalysis Letters* **2023**	**RP-HPLC** **Column:** Kromasil 100-5 column, UV detector 224 nm **Mobile phase** - Acetonitrile:water (52:48) **Mode:** Gradient **Flow rate**-1.0 mL/min**.**	71
Determination of the Chemical Stability of Dapagliflozin by LC/DAD and MS/MS Methods	*Journal of Chromatographic Science* **2022**	**LC/DAD and MS/MS** **Column:** core-shell RP-18 column **M. P:** Acetonitrile : water **Detection wavelength:** **Mode:** Isocratic	72
A New Analytical Method Development and Validation for the Estimation of Dapagliflozin by Using Reverse Phase-High Performance Liquid Chromatography	*International Journal Of Advanced Research In Medical & Pharmaceutical Sciences,* **2021**	**RP-HPLC** **Column:** Develosil ODS HG-5 RP C18, 5µm, 15cmx4.6mm **M.P:** Methanol : Phosphate buffer (0.02M, pH-3.6) 45:55 %v/v **Mode:** Isocratic **Detection wavelength**: 255nm **Flow Rate:** 1.0 ml/min **RT :** 3.254 min	22
RP-HPLC Method for Estimation of Dapagliflozin from its Tablet	*International Journal of Chem Tech Research,* **2018**	**RP-HPLC** **Column:** Princeton C18 **M.P:** Acetonitrile: 0.1% Triethylamine (pH-5.0) (50:50%v/v) **Mode:** Isocratic **Detection wavelength**: 224nm **Flow Rate:** 1.0 ml/min **RT :** 5.163min	50
A New RP-HPLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form	*International Journal of Drug Development and Research,* **2017**	**RP-HPLC** **Column:** Waters C18, 5 µm particle size, 25 cm × 4.6 mm **M. P:** Phosphate buffer and acetonitrile (60:40 %v/v) **Mode:** **Detection wavelength:** 237 nm **Flow Rate:** 1ml/min **RT DGZ:** 3.461 min	51
Development And Validation Of Dapagliflozin By Reversed-Phase High-Performance Liquid Chromatography Method And It's Forced Degradation Studies	*Asian Journal of Pharmaceutical and Clinical Research,* **2017**	**RP-HPLC** **Column:** hypersil BDS (250 mm × 4.6 mm, 5 µ) **M. P:** buffer:acetonitrile (60:40) **Mode:** **Detection wavelength:** 245 nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 2.79 min	52
A New RP-HPLC Method	*International Journal*	**RP-HPLC**	80

Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form	*of Drug Development and Research,* **2013**	**Column:** hypersil BDS (250 mm × 4.6 mm, 5 µ) **M. P:** Acetonitrile and 0.1% Ortho phosphoric acid (50:50%v/v) **Mode:** isocratic **Detection wavelength:** 245 nm **Flow Rate:** 1ml/min **RT DGZ:** 2.226 min	

Reported Methods of Dapagliflozin in combination with other drugs.

Analytical Method Development and Validation of Teneligliptin and Dapagliflozin API In Marketed Formulation	*International Journal of Pharmaceutical Sciences and Research,* **2024**	**RP-HPLC** **Column:** Prontosil C18 **M. P.:** Acetonitrile: 3.5 pH Potassium dihydrogen phosphate buffer (60:40 v/v) **Detection wavelength:** 227 nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 3.61 min **RT TNG:** 2.37 min	53
Stability-Indicating HPLC Method Development and Validation for the Simultaneous Determination of Vildagliptin and Dapagliflozin in Pharmaceutical Dosage Form	*International Journal of Drug Delivery Technology,* **2024**	**RP-HPLC** **Column:** Thermo Hypersil Gold C18 column **M. P.:** Acetonitrile (ACN) and water (40: 60 % v/v) (adjusted with O-H3PO4 to pH 3) **Mode:** Isocratic **Detection wavelength:** 213 nm **Flow Rate:** 1ml/min **RT DGZ:** 8.3 min **RT VGL:** 2.9 min	54
Novel Analytical Method for Combined Dapagliflozin and Vildagliptin in Bulk and Pharmaceutical Dosage Form Using HPLC	*Archives of Pharmacy Practice,* **2024**	**RP-HPLC** **Column:** Agilent C18 (150 x 4.6 mm, 5 mm) **M. P.:** Orthophosphoric acid: Acetonitrile (pH 5) **Mode:** Isocratic **Detection wavelength:** 224 nm **Flow Rate:** 0.7 ml/min **RT DGZ:** 3.5 min **RT Vidagliptin:** 2.1 min (Vildagliptin)	55
Quantitative Estimation and Validation of Dapagliflozin And Linagliptin Hydrochloride In Pharmaceutical Dosage Form By RP HPLC	*African Journal of Biomedical Research,* **2024**	**RP-HPLC** **Column:** Thermo Scientific Syncronis C8, (250 mm × 4.6 mm, 5µm) **Mobile Phase:** Phosphate buffer: acetonitrile (30:70 %v/v) **Mode:** Binary Gradient **Detection wavelength:** 224 nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 3.3 min **RT Linagliptin:** 2.3 min	56
A New Stability Indicating HPLC Method for Related Substances in Dapagliflozin	*International Journal of Drug Delivery Technology,* **2024**	**RP-HPLC** **Column:** Princeton C18 column **M. P.:** Acetonitrile and 0.1% Triethylamine (50:50 %v/v) **Mode:** Isocratic **Detection wavelength:** 224 nm **Flow Rate:** 1ml/min **RT DGZ:** 5.163 minutes	57
Analytical Method Development and Validation of Dapagliflozin by RP HPLC Method in Tablet Dosage Form	*International Journal of Pharmaceutical Sciences,* **2024**	**RP-HPLC** **Column:** Inertsil ODS-3V **M. P.:** Acetonitrile: Water (50: 50 % v/v) **Mode:** Isocratic **Detection wavelength:** 223nm	58

		Flow Rate: 1.0 ml/min **RT DGZ:** 4.60 min	
RP-HPLC Method Development and Validation for the Simultaneous Estimation of Dapagliflozin Propanediol Monohydrate and Linagliptin in Tablet Dosage Form	*African Journal of Biomedical Research,* **2024**	**RP-HPLC** **Column:** Qualisil5 BDS C18 column (250×4.6mm,5µm) **M. P:** 0.1% O-Phosphoric acid pH adjusted to 4 with TEA: Acetonitrile (45:55%v/v) **Mode:** Isocratic **Detection wavelength:** 239nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 3.875 min **RT LGN:** 5.275 min	59
Simultaneous Estimation of Dapagliflozin and Saxagliptin: Analytical Method Development and Validation	*International Journal for Pharmaceutical Research Scholars,* **2024**	**RP-HPLC** **Column:** Luna C18 (150 mm × 4.6 mm, 5 µm) **M. P.:** Phosphate Buffer pH 3.0: Acetonitrile (45:55 %v/v) **Mode:** Isocratic **Detection wavelength:** 228nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 6.90 min **RT Saxagliptin:** 2.36 min	60
RP – HPLC Method Development and Validation for Simultaneous Estimation of Dapagliflozin Propanediol Monohydrate and Linagliptin	*International Journal of Pharmaceutical Sciences Review and Research,* **2023**	**RP-HPLC** **Column:** shim – pack solar C18 (250mm × 4.6mm, 5 µm) **M. P.:** Acetonitrile: Phosphate buffer (pH - 3 adjusted with 0.1 % OPA) (60:40 %v/v) **Mode:** Isocratic **Detection wavelength:** 225nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 4.002 min **RT Linagliptin:** 2.344 min	61
Method Development and Validation of Dapagliflozin by RP-HPLC	*Journal of Pharmaceutical Negative Results,* **2022**	**RP-HPLC** **Column:** Inspire (4.6 x 150mm, 5µm) **M. P.:** Methanol and Water (80:20 %v/v) **Mode:** Isocratic **Detection wavelength:** 235nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 4.422 min	62
A Review on Analytical Methods of Dapagliflozin: An Update	*International Journal of Pharmaceutical Quality Assurance,* **2020**	**RP-HPLC** **Column:** **M. P.:** Methanol : Acetonitrile : Orthophosphoric acid (70:25:5 %v/v) **Mode:** Isocratic **Detection wavelength:** 246nm **Flow Rate:** 1ml/min **RT DGZ:** 2.797 min	63
Method Development and Validation of a Stability-Indicating Reversed-Phase Liquid Chromatographic Method for the Simultaneous Estimation of Metformin and Dapagliflozin in Presence of their Degradation Products	*International Journal of Pharmaceutical Sciences Review and Research,* **2019**	**RP-HPLC** **Column:** Hypersil C18, 250x4.6 mm **M. P.:** 50 mM potassium dihydrogen phosphate buffer (pH 3.0): methanol (40:60 %v/v) **Mode:** Isocratic **Detecti.on wavelength:** 255 nm **Flow Rate:** 1.0 ml/min **RT DGZ:** 5.74 min **RT MTF:** 3.78 min	64
Development and validation of dapagliflozin by reversed-phase high-performance liquid chromatography method and it's forced degradation studies	*Asian Journal of Pharmaceutical and Clinical Research,* **2017**	**RP-HPLC** (245 nm or 224 nm). **Column:** Hypersil BDS C18 (250 mm × 4.6 mm, 5 µ) **Mobile Phase:** Buffer: Acetonitrile (60:40) **Flow Rate:** 1 ml/min	65

UV METHOD OF DAPAGLIFLOZIN

Sr. No	Drugs	Analytical method	Description	Ref. No.
1	**Dapagliflozin**	**UV spectroscopy** **1. zero order** **2. first order** **3. second order**	**Solvent** = Methanol **Wavelength** = **Zero order** = 224 nm **1st order** = 220 nm **2nd order** = 235.5 nm	**(**10)
2	**Dapagliflozin**	**UV-spectroscopy**	**Solvent** – Methanol **Wavelength** =225 nm	(11)
3	**Dapagliflozin metformin HCl**	**UV-spectroscopy**	**Solvent** – Methanol **(1) Wavelength** =235 nm **(2) Wavelength** =272 nm	(12)
4	**Dapagliflozin saxagliptin**	**UV-spectroscopy**	**Solvent** – phosphate buffer (6.8) v/v **Wavelength $_d$** =222 nm **Wavelength s**= 276 nm	(13)
5	**Dapagliflozin Saxagliptin metformin HCL**	**UV-spectroscopy**	**Solvent = water** **Wavelength** =223 nm **Wavelength** = 212 nm **Wavelength** = 232.6 nm	(14)
6	**Dapagliflozin linagliptin**	**HPTLC**	**Solvent: -** Chloroform;methanol;Triethylamine (7:2:1:0.2) v/v **D(R_p)** = 0.23 **L(Rf)** = 0.40	(17)
7	**Dapagliflozin metformin**	**UV-spectroscopy**	**Solvent** = methanol **Wavelength** = 275 nm **Wavelength** = 245 nm	(18)
8	**Dapagliflozin sitaglipstin**	**UV-Visible**	**Solvent** = methanol **Wavelength** =224 nm **Wavelength** = 263 nm	(19)
9	**Dapagliflozin Teneligliptin**	**UV-spectroscopy =** **(1) Simultaneous equation** **(2) Q-absorbance Ratio** **(3) First derivative (Zero crossing)**	**Solvent**-Distilled water **(1) Wavelength $_D$** =223 nm **Wavelength$_T$** =243 nm **(2)Wavelength$_D$** =223 nm **Wavelength$_T$** =230 nm **(3)Wavelength$_D$** =237 nm **Wavelength$_T$** =254 nm	(23)
10	**Dapagliflozin Saxagliptin metformin**	**UV-spectroscopy= Visible** *Asian Journal of Pharmaceutical Analysis* **(2022)**	**Solvent**-Methanol: Water (80:20) v/v **(1) Wavelength $_d$** =272 nm **(2) Wavelength $_s$** =212 nm **(3) Wavelength $_m$**=232 nm	(24)
11	**Dapagliflozin Vildagliptin** *Journal of Applied Pharmaceutical Science* **(2023**	**UV-spectroscopy=** **(1) Simultaneous Equation Method** **(2) Absorbance Ratio Method** **(3) Second Derivative Zero Crossing Method** **(4) Ratio Difference Spectroscopic method** **(5) First Derivative of Ratio spectra Method**	**(1) Wavelength$_D$** =223 nm **Wavelength$_V$** =210 nm **(2) Wavelength$_D$** =223 nm **Wavelength$_V$** =219.2 nm **(3) Wavelength$_D$** =290.6 nm **Wavelength$_V$** =219.2 nm **(4) Wavelength$_D$** =236&242 nm **Wavelength$_V$**=208.4&215 nm **(5) Wavelength$_D$** =226 nm **Wavelength$_V$** =215.6 nm	(25)

Reported methods for Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate in combination.

Title	*Name of Journal with year of Publication*	Summary	Ref. No.
Development and Validation of RP-HPLC Method For Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate in pharmaceutical dosage form	*International Journal of Scientific Research and technology,***2026**	**RP-HPLC** **Column:** C18 column **(250 x4.6mm,5µm)** **M. P:** Methanol : Phosphate buffer(60:40) pH 3.8 **Mode:** Isocratic **Detection wavelength:** 225-230 nm **Flow Rate: 0.2 ml/min** **RT DGZ:** 2.99 min **RT BISO:** 3.64 min	**68**
Method Development and Validation for Simultaneous estimationof Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate by using Stability IndicatingRP-HP LC.	Discover chemistry **2026**	**RP-HPLC** **Column:** Kromasil 100 C18 column (250 x4.6mm,5µm) **M. P:** Methanol : Water (80:20) pH 3.0(0.1% Formic acid) **Mode:** Isocratic **Detection wavelength:** 224 nm **Flow Rate: 0.8 ml/min RT DGZ:** 2.10 min **RT BISO:** 5.84 min	**73**
Greenness assessment and stability-indicating HPTLC method for the concurrent analysis of dapagliflozin propanediol monohydrate and bisoprolol fumarate in a novel combined oral formulation	Springer publications **2025**	**HPTLC** **STATIONARY PHASE :** Silica gel 60 F_{254} plates (10 * 10cm, 0.20 mm) **Mobile Phase (Solution**): A mixture of Toluene : Methanol : Ammonia in a volume ratio of 6:2:1(v/v/v).	**74**
Stability IndicatingRP-HP LC Method for Development and Validation Simultaneous estimationof Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate in synthetic mixture	Asian journal of pharmaceutical research **2025**	**RP-HPLC** **Column: Agilent Zorbax C18column (150 x4.6mm,5µm)** **M. P.:** (0.1% TEA : Acetonitrile) (66:33)pH 3.0 OPA **Mode:** Isocratic **Detection wavelength:** 224 nm **Flow Rate: 1.5 ml/min RT DGZ:** 2.99 min **RT BISO:** 9.35 min	**75**
Development and Validation of RP-HPLC Method For Simultaneous Estimation of Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate in Synthetic Mixture	*International Journal of Pharmaceutical Sciences,* ***2025***	**RP-HPLC** **Column:** HYPERSIL ODS C18, 250 mm*4.6 mm **M. P.:** Acetonitrile: water (75:25 %v/v) **Mode:** Isocratic **Detection wavelength:** 272 nm **Flow Rate: 1.0 ml/min RT DGZ:** 15.11 min **RT MTF:** 6.11 min	**66**
Accelerated Stability Indicating LC Method for Simultaneous Quantification of Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate	*Wiley ,* ***2025***	**Thin-Layer Chromatography (TLC)** **S.P.:** Precoated silica gel G60 F254 aluminum sheet (10 × 10 cm, 0.2 mm layer thickness) **M.P.:** Methanol:Ethyl acetate:25% ammonia (0.5:6:0.3, %V/V) **Detection wavelength:** 223 nm **RF value of DGZ:** 0.24 **RF Value of BSL:** 0.46	**81**

3. CONCLUSION

Regardlessof this fixed-dose combination, the current lack of an official pharmacopeial standard assay procedure for the combined dosaghe form which has gave researchers to develop and validate a variety of new independent testing methods for their simultaneous estimation. These established analytical techniques for quality control like UV-Vis Spectroscopic and chromatographic methods like RP-HPLC, HPTLC, and LC-MS/MS, with a growing industrial significance on the sustainable and non toxic green analytical chemistry. This review serves as a complete resource that has various published method on combined and individual formulations.

4. REFRENCE

1. https://go.drugbank.com/drugs/DB00612
2. https://go.drugbank.com/drugs/DB06292
3. https://en.wikipedia.org/wiki/Dapagliflozin
4. https://en.wikipedia.org/wiki/Bisoprolol
5. https://www.chemicalbook.com/article/bisoprolol-fumarate-indications-mechanism-of-action-and-side-effects.htm
6. https://www.chemicalbook.com/article/dapagliflozin-a-breakthrough-in-diabetes-management-and-beyond.htm
7. Chakravarthi K. S. S, K., et al. B Development and Validation of RP-HPLC Method for Estimation of Bisoprolol Fumarate In Bulk and Tablets.
8. M. Trivedi, et al. Single-Run RP-HPLC Method for Comprehensive Separation of Nine Bisoprolol Fumarate Impurities Aligned with USP and EP.
9. Safwan Ashour, et al. Development and Validation of Bisoprolol Fumarate In Bulk and Tablets.
10. Gajanan Vithoba Manthe, Krishna Radheshyam Gupta, and Atul Trymbatrao Hemik, "Estimation of Dapagliflozin From its Tablet Formulation by UV-Spectroscopy," Pharm Methods, 2017; 8(2): 102-107.
11. Jani BR, Shah KV, and Kapupara PP, "Development and validation of UV Spectroscopy method for simultaneous Estimation of Dapagliflozin," International Journal of Research & Development in Pharmacy and Life Science, 2015; 4(3): 1569-1576.
12. Jani BR, Shah KV, and Kapupara PP, "Development and Validation of UV Spectroscopy First Derivative Method of Simultaneous Estimation of Dapagliflozin & metformin HCL in Synthetic Mixture," Journal of Bioequivalence Studies, 2015; 1(1): 102.
13. Raghvendra Singh Bhaduria and Vikas Agarwal, "Development and Validation of UV Spectroscopy method for simultaneous estimation of dapagliflozin & Saxagliptin in marked formulation," Journal of Drug Delivery and Therapeutics, 2019; 9(4-s): 1160-1164.
14. Dhanya B. Sen, Sohil Jatu, Rajesh A. Maheshwari, Arti Sachin Zanwar, Rama Swamy Velmurugan, and Ashim Kumar Sen, "New Eco-Friendly UV Spectroscopy Methods of Simultaneous Assessment of Dapagliflozin, Saxagliptin, Metformin in Ternary Mixture," Indian Journal of Pharmaceutical Education and Research, 2023; 57(2): 559-569.
15. Shraddha Mahabali, Ganesh Gajeti, and Mallinath Kalshetti, "RP-HPLC & UV Spectroscopy Method Development and validation for Estimation of Dapagliflozin in bulk and pharmaceutical dosage Form," Journal of Cluster Science, 2024; 1-12.
16. Waker Siddiqui, Zulcaif Hussain Ummar, Sufyan Junaid, Unmai Muhammad Waqas, Maria Gul, and Mubashra Gul, "Method Development and Validation of metformin HCL & Dapagliflozin by using RP-HPLC," AK Journal, 2024.
17. Anchal Shukla, Usman Gani Chhalotiya, Dimal Shah, Jinal Tandal, Heta Kachhiya, and Mital Parmar, "Development and validation of stability Indicating HPLC method for simultaneous estimation of Dapagliflozin & Linagliptin," Discover Chemistry, 2024; 1(4).
18. Deepak Dalal, Ravi Kant, Kavita Attri, Kiran Sharma, Meena, and Kashi Danavat, "Spectrophotometric Absorption Correction Methods for the Estimation of Fixed-dose Combination of Dapagliflozin & Metformin HCL," Indian Journal of Pharmaceutical Education and Research, 2024; 58(1): 291-296.
19. Mayank Yadav, Rekha Chautin, Ranjit Singh, and Neha Tiwari, "UV-spectroscopy approaches for concurrent assessment of Sitagliptin & Dapagliflozin," African Journal of Biological Sciences, 2024; 6(9): 2187-2663.
20. Bhavesh H. Patel and Nishit H. Perdiya, "Simultaneous estimation and stability indication method of Vildagliptin & dapagliflozin by RP-HPLC in pharmaceutical dosage form," Journal Publication, 2024; (1).
21. Chaudhary Ujwal, Sahu Jagdish K, and Dande Payal K, "Analytical method development validation and force degradation study of Dapagliflozin by RP-HPLC," Drug Metabolism and Bioanalysis Letters, 2023; 16(2): 240-252.
22. S. Sravanthi, Neha Zarin, B. Shruti, D. Ramya Krishna, and A. Manjeera, "New analytical method development and validation for the estimation of Dapagliflozin by using reverse phase HPLC," International Journal of Advanced Research in Medical and Pharmaceutical Sciences, 2021; 6.
23. Anokhi Patel, Preeti Jadeja, and Dr. Rajashree Mashru, "Analytical method Development and validation for simultaneous estimation of Dapagliflozin and Teneligptin Hydrobromide hydrate synthetic mixture by three different UV-spectrophotometry methods," World Journal of Pharmaceutical Research, 2022; 11(7): 770-785.
24. Barbuda Priya, Jawar Mukkund, and Burange Prashant, "Method development using UV-visible spectrometer of the simultaneous estimation of Metformin (MET), Saxagliptin (SXG) and Dapagliflozin (DGF) in Marketed formulation," Asian Journal of Pharmaceutical Analysis, 2022; 12(4): 234-247.
25. Ashim Kumar Sen, Satish B. Kataria, Dhanya B. Sen, Rajesh A. Maheshwari, Arti S. Zanwar, and Ramaswamy Velmurugan, "Various Innovative UV spectroscopic methodologies for Concurrent estimation of Dapagliflozin and Vildagliptin in combined tablet," Journal of Applied Pharmaceutical Science, 2023; 13(09): 213-223.
26. Indian Pharmacopoeia. Volume II. "Government of India ministry of health and family welfare, published by Indian Pharmacopoeial commission", Government of India Ghaziabad, 2018; 1392: 1616.
27. The United States Pharmacopoeia (USP 29), The National Formulary (NF 24). United State

Pharmacopieal Convection Inc. Rockville, U.S.A: 2006; 292-294.
28. European Pharmacopoeia, 8th edition, European Directorate for the Quality of Medicines and Healthcare, Council of Europe, Strasbourg, 2014. (Monograph for Bisoprolol fumarate 01/2012:171 published on 1 January 2014)
29. British Pharmacopoeia, Stationary Office on Behalf of the Medicines and Healthcare Products Regulatory Agency(MHRA), 2018. Monograph for Bisoprolol fumarate in British Pharmacopoeia published on 1 January 2018. Available from: https://www.pharmacopoeia.com
30. Deore BL, Wagh SK. Development and validation of RP-HPLC method for estimation of Bisoprolol Fumarate in bulk and tablets. Vidyapharma: Peer Reviewed Journal for Pharmaceutical, Chemical Sciences and Ayurveda. 2024; (4)1.
31. Aade MM. Development and Validation of Analytical Method for Estimation of Bisoprolol Fumarate in Bulk and Solid Dosage Form by RP-HPLC. Int J Pharm Res Appl. 2023; 8(6): 1712-9.
32. Gibril ABM, Rudwan EH. Design of Optimized RP-HPLC Method for Quantitative Analysis of Bisoprolol Fumarate in Bulk and Pharmaceutical Dosage Form. Sch Int J Chem Mater Sci. 2023; 6(4): 188-92.
33. Dhandar AG, Chaudhari SR, Ganorkar SB, Patil AS, Surana SJ, Shirkhedkar AA. An insight on analytical profile on Bisoprolol Fumarate- A selective Beta-1 adrenoreceptor blocker. J Pharm Transl Res. 2017; 5(2): 101-15.
34. Mahu SC, Spac AF, Ciobanu C, Hancianu M, Agoroael L, Butnaru E. Quantitative Determination of Bisoprolol Fumarate by HPLC. Rev. Chim. 2016; 67(3).
35. Konam K, Soujanya J, Sasikala M, Kumar AK. Development and validation of RP-HPLC method for the determination of Bisoprolol Fumarate tablets. Int J Res Pharm Nano Sci. 2013; 2(1): 57-67.
36. Atmakuri LR, Ismail KM, Ghanta VK, Vallamkonda B, Alluri R, Mamidi SVSA. A Novel Analytical Method for Simultaneous Quantification of Bisoprolol and Cilnidipine by Reversed-Phase HPLC in Pure and Tablet Dosage Form. Biomed Pharmacol J. 2025; 18(2).
37. Patil RB, Deshmukh SB. Development and validation of RP-HPLC method for simultaneous estimation of rosuvastatin and bisoprolol fumarate in bulk and formulations. International Journal of Health Sciences. 2022; 6.
38. Patil RB, Deshmukh SB. Development and validation of RP-HPLC method for simultaneous estimation of rosuvastatin and bisoprolol fumarate in bulk and formulations. International Journal of Health Sciences. 2022; 6.
39. Piponski M, Balkanov T, Logoyda L. Development and validation of a fast and simple HPLC method for the simultaneous determination of bisoprolol and enalapril in solid pharmaceutical dosage form, with using chaotropic strong chaotropic perchlorate ani. Pharmacia. 2021; 68(1): 69-77.
40. Pawar S, Tamboli A, Patil S. RP-HPLC Method Development and Validation for Simultaneous Estimation of Bisoprolol Fumarate and Cilnidipine in Pharmaceutical Dosage Form. J Pharm Sci Bioscientific Res. 2020; 10(2): 149-155.
41. Logoyda L, Kovalenko S, Abdel-Megied AM, Zhulkevych I, Drapak I, Demchuk I, et al. HPLC method development for the analysis of bisoprolol in combined dosage form containing bisoprolol and enalapril and in vitro dissolution studied. Int J Appl Pharm. 2019; 11(3): 186-94.
42. Patel H, Damahe DP, Narkhede SB. RP-HPLC Method Development and Validation for Simultaneous Estimation of Cilnidipine and Bisoprolol Fumarate in Tablet Dosage Form. International Journal of ChemTech Research. 2019; 12(1): 269-276.
43. Kumar RA, Thomas A. Simultaneous estimation of bisoprolol fumarate and cilnidipine in tablet dosage form using rp-hplc method. Int J Pharm Bio Sci. 2018; 9(4): 195-199.
44. Barge VU, Gaikwad RB, Chaudhari FM, Kande TR. Development and Validation of Analytical Method for Simultaneous Estimation of Bisoprolol Fumarate and Telmisartan by Using RP-HPLC Method. Int J Pharm Clin Res. 2018; 10(8): 219-23.
45. Induri M, Raju MB, Prasad YR. Validated and Stability Indicating Liquid Chromatography Method for Quantification of Bisoprolol Fumarate in Tablet Dosage Form. Int J Pharm. 2012; 2(1): 64-70.
46. Patel LJ, Suhagia BN, Shah PB, Shah RR. Simultaneous estimation of Bisoprolol Fumarate and Hydrochlorothiazide in tablet dosage form by RP-HPLC method. Indian J Pharm Sci. 2007; 69(6): 834-6.
47. United States Pharmacopeia (2023). USP Monographs, Dapagliflozin Propanediol. USP-NF. Rockville, MD: United States Pharmacopeia.
48. Sanagapati M, K D, Reddy NG, S S. Development and Validation of stability-Indicating RP-HPLC method for determination of Dapagliflozin. J. Adv. Pharm. Edu. & Res. 2024; 4(3): 350-3.
49. Sravanthi S, Zarin N, Shruthi B, Krishna DR, Manjeera A. A New Analytical Method Development and Validation for the Estimation of Dapagliflozin by Using Reverse Phase-High Performance Liquid Chromatography. Int J Adv Res Med Pharm Sci. 2021; 6(4).
50. Mante GV, Hemke AT, Umekar MJ. RP-HPLC Method for Estimation of Dapagliflozin from its Tablet. International Journal of ChemTech Research. 2018; 11(01): 242-8.
51. Debata J, Kumar S, Jha SK, Khan A. A New RP-HPLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form. Int J Drug Dev & Res. 2017; 9(2).
52. Basha SS, Sravanthi P. Development and validation of dapagliflozin by reversed-phase high-

performance liquid chromatography method and it's forced degradation studies. Asian Journal of Pharmaceutical and Clinical Research. 2017; 10(11).
53. Kunchamwar A, Jain V. Analytical method development and validation of Teneligliptin and Dapagliflozin API in marketed formulation. Int J Pharm Sci Res. 2024; 15(1): 170-6.
54. Deshmukh SB, Wagh PA, Yadav SS, Mane MB. Stability-Indicating HPLC Method Development and Validation for the Simultaneous Determination of Vildagliptin and Dapagliflozin in Pharmaceutical Dosage Form. 2024; 14(3): 1599-1603.
55. Khagga B, Nandini M, Sowjanya D, Rambabu D, Mogili S. Novel Analytical Method for Combined Dapagliflozin and Vildagliptin in Bulk and Pharmaceutical Dosage Form Using HPLC. 2024; 15(4): 5-9.
56. Khanduri P, Gahtori A. Quantitative Estimation And Validation Of Dapagliflozin And Linagliptin Hydrochloride In Pharmaceutical Dosage Form By RP-HPLC. Afr J Biomed Res. 2024; 27(3s): 2282-91.
57. Chavan B, Birajdar A, Bhusnar H, Yadav J, Badadhe S. A New Stability Indicating HPLC Method for Related Substances in Dapagliflozin. Int J Drug Deliv Technol. 2024; 14(1): 367-72.
58. Bhokare M, Ige P. Analytical Method Development and Validation of Dapagliflozin By RP-HPLC Method In Tablet Dosage Form. International Journal of Pharmaceutical Sciences. 2024; 2(7): 1718-28.
59. Ghode PD, Kapse R, Sayare A, Pachauri A, Kandekar U, Deshpande T, et al. RP-HPLC Method Development and Validation for the Simultaneous Estimation of Dapagliflozin Propanediol Monohydrate and Linagliptin in Tablet Dosage Form. Afr J Biomed Res. 2024; 27(3s): 242-9.
60. Panchabhai VB, Chavan K, Attar MS, Sakhare RS. Simultaneous Estimation of Dapagliflozin and Saxagliptin: Analytical Method Development and Validation. Int J Pharm Sci. 2024; 2(8): 2435-45. doi:10.5281/zenodo.13171545.
61. Patel YN, Patel A. RP - HPLC Method Development and Validation for Simultaneous Estimation of Dapagliflozin Propanediol Monohydrate and Linagliptin. Int J Pharm Sci Rev Res. 2023; 81(2): 97-103.
62. Gaikwad AV, Gawade AS, B H, Mantry S, Kale A, Kale J. Method Development and Validation of Dapagliflozin by RP-HPLC. Pharmacognosy and Natural Product Research. 2022; 13(6): 506-71.
63. Pathak S, Mishra P. A Review on Analytical Methods of Dapagliflozin: An Update. International Journal of Pharmaceutical Quality Assurance. 2020; 11(3): 355-60.
64. Kotecha N, Patel J. Method Development and Validation of A Stability-Indicating Reversed-Phase Liquid Chromatographic Method for the Simultaneous Estimation of Metformin and Dapagliflozin in Presence of their Degradation Products. Int J Pharm Sci Rev Res. 2019; 56(2): 1-6.
65. Shaik S, Sravanthi P. Development and validation of dapagliflozin by reversed-phase high-performance liquid chromatography method and it's forced degradation studies. A J of Pharm and Cli Res. 2017; 10(11): 101.
66. Dhruvi V, Dhirendra Kumar T, Khyati B, Dr. Santosh K. Development and Validation of RP-HPLC Method For Simultaneous Estimation of Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate in Synthetic Mixture. Int. J. of Pharm. Sci. 2025; 3(6): 1798-1821.
67. Valiya G, Kachhiya H, Patel R, et al. Stability-indicating instrumental thin-layer chromatography method for the quantification of dapagliflozin propanediol monohydrate and bisoprolol fumarate with implementation of fractional factorial design. J Planar Chromat. 2025.
68. Jayshree Raut, Sachin Kale, and Kailash Biyani, et al. Development and Validation Of RP-HPLC Method for Dapagliflozin and Bisoprolol In Bulk and Pharmaceutical Dosage Form. International Journal of Scientific Research and technology, 2026
69. Kavana D. C, et al. A novel uv spectrophotometric method development and validation of dapagliflozin in bulk and pharmaceutical dosage form. World Journal of Pharmaceutical Research,2025
70. Ujwal Chaudhari, et al. Analytical Method Development, Validation and Forced Degradation Study of Dapagliflozin by RP-HPLC. Drug Metabolism and Bioanalysis Letters 2023
71. Emily Chan-Jiang, et al. Determination of the Chemical Stability of Dapagliflozin
72. LC/DAD and MS/MS Methods. Journal of Chromatographic Science 2022
73. R. Patel, et al. Method Development and Validation for Simultaneous estimationof Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate by using Stability IndicatingRP-HP LC.Discover chemistry 2026.
74. Gopal Valiya, et al. Greenness assessment and stability-indicating HPTLC method for the concurrent analysis of dapagliflozin propanediol monohydrate and bisoprolol fumarate in a novel combined oral formulation. Springer publications 2025.
75. Disha H., et al. Stability IndicatingRP-HP LC Method for Development and Validation Simultaneous estimationof Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate in synthetic mixture. Asian journal of pharmaceutical research 2025.
76. Safwan Ashour, et al. Development and Validation of Bisoprolol Fumarate In Bulk and Tablets. Journal for Pharmaceutical, Chemical Sciences and Ayurveda, 2024.
77. A. Abd Alrada, et al. Sustainable green spectrophotometric determination of bisoprolol and amlodipine via diazotization–coupling approach in

pharmaceutical and biological matrices Science direct 2026.
78. Saurabh Shukla, et al. Development of stability indicating greener rp-hplc method for the analysis of drugs used for combined hypertension therapy in pharmaceutical preparations using analytical quality by design World Journal of Pharmaceutical Science and Research, 2026.
79. Jitendra Debata, Sundeep Kumar, et al. A New RP-HPLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form. 2013.
80. A New RP-HPLC Method Development and Validation of Dapagliflozin in Bulk and Tablet Dosage Form. International Journal of Drug Development and Research, 2013.
81. Gopal Valiya, et al. Accelerated Stability Indicating LC Method for Simultaneous Quantification of Dapagliflozin Propanediol Monohydrate and Bisoprolol Fumarate, Wiley, 2025.