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Overview on Analytical Methods for Simultaneous Estimation of Bisoprolol Fumarate and Telmisartan

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Abstract

This article reviews the development and validation of High-Performance Liquid Chromatography (HPLC) methods, particularly Reverse Phase HPLC (RP-HPLC), for the simultaneous estimation of bisoprolol fumarate and telmisartan in pharmaceutical formulations. Both drugs are essential in managing hypertension and cardiovascular diseases, and reliable analytical methods are crucial for quality control in their production. The review highlights various RP-HPLC methods with different chromatographic conditions, including stationary phases, mobile phase compositions, flow rates, and wavelengths. These methods have been validated for precision, accuracy, and regulatory compliance, ensuring efficient and cost-effective analysis. The development of such validated RP-HPLC methods supports the effective quality control of combination therapies, enhancing patient care and treatment outcomes.

Keywords: Bisoprolol fumarate, Telmisartan, RP-HPLC.

Introduction

The prevalence of hypertension and related cardiovascular diseases has risen significantly in recent years, making effective management of these conditions a top priority in healthcare. Among the pharmacological agents available, bisoprolol fumarate and telmisartan have emerged as key players in the treatment landscape. Bisoprolol is a selective beta-1 adrenergic receptor blocker, widely used to lower heart rate and reduce myocardial oxygen demand, making it particularly effective for patients with heart failure and hypertension. Telmisartan, on the other hand, is an angiotensin II receptor antagonist that works by inhibiting the effects of angiotensin II, a potent vasoconstrictor. This mechanism results in vasodilation and a subsequent decrease in blood pressure. [1,2]

The combination of bisoprolol and telmisartan offers a synergistic therapeutic effect, addressing multiple pathways involved in hypertension and improving overall cardiovascular health. The concurrent use of these medications not only enhances patient compliance by reducing pill burden but also optimizes blood pressure control and minimizes the risk of cardiovascular events. [3]

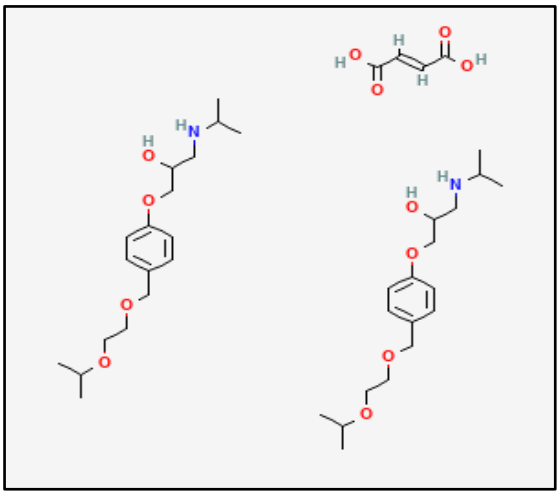

Figure:1 Bisoprolol fumarate

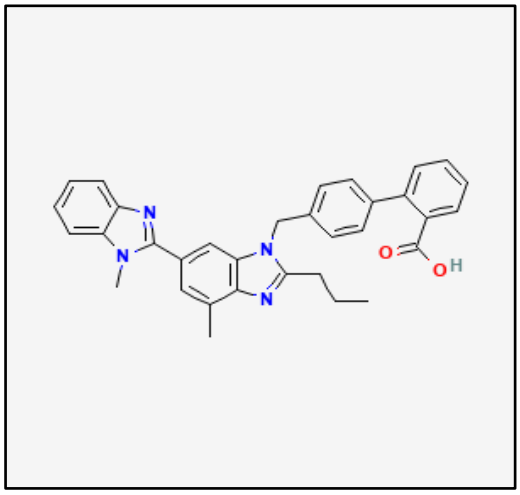

Figure:2 Telmisartan

Given the importance of these drugs, accurate and reliable analytical methods for their estimation in pharmaceutical formulations are essential. High-Performance Liquid Chromatography (HPLC), particularly Reverse Phase HPLC (RP-HPLC), has become a standard technique in pharmaceutical analysis due to its high sensitivity, precision, and ability to separate complex mixtures. RP-HPLC allows for the effective separation and quantification of compounds based on their hydrophobicity, making it well-suited for the simultaneous analysis of bisoprolol and telmisartan. [4]

Despite the availability of various analytical methods, there is a need for validated RP-HPLC methods that can efficiently analyze both compounds in a single run. Such methods not only streamline the analytical process but also enhance the reliability of quality control in pharmaceutical manufacturing. Furthermore, validation of these methods is crucial to ensure their suitability for routine analysis in compliance with regulatory standards. [5,6]

This study aims to develop and validate an RP-HPLC method for the simultaneous estimation of bisoprolol fumarate and telmisartan. The objectives include establishing optimal chromatographic conditions, validating the method according to established guidelines, and demonstrating its applicability for quality control purposes. By addressing these objectives, the study contributes to the growing body of knowledge that supports effective therapeutic regimens for hypertension, ultimately aiming to improve patient outcomes and enhance the quality of healthcare.

Detail literature survey of Bisoprolol fumarate and Telmisartan

Table:1 Official methods for assessment of Bisoprolol fumarate:

Sr. No.	Official	Method	Description	Ref No.
1.	Indian Pharmacopoeia (2022)	Liquid Chromatography (API)	**Stationary phase:** A stainless-steel column 125 × 4.6 mm, packed with octylsilane bonded to porous silica (5 µm) **Mobile phase:** To 1000ml of solvent mixture, add 5ml of diethylamine and 2.5ml of formic acid. Mix and filter, make necessary adjustment if necessary to obtain desired resolution. **Flow rate:** 1 mL/min **Wavelength:** 273nm	7

Table:2 Official methods for assessment of Telmisartan:

Sr No.	Official	Method	Description	Ref No.
1	Indian Pharmacopoeia (2022)	Liquid Chromatography (API)	**Stationary phase:** A stainless-steel Column 125 × 4 mm, packed with octadecyl silane bonded to porous silica (5 µm) **Mobile phase:** Intensil C_{18} column **Mobile phase:** Phosphate buffer (pH 2.4): Acetonitrile (60:40 % v/v) **Flow rate:** 1 mL/min. **Wavelength:** 230nm	8

Table:3 Reported methods for assessment of Bisoprolol fumarate

Sr. No.	Title	Description	Ref No.
UV-VISIBLE SPECTROSCOPY			
1	Development and Validation of **UV Spectroscopic Method** for the Determination of Bisoprolol fumarate Tablets.	**Solvent:** Water **Wavelength:** 223nm **Linearity:** 2-12 µg/mL	9
2	New Validated **UV Spectrophotometric Method** for the Quantification of Bisoprolol fumarate in its Pharmaceutical Dosage Form.	**Solvent:** 0.1N HCL **Wavelength:** 268nm **Linearity:** 10-60 µg/mL	10

3	Development and Validation of **UV Spectrophotometric Method** for Determination of Bisoprolol fumarate in Bulk and Pharmaceutical Dosage Forms.	**Solvent:** Water **Wavelength:** 271nm **Linearity:** 5-25 µg/mL	11
4	Development and Validation of **UV Spectrophotometric Method** for the Determination of Bisoprolol in Bulk Material and in Tablets.	**Solvent:** Methanol **Wavelength:** 273nm **Linearity:** 10-60 µg/mL	12
5	**Spectrophotometric Method** for Simultaneous Estimation of Amlodipine besylate and Bisoprolol fumarate in Pharmaceutical Preparations.	**Solvent:** 10% Methanol **Wavelength:** Bisoprolol fumarate: 222nm Amlodipine besylate: 365nm **Linearity:** Bisoprolol fumarate: 5-100 µg/mL Amlodipine besylate: 5-100 µg/mL	13
6	Development and Validation of **UV Spectrophotometric Method** for the Simultaneous Estimation of Cilnidipine and Bisoprolol fumarate in Tablet Dosage Form.	**Solvent:** Methanol **Wavelength:** Bisoprolol fumarate: 224nm Cilnidipine: 241nm **Linearity:** Bisoprolol fumarate: 2-6 µg/mL Cilnidipine: 4-12 µg/mL	14
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY			
7	Quantitative Determination of Bisoprolol fumarate by **HPLC Method** validation.	**Stationary phase:** Eclipse XDB C_{18} column (150 × 4.6 mm, 5 µm) **Mobile phase:** Water: Methanol: Acetonitrile (50:30:20 % v/v/v) **Flow rate:** 1 mL/min **Wavelength:** 225nm	15
8	Development and Validation of **Stability Indicating RP-HPLC Method** for the Estimation of Bisoprolol fumarate in Bulk and Pharmaceutical Dosage Form.	**Stationary phase:** Sunsil C_{18} column (150 × 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile: Water (60:40 % v/v) **Flow rate:** 0.8 mL/min **Wavelength:** 223nm	16
9	Development and Validation of Analytical Method for Estimation of Bisoprolol fumarate in Bulk and Solid Dosage Form by **RP-HPLC**.	**Stationary phase:** RP C_{18} analytical column (250 × 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile: Water (pH 3.0) (70:30 % v/v) **Flow rate:** 0.8 mL/min **Wavelength:** 224nm	17

10	Development and Validation of **HPLC-dad method** for the Determination of Bisoprolol in Tablet Dosage Forms.	**Stationary phase:** Waters Symmetry C_{18} column (150 × 3.9 mm, 5 µm) **Mobile phase:** Acetonitrile: Phosphate buffer (25:75 % v/v) **Flow rate:** 1.4 mL/min **Wavelength:** 226nm	18
11	**RP-HPLC Method** for Simultaneous Estimation of Bisoprolol fumarate and Hydrochlorothiazide in Tablet Formulation.	**Stationary phase:** Inertsil 3V C_{18} column (250 × 4.6 mm, 5 µm) **Mobile phase:** 0.1 M Potassium dihydrogen phosphate buffer: Acetonitrile (70:30 % v/v) **Flow rate:** 1.0 mL/min **Wavelength:** 228nm	19
12	Development and Validation of **RP-HPLC Method** for Simultaneous Estimation of Rosuvastatin and Bisoprolol fumarate in Bulk and Formulations.	**Stationary phase:** C_{18} column **Mobile phase:** Methanol: Phosphate buffer (pH 3.5) (45:55 % v/v) **Flow rate:** 1.0 mL/min **Wavelength:** 245nm	20
HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY			
13	Estimation of Bisoprolol fumarate in Pharmaceutical Preparation by **HPTLC.**	**Stationary phase:** Merck HPTLC plate precoated 60 F_{254} silica gel on aluminum sheet. **Mobile phase:** Methanol: Toluene: Ammonia (2:4:0.1 % v/v/v) **Wavelength:** 229nm	21
14	Analysis of Bisoprolol fumarate and Amlodipine besylate in Tablet Dosage Form by Using **HPTLC.**	**Stationary phase:** Precoated silica gel HPTLC aluminium plate 60 F_{254} **Mobile phase:** Chloroform: Ethanol: Glacial acetic acid (2:8:0.1 % v/v/v) **Wavelength:** 231nm	22

Table:4 Reported methods for assessment of Telmisartan:

Sr. No.	Title	Description	Ref No.
UV-VISIBLE SPECTRSCOPY			
1	Development of **UV Spectrophotometric Method** for Estimation and Validation of Telmisartan as a pure API.	**Solvent:** Ethanol (95%), 0.1N Sodium bicarbonate **Wavelength:** 240nm	23

		Linearity: 2-14 µg/mL	
2	**UV Spectrophotometric Method** Development and Validation for Telmisartan in Bulk and Tablet Dosage Form.	**Solvent:** 0.1N NaOH: Distilled water (20:80) **Wavelength:** 234nm **Linearity:** 2-10 µg/mL	24
3	**UV-Spectrophotometric Method** for Estimation of Telmisartan in Bulk and Tablet Dosage Form.	**Solvent:** 0.1N NaOH **Wavelength:** 234nm **Linearity:** 4-24 µg/mL	25
4	Validation of Telmisartan by **UV-Spectrophotometry Method.**	**Solvent:** 0.1N NaOH **Wavelength:** 295nm **Linearity:** 4-24 µg/mL	26
5	**Absorbance Correction Method** for Estimation of Telmisartan and Metoprolol succinate in Combined Tablet Dosage Forms.	**Solvent:** Methanol **Wavelength:** Telmisartan: 296nm Metoprolol: 223nm **Linearity:** Telmisartan: 2-16 µg/mL Metoprolol: 3-24 µg/mL	27
6	**First Order Derivative and UV Spectrophotometric Methods** for Simultaneous Determination of Telmisartan and Azelnidipine in Bulk and Tablet Dosage Form.	**Solvent:** Methanol **Method A:** Simultaneous equation method **Wavelength:** Azelnidipine: 220nm Telmisartan: 324nm **Method B:** First order derivative spectroscopy method **Wavelength:** Azelnidipine: 244nm Telmisartan: 220nm **Linearity:** Azelnidipine: 3.2-16 µg/mL Telmisartan: 16-80 µg/mL	28
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY			
7	**RP-HPLC Method** for Estimation of Telmisartan in Human Plasma.	**Stationary phase:** Hibar C_{18} column (250 × 4.6 mm, 5 µm) **Mobile phase:** Ammonium Formate solution: Methanol (pH 4.0) (70:30 % v/v) **Flow rate:** 1 mL/min **Wavelength:** 275nm	29
8	**RP-HPLC Method** Development and Validation for Estimation of Telmisartan in Bulk and Tablet Dosage Form.	**Stationary phase:** RP C_{18} column (250 × 4.6 mm, 5 µm) **Mobile phase:** 0.025M potassium dihydrogen phosphate: Acetonitrile: Methanol (45:50:5 % v/v/v)	30

		Flow rate: 1 mL/min. **Wavelength:** 216nm	
9	Development and Validation of **RP - HPLC Method** for the Estimation of Telmisartan in Bulk and Tablet Dosage Form.	**Stationary phase:** Zorbax-SB-18 ;(ODS) column (150 × 4.6 mm, 3.5 µm) **Mobile phase:** Pentane sulphonic acid sodium salt mono hydrate, add 1ml of Perchloric acid and adjust the pH-2.7±0.05 with Triethyl amine: Methanol (40:60 % v/v) **Flow rate:** 1.2 mL/min. **Wavelength:** 230nm	31
10	Development and Validation of **RP - HPLC Method** for the Estimation of Telmisartan in Bulk Drug Using Internal Standard.	**Stationary phase:** Phenomenex C_{18} column (250 × 4.6 mm, 5 µm) **Mobile phase:** 10mM potassium di hydrogen phosphate buffer: methanol (20:80 % v/v) pH adjusted to 5.8 with 10 % v/v ortho phosphoric acid **Flow rate:** 0.8 mL/min. **Wavelength:** 296nm	32
11	**A Stability Indicating RP-HPLC Method** Development and Validation for the Simultaneous Estimation of Azelnidipine and Telmisartan in a Fixed Dose Combination.	**Stationary phase:** Inertsile C_{18} column (150 × 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile: Buffer (25:75 % v/v) **Flow rate:** 1.5 mL/min **Wavelength:** 254nm	33
12	Validated **RP-HPLC Method** for Simultaneous Estimation of Rosuvastatin calcium and Telmisartan in Pharmaceutical Dosage Form.	**Stationary phase:** Inertsil 3V C_{18} column (250 × 4.6 mm, 5 µm) **Mobile phase:** Ammonium Dihydrogen Phosphate Buffer solution: Methanol (pH 3.0) (65:35 % v/v) **Flow rate:** 1.5 mL/min **Wavelength:** 298nm	34
HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY			
13	**Stability Indicating HPTLC** Determination of Telmisartan in Bulk and Tablets.	**Stationary phase:** TLC aluminium plates precoated with silica gel $60F_{254}$ **Mobile phase:** Ethyl acetate: dichloroethane: Methanol (6:2:1 % v/v) **Wavelength:** 295nm	35
14	Development and Validation of **HPTLC Method** for Simultaneous Estimation of Amlodipine besylate, Hydrochlorothiazide	**Stationary phase:** Pre-coated with silica gel plate $60F_{254}$ **Mobile phase:** Chloroform: Butanol: Ammonia (6:4:0.1 % v/v/v)	36

	and Telmisartan in Their Combined Tablet Dosage Form.	**Wavelength:** Amlodipine besylate: 237.5nm, Hydrochlorothiazide: 270nm, Telmisartan: 297nm	

Table:5 Reported method for combination of Bisoprolol fumarate and Telmisartan:

Sr. No.	Title	Description	Ref No.
1	Development and Validation of Analytical Method for Simultaneous Estimation of Bisoprolol fumarate and Telmisartan by Using **RP-HPLC Method.**	**Stationary phase:** Waters X Bridge RP C_{18} column (250 × 4.6 mm, 5 µm) **Mobile phase:** Methanol: Water (75:25 % v/v) **Flow rate:** 1 mL/min **Wavelength:** 231nm	37
2	Development and Validation of **RP -HPLC Method** for Simultaneous Estimation of Bisoprolol fumarate and Telmisartan in Bulk and Pharmaceutical Formulation.	**Stationary phase:** C_8 Column (150 × 4.6 mm, 5 µm) **Mobile phase:** Ammonium formate, Acetonitrile: Methanol (50:50 % v/v) **Flow rate:** 1 mL/min **Wavelength:** 231nm	38
3	Development and Validation of **RP-HPLC Method** for the Simultaneous Estimation of Bisoprolol fumarate and Telmisartan from Pharmaceutical Formulations.	**Stationary phase:** C_{18} Column (150 × 4.6 mm, 5 µm) **Mobile phase:** 0.1% of Tri fluroacetic acid in Water: Acetonitrile (80:20 % v/v) **Flow rate:** 1 mL/min **Wavelength:** 227nm	39

Conclusion:

This article emphasizes the significance of Reverse Phase High-Performance Liquid Chromatography (RP-HPLC) in the simultaneous estimation of bisoprolol fumarate and telmisartan in pharmaceutical formulations. RP-HPLC is a precise, sensitive, and reliable technique, ideal for separating complex mixtures and accurately quantifying both drugs. Various validated RP-HPLC methods, optimized with different chromatographic conditions, demonstrate its flexibility and robustness in quality control of both bulk and tablet formulations. These methods streamline the analysis process, improve efficiency, and reduce costs for manufacturers, while ensuring compliance with regulatory standards. The development and validation of these methods are vital for supporting the production of combination therapies, ultimately benefiting patient care and treatment outcomes.

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