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Review of Chromatographic and Spectrophotometric Methods for the estimation of Nebivolol 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 Nebivolol hydrochloride 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: Nebivolol hydrochloride, Telmisartan, RP-HPLC.

I. 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, Nebivolol hydrochloride and telmisartan have emerged as key players in the treatment landscape. Nebivolol hydrochloride 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 Nebivolol hydrochloride 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]

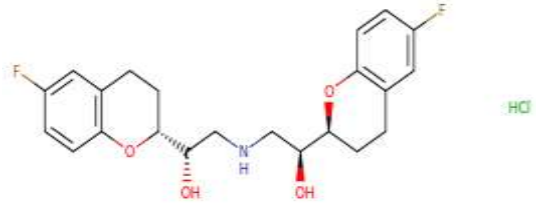

Figure1: Structure of Nebivolol hydrochloride

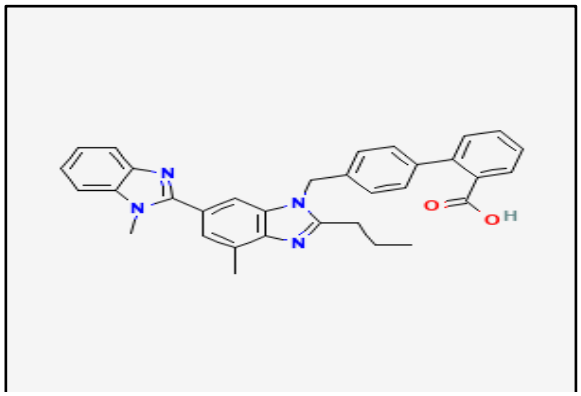

Figure2:Structure of Telmisartan

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

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compounds based on their hydrophobicity, making it well-suited for the simultaneous analysis of Nebivolol hydrochloride and telmisartan.

Despite the availability of various analytical methods, there is a need for validated RP-HPLC methods that can efficiently analyse 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. [4,5]

This study aims to develop and validate an RP-HPLC method for the simultaneous estimation of Nebivolol hydrochloride 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 Nebivolol hydrochloride and Telmisartan

Table:1 Official methods for assessment of Nebivolol hydrochloride:

Sr. no.	Official in	Method	Description	Ref No.
1.	Indian Pharmacopoeia (2022)	Liquid Chromatography	**Stationary phase:** A stainless-steel column (250 x 4.6 mm), packed with porous silica with bonded phenyl groups (5 µm). **Mobile phase:** Mixture of 28 volumes of acetonitrile, 72 volumes of buffer solution prepared by dissolving 3.4 gm tetrabutylamonium hydrogen sulphate in 1000 ml of water and 0.3 volume of diethylamines. **Flow rate:** 1 mL/min **Wavelength:** 220 nm	**6**

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:** IntensilC_{18} column **Mobile phase:** Phosphate buffer (pH 2.4): Acetonitrile (60:40 % v/v) **Flow rate:** 1 mL/min. **Wavelength:** 230nm	**7**

Table:3 Reported methods for assessment of Bisoprolol fumarate

Sr No.	Title/Method	Description	Ref No.
UV VISIBLE SPECTROSCOPY			
1	**UV Spectrophotometric Method** for the Estimation of Nebivolol HCL in Bulk And Pharmaceutical Formulations.	**Solvent :**Methanol: phosphate buffer pH 6.8 (10:90 % v/v) **Wavelength :**282 nm **Linearity :**10-50 µg/mL	**8**
2	**UV Spectrophotometric Method**	**Solvent :** Methanol: 0.01N HCl	**9**

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	Development and Validation for Estimationof Nebivolol hydrochloride as API and in Pharmaceutical Dosage Form.	(10:90% v/v) **Wavelength :**281nm **Linearity :**10-60 µg/mL	
3	**Spectrophotometric Method** for the Determination of Nebivolol hydrochloride inBulk and Pharmaceutical Formulations	**Solvent :**Methanol **Wavelength :**281 nm **Linearity :**4-60 µg/mL	**10**
4	Simultaneous Quantification of Nebivolol hydrochloride and Hydrochlorothiazide by **First Derivative UV-Spectroscopy**	**Solvent :**10% Methanol **Wavelength :** Nebivolol - 272.2 nm Hydrochlorthiazide– 280 nm **Linearity :** Nebivolol- 4-24 µg/ mLHydrochlorthiazide- 2-32 µg/ mL	**11**
5	Simultaneous Estimation of Nebivolol hydrochloride and Amlodipine besylate by **UV Spectrophotometric Method**	**Solvent :** Methanol **Wavelength :** Nebivolol – 280 nm Amlodipine besylate – 239 nm **Linearity :** Nebivolol - 10- 90 µg/ mL Amlodipine besylate - 10- 45 µg/ mL	**12**
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY			
6	**Reverse Phase HPLC method** for determination of Nebivolol in pharmaceutical preparations	**Stationary phase:** Ace C_{18} column **Mobile phase:** Methanol: Acetonitrile: 0.02 M Potassium dihydrogen phosphate (60:30:10 % v/v/v; pH 4.0) **Flow rate:**2.6 mL/min **Wavelength:** 280 nm	**13**
7	Stability Indicating **RP-HPLC** Estimation of Nebivolol hydrochloride in Pharmaceutical Formulations	**Stationary phase:**phenomenex Gemini C_{18}column (150 x 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile: Water (60:40 % v/v) **Flow rate:**0.8 mL/min **Wavelength:** 223 nm	**14**
8	Liquid chromatographic impurity profiling of Nebivolol hydrochloride from bulk drug	**Stationary phase:** C_{18} column (250 ×4.6 mm, 5 µm) **Mobile phase:** Methanol: water (80:20 % v/v, (pH 7.2, adjusted by adding 0.2 M glacial acetic acid into 0.2 M triethyl amine) **Flow rate:**1 mL/min **Wavelength:** 222 nm	**15**
9	A Validated **RP-HPLC Method** for Simultaneous Estimation of Nebivolol and Hydrochlorothiazide in Tablets	**Stationary phase:** Phenomenex Gemini C_{18} (250 × 4.6 mm, 5 µm) **Mobile phase:** acetonitrile: 50mM ammonium acetate (adjusted to pH 3.5	**16**

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		using orthophosphoric acid) (70:30 % v/v) **Flow rate:**1.0 mL/min **Wavelength:** 254 nm	
10	Simultaneous Estimation of Nebivolol hydrochloride and Valsartan using **RP HPLC**	**Stationary phase:** HIQ silane C_{18} column (250×4.6 mm, 5 µm) **Mobile phase:** Methanol:water (80:20 % v/v) **Flow rate:**1.0 mL/min **Wavelength:** 289 nm	**17**
HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY			
11	A Validated **HPTLC Method** for Determination of Nebivolal from Tablets	**Stationary phase:**Aluminum plates pre-coated with silica gel 60 F_{254}. **Mobile phase:** Ethyl acetate: Methanol: 25% Ammonia (8:2:0.1 % v/v/v) **Wavelength:** 285 nm	**18**
12	Development and Validation of a **Stability Indicating HPTLC Method** for Analysis of Nebivolol hydrochloride and Hydrochlorothiazide in the Bulk Material and in Pharmaceutical Dosage Forms	**Stationary phase:** Silica gel 60 F_{254} plates **Mobile phase:** Ethyl acetate: Methanol: Acetic acid (6.5:1:0.5 % v/v/v) **Wavelength:** Nebivolol-280 nm Hydrochlorthiazide- 270 nm	**19**

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 **Linearity:** 2-14 µg/mL	**20**
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	**21**
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	**22**
4	Validation of Telmisartan by **UV-Spectrophotometry Method.**	**Solvent:** 0.1N NaOH **Wavelength:** 295nm **Linearity:** 4-24 µg/mL	**23**
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	**24**
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	**25**

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		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	
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY			
7	**RP-HPLC Method** for Estimation of Telmisartan in Human Plasma.	**Stationary phase:** HibarC_{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	**26**
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) **Flow rate:** 1 mL/min. **Wavelength:** 216nm	**27**
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	**28**
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	**29**
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:** InertsileC_{18} column (150 × 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile: Buffer (25:75 % v/v) **Flow rate:** 1.5 mL/min **Wavelength:** 254nm	**30**
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 %	**31**

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		v/v) **Flow rate:** 1.5 mL/min **Wavelength:** 298nm	
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	**32**
14	Development and Validation of **HPTLC Method** for Simultaneous Estimation of Amlodipine besylate, Hydrochlorothiazide and Telmisartan in Their Combined Tablet Dosage Form.	**Stationary phase:** Pre-coated with silica gel plate $60F_{254}$ **Mobile phase:** Chloroform: Butanol: Ammonia (6:4:0.1 % v/v/v) **Wavelength:** Amlodipine besylate: 237.5nm, Hydrochlorothiazide: 270nm, Telmisartan: 297nm	**33**

Table:5 Reportedmethod for combination of Nebivolol hydrochloride and Telmisartan:

Sr. no	Title/method	Description	Ref No.
1	Dissolution Method Development and Validation for Combination Dosage Form of Telmisartan and Nebivolol hydrochloride Tablets using, UV Spectrophotometric Method	**Solvent :**0.1N HCl, phosphate buffer, SFG (without enzyme) solution **Wavelength :** Nebivolol -281nm Telmisartan– 296 nm **Linearity :** Nebivolol- 2-12 µg/ mL Telmisartan - 2-12 µg/ mL	**34**
2	Novel **Reverse-phase High-performance liquid chromatography method** development and validation for estimation of telmisartan and nebivolol hydrochloride in pharmaceutical dosage form	**Stationary phase:** C_{18} Shim-pack column (150 × 4.6 mm, 5 µm) **Mobile phase:** Acetonitrile: Buffer (potassium dihydrogen orthophosphate pHadjusted 3.1with orthophosphoricacid) ina ratioof 40:60 % v/v **Flow rate:** 1.2 mL/min **Wavelength:** 280 nm	**35**
3	**Stability indicating assay method** development and validation for nebivolol and telmisartan in its combined pharmaceutical dosage form	**Stationary phase:** Agilent C_{18}column (250 x 4.6mm, 5µm) **Mobile phase:** Acetonitrile: 0.05 M (pH 6.5) Disodiumhydrogen (NA_2HPO_4) buffer **Flow rate:** 1 mL/min **Wavelength:** 235 nm	**36**
4	**First order derivative spectrophotometric and HPTLC method** for simultaneous estimation of telmisartan and nebivolol in their combined dosage form	**Stationary phase:** precoated plate of 200-µm layers of silica gel 60 F_{254} **Mobile phase:** Toluene: Ethyl Acetate: Methanol: 25% Ammonia (6: 3: 3: 0.2 % v/v/v/v) **Wavelength:** 290 nm	**37**

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II. CONCLUSION:

This article emphasizes the significance of Reverse Phase High-Performance Liquid Chromatography (RP-HPLC) in the simultaneous estimation of Nebivolol hydrochloride 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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