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AN UPDATED REVIEW ON ANALYTICAL METHODS FOR THE AZELNIDIPINE AND TELMISARTAN IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT: Hypertension, also known as high blood pressure, occurs when the force of blood against the artery walls is excessively high the force of blood against the artery wall is too high. Hypertension is a very common disorder, particularly in past middle age. For improvement activity of hypertension, Azelnidipine and Telmisartan are newer combination in the market which is effective in hypertension. This combination was developed to improve medication for stage II hypertension. Azelnidipine is a Calcium channel blocker, and Telmisartan is an Angiotensin II receptor blocker. This review provides information about different analytical methods for estimating Azelnidipine and Telmisartan individually or in combination with other drugs, such as UV spectrophotometry, HPTLC, HPLC, and LC-MS. All reported methods were found to be simple, accurate, economical, precise, and reproducible. This review focuses on the recent analytical method development of Azelnidipine and Telmisartan in their combined dosage form. It also includes a stability-indicating analytical method for determining Azelnidipine and Telmisartan.

INTRODUCTION: Azelnidipine is a dihydropyridine calcium channel blocker. Azelnidipine is L and T calcium channel blocker. It is sold in Japan by Daiichi-Sankyo Pharmaceuticals, Inc. Unlike nicardipine; it has a gradual onset and a long-lasting hypoglycaemic effect, with little increase in heart rate. The Drug Controller General of India (DCGI) has approved the use of Azelnidipine in India. It was launched under the Azusa (Ajanta Pharma Ltd.) brand in 2020¹.

Mechanism of Action of Azelnidipine: Azelnidipine inhibits trans-membrane Calcium influx through the voltage-dependent channels of smooth muscles in vascular walls. Calcium channels are classified into various categories, including L-type, T-type, N-type, P/Q-type, and R-type Calcium channels. Normally, calcium induces smooth muscle contraction, contributing to hypertension. When calcium channels are blocked, the vascular smooth muscle does not contract, resulting in the relaxation of vascular smooth muscle walls and decreased blood pressure².

Telmisartan: Telmisartan, sold under the brand name Micardis among others, is a medication that is widely prescribed for the treatment of high blood pressure, heart failure, and diabetic kidney disease. It is considered to be a reasonable initial treatment option for individuals with high blood pressure, and

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it is typically administered orally. In addition to the standalone form, Telmisartan is available in combination with hydrochlorothiazide, cilnidipine, and amlodipine. It is worth noting that Telmisartan stands out from other drugs in its class due to its relatively high average dosage of 80 mg/day.

Mechanism of Action of Telmisartan:

Telmisartan is an angiotensin II receptor blocker (ARB). It works by blocking a substance in the body that causes blood vessels to tighten. As a result, telmisartan relaxes the blood vessels. This lowers blood pressure and increases the supply of blood and oxygen to the heart⁴.

Physical and Chemical Property: Azelnidipine is light yellow to yellow crystalline powder. IUPAC name is 3-[1- (Benzilydrylazetid-3-yl)] 5-

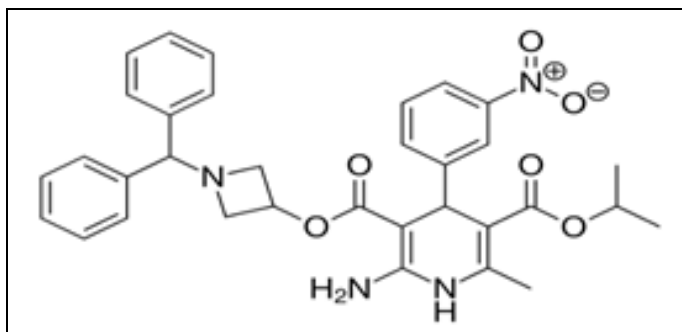


FIG. 1: CHEMICAL STRUCTURE OF AZELNIDIPINE⁷

isopropyl- 2- amino-6-methyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3, 5-dicarboxylate. The molecular formula of Azelnidipine is C₃₃H₃₄N₄O₆. Molecular weight is 582.646 g/mol. It is insoluble in water, slightly soluble in methanol, soluble in ethyl acetate, freely soluble in acetone, and in acetic acid⁵.

Telmisartan is white to off-white crystalline powder. IUPAC name is 2-(4-[[4-methyl-6-(1-methylbenzimidazol-2-yl)-2-propylbenzimidazol-1-yl] methyl] biphenyl)-benzoic acid. Molecular formula of Telmisartan C₃₃H₃₀N₄O₂. Molecular weight is 514.6 g/mol. It is insoluble in water, sparingly soluble in dichloromethane, strong acid, and organic solvents and soluble in strong base and methanol⁶.

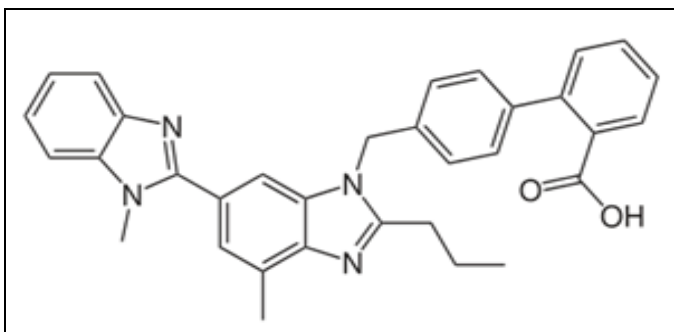


FIG. 2: CHEMICAL STRUCTURE OF TELMISARTAN⁸

TABLE 1: OFFICIAL METHOD FOR ASSESSMENT OF AZELNIDIPINE

Sr. no.	Official In	Method	Description
1.	Indian Pharmacopoeia (2018) ⁹	Liquid Chromatography	Column: Octadecylsilane Silica (25cm x 4.6 mm, 5μ) Mobile phase: 0.03 M potassium dihydrogen orthophosphate in water: Acetonitrile (50:50) v/v Wavelength: 256 nm Flow rate: 1.0 ml/min Injection volume :20 μL

TABLE 2: REPORTED METHODS FOR ASSESSMENT OF AZELNIDIPINE

Sr. no.	Title/Method	Description
1.	Validated Stability-Indicating RP-HPLC Method for the Simultaneous Determination of Azelnidipine and Olmesartan in their Combined Dosage Form ¹⁰ .	Column: Hypersil GOLD C18 (150 mm × 4.6mm, 5 μm) Mobile Phase: Methanol: Acetonitrile: Water (40:40:20) v/v/v Flow rate: 0.5 mL/min Wavelength : 260 nm Linearity: AZL – 2 - 48 μg/ml OLM- 2.5 - 60 μg/ml Retention Time: AZL -8.56min. OLM - 3.04 min
2.	UV Spectrophotometric method development and Validation for Determination of Azelnidipine in Pharmaceutical Dosage Form ¹¹ .	Model: Shimadzu 1800 UV Visible spectrophotometer Solvent: Methanol Wavelength (nm): 255nm Linearity: 2 - 14 μg/ ml
3.	Validation and Forced Stability- Indicating HPTLC Method For Determination of Azelnidipine ¹² .	Stationary Phase: Silica gel 60 F254 (20cm × 10cm, 0.2mm) Mobile Phase: Chloroform: Ethyl acetate: methanol 6.5:3.5: 0.1 (v/v/v) Wavelength: 255nm Linearity: 300-800ng/band

4.	Simultaneous Determination of Azelnidipine and Olmesartan medoxomil by First Derivative Spectrophotometric Method ¹³ .	Rf Value: 0.59,0.60 Model: Shimadzu – 1800 UV Visible Spectrophotometer Solvent: Methanol Method: 1. First Derivative Spectrophotometric method Wavelength (nm): AZL - 217nm OLM- 239.4 nm Linearity: 4 - 32 µg/ ml
5.	Spectrophotometric estimation of Azelnidipine in Bulk and Pharmaceutical dosage form by second order derivative methods ¹⁴ .	Model: Shimadzu 1800 UV Visible Spectrophotometer Solvent: Methanol Method: 1. Second Derivative Spectrophotometric method Wavelength: 233.8 nm Linearity: 1 - 20 µg / ml
6.	Method Development and Validation of Azelnidipine by RP-HPLC ¹⁵ .	Column: C18 column (250 mm x 4.5 mm, 5 µm) Mobile Phase: Methanol: Water (75:25) v/v,0.1% glacial acetic acid. Flow rate: 1 mL/min Wavelength: 254nm Linearity: 10 - 50 µg/ml Retention Time: 6.13 min.
7.	RP-HPLC Method Development and Validation of Azelnidipine ¹⁶ .	Column: C18 column (250 mm x 4.5 mm, 5µm) Mobile Phase: Methanol: Water (80:20) v/v, Orthophosphoric acid (pH-3) Flow rate: 1 mL/min. Wavelength: 257 nm Linearity: 20-100µg/ml Retention Time: 6.5 min.
8.	Sensitive Analysis of Azelnidipine and Related Derivative in Human Plasma by Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry ¹⁷ .	Column: C18 (50 mm × 2.1 mm.,1.7 µm) Mobile Phase: A (20 mm Ammonium acetate aqueous solution) B (0.1 % formic acid in Acetonitrile) Flow Rate: 0.5 mL/min Linearity: 0.01-10 mg/ml Retention Time: AZL -1.38 min. IS -1.26 min.
9.	Simultaneous determination of Azelnidipine and two metabolites in Human Plasma using Liquid chromatography-tandem mass spectrometry ¹⁸ .	Column: Intersil ODS-3 C18 (2.1 mm × 150 mm,5µm) Mobile Phase: Methanol: Water: Acetic Acid (800:200:0.2) v/v Flow rate: 0.2ml/min. Wavelength: 256nm Linearity: 0.5-40 mg/ml Retention Time: AZL –3.6min. M-1(Aeromatized form)-10.2min. M-2(Hydroxylated Form)-6.8min.
10.	Stability Indicating Analytical Method Development and Validation for Estimation of Azelnidipine ¹⁹ .	UV Spectrophotometric method: Solvent: Methanol: Water (80:20) v/v Method 1- Zero order Spectrophotometric method Method 2 -First order Derivative Spectrophotometric method Wavelength: Method 1 -257 nm Method 2- 242.6 nm Linearity: 2-10µg/ml Method 3 – RP HPLC Method Column: ODS C18 (250mm×4.6mm.,5µm) Mobile phase: Sodium dibasic Phosphate Buffer: Acetonitrile: Methanol (10:50:40) v/v/v, orthophosphoric acid (pH - 4.5) Flow rate: 1mL/min, Wavelength: Method 3 -256nm, Linearity: 2-12µg/ml Retention Time: 6.1 min.
11.	Simultaneous Determination of Azelnidipine and Olmesartan Medoxomil in Pharmaceutical Dosage Forms by UFLC Method ²⁰ .	Column: ODS (250mm x 4.6mm, 5µm) Mobile Phase: Methanol: Water (85:15) v/v Flow Rate: 1.5ml/min. Wavelength: 255nm Linearity: 2-16 mg/ml

		Retention Time: AZL - 6.80 min. OLM -1.72 min.
12.	Analytical method development and Validation of Azelnidipine by UV-visible spectroscopy ²¹ .	Double Beam UV- visible spectrophotometer with 1.0cm matching quartz Wavelength: 200-400 nm
13.	Development and Validation of RP-HPLC method for quantification of Azelnidipine in tablet ²² .	Solvent: Distilled grade water Methanol Column: Luna C18 (150 x 4.6mm, 5µm) Mobile phase: Acetonitrile: Water (90:10) Flowrate: 1ml/min Wavelength: 255nm Injection volume: 20µl Retention time- 3.5 min Run time- 10 min
14.	Development and Validation of Stability Indicating RP-HPLC Method for Azelnidipine for bulk drug ²³ .	Column: Phenomenex Hyper Clone C18 column (250 × 4.6 mm, 5µm) Mobilephase: methanol: water 75:25% v/v Flow rate: 1ml/min Wavelength: 256nm Retention time- 3.5 min Run time- 10 min
15.	Stability-Indicating LC Method for Quantification of Azelnidipine: Synthesis and Characterization of Oxidative Degradation Product ²⁴ .	Mobile phase: phosphate buffer (pH 3.0) methanol 10:90% v/v Flow rate: 1.0 mL/min Wavelength: 256 nm
16.	Mathematically Processed UV Spectroscopic Method for Quantification of Chlorthalidone and Azelnidipine in Bulk and Formulation ²⁵ .	Model: UV spectrophotometer (1650, Shimadzu, Japan) Wavelength: 238.5 nm and 239.5 nm for CTL and 272.1 nm and 342.1 nm for AZE, respectively Solvent: Absolute ethyl alcohol (ethanol)
17	Special Emphasis on Bio-analytical Method development and Validation of an Anti-Hypertensive Drug Azelnidipine by LC-ESI-MS/MS in Healthy Human Volunteer's Blood Plasma ²⁶ .	Column: C18 Phenomenex Kinetex (50x3mm, 5µ) Mobilephase: 0.1% Formic Acid in Acetonitrile and Milli-Q water with 10mM Ammonium acetate Flow rate: 0.5 ml/min Retention time- 3.5 min Injection Volume- 10 µl Run time- 7 min

TABLE 3: OFFICIAL METHOD FOR ASSESSMENT OF TELMISARTAN

Sr. no.	Official In	Method	Description
1.	Indian Pharmacopoeia (2018) ²⁷	Liquid Chromatography	Stationary Phase: A stainless steel Column 12.5 cm×4mm, packed with octadecylsilane bonded to porous silica (5 µm) Mobile Phase: A) Dissolve 2.0 g of Potassium Dihydrogen Phosphate and 3.8g of Sodium Pentane sulphonate monohydrate in water, adjust to pH 3 with orthophosphoric acid dilute to 1000ml with water. B) A Mixture of 20 Volume of Methanol and 80 Volume of Acetonitrile. (20 :80) v/v Flow rate: 1ml/min. Wavelength: 230nm Injection Volume: 10µL

TABLE 4: REPORTED METHODS FOR ASSESSMENT OF TELMISARTAN

Sr. no.	Title/Method	Description
1.	RP-HPLC Method Development and Validation for estimation of Telmisartan in bulk and tablet dosage form ²⁸ .	Column: RP18, column (250×4.6mm) Mobile phase: 0.025M potassium dihydrogenphosphate: acetonitrile: methanol (45:50:5) Flow rate: 1ml/min Wavelength: 216 nm
2.	Method development and validation of Telmisartan in bulk and pharmaceutical	Model: Shimadzu, model 1700 Wavelength: 298nm

	dosage forms by UV spectrophotometric method ²⁹ .	Solvent: Methanol: Water (90: 10)
3.	UV-spectrophotometric analytical method development and Validation for determination of Telmisartan in pharmaceutical drug and drug product ³⁰ .	Model: U.V. visible double beam spectrophotometers SL210 Elico Wavelength: 200-400 nm Solvent: Water and Methanol
4.	Stability Indicating assay of Telmisartan in tablets ³¹ .	Column: Kromasil C18 (4.6 × 150 mm, 5 μm) Mobile phase: 0.01 M Phosphate buffer (pH: 3) and Acetonitrile in ratio of (40:60%) Flow rate: 2ml/min Wavelength: 226 nm Retention time- 2.728 min
5.	Stress degradation studies on Telmisartan and development of a validated method by UV spectrophotometry in bulk and pharmaceutical dosage forms ³² .	Model: A double beam UV-Visible spectrophotometer (Shimadzu-1800) with UV probe 2.31 software Wavelength: 200–380nm Solvent: Methanol
6.	Determination of Telmisartan by HPTLC – A Stability Indicating Assay ³³ .	Mobile phase: chloroform–methanol 8.6:1.4 (v/v) containing 0.1% ammonia HPTLC plate: 10 cm × 20 cm aluminum-backed Wavelength: 297 nm Scanning speed: 5 mm s ⁻¹ Source of radiation: deuterium lamp
7.	Stability Indicating HPLC method for the determination of Telmisartan in bulk drug and in pharmaceutical dosage form ³⁴ .	Model: M/S Shimadzu HPLC system with a photodiode array detector system (SPD – M20A) Column: Phenomenex luna ODS, (25 cm x 4.6 mm OD, 5μ, pore size 100Å°) Mobile phase: phosphate buffer and acetonitrile 60: 40 Flow rate: 1.5ml/min Wavelength: 230 nm Retention time: 2.728 min Run time: 30 minutes
8.	Stability-Indicating RP-HPLC Method for Analysis of Telmisartan in the Bulk Drug and in Formulations ³⁵ .	Model: Jasco model PU 1580, intelligent HPLC pump, an AS-1555 sampler with auto injecting facility Column: C18 column Mobile phase: Methanol: Water 80:20 (v/v) Flow rate: 1.0ml/min Wavelength: 225 nm Retention time: 4.85 ± 0.05 min
9.	Stability Indicating HPTLC method for simultaneous determination of Telmisartan and Ramipril in tablets ³⁶ .	HPTLC plates: (Merck) precoated with silica gel 60F254 aluminium sheets Mobile phase: toluene: acetonitrile: formic acid: water (5:5:0.3:1) Wavelength: 212 nm
10.	Development and Validation of Stability Indicating HPTLC and HPLC Methods for Simultaneous Determination of Telmisartan and Atorvastatin in their Formulations ³⁷ .	For RP-HPLC: Column: Phenomenex Luna C ₁₈ Mobile phase: acetonitrile: 0.025 M ammonium acetate (38: 52%, v/v) Flow rate: 1.0ml/min Wavelength: 281 nm For HPTLC: HPTLC plates: Silica gel 60 F ₂₅₄ Mobile phase: toluene-methanol-ethyl acetate-acetic acid (5: 1: 1: 0.3, v/v) Wavelength: 279 nm
11.	A validated stability indicating HPTLC method for simultaneous estimation of Ramipril and Telmisartan ³⁸ .	HPTLC plates: TLC plate precoated with Silica gel 60 F254 Mobile phase: Methanol: Chloroform (1:6) v/v Wavelength: 210 nm
12.	Development and Validation of stability-indicating HPTLC method for simultaneous determination of Telmisartan and Cilnidipine in combined tablet dosage	HPTLC plates: Precoated silica gel aluminium plate 60 F254(10 ×10) with 250μm thickness Mobile phase: Toluene: Methanol: Glacial acetic acid (8: 2: 1, v/v/v)

	form ³⁹ .	Wavelength: 260 nm Retention factor: Telmisartan 0.38 ± 0.004 and cilnidipine 0.62 ± 0.007 Column: Oyster ODS3 (150 × 4.6 mm, 5 μm) Mobile phase: phosphate buffer with 1.1 g octane-1-sulfonic acid sodium salt having pH 2.5 and acetonitrile, with a proportion of 500:500, v/v Flow rate: 1.0 mL/min
13.	Stability-Indicating RP-HPLC method development and Validation for simultaneous estimation of Telmisartan and Rosuvastatin calcium in bulk and in tablet dosage form ⁴⁰ .	Column: Inertsil ODS 3V (250 x 4.6 mm, 5μm) Flow rate: 1.3 mL/min Wavelength: 260 nm Buffer: 1 % (v/v) triethylamine in potassium hydrogen orthophosphate (pH 2.5) and acetonitrile buffer
14.	Stability-Indicating HPLC method for simultaneous estimation of low-level impurities of Telmisartan and Hydrochlorothiazide in tablet dosage forms ⁴¹ .	Column: C18, 250×4.6 mm column of 5.0μm particle packing Flow rate: 1.0 mL/min Wavelength: 210nm Detector: photodiode array
15.	Stability indicating reverse-phase high-performance liquid chromatography method development and Validation for simultaneous estimation of Telmisartan and Benidipine hydrochloride in pharmaceutical dosage form ⁴² .	Column: C18 250×4.6mm, 5 μm Mobile phase: Acetonitrile (ACN): buffer pH 3.0 with Orthophosphoric acid (68: 32) Flow rate: 1.0 mL/min Wavelength: 245nm Detector: photodiode array
16.	Stability Indicating Simultaneous Validation of Telmisartan and Cilnidipine with Forced Degradation Behavior Study by RP-HPLC in Tablet Dosage Form ⁴³ .	Column: C18 column having dimensions of 4.6×250 mm and particle size of 5μm Mobile phase: 0.01 M potassium dihydrogen phosphate buffer (adjusted to pH 3.4 using orthophosphoric acid): methanol: acetonitrile (15:15:70 v/v/v) Flow rate: 1.0 mL/min Wavelength: 210nm Retention Time: ramipril (R _t : 3.68 min) and telmisartan (R _t : 4.98 min)
17.	RP-HPLC Estimation of Ramipril and Telmisartan in Tablets ⁴⁴ .	Column: C18 kinetex column (250 × 4.6 mm, 5 μm) Mobile phase: Acetonitrile: 20mM phosphate buffer (pH 3.0) (60:40 %, v/v) Flow rate: 1.0 mL/min Wavelength: 258nm
18.	Development and Validation of RP-HPLC Method for simultaneous estimation of Telmisartan, Amlodipine Besylate, and Hydrochlorothiazide in their tablet dosage form ⁴⁵ .	Column: Hypersil BDS C18 Column (100 mm x 4.6 mm, 5μ.) Mobile Phase: Phosphate Buffer (pH 3.6): Acetonitrile (60:40) v/v Flow rate: 1 mL/min. Wavelength: 234 nm Linearity: TEL -10–150μg/ml AMLB -1–20 μg/ml Retention Time: TEL – 4.1 min. AMLB– 2.6 min.
19.	Development And Validation of a Stability Indicating RP-HPLC Method For Simultaneous Determination of Telmisartan and Amlodipine in Combined Dosage form ⁴⁶ .	Column: Poroshell 120EC-C18 column (4.6 x 50mm, 2.7μm) Mobile Phase: Acetonitrile: 50mM ammonium acetate buffer (45:55) v/v, (pH 4.5) acetic acid. Flow rate: 1ml/min. Wavelength: 290 nm
20.	Stability-Indicating RP-UHPLC Method For Determination of Telmisartan in Drug Substance and Marketed Formulation ⁴⁷ .	Column: Waters X Bridge RP C18(250mm x 4.6 mm, 5 μm) Mobile Phase: Methanol and water (75:25 v/v) Flow Rate: 1ml/min. Wavelength: 231 nm Linearity: BIS:5-25μg/ml TEL: 40-200μg/ml Retention Time: BIS-5.7 min. TEL -7.6min.
21.	Development and Validation of Analytical Method for Simultaneous Estimation of Bisoprolol Fumarate and Telmisartan by Using RP HPLC Method ⁴⁸ .	Column: C18G (250 mm × 4.6 mm, 5 μm) Mobile Phase: Potassium dihydrogen phosphate buffer (10mM): Methanol: Acetonitrile (30:10:60) v/v/v (pH 5.8) Flow rate: 1.0 mL/min.
22.	A New RP-HPLC method for simultaneous estimation of Telmisartan and Cilostazol in the synthetic mixture ⁴⁹ .	

23. Method Development and Validation for Simultaneous Estimation of Telmisartan and Chlorthalidone by RP-HPLC in Pharmaceutical Dosage Form ⁵⁰ .	<p>Wavelength: 257 nm Linearity: TEL -2-10 µg/ml, CIL- 4-20 µg/ml Retention Time: TEL: 9.6 min. CIL: 5.49 min. Column: CAPCELL C18 (250mm×4.6mm, 5µm) Mobile Phase: Potassium di hydrogen ortho phosphate buffer: Acetonitrile: Methanol (35:45:20) v/v/v (pH 3.5) Ortho phosphoric acid Flow Rate:0.8 mL/min.</p>
24. Development and Validation RP-HPLC Method for Simultaneous Estimation of Telmisartan and Nifedipine in Synthetic Mixture ⁵¹ .	<p>Wavelength:296nm Linearity: TEL -20- 100µg/mL, CHLT: 6.25-31.25 µg/mL Retention Time: TEL- 4.97 min. CHLT: 3.46 min. Column: Phenomenex Luna C18(250mm×4.6mm,5µ) Mobile Phase: ACN: Water: Methanol (10:20:70 v/v/v) pH 3.8 Wavelength: 234 nm Flow rate: 1 ml/min</p>
25. Development and Validation of Rapid RP-HPLC Method for the Detection and Quantification of Telmisartan Incorporated in Dosage Forms and Plasma ⁵² .	<p>Linearity: TEL: 4-20 µg/ml, NIF: 2-10 µg/ml Retention Time: TEL: 2.563 min NIF: 4.403 min Column: C18 column (4.6 mm×250 mm, 5 µm) Mobile Phase: Acetonitrile: Methanol: 0.01 M sodium dihydrogen orthophosphate (41:10:49) v/v/v (pH 3.0) Orthophosphoric acid Wavelength: 291 nm Flow rate: 0.8 mL/min Linearity: 0.1-10µg/ml Retention Time: 2.4 min.</p>
26. A Validated RP-HPLC Method for Tablets Containing Amlodipine Besylate and Telmisartan HCl as Active Pharmaceutical Ingredient ⁵³ .	<p>Column: Phenomenex C18 (250 mm × 4.6 mm, 5 µm) Mobile Phase: 0.02M Ammonium Phosphate buffer: Acetonitrile: Methanol (40:35:25) v/v/v Flow rate: 1.0mL/min. Wavelength: 254nm: TEL – 0.8 -160 µg/ml AMLB – 0.1-2 µg/ml Retention Time: TEL -2.65 min. AMLB – 4.996 min.</p>
27. Analytical Method Development and Validation for The Simultaneous Estimation of Metformin and Telmisartan in Bulk and Pharmaceutical Dosage Forms Using RP-HPLC Method ⁵⁴ .	<p>Column: BDS (250mm x 4.6 mm, 5 µ) Mobile Phase: Buffer: Acetonitrile: Methanol (35:55:10) v/v/v Flow rate: 1mL/min Wavelength: 237nm Linearity: MET: 5-30µg/ml TEL: 62.5-375µg/ml Retention Time: MET- 2.4 min. TEL-3.2 min.</p>
28. Development and Validation of Bioanalytical HPLC Method For Estimation of Telmisartan in Rat Plasma: Application to Pharmacokinetic Studies ⁵⁵ .	<p>Column: Phenomenex Luna® C8 (300mm× 4.6 mm,5µ) Mobile Phase: Methanol: Acetonitrile (70:30 (v/v) Flow rate: 1 ml/min Wavelength: 190-800 nm Linearity: 10 - 1000 µg/ml Retention Time: 2.3 min.</p>
29. Analytical Method Development and Validation for the Simultaneous Estimation of Telmisartan and Atorvastatin in Bulk and Tablet Dosage Form ⁵⁶ .	<p>Column: Inertsil-ODS C18 (250mm×4.6mm,5µ) Mobile Phase: Methanol:water(50:50) v/v Wavelength: 250 nm Flow rate:1mL/min Linearity: 20 to 80 µg/ml Retention Time: TEL -2.4 min. ATC – 3 min.</p>
30. Development and Validation of HPTLC Method for Simultaneous Estimation of Amlodipine Besylate, Hydrochlorothiazide and Telmisartan in Their Combined tablet dosage form ⁵⁷ .	<p>Stationary phase: pre-coated with silica gel 60F254(10×10 cm) Mobile Phase: Chloroform: Butanol: Ammonia (6: 4: 0.1) v/v/v Flow Rate: 1 mL /min. Wavelength: AML- 237.5 nm, HCTZ - 270 nm, TLM- 297nm Retention Time: AML – 3.2 min. HCTZ – 3.1 min. TEL – 3.5 min.</p>
31. Simultaneous Estimation of Telmisartan and Atorvastatin calcium in API and tablet dosage form ⁵⁸ .	<p>Column: Boston ODS C18 (250mm x 4.6 mm, 5 µ) Mobile Phase: Methanol: Acetonitrile: buffer (35:25:40) v/v Flow rate: 1.0mL/min. Wavelength: 235nm Linearity: 60-140µg/ml Retention Time: TEL -3.5 min. ATC -2.3 min.</p>

32.	A Fast and Validated Reversed-Phase HPLC Method for Simultaneous Determination of Simvastatin, Atorvastatin, Telmisartan and Irbesartan in Bulk Drugs and Tablet Formulations ⁵⁹ .	<p>Column: C18 (75 mm × 4.6 mm ,3.5 μ)</p> <p>Mobile Phase: Ammonium acetate buffer (10 mM (pH 4.0): Acetonitrile (40:60) v/v</p> <p>Flow rate: 1mL/min</p> <p>Linearity: 1–16 μg/mL</p> <p>Wavelength: 220nm</p> <p>Retention Time: IRB – 1.20 min. ATV – 1.82 min. TLM – 2.40 min. SMV – 6.03 min.</p>
33.	Analytical Method Development and Validation of First Order Derivative Spectrophotometric Method for Simultaneous Estimation of Telmisartan and Metformin Hydrochloride in their Combined Pharmaceutical Dosage Form ⁶⁰ .	<p>Model: Shimadzu model1700</p> <p>Diluents: Methanol: Water (50: 50) v/v</p> <p>Method: First Order Derivative</p> <p>Linearity: TEL- 6-16 μg/mL MET- 6-16 μg/mL</p> <p>Wavelength: TEL- 251 nm MET- 217 nm</p>
34.	QbD-based development of HPLC method for simultaneous quantification of Telmisartan and Hydrochlorothiazide impurities in tablets dosage form ⁶¹ .	<p>Column: Kromosil C18(125mm× 4.0 mm, 5 μm), Inertsil ODSV (150 mm 4.6 mm, 3.5 μm)</p> <p>Mobile Phase:</p> <p>Solvent A: Potassium dihydrogen phosphate buffer, (pH 3.5) 1%Ortho phosphoric acid solution</p> <p>Solvent B: Purified water and acetonitrile (100:900) v/v</p> <p>Flow rate: 1.0 mL/min.</p> <p>Wavelength: 230 nm</p> <p>Linearity: TEL -1.5 μg/mL HCZ - 0.6 μg/ml</p> <p>Retention Time: 3.2 min.</p>
35.	Method Development and Validation of Simultaneous Estimation of Cilostazol and Telmisartan ⁶² .	<p>Model: Shimadzu model 1700 double beam UV-Visible spectrophotometer S</p> <p>solvent: Methanol</p> <p>Methods: 1. Simultaneous Equation method 2. Absorbance Ratio method</p> <p>Wavelength: TEL- 258 nm, 237.5 nm CLZ– 258 nm, 237.5nm</p> <p>Linearity: TEL-1 -5 μg/ml CLZ - 4-20 μg/ml</p>
36.	RP-HPLC method for estimation of Telmisartan in human plasma ⁶³ .	<p>Column: HibarC18 (250 mm x 4.6 mm ,5 μm)</p> <p>Mobile Phase: Ammonium Formate solution (pH 4.0): Methanol (70:30), v/v</p> <p>Flow Rate: 1 mL/min</p> <p>Wavelength: 275 nm</p> <p>Linearity: 0.1-1.5 (μg/ml)</p> <p>Retention Time: 3.7 min.</p>
37.	Development and Validation of RP-HPLC Method for Estimation of Telmisartan in Bulk and Tablet Dosage Form ⁶⁴ .	<p>Column: C18 sun fire column (250mmx4.6mm,5μm)</p> <p>Mobile Phase: Potassium di-hydrogen Phosphate: Acetonitrile (60:40) v/v</p> <p>Flow Rate: 1mL/min</p> <p>Wavelength:243nm</p> <p>Linearity: 50 -150 μg/ml</p> <p>Retention Time: 3.4 min.</p>
38.	Analytical Method Development and Validation for the Simultaneous Estimation of Telmisartan and Hydrochlorthiazide by RP HPLC method in Bulk and Tablet Dosage Form ⁶⁵ .	<p>Column: Agilent C18 (4.6 mm×150mm,5μ)</p> <p>Mobile Phase: Methanol: Acetonitrile (70: 30) v/v</p> <p>Flow rate: 1ml/min</p> <p>Wavelength: 240nm</p> <p>Linearity: TEL: 15- 55μg/ml HCTZ :50 -250μg/ml</p> <p>Retention Time: TEL-1.8min. HCTZ-2.4min.</p>
39.	Development and Validation of UV Visible Spectrophotometric Method for Estimation of Cilnidipine and Telmisartan in Bulk and Dosage Form ⁶⁶ .	<p>Model: Shimadzu UV/Visible double beam spectrophotometer (Model 1700)</p> <p>Solvent: Acetonitrile</p> <p>Wavelength: TEL -241nm CIL - 203nm</p> <p>Linearity: TEL -0.5-2.5 μg/ml CIL - 2-10μg/ml</p>
40.	UV Spectrophotometric method development and Validation for Telmisartan in Bulk and Tablet Dosage Form ⁶⁷ .	<p>Model: Shimadzu UV- 1700</p> <p>Solvent: 0.1 N NaOH, Distilled water</p> <p>Wavelength: 234nm</p> <p>Linearity: 2-10 μg/ml</p>

41.	Dissolution Method Development and Validation for Tablet Dosage form of Telmisartan Using UV Spectrophotometric Method ⁶⁸	Model: Double beam UV visible spectrophotometer Shimadzu UV 1800 Diluent: Methanol Wavelength: 296nm Linearity: 2-12 µg/ml
42.	UV-Spectrophotometric Determination for Simultaneous Estimation of Amlodipine Besylate and Telmisartan in Combination ⁶⁹	Model: UVA 1002 E Solvent: 0.1 N HCL Method: 1. Absorbance correction method, 2. Absorbance ratio Method Wavelength: TELM -292 nm AMLB- 326 nm Linearity: Method 1. – Absorbance correction method TEL - 3-24 µg/ml AMLB - 0.5-20 µg/ml Method 2. - Absorbance ratio Method TEL- 3-24 µg/ml AMLB- 0.5-15.5 µg/ml
43.	Development of UV spectrophotometric method for estimation and Validation of Telmisartan as a pure API ⁷⁰	Model: Shimadzu UV1800 UV-Visible double beam spectrophotometer Solvents: Ethanol (95%), 0.1 N NaHCO ₃ Wavelength: 240nm Linearity: 2-14 µg/ml
44.	Absorbance correction method for estimation of Telmisartan and Metoprolol succinate in combined tablet dosage forms ⁷¹	Model: UV-Visible double beam spectrophotometer Shimadzu UV1800 Solvent: Methanol Method: Absorbance correction method Wavelength: TEL - 296nm MET - 223nm Linearity: TELM - 2-16 µg/ml MET- 3 -24 µg/ml
45.	Development and Validation of a Solvent Extraction UV Spectrophotometric Method for the Estimation of Rosuvastatin Calcium and Telmisartan in Combined Dosage Form ⁷²	Model: UV-Visible double beam spectrophotometer Shimadzu 1800 Solvents: Telmisartan- methanol and Rosuvastatin Calcium-phosphate buffer pH 5.5 Wavelength: Rosuvastatin Calcium-242.8nm and Telmisartan- 295.2 nm
46.	Analytical Method Development and Validation for Telmisartan, Chlorthalidone and Amlodipine by UV- Spectroscopic Method ⁷³	Model: JASCO-V-530. UV-Visible Spectrophotometer Solvents: Methanol Wavelength: 311nm- Telmisartan, 228nm-Chlorthalidone and 253nm- Amlodipine)

TABLE 5: REPORTED METHODS FOR ASSESSMENT OF AZELNIDIPINE AND TELMISARTAN

Sr. no.	Title/Method	Description
1.	Development of HPLC stability demonstrating methodology for quantifying Azelnidipine and Telmisartan in tablets and bulk ⁷⁴	Column: 250 mm length C18 column (Supelco, 4.6 mm inner diameter, 5.0 µm particle size) Mobile phase: 0.1M Na ₂ SO ₄ (pH 3.6) and acetonitrile (55: 45% v/v) Flow rate: 1.0 mL/min Wavelength: 258nm Detector: photodiode array
2.	Analytical Method Development and Validation of Azelnidipine and Telmisartan by RP HPLC Method ⁷⁵	Column: C18 (4.6 × 150 mm, 5 mm) Mobile phase: Buffer 0.01 N KH ₂ PO ₄ : Acetonitrile (45:55 % v/v) Flow rate: 1.0 mL/min Wavelength: 290nm
3.	Stability Indicating RP-HPLC Method Development and Validation for the Simultaneous Estimation of Telmisartan and Azelnidipine in Tablet Dosage Form ⁷⁶	Retention time: Azelnidipine- 2.131 min Telmisartan- 2.593 min Column: Hyperchrom ODS C18 Column (250*4.6mm) Mobile phase: Buffer 0.05M Potassium dihydrogen ortho phosphate Buffer (pH-4.0): Methanol (60:40) Flow rate: 1.0 mL/min Wavelength: 215nm
4.	Telmisartan and Azelnidipine quantification employing HPLC chromatogram; Stability	Retention time: Telmisartan- 3.440min Azelnidipine- 5.693min. Column: C18 Kromasil stationary column (5 µm, 250 mm × 4.6 mm)

	investigation on Telmisartan and Azelnidipine ⁷⁷	Mobile phase: 0.1M NaH ₂ PO ₄ solution (pH 3.5) and methanol at a comparative volume ratio of 50% each. Flow rate: 1.0 mL/min Wavelength: 256nm
5.	A stability indicating RP-HPLC method validation for simultaneous estimation of Azelnidipine and Telmisartan in a fixed-dose combination ⁷⁸	Column: Inertsil C-18 Column with 150×4.6 mm× 5 μm Mobile phase: Acetonitrile and buffer Flow rate: 1.5 mL/min Wavelength: 254nm
6.	Development and Validation of UV Spectrophotometric method for the simultaneous estimation of Azelnidipine and Telmisartan in combined dosage form ⁷⁹	Model: JASCO double beam UV-vis spectrophotometers Wavelength: 200-400 nm Solvent: Methanol
7	RP-HPLC Method for Determination of Azelnidipine and Telmisartan in Pharmaceutical Dosage Form ⁸⁰	Column: Intersil C18 column (250 × 4.6mm × 5μm) Mobile phase: Acetonitrile: 5 millimolar phosphate buffer pH 4.6 (70:30 v/v) Flow rate: 1mL/min Wavelength: 255nm
8	Method development and Validation for Simultaneous Quantification of Azelnidipine and Telmisartan in Pharmaceutical dosage form by UV ⁸¹ .	Model: JASCO double beam UV-vis spectrophotometers Wavelength: 200-400 nm Solvent: Methanol
9	Analytical method development and validations for simultaneous estimation of antihypertensive drugs ⁸²	Column: C 18 column (250mm x 4.6mm, 5μm) Mobile phase: A- (0.1% formic acid in water as an aqueous phase) B- (acetonitrile as an organic modifier) Flow rate: 0.8 ml/min Wavelength: 260nm Retention time: Telmisartan- 5.950 min Azelnidipine: 7.293min

CONCLUSION: This review article presents the Physicochemical properties and Pharmacological actions of Azelnidipine and Telmisartan. The presented review gives information about the various methods reported in the literature for determining Azelnidipine and Telmisartan, including official pharmacopeial assay methods.

This review concluded that different analytical methods are reported for the estimation of Azelnidipine and Telmisartan individually and other combinations like UV Spectroscopy, HPLC, HPTLC, and LC-MS. Hence, all methods were simple, accurate, precise, and reproducible. The Literature review focuses on various UV and HPLC methods reported for Azelnidipine and Telmisartan in fixed-dose combinations. This review will help develop the analytical methods for this new combination and give knowledge about both hypertensive drugs' characteristics.

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