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An Updated Review on Analytical Methods for Estimation of Benidipine Hydrochloride and Telmisartan

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ABSTRACT

Hypertension (HT) is a very common disorder, particularly for past middle age. It is not a disease in itself, but is an important risk factor for cardiovascular mortality and morbidity. For improved treatment of hypertension, Telmisartan and Benidipine HCl is the newer combination in market, this combination was developed to improve medication for Stage II hypertension. The aim of this review is to focus on comprehensive update of different analytical methods used for estimation of anti-hypertensive drugs like Telmisartan and Benidipine HCl for the treatment of hypertension. This review delivers a detail description on different analytical methods like UV and RP-HPLC for Telmisartan and Benidipine HCl individually and combination with other drugs. For this review, data searches were conducted by scientific papers in the literature as well as in official compendium. All reported methods are found to be simple, accurate, economic, precise and reproducible in nature.

Keywords: Hypertension, Benidipine HCl, Telmisartan, Analytical Methods, UV-Spectrophotometry, RP-HPLC.

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INTRODUCTION

Blood pressure is the force exerted by circulating blood against the walls of the arteries, the major blood vessels in the body. Blood pressure is written as two numbers. The first (systolic) number represents the pressure in blood vessels when the heart contracts or beats. The second (diastolic) number represents the pressure in the vessels when the heart rests between beats. Hypertension is diagnosed if, when it is measured on two different days, the systolic blood pressure readings on both days is ≥140 mmHg and/or the diastolic blood pressure readings on both days is ≥90 mm Hg. Medications for hypertension include Diuretics: thiazides, chlorthalidone, and indapamide, Beta-blockers and alpha-blockers, Calcium channel blocker, Central alphaa$_1$ agonists, Peripheral adrenergic inhibitor, Vasodilators, Angiotensin-converting enzyme (ACE) inhibitors, Angiotensin receptor blockers [1].

Benidipine Hydrochloride is a dihydropyridine type of Calcium channel blockers used for the treatment of hypertension and angina pectoris. Chemically it is 5-*O*-[(3*R*)-1-benzylpiperidin-3-yl]3-*O*-methyl(4*R*)-2,6-dimethyl-4-(3-nitrophenyl)-1,4 dihydropyridine-3,5-dicarboxylate; It is very soluble in formic acid, soluble in methanol, slightly soluble in ethanol and practically insoluble in water. It acts by inhibiting trans membrane Ca^{2+} influx through the voltage dependent channels of smooth muscles in vascular walls [1]. List of some available trade names of Benidipine Hydrochloride are listed in Table 1.

Telmisartan belongs to Angiotensin receptor blockers with chemical name 2-[4-[[4-methyl-6-(1-methylbenzimidazol-2-yl)-2-propylbenzimidazol-1yl] methyl] phenyl] benzoic acid. It is soluble in strong base & methanol, and sparingly soluble in strong acid (except HCL). It interferes with the binding of angiotensin II to the angiotensin II AT_1-receptor by binding reversibly and selectively to the receptors in vascular smooth muscle and the adrenal gland. Angiotension II is a vasoconstrictor, which also stimulates the synthesis and release of an aldosterone blockage of its effects results in decrease in systemic vascular resistance [2-3]. List of some available trade names of Telmisartan are listed in Table 2.

Both combination of Telmisartan and Benidipine drugs are used for the treatment of hypertension effectively. They work by relaxing the blood vessels and making the heart more efficient at pumping blood throughout the body. Literature survey revealed that the reported methods like UV and stability indicating RP-HPLC methods development and validation for estimation of Telmisartan and Benidipine HCl in bulk and pharmaceutical dosage form individually and in fixed dose combination. The aim of the present review depicts the information about the various methods reported for the determination of Telmisartan and Benidipine including official

pharmacopoeial methods [4-6]. List of fixed dose Combination of Benidipine Hydrochloride and Telmisartan are shown in Table 3. Chemical structure of Benidipine Hydrochloride and Telmisartan are shown in figure 1.

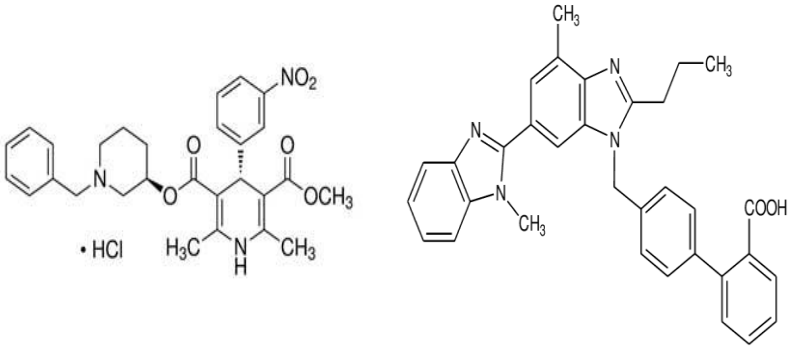

Figure 1: Chemical structure of (a) Benidipine Hydrochloride (b) Telmisartan

Table 1: List of available trade names of Benidipine Hydrochloride [4]

S. No.	Brand Name	Name of the drug and Strength	Manufactured Company
1	Benitowa-8	Benidipine Hydrochloride-8mg	Akums Drugs and Pharmaceuticals Ltd-India
2	Bengreat-4	Benidipine Hydrochloride-4mg	Synokem Pharmaceuticals Ltd-India
3	Beniduce-8	Benidipine Hydrochloride-8mg	Synokem Pharmaceuticals Ltd-India
4	Beniflo-8	Benidipine Hydrochloride-8mg	Ajanta Pharma Ltd-India
5	Benistar-8 Benistar-4	Benidipine Hydrochloride-8 mg and 4mg	Elbrit Life Sciences Pvt Ltd-India
6	Benlong-8	Benidipine Hydrochloride-8mg	Micro Labs Ltd-India

Table 2: List of available trade names of Telmisartan [5]

S.No.	Brand Name	Name of the Drug and Strength	Manufactured Company
1	Tesian -80	Telmisartan -80 mg	Next well Pharmaceuticals Pvt Ltd -India
2	Uzitel-40	Telmisartan -40 mg	Dr. Kumar's Pharmaceuticals -India
3	Telin-40	Telmisartan -40 mg	Pharma Drugs and Chemicals -India
4	Telista-20 Telista-40	Telmisartan -20 mg Telmisartan -40 mg	Lupin Ltd- India
5	Telsartan™- 40	Telmisartan -40 mg	Dr. Reddy's Laboratories Ltd-India
6	Venpres-40	Telmisartan -40 mg	Lee ford Healthcare Ltd (Generics)-India
7	Watson-40	Telmisartan -80 mg	Californa pet Pharmacy.Com -USA

Table 3: List of fixed dose Combination of Benidipine Hydrochloride and Telmisartan [6]

S. No.	Brand Name	Name of the Drug and Strength	Manufactured Company
1	Benidin^{TM} -T	Benidipine Hydrochloride and Telmisartan- 4 mg & 40 mg	Lloyd Healthcare Pvt Ltd- India
2	Benitowa-TM	Benidipine Hydrochloride and Telmisartan- 4 mg & 40 mg	Salutem Pharmaceuticals Pvt Ltd-India
3	Inzit-TL40	Benidipine Hydrochloride and Telmisartan- 4 mg & 40 mg	Eris Life Sciences Pvt Ltd-India
4	Benkair-T	Benidipine Hydrochloride and Telmisartan- 4 mg &40 mg	Sag Health Science Pvt Ltd-India
5	Benizex-T	Benidipine Hydrochloride and Telmisartan- 4 mg &40 mg	Zenacts Pharma Pvt Ltd-India
6	Binastar^{TM}-TL	Benidipine Hydrochloride and Telmisartan- 4mg & 40 mg	Jabs Biotech Pvt Ltd-India

Table 4: Official Methods for Benidipine HCl and Telmisartan

S. No.	Drug and Official in	Method	Description	Ref.
1	Benidipine Hydrochloride Japanese Pharmacopoeia (2017)	Liquid Chromatography	**Column:** A stainless steel column 4.6 mm in inside diameter and 10 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (3 mm in particle diameter) **Column temperature:** A constant temperature of about 25ºC. **Mobile phase:** A mixture of 0.05 mol/L potassium dihydrogen phosphate TS (pH 3.0), methanol and tetrahydrofuran (65:27:8) **Detector:** An ultraviolet absorption photometer (wavelength: 237 nm) **Flow rate:** Adjust so that the retention time of Benidipine is about 20 minutes **Time span of measurement:** About 2 times as long as the retention time of Benidipine, beginning after the solvent peak	1
2	Telmisartan Indian Pharmacopoeia (2018)	Liquid Chromatography	**Stationary Phase (Column):** A Stainless-steel Column 12.5cm ×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 1000 ml with water. B) A Mixture of 20 Volume of Methanol and 80 Volume of Acetonitrile (20:80 v/v) **Flow Rate:** 1ml/min. **Wavelength:** 230 nm; **Injection Volume:** 10 ml	2
3	Telmisartan Japanese Pharmacopoeia	Liquid Chromatography	**Stationary Phase (Column):** A Stainless-Steel Column (12.5 cm× 4 mm × 5 µm) **Mobile phase:**	3

(2018)	A) Dissolve 2 g of potassium dihydrogen phosphate and 3.4 g of sodium1-pentanesulphonate in 1000mL of water, adjusted to pH 3 with dilute orthophosphoric acid. B) A Mixture of Acetonitrile and Methanol (4:1 v/v) **Flow Rate:** 1.0 ml/min **Wavelength:** 230 nm

Table 5: **Reported methods on Telmisartan**

S.No.	Method	Description	Ref.No.
1	UV	**Solvent:** Methanol: Water (90:10) **Wavelength:** 298 nm **Linearity Range:** 5-45 mg/mL **LOD:** 0.165 µg/ml; **LOQ:** 0.503 µg/ml	8
2	UV	**Solvent:** 95% ethanol: 40% 0.1N $NaHCO_3$(60:40) **Wavelength:** 240 nm **Linearity Range:** 2-14 µg/ml **LOD:**0.063 µg/ml; **LOQ:** 0.1912 µg/ml	8
3	UV	**Solvent:** Methanol **Wavelength:** 296 nm **Linearity Range:** 2-12 µg/ml	10
4	UV	**Solvent:** Methanol **Wavelength:** 296 nm **Linearity Range:** 4-16 µg/ml	11
5	UV	**Solvent:** Water&0.1N NaOH **Wavelength**: 234 nm **Linearity Range:** 4-24 µg/ml	12
6	HPLC	**Stationary Phase:** Chromosil C18 (250mm×4.6mm,5µm) **Mobile Phase:** Methanol: 0.1% orthophosphoric acid: Acetonitrile (80:5:15 v/v/v) **Flow Rate:** 1.5 ml/min **Wavelength:** 256 nm **Retention time:** 2.7 min **Linearity Range:** 12 ppm **Injection volume:** 20 µL	13
7	HPLC	**Stationary Phase:** C8 (150mm×4.6mm, 3.5µm) **Mobile Phase:** Methanol: Phosphate buffer (60:40) **Wavelength:** 230 nm **Flow Rate:** 0.5 ml/min **Retention time:** 2.6 min **Linearity Range:** 20-100 µg/ml	14
8	HPLC	**Stationary Phase:** C18(250mm×4.6mm, 5µm) **Mobile Phase:** Sodium dihydrogen phosphate buffer(pH3): Acetonitrile (42:58v/v) **Flow Rate:** 1.2 ml/min **Run time:** 4.2 min **Linearity Range:** 40-1600 ng/min **LOD:** 40 ng/min; **LOQ:** 2.8 ng/min	15
9	HPLC	**Stationary Phase:** Hypersil C18 BDS (250mm×4.6mm, 5µm) **Mobile Phase:** Acetonitrile: Methanol (60:40) **Flow Rate:** 1.2 ml/min **Wavelength:** 245 nm	16
10	HPLC	**Stationary Phase:** C18 Phenyl column (250mm×4.6mm,5µm) **Mobile Phase:** Acetonitrile: Phosphate buffer (90:10) **Flow Rate:** 0.8 ml/min **Run time:** 10 min **Retention time:** 7min	17

		Linearity Range: 2-14 µg/min **Injection Volume:** 10 µL **Theoretical Plates:** 3345 **LOD:** 0.72 ng/ml; **LOQ:** 2.02 ng/ml	
11	HPLC	**Stationary Phase:** X-bridge C18(150mm×4.6mm,3.5µm) **Mobile Phase:** Water: Acetonitrile (10:90) **Flow Rate:** 1 ml/min **Wavelength:** 290 nm **Run Time:** 45min **Linearity Range:** 0.08-500 µg/ml **LOD:** 0.023 µg/ml; **LOQ:** 0.190 µg/ml	18
12	HPLC	**Stationary Phase:** Prontosil ODS AnalyticalC18(250mm×4.6mm,5µm) **Mobile Phase:** Acetonitrile: Buffer (90:10%v/v) **Flow Rate:** 1 ml/min **Wavelength:** 259 nm (Excitation), 399 nm (Emission) **Run Time:** 45 min **Linearity Range:** 10-90 ng/ml **LOD:** 3.36 ng/ml; **LOQ:** 9.16 ng/ml **Theoretical Plates:** 2045.6	19
13	HPLC	**StationaryPhase:**RP18column (250mm × 4.6 mm, 5 µm) **Mobile Phase:** 0.025M KH_2PO_4: Acetonitrile: Methanol (45:50:5) **Flow Rate:** 1ml/min **Wavelength:** 216 nm **Injection Volume:** 20 µL **Linearity Range:** 100-500 ng/ml **LOD:** 27 ng/ml; **LOQ:** 83 ng/ml	20

Table 6: Reported methods on Benidipine Hydrochloride

S. No.	Method	Description	Ref. No.
1	UV	**Wavelength:** 355 nm **Linearity range:**1–3.5 µg/ml **Solvent:** Methanol **LOD:** 0.0454 µg/ml **LOQ:** 0.1375 µg/ml	21
2	UV	**Wavelength:** 236 nm **Linearity range:** 3-18 µg/ml **Solvent:** Methanol **LOD:** 0.20 µg/ml **LOQ:** 0.60 µg/ml	22
3	UV	**Wavelength:** 230.2-241.5 nm **Linearity range:** 0.2-2 µg/ml **Solvent:** Methanol **LOD:** 0.58 µg/ml **LOQ:** 1.73 µg/ml	23
4	UV	**Wavelength:** 357 nm **Linearity range:**10-35 µg/ml	24

		Solvent: methanol **LOD:** 1.56 µg/ml **LOQ:** 4.69 µg/ml	
5	UV	**Solvent:** Chloroform **Wavelengths:** Bcg-408.5 nm BPB-404 nm TB-570 nm **Linearity ranges:** BCG- 0-60 µg/ml BPB-0-40 µg/ml TB-0-30 µg/ml	25
6	HPLC	**Stationary phase:** C_{18}(100:4.6:3) **Column:** (Hypersil BDS) **Mobile phase:** Phosphate buffer: methanol: THF (65:27:8) **Injection volume:** 20 µL **Flow rate:** 0.75 ml/min **Retention time:** 20 min **LOD:** 0.03 µg/ml **LOQ:** 0.09 µg/ml	26
7	HPLC	**Stationary phase:** Xterra RP_{18} column **Mobile phase:** Acetonitrile: water(55:45) **Injection volume:** 20µL **Flow rate:** 1 ml/min **Retention time:** 5 min **Linearity range:** 0.25-15 µg/ml	27

Table 7: Reported methods for Benidipine Hydrochloride and Telmisartan in combination

S.No.	Method	Description	Ref. No.
1	UV	**Solvent:** Methanol **Wavelength:** 228.35to245.3nm BEN**,** 280.21to315.39nm TEL **Linearity Range:**1-5 µg/ml BEN; 10-50 µg/ml TEL **LOD:**0.184 µg/ml BEN; 0.559µg/ml TEL **LOQ:**1.09 µg/ml BEN;3.33 µg/ml TEL	28
2	HPLC	**Stationary Phase:** LC-20ATC18(250 ×4.6 mm,2.6 µm) **Mobile Phase:**0.05MKH_2PO_4: Methanol (50:50) **Flow Rate:** 1ml/min **Wavelength:** 220nm **Injection Volume:**20µL **Run Time:** 8min **Linearity Range:**20-60 µg/ml TEL; 2-6 µg/ml BEN **LOD:**0.855 µg/ml TEL; 0.133 µg/ml BEN **LOQ:** 2.589 µg/ml TEL; 0.402 µg/ml BEN **Theoretical Plates:**4361TEL;7978BEN **Retention time:** 3.273min TEL;4.807min BEN	29
3	HPLC	**Stationary Phase:** (250mm×4.6mm,5µm) **Mobile Phase:** Phosphate buffer(pH4): Methanol (50:50) **Flow Rate:** 1ml/min **Wavelength:** 210nm **Injection Volume:** 20µL	30

		Run Time: 8min **Linearity Range:** 20-60 µg/ml TEL**,** 2-6 µg/ml BEN **LOD:**0.855µg/ml TEL; 0.133 µg/ml BEN **LOQ:** 2.589 µg/ml TEL; 0.402 µg/ml BEN **Theoretical Plates:**4361TEL; 7978BEN **Retention time:**3.273min TEL; 4.807min BEN	
4	HPLC	**Stationary Phase:** Phenomenax C-18 column (250mm×4.6mm,5µm) **Mobile Phase:** Methanol: Acetonitrile: water (70:20:10) **Flow Rate:**0.8 ml/min **Wavelength:**237 nm **Injection Volume:** 20µL **Run Time:** 8 min **Linearity:**2-10 µg/ml TEL; 5-25 µg/ml BEN **LOD:**0.19 µg/ml TEL; 2.94 µg/ml BEN **LOQ:**2.57 µg/ml TEL; 1.19 µg/ml BEN **Retention time:**5.021 min TEL; 2.412 min BEN	31

CONCLUSION:

This review article presents with Physico-chemical properties, Pharmacological actions, and some trade names of marketed formulations of Benidipine HCl and Telmisartan. The presented review depicts the information about the various methods available in the literature for the determination of Benidipine and Telmisartan including official pharmacopoeial assay methods. According to this review it was concluded that the different analytical methods are reported for estimation Benidipine and Telmisartan individual and other combination like UV Spectroscopy, HPLC. Hence all methods found to be simple, accurate, economic, precise and reproducible in nature. For Telmisartan, Five UV Papers and eight HPLC Papers and Benidipine Hydrochloride, Five UV Papers and Two HPLC Papers are reported. Combination of Benidipine Hydrochloride and Telmisartan, one UV and three RP-HPLC papers are reported for estimation of two drugs. This review helps in future for new analytical method development and also gives knowledge about characteristics of both drugs.

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CONFLICTS OF INTEREST STATEMENT:

All the authors declare that they do not have any conflicts of interest

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