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Review Article

CHROMATOGRAPHIC METHOD FOR IRBESARTAN AND ITS COMBINATION WITH OTHER DRUG

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ABSTRACT

Chromatographic method is most useful analytical method that gives estimation, impurity profiling, assay and compedial method for single and combination of drug. Irbesartan is classified as an angiotensin II receptor type 1 antagonist. Angiotensin II receptor type 1 antagonists are widely used in treatment of diseases like hypertension, heart failure, myocardial infarction and diabetic nephropathy. The clinical and pharmaceutical analysis of this drug requires effective analytical procedures for quality control and pharmacodynamics and pharmacokinetic studies as well as stability study. An extensive survey of the literature published in various analytical and pharmaceutical chemistry related journals has been conducted and the instrumental analytical methods which were developed and used for determination as single or combination with other drugs in bulk drugs, formulations and biological fluids have been reviewed. This review covers the most recent many chromatographic methods including Residue by HPLC, HPTLC, RP HPLC and liquid chromatography tendam mass spectroscopy were reported.

Keyword: Irbesartan, Analytical Method, HPLC, Anti hypertensive drug, Angiotensin II receptor antagonist.

INTRODUCTION

Irbesartan, an angiotensin II receptor antagonist, is used mainly for the treatment of hypertension [1]. It is an orally active nonpeptide tetrazole derivative. IUPAN name of irbesartan is 2-butyl-3-({4- [2-(2H-1, 2, 3, 4-tetrazol-5-yl) phenyl] phenyl} methyl)-1, 3-diazaspiro [4.4] non-1-en-4-one [2]. These are organic compounds containing a biphenyl attached to a tetrazole (table 1). A carbon atom of the biphenyl moiety is boned to a carbon or the nitrogen atom of the tetrazole moiety so it's highly selective for angiotensin II receptor.

Table 1: Structural identification of Irbesartan [3]

S. No.	Class	Identification
1	Primary class	Organic compound
2	Super class	Heterocyclic Compound
3	Class	Azoles
4	Subclass	Tetrazole derivative
5	Direct parent	Biphenyltetrazoles and Derivatives
6	Alternative parent	Biphenyls and Derivatives; Imidazolinones; Tertiary Carboxylic Acid Amides

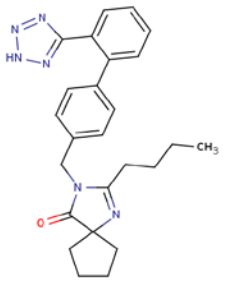

Fig. 1: Structure of Irbesartan [4]

Appearance is white or almost white, crystalline powder. Solubility is given in practically insoluble in water, sparingly soluble in methanol, slightly soluble in methylene chloride. It shows polymorphism.

Mechanism of action

Irbesartan is a nonpeptide tetrazole derivative and an angiotensin II antagonist that selectively blocks the binding of angiotensin II to the AT1 receptor [1.] In the renin-angiotensin system, angiotensin I is converted by angiotensin-converting enzyme (ACE) to form angiotensin II. Angiotensin II stimulates the adrenal cortex to synthesize and secrete aldosterone, which decreases the excretion of sodium and increases the excretion of potassium. Angiotensin II also acts as a vasoconstrictor in vascular smooth muscle. Irbesartan, by blocking the binding of angiotensin II to the AT1 receptor, promotes vasodilation and decreases the effects of aldosterone. The negative feedback regulation of angiotensin II on renin secretion is also inhibited, but the resulting rise in plasma renin concentrations and consequent rise in angiotensin II plasma concentrations do not counteract the blood pressure–lowering effect that occurs. Irbesartan is a specific competitive antagonist of AT1 receptors with a much greater affinity (more than 8500-fold) for the AT1 receptor than for the AT2 receptor and no agonist activity.

Rapid and complete with an average absolute bioavailability of 60-80 %. Food has no effect on bioavailability. it is also used in diabetic nephropathy with an elevated serum creatinine and protein uria (>300 mg/day) in patients with type 2 diabetes and hypertension. Irbesartan is also used as a second line agent in the treatment of congestive heart failure [6].

Combination of Irbesartan

1. Irbesartan+hydrochlorthaizide
2. Irbesartan+losartan
3. Irbesartan+valsartan
4. Irbesartan+amlodipine
5. Irbesartan+Celiprolol, Bisoprolol
6. Irbesartan+other angiotensin receptor II blocker

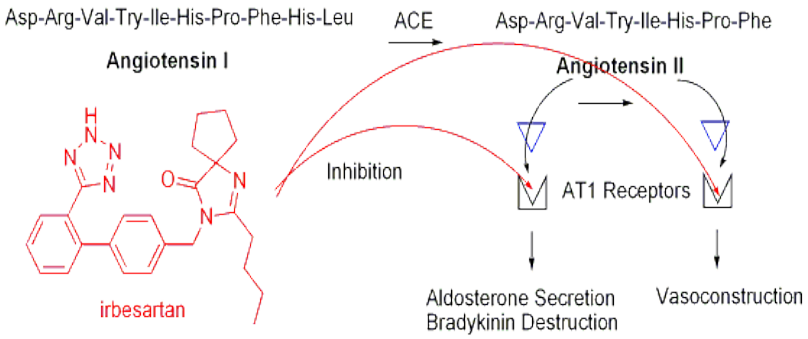

Fig. 2: Mechanism of Irbesartan [5]

Marketed formulation of Irbesartan [3, 6]

Irbesartan formulation:

- Avapro, Avalide,
- Xarg, Irovel, Irbestin

Irbesartan combination formulation

- Irovel –H, Irbestin –H,
- Xarg-H, vapro –H

Analytical method

Compendial method

Irbesartan is official in European Pharmacopoeia and United State Pharmacopoeia.

Reported method

Chromatographic methods

The high-pressure liquid chromatography (HPLC)for residue determination and simultaneous estimation of single and combination drug and also used in impurity profiling. HPTLC method is widely used chromatographic methods in the analysis of irbesartan in plasma and pharmaceutical dosage form. RP HPLC method also developed for determination of concentration of irbesartan in human serum and also for simultaneous determination in synthetic mixture, combination dosage form like hydrochlorthaizide, losartan, valsartan. UP-HPLC is used for determination of combination of hydrochlorthiazide and irbesartan.

Stability indicating method

Stability indicating method is used to check out the stability of drug in various conditions. Here irbesartan is studied by RP-HPLC, HPTLC, and also LC/MS/MS for stability study.

DISCUSSION

Presented systematic review covers the current analytical methods for the determination of Irbesartan and its combination in pharmaceutical and biological samples like serum and plasma. HPLC method was found to be most widely used for Irbesartan. Various chromatographic conditions are presented in table. The sensitivity, specificity, and better separation efficiency enable HPLC to be used frequently for simultaneous qualitative and quantitative determination of Irbesartan.

Table 2: Summary of compendial method of irbesartan [7, 8]

Title	Pharmacopoeia	Method	Detail	Reference
Identification	European Pharmacopoeia	Infrared absorption spectrophotometry	I. R spectroscopy is perform with irbesartan CTR and method is solid state analysis	7
Assay	European Pharmacopoeia	Potentiometric titration method	Solvent is used 0.1 M perchloric acid, determining the end-point potentiometric ally	7
Identification	United State Pharmacopoeia	Infrared absorption spectrophotometry	I. R spectroscopy is perform with mixture of potassium bromide in solid state analysis	8
Assay	United State Pharmacopoeia	High performance liquid chromatography	Phosphate buffer(pH 3.2):acetonitrile (63:37 v/v) as mobile phase and column is (25 mm x 4 mm, 2.5micron)	8

Table 3: Summary of Chromatographic method of Irbesartan [9–35]

Title	Method	Mobile phase	Stationary phase	Wave length	Reference
Development and validation of HPLC assay for estimation of Irbesartan in Human Plasma	RP-HPLC	acetonitrile-ammonium acetate buffer (pH 4.0, 20 mm) (40:60 v/v),	Agilent Eclipse C18 column (5µ, 4.6 mm x 150 mm)	245 nm	9
RP-HPLC-DAD method for determination of irbesartan in bulk and tablet dosage form	RP-HPLC-DAD	Methanol-phosphate buffer(pH 3.0)(50:50v/v)	Xterra C18 column (5µ, 4.6 mm x 150 mm)	209 nm	10
Content Determination of Irbesartan in Serum by HPLC	HPLC	Water-methanol-phosphoric acids (gradient dilution)	µBond park C 18 (5µ, 7.8 mm×300 mm)	245 nm	11
Development and validation of a sensitive RP-HPLC-PDA method For assay of irbesartan in pure and pharmaceutical dosage Forms	RP-HPLC-PDA	Methanol-formic acid (0.02% v/v in water (70:30)	Phenomenex C18 column (250 x 4.6 mm, 5 µ)	234 nm	12
Development and validation of HPLC method for the estimation of irbesartan in pharmaceutical dosage form	HPLC	methanol, acetonitrile and 2% OPA (40:40:20, v/v/v)	Inertsil ODS C-18, 5µm column having 250 x 4.6 mm	260 nm	13

Hplc determination of irbesartan in human plasma: its application to pharmacokinetic studies	HPLC	acetonitrile: 0.1% formic acid (37:63, v/v)	Zorbax Xclipse XDB C18 column (150 × 4.6 mm, i.d., 5 µm)	250 nm 370 nm	14
Simultaneous hplc determination of irbesartan and hydrochlorthaizide in pharmaceutical dosage form	HPLC	Buffer(pH 5.5)-acetonitrile (65:35 v/v)	Ace 5-C18 column (250 x 4.6 mm, 5 µ)	260 nm	15
HPLC method with monolithic column for simultaneous Determination of irbesartan and hydrochlorothiazide in tablets	HPLC	phosphate buffer (pH 4)/acetonitrile (50:50, V/V)	Chromolith® Performance RP-18e column (250 x 4.6 mm, 5 µ)	270 nm	16
Simultaneous determination of irbesartan and Hydrochlorothiazide in human plasma using HPLC Coupled with tandem mass spectrometry: Application To bioequivalence studies	HPLC	2.5% formic acid, methanol and acetonitrile (40:45:15, v/v/v (%))	Ace 5-C18 column (50 mm × 4 mm, 3 µm)	260 nm	17
Simultaneous Analysis of Irbesartan and Hydrochlorothiazide: An Improved HPLC Method	HPLC	methanol-tetrahydrofuranacetate buffer 47:10:43 v/v/v,	Supelcosil C18 (150 mm × 4.6 mm, 5 micron particle size)	271 nm	18
Development and validation of rp-hplc method for simultaneous estimation of irbesartan and hydrochlorothiazide in bulk and pharmaceutical dosage forms	RP-HPLC	Methanol: Acetonitrile: Buffer (10 mm potassium dihydrogen phosphate pH6.8)(40:30:30%v/v/v)	Agilent ODS UG 5 Column 250 mmX 4.5 mm Dimension	264 nm	19
RP-HPLC Method for the Simultaneous Estimation of Irbesartan and Hydrochlorthiazide in Pharmaceutical Dosage Form	RP-HPLC	sodium acetate buffer: acetonitrile (45:55).	Hypesil BDS RP-18, 150 x 4.6 mm, 5	260 nm	20
Development and validation of a RP-HPLC-PDA method for Simultaneous estimation of Hydrochlorothiazide and Irbesartan	RP-HPLC-PDA	methanol: THF: acetate buffer (60:10:30v/v)	symmetry C18 column (250 mm x 4.6 mm, 5.0 µ particle size)	271 nm	21
HPLC–DAD Analysis of Hydrochlorothiazide and Irbesartan in Hypertensive Patients	HPLC–DAD	acetonitrile–phosphate buffer (pH 3.6)(gradiant mixture)	C4 column symmetry (250 mm x 4.6 mm, 5.0 µ)	242 nm	22
Development & Validation of a High Performance Liquid Chromatography Method for Simultaneous Determination of Irbesartan	HPLC	methanol: acetonitrile: 0.005 M KH2PO4 (pH 4.7)(40: 30: 30)	PhenomenEX Luna (250 mm x 4.6 mm, 5.0 µ particle size)	260 nm	23
Development and validation of reverse phase high Performance liquid chromatography method for Simultanious estimation of amlodipine besylate and Irbesartan in synthetic mixture.	RP-HPLC	acetonitrile: methanol: water, pH 3.0 (25: 20: 55, v/v/v)	Phenomenex C18, 250 mm × 4.6 mm, 5µ	238 nm	24
Quantitative Determination of three Angiotensin-II-receptor Antagonists in Presence of Hydrochlorothiazide by RP-HPLC in their Tablet Preparations	RP-HPLC	0.025M potassium dihydrogen phosphate: acetonitrile (65:35 v/v)	Ace 5-C18 column (250 mm × 4.6 mm, 5 µm)	220 nm	25
Novel Validated Chromatographic Method for Determination of Some Anti-hypertensive Drugs	RP HPLC	phosphate buffer pH = 3.2:acetonitrile (60:40, v/v)	Atlantis C18 column (250 mm × 4.6 mm, 5 µm)	260 nm	26
Fast screening method for the determination of angiotensin II receptor antagonists in human plasma by high-performance liquid chromatography with fluorimetric detection	HPLC	acetonitrile–5 mM acetate buffer, pH 4(gradiant mixture)	µBondapak C18, (250 mm × 4.6 mm, 5 µm)	250 nm	27
Development and Validation of RP-HPLC Method for the Estimation of Valsartan, Losartan and Irbesartan in Bulk and Pharmaceutical Formulation	RP-HPLC	acetonitrile: phosphate potassium buffer (pH= 3) (gradiant mixture)	Phenomenex C18, 250 mm × 4.6 mm, 5µ	254 nm	28
Identification and determination of selected angiotensin ii Receptor antagonist group drugs by HPLC method	HPLC	0.1 mol/l sodium acetate (pH = 5.5) ñ acetonitrile ñ methanol in 35:9:6 v/v/v	Zorbax SB-C18, 250 mm × 4.6 mm, 5µ	230 nm	29
Simultaneous determination of olmesartan medoxomil and irbesartan and hydrochlorothiazide in pharmaceutical formulations and human serum using high performance liquid chromatography.	HPLC	acetonitrile-0.2% acetic acid aqueous solution (50:50, v/v)	micro-Bondapak, C18 column (15 cm x 4.6 mm, 5 microm),	220NM	30
Simultaneous determination of the acid/base antihypertensive drugs Celiprolol, bisoprolol and irbesartan in human plasma by liquid Chromatography	HPLC	Acetonitril-Methenol (60:40)	Kromosil C18, 250 mm × 4.6 mm, 5µ	260NM	31
RP-HPLC method for simultataneous	RP-HPLC	0.05 M sodium dihydrogen	Hypersil BDS (Length 250	220NM	32

determination of irbesartan, losartan, hydro-chlorothiazide and chlorthalidone		phosphate buffer and acetonitrile (Gradient ratio)	mm × Diameter 4.6 mm Particle size 5 µm)		
Validated HPTLC method for simultaneous estimation of Irbesartan and Hydrochlorthiazide in a tablet dosage form	HPTLC	acetonitrile: ethyl acetate (8:2 v/v).	silica gel 60F [254].	260NM	33
Development and validation of a HPTLC method for The simultaneous estimation of irbesartan and Hydrochlorothiazide in tablet dosage form.	HPTLC	acetonitrile: chloroform: glacial acetic acid (7:3:0.1 v/v/v).	precoated silica gel 60F [254].	260 nm	34
Simultaneous determination of irbesartan and hydrochlorothiazide inhuman plasma by ultra-high performance liquid chromatography tandem mass spectrometry	UP-HPLC	0.1% formic acid in water-acetonitrile (6.5:3.5)	Acquity BEH C18 column (2.1 mm × 50 mm, 1.7 m particle size)	254 nm	35

Table 4: Stability indicating method for Irbesartan [36–39]

Title	Method	Mobile phase	Stationary phase	Wave length	Ref.
A validated stability indicating liquid chromatographic method for determination of process related impurities and degradation behaviour of Irbesartan in solid oral dosage	Stability indicating RP HPLC	Acetonitrile-0.55% v/v ortho phosphoric acid, pH adjusted to 3.2 with triethyl amine (95:5 v/v)	Hypersil Octadecylsilyl(4.6 mm× [15]0 mm, 3µm)	220 nm	36
Development and validation of stability indicating RP-HPLC method for irbesartan and hydrochlorothiazide in bulk drug. and **Table**t dosage form	Stability indicating HPLC	50 mm Ammonium acetate: Acetonitrile (pH 5.5) (70:30v/v)	EnableC [18]G([25]0 mmx4.6 mm, 5µm)	235 nm	37
A validated stability indicating HPTLC method for simultaneous Estimation of irbesartan and hydrochlorothiazide.	Stability indicating HPTLC	Acetonitrile: Chloroform (5:6 v/v)	precoated Silica gel 60F254	270 nm	38
Stability Indicating LC Method for Simultaneous Determination of Irbesartan and Hydrochlorothiazide in Pharmaceutical Preparations	Stability indicating LC/MS/MS	0.1% formic acid in water-acetonitrile (65:35 v/v)	-	-	39

The other analytical method like RP-HPLC, HPTLC, LC/MS/MS, UV, VOLTAMETRY, ELECTROCHEMICAL METHOD is also used for determination of Irbesartan in blood, serum, pharmaceutical dosage form, synthetic mixture and also stability study but most preferably high performance and other chromatography method is used for identification, separation, assay, impurity profiling, etc study. The presented information is useful for the future study for researcher involved in formulation development and quality control of Irbesartan.

CONFLICT OF INTERESTS

Declared None

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