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ANALYTICAL METHOD FOR DETERMINATION OF INDAPAMIDE IN MARKETED PHARMACEUTICAL PREPARATION: A MINI REVIEW

Anu Chaudhary

DEPARTMENT OF QUALITY ASSUARANCE, MAHATMA GHANDHI COLLEGE OF PHARMACEUTICAL SCIENCES

ABSTRACT

Indapamide is a Thiazide like diuretic drug which is used in treatment of Hypertension, as well as in edema, Heart attack, stroke and heart failure in persons with high blood pressure. It is available as single component and multicomponent in marketed formulations.

This article aims to study comprehensively about the previously reported various analytical methods used in determination of Indapamide.The various analytical method including in the analysis of indapamide are chromatographic method, LC-MS (Liquid Chromatography-mass spectroscopy), GC-MS (Gas chromatography-mass spectroscopy),spectrofluorometric and UV Visible spectrophotometry techniques for estimation of Indapamide in biological samples, bulk and pharmaceutical formulation.

Keyword: Indapamide, HPLC, HPTLC, UV Spectrophotometry, LC-MS and GC-MS

1. INTRODUCTION

Indapamide is a mild diuretic drug of class thiazides which is also useful in the treatment of hypertension (to lower Blood pressure), as well as in edema (to reduce extra fluid from the body), sometimes useful in Heart failure. It comes as tablets and modified release tablets. It shows synergy with perindopril to improve anti-hypertensive activity.

1.1. Chemistry

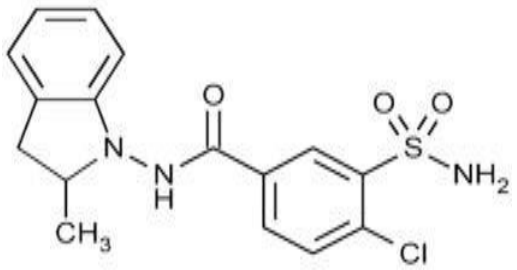

Fig.1. chemical structure of Indapamide

According to IUPAC nomenclature indapamide is 3-(aminosulfamoyl)-4-chloro-N-(2,3-dihydro-2-methyl-1H-indol-1-yl) benzamide moiety. Its molecular formula is reported as C16H16ClN3O3S and its molecular mass is 365.8 g/mol. It is white to yellow white crystallinepowder with odorless property and it is stated to be soluble in ethanol, acetic acid, methanol, ethyl acetateand very slightly soluble in chloroform.

1.2. Mechanism of Action: -

Indapamide controls hypertension by inhibiting reabsorption of sodium (Na+) and chloride (Cl-) ions from distal convoluted (DCT) in the kidneys byblocking the Na+-Cl- symporter similar to other thiazides.

1.3. Pharmacokinetics: -

Rapidly absorption from the gastrointestinal tract (G.I.T)within 0.5 to 1 hour after an oral administration, reaching peak concentration of 140ng/ml after a 10mg oral dose. Repeated dose cannot alter the kinetics of drug Its plasma protein binding is 79% and half-life is of 16 hours.

1.4. Recommended doses and Dosage forms

Indapamide is available in tablet formulations. The Recommended Dose is Daily 1.25- 2.5mg.

1.5. Adverse Effect

In general, most adverse effects are Dizziness, Headache, Fatigue, Muscle Cramps, Asthenia, GIT disturbances, Electrolyte Imbalance Hypokalemia, Hypochloremia, Hyponatremia).

1.6. Contraindications: -

Indapamide is contraindicated in Sulphonamides, Severe Kidney Failure, Hepatic encephalopathy, low BloodPotassiumlevelandpregnancyor Breastfeeding.

2. OBJECTIVE

The Objective this review is to assemble the analytical method published for analysis of Indapamide in Biological matrices, Bulk and pharmaceutical formulation.

3. ANALYTICAL METHOD

There are various analytical methods used in the determination of marketed formulation of indapamide and in biological fluids. The following methods are reported during the literature survey and studied here comprehensively. These analytical methods are used in a specific condition.

The various analytical methods include in this article are UV spectrophotometry, HPLC (High performance liquid chromatography), HPTLC (High performance thin layer chromatography), GC-MS (Gas chromatography -mass spectroscopy), LC-MS (Liquid chromatography -mass spectroscopy).

3.1. Spectrophotometry: -

In the literature survey were found that 12 UV spectrophotometric methods have been reported for estimation of Indapamide Single and in combined dosage form.

Table.1 illustrates the summery of the reported UV spectrophotometric methods indicating sample matrix used, Lambda Max, linearity range.

Table no.1 Summary of UV spectroscopic methods of Indapamide

Sr.no.	Name of Drug	Sample	Method		Wavelength (nm)		Solvent
					Indapamide	Other drug	
1.	IND+PNP	Tablet	A	Simultaneous Equation	210.4	285.8	Methanol
			B	Absorption Correction			
2.	IND+TEL	Capsule	A	Simultaneous equation	242	294	Methanol
			B	Absorbance ratio	254		
			C	Multicomponent mode	242		
3.	ATN+IND	Tablet, capsule	A	First Derivative	252.8	-	Methanol
			B	Second Derivative	260.4	-	
4.	IND+ ADB	Tablet	A	Simultaneous Equation	240	237	Methanol
			B	AUC	255-245	242-232	
			C	Absorbance ratio	237	237	
5.	IND+ADB			Absorption		360	
		Tablet	A	Correction	242		Menthol
			B	First Deviation		238	

Where- [AUC-Area under curve; ADB-Amlodipine Besylate; ATN-Atenolol; TEL-Telmisartan; IND-Indapamide; PNP-Perindopril]

3.2. ChromatographicMethod: -

The High-performance liquid chromatography (HPLC) method is used for residue determination of single and combination drug and is also used to determine impurity.

Table no.2 shows the summarize reported chromatographic method indicating sample, method, mobile phase and wavelength.

Table no. 2 summary chromatographic method of Indapamide

Sr.no.	Drug Name and combination	Sample	Method	Mobile phase	Wavelength
1	IND+PNP	Tablet	RP-HPLC	PDP Buffer: Acetonitrile (63:35v/v) pH 2.6	215nm
2.	IND+LSP	Capsule	HPLC	Methanol: water (50:50 v/v) pH 3.1	206nm
3.	IND	Tablet	HPLC	Phosphate Buffer: Acetonitrile (90:10 v/v) pH 3.1	242nm
4.	NBL+IND	Tablet	HPLC	KH_2PO_4: Triethylamine: Acetonitrile (40:0.5:60 v/v)	286nm
5.	OLM+IND	Tablet	HPTLC	Toluene: Chloroform: Ethanol (4:4:1 v/v)	254nm

Where-

[IND-Indapamide; RP-HPLC- Reverse phase high performance liquid chromatography; HPLC- High performance liquid chromatography; HPTLC-High performance liquid chromatography; ADB-Amlodipine Besylate; AML- Amlodipine; ATN-Atenolol; DCM-Dichloromethane; GAA-Glacial acetic acid; IPLC-Ion pair liquid chromatography

; KH2PO4-Potassium dihydrogen orthophosphate; LSP-Lisinopril; NBL-Nebivolol OLM-Olmisarthan; OPA- Orthophosphoric acid; PDP-Potassium dihydrogen phosphate; PNP-Perindopril; PNPE-Perindopril Ebrumine; RP- UPLC-Reverse phase – Ultra performance liquid chromatography; SDS-Sodium dodecyl sulphate; TEL- Telmisartan; UPLC-Ultra performance]

3.3. Spectrofluorometricmethod: -

The previous method first and second were based on oxidative coupling of indapamide with 3-methyl-2-benzothialidone hydrazine HCl in the presence of cerium ammoniumsulphate

(acidic medium) and quenching effect on florosence due to excess cerous ions are at emission **λ**max 350 nm and the excitation at**λ**max 300nm with linearity 1.2 to 9.6µg/ml with a recovery 99.27%.

The sensitive fluorescence method is used for the determination of linearity of 0.025 to 2.0 µg/ml the concentration of Indapamide of 0.05µg/ml can be detected by reacting indapamide with sodium hydroxide followed by addition of formaldehyde in given 20 mg of drug. The fluorescence at emission **λ**maxis 356nm and excitation**λ**max is 284nm.

3.4. GC-MS (Gas chromatography - mass spectroscopy) Method: -

Indapamide determination in human urine by using GC-MS technique in the retention time of 7.465 min.is found to bein segment range of 7.2-7.9 min. and separation at Ions at 407 m/z.

3.5. LC-MS (Liquid chromatography-mass spectroscopy) Method: -

A. LC-MS is used for the determination of indapamide in Human blood. The separation were performed on a symmetry C-18silica column (150×3.9mm id, 5µm) using mobile phase as Acetonitrile: Water (60:40 v/v), Indapamide sample and IS(propyl paraben) were detected at m/z 364 for Indapamide and

m/z 179 for propyl paraben with linear calibration range of 2.0-120µg/ml.

B. This method is also used for the determination of Indapamide in human plasma. The separation was performed on a C18 column having mobile phase of 10mM Ammonium acetate:Methanol (22:78 v/v). Indapamide was also estimatedby using Electrospray ionization with the selected ions monitoring mode using target ions at m/z 364.3 for Indapamide and m/z 492.4 for the IS (propyl paraben) with linearity of 0.1-100ng/ml for Indapamide. The mean recovery 90.5- 93.95%.
C. A simple, sensitive and rapid LC-MS method for Quantification of Indapamide in human plasma determination. The compounds were separated on a stainless-steel column (C18 shim-pack 5µm 150×2.0mm I.D., shimadzu) and separated ions monitoring at m/z 364.0 Indapamide and chlorpropamide m/z 275.0 with linear range 0.5 to 100ng/ml with a coefficient of determination(r) of 0.9998. [Yan Liang t al., 2006.]

4. CONCLUSION

This reviews articles presented the analytical methods for the estimation of Indapamide & its combination in pharmaceutical dosage form and biological sample like Blood, serum or plasma the literature survey of analytical data exhibit that HPLC methods are primarly for the analysis of Indapamide in single and in combination with other drugs in various formulation type of dosage form the other analytical methods like RP-HPLC, HPTLC, LC- MS, GC-MS, UV spectrometry,Spectro-fluorometry and stability indicating methods by HPLC used for the estimation of Indapamide in single and its combined dosage form, biological sample like blood, serum or plasma and milk.

The presented information is useful for future prospective study for researcher in formulation development, Bio analytical research and Quality control of Indapamide.

ACKNOWLEDGEMENT: XYZ

CONFLICT OF INTEREST: - NONE

5. DECLERATION

I hereby declare that the work incorporated in the present project report entitled

"Analytical Method for Determination of Indapamide in Marketed pharmaceutical preparation: A Mini Review" is my own work and is original. This work (in part or full) has not been previously submitted to any University for the award of Degree

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