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A REVIEW ON ANALYTICAL METHODS FOR INDIVIDUAL AND SIMULTANEOUS ANALYSIS OF LISINOPRIL AND HYDROCHLOROTHIAZIDE(HCTZ)

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ABSTRACT

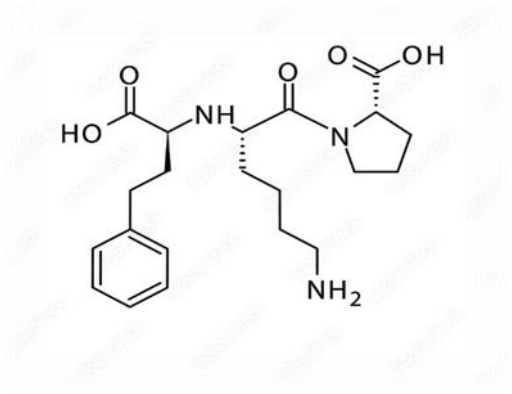
Lisinopril is an (ACE) angiotensin-converting enzyme inhibitor and is used in the treatment of high blood pressure, heart failure, and heart attacks. It works by blocking the production of a potent blood vessel constrictor (angiotensin II), leading to relaxed blood vessels, reduced fluid volume, and lower blood pressure. Hydrochlorothiazide is a diuretic drug used for treatment of high blood pressure(hypertension) and accumulation of fluid (edema). It works by blocking salt and fluid reabsorption from the urine in the kidneys, causing increased urine output (dieresis). The combination of lisinopril and hydrochlorothiazide provides a synergistic approach to managing Hypertension. This combination is effective, well-tolerated, and convenient. Numerous analytical methods have been developed for the determination of lisinopril and hydrochlorothiazide. These methods include a reverse phase chromatography method with UV detection (HPLC-UV), A high performance thin layer chromatography (HPTLC), UV Spectrophotometric, A reverse phase high performance liquid chromatography (RP-HPLC), A liquid chromatography-tandem mass spectrometry (LC-MS/MS).

KEYWORDS: Lisinopril, Hydrochlorothiazide, Hypertension, RP-HPLC, LC-MS/MS, UV Spectroscopy.

1.INTRODUCTION

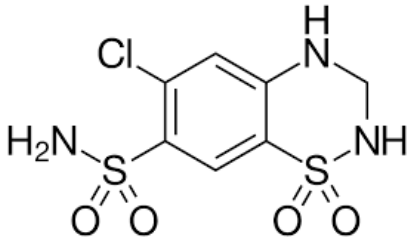
1.1 LISINOPRIL[1-2]

Lisinopril is used in high blood pressure (hypertension), congestive heart failure, and in heart attack, also in renal and retinal complications of diabetes. It also exhibits haemodynamic effects. It is an active site directed inhibitor. It promotes natriuresis and useful in preventing diabetic retinopathy in the patients of type II diabetes. Its onset of action is 1-2 hours. Duration of action is 24 hours. Absorption of the lisinopril is slowly and moderately from GI tract(oral) and peak plasma concentration obtain after 7 hours. interactions with drugs and foods. The drug distribution is up to 25%. It is excreted unchanged in urine and does not undergo metabolism. The drug is given orally in case of hypertension.



1.2 HYDROCHLOROTHIAZIDE[3]

Hydrochlorothiazide is used alone or in combination with other medications to treat high blood pressure. Hydrochlorothiazide is used to treat edema (fluid retention; excess fluid held in body tissues) caused by various medical problems, including heart, kidney, and liver disease and to treat edema caused by using certain medications including estrogen and corticosteroids. Hydrochlorothiazide is in a class of medications called diuretics ('water pills'). It works by causing the kidneys to get rid of unneeded water and salt from the body into the urine.



High blood pressure is a common condition and when not treated, can cause damage to the brain, heart, blood vessels, kidneys and other parts of the body. Damage to these organs may cause heart disease, a heart attack, heart failure, stroke, kidney failure, loss of vision, and other problems. In addition to taking medication, making lifestyle changes will also help to control your blood pressure. These changes include eating a diet that is low in fat and salt, maintaining a healthy weight, exercising at least 30 minutes most days, not smoking, and using alcohol in moderation.

2. ANALYTICAL METHODS FOR INDIVIDUAL DRUGS:

The main purpose of analytical method development and validation is to prove that the proposed analytical method is accurate, specific, precise and robust for the particular drugs.

2.1 Lisinopril

2.1.1 UV Spectrophotometric Method

Sr. No.	Title	Description	Reference
1	Development and Validation of UV Spectrophotometric Method for the Estimation of Lisinopril in Bulk and Pharmaceutical Formulation	**λmax:** 218 nm **Linearity:** 2-12 µg /ml **Solvent:** 0.1 N NaOH	4
2	Spectrophotometric Determination of Lisinopril in Pharmaceuticals Using Ninhydrin- a Modified Approach	**λmax:** 420 nm **Linearity:** 5-50 µg /ml **Solvent:** DMF, DMSO, Acetone or methanol	5
3	Development And Validation of Uv Spectrophotometric Estimation of Lisinopril Dihydrate in Bulk and Tablet Dosage Form Using Area Under Curve Method.	**λmax:** 212nm **Linearity:** 5-25µg/ml **Solvent:** double distilled water	6
4	Development And Validation of a Uv Spectrophotometric Method for The Determination of Lisinopril Both in Bulk and Marketed Dosage Formulations	**λmax:** 206nm **Linearity:** 10-50 µg/ml **Solvent:** distil water	7

2.1.2 High performance liquid chromatography (HPLC)

Sr. No.	Title	Description	Reference
1	HPLC method validation for quantification of lisinopril.	**Column**: Agilent Zorbax Bonus-RP column **Particle Size**: 5µm **Detector**: DAD detector **λmax**: 215 nm **Mobile Phase:** methanol and trifluoroacetic acid 50:50 v/v **Flow Rate**: 1 ml/min **Retention Time:** 2.18 min **Linearity**: 3–7 µg/mL	8

2	Development and validation of RP-HPLC method for the estimation of lisinopril in bulk and pharmaceutical dosage form.	**Column**: Phenomenax column C18 (ODS). **Particle Size:** 5µm **Detector**: PDA detector **λmax**: 237 nm **Mobile Phase:** Acetonitrile: Buffer 0.1M (70:30 % v/v) **Flow Rate**: 1 ml/ min **Retention Time:** 3.444 min **Linearity**: 2-10 µg/mL	**9**
3	Development, Estimation and Validation of Lisinopril in Bulk and its Pharmaceutical Formulation by HPLC Method.	**Column**: reverse phase xterra C8 column **Particle Size**: 3.5 µm **Detector**: PDA detector **λmax**: 215 nm **Mobile Phase**: phosphate buffer and methanol in the ratio of 35:65v/v. **Flow Rate**: 0.8 ml/ min **Retention Time:** 2.298 min **Linearity:** 20-60 µg/ml	**10**
4	Development And Validation of a Fast, Simple, Cost-Effective and Robust Hplc Method for Lisinopril Determination in Solid Pharmaceutical Dosage Forms	**Column**: C18 column **Particle Size**: 0.1 µm **Detector**: UV detector **λmax**: 214 nm **Mobile Phase:** ammonium dihydrogen phosphate buffer (pH 7.2; 20 mM) and methanol (60:40, v/v) **Flow Rate**: 1.1 ml/min **Retention Time:** 3.0 minutes **Linearity:** 5-50 µg/mL	**11**
5	RP-HPLC Method For the Determination of Lisinopril in Active Pharmaceutical Ingredients, Dosage Forms and Human Serum	**Column**: Hypersil ODS C18 and Purospher Start C18 **Particle Size**: 5µm **Detector**: UV detector **λmax**: 225 nm **Mobile Phase**: methanol: acetonitrile: water (80:17.5:2.5 v/v/v) **Flow Rate**: 1 ml/ min **Retention Time:** 2.0 min **Linearity:** 2.5-100 µgmL−1	**12**
6	RP-HPLC Method For the Simultaneous Determination of Lisinopril and Nsaids In API, Pharmaceutical Formulations and Human Serum	**Column**: A Purospher star C18 **Particle Size**: 5µm **Detector**: UV–VIS detector **λmax**: 225 nm **Mobile Phase**: methanol: water: acetonitrile (80:17.5:2.5 v/v) **Flow Rate**: 1.0 mL·min–1 **Retention Time:** 2.2 min **Linearity:** 2.5 - 100 µg·mL–1	**13**

2.1.3 LC-MS/MS

Sr. No.	Title	Description	Reference
1	A new LC/MS/MS method for determination of lisinopril in human plasma.	**Column:** Zorbax SB-C18 column. **Mobile phase:** 11:89 (v/v) acetonitrile and 0.1% (v/v) trifluoroacetic acid in water. **Flow rate:** 1 ml /min **Sample volume:** 0.25 ml **Linearity:** 0.2–10 µg/mL	14
2	Rapid Determination of Lisinopril Level in Human Plasma by LC-MS/MS	**Column:** Atlantis dC18 column **Mobile phase:** (5 mM ammonium formate and acetonitrile; 30:70, v: v). **Flow rate:** 0.30 ml/minute **Sample volume:** 1.0 ml **Linearity:** 1.0-200 ng/ml	15

2.1.4 LC MS

Sr. No.	Title	Description	Reference
1	Development and Validation of LC–MS Method for the Determination of Lisinopril in Human Plasma and its Application in a Bioequivalence Study	**Column:** Thermo Hypersil-HyPURITY C18 reversed-phase column **Mobile phase:** formic acid solution (pH 2.9)–methanol–acetonitrile (58:25:17, v/v) **Flow rate:** 0.20 mL/min. **Sample volume:** 0.25 mL **Linearity:** 2.5–320 ng/mL	16

2.1.5 High performance thin layer chromatography (HPTLC)

Sr. No.	Title	Description	Reference
1	Development of analytical method and validation for determination of Lisinopril dihydrate in bulk drug and dosage form using HPTLC method	**Stationary phase**: silica gel precoated aluminum 60F254 plates **Mobile phase**: n-butanol: methanol: ammonia in the ratio of 3.0: 1.0: 1.0 (v/v/v) **Detection**: UV detection **Rf-Lisinopril:** 0.58 **λmax**: 215 nm	17

2.2 Hydrochlorothiazide

2.2.1 UV Spectrophotometric method

Sr. No.	Title	Description	Reference
1	Analytical method development and validation for estimation of Hydrochlorothiazide content using UV-spectroscopic technique.	**λmax**: 271 nm **Linearity:** 5-25µg/mL **Solvent:** Water and Ethanol	18
2	Simultaneous UV spectrophotometric estimation of enalapril maleate and hydrochlorothiazide in tablets	**λmax**: 272nm **Linearity:** 5-30µg/mL **Solvent:** Potassium dihydrogen ortho phosphate, Sodium hydroxide and Methanol	19

2.2.2 High performance liquid chromatography (HPLC)

Sr. No.	Title	Description	Reference
1	Stability Indicating HPLC Method for the Determination of Hydrochlorothiazide in Pharmaceutical Dosage form.	**Column**: reversed phase C18 column **Particle size:** 5µm **Detector**: UV detector **λmax**: 270 nm **Mobile Phase**: Methanol: Buffer (60:40 v/v) **Flow Rate**: 1 ml/ min **Retention Time:** 1.23 min **Linearity:** 60-140 µg/ml	**20**
2	Development and Validation of RP-HPLC Method for the Determination of Hydrochlorothiazide in Bulk Drug and Pharmaceutical Dosage Form.	**Column**: C_{18}Inertsil ODS-3 and C_{18}Zorbax Eclipse Plus. **Particle size:** 5µm **Detector**: PDA detector **λmax**: 272 nm **Mobile Phase:** 50: 50 v/v acetonitrile: water **Flow Rate**: 1 ml/ min **Retention Time:** 3.5 min **Linearity:** 0.5 and 1.5µg/ml	**21**
3	Development and validation of an RP-HPLC method for the estimation of hydrochlorothiazide in tablet dosage forms.	**Column**: Kromasil C_{18} column **Particle size:** 5µm **Detector**: UV detector **λmax**: 254 nm **Mobile Phase:** phosphate buffer and acetonitrile (50:50 v/v) **Flow Rate**: 0.6 ml/ min **Retention Time:** 3.47 min **Linearity:** 20-60µg/ml	**22**
4	Development of Reverse-Phase HPLC Method for Simultaneous Analysis of Metoprolol Succinate and Hydrochlorothiazide in a Tablet Formulation	**Column**: reverse phase C-18 column **Particle size:** 5µm **Detector**: UV-detector **λmax**: 222 nm **Mobile Phase :** 50mM di-sodium hydrogen phosphate:methanol:acetonitrile ratio of 525:225:250 **Flow Rate**: 1 ml/min **Retention Time:** 3.04 min **Linearity:** 2 - 32 µg/ml	**23**
5	RP-HPLC Stability-indicating Method for Estimation of Irbesartan and Hydrochlorothiazide in Bulk and Pharmaceutical Dosage Form	**Column**: reverse phase C-18 column **Particle size:** 5µm **Detector**: UV-detector **λmax**: 210 nm **Mobile Phase:** 50 mM potassium di-hydrogen orthophosphate:acetonitrile (55:45, V/V) buffe **Flow Rate**: 1.3 mL min–1, **Retention Time:** 3 min **Linearity:** 10 - 100 µg mL–1	**24**
6	Development and validation of RP-HPLC	**Column**: LiChrosorbR C18	**25**

	method for simultaneous estimation of nebivolol hydrochloride and hydrochlorothiazide in combined tablet dosage form	**Particle size:** 5µm **Detector**: UV-detector **λmax**: 286 nm **Mobile Phase:** methanol and water in the proportion of 80:20 (v/v) **Flow Rate**: 1.6 ml/min **Retention Time:** 1.64min **Linearity:** 2-70 µg/ml	
7	Simultaneous Determination of Olmesartan and Hydrochlorothiazide in Combined Pharmaceutical Dosage Form by Rp-Hplc Method	**Column**: Chromosil C-18 **Particle size:** 5µm **Detector**: UV-detector **λmax**: 259 nm. **Mobile Phase:** methanol, acetonitrile and TEA in the ratio of 46:50:04 (v/v/v) **Flow Rate**: 1.0 ml/min **Retention Time:** 3.5 min **Linearity:** 10-60 µg/ml	**26**

2.2.3 LC-MS/MS

Sr. No.	Title	Description	Reference
1	Simultaneous determination of candesartan and hydrochlorothiazide in human plasma by LC-MS/MS	**Column:** Zorbax eclipse C18 **Mobile phase:** acetate buffer: acetonitrile (25:75%, v/v) **Flow rate:** 1 mL/min **Sample volume:** 15 µL **Linearity:** 3.12 - 262.07 ng/mL	**27**

2.2.4 LC MS

Sr. No.	Title	Description	Reference
1	Novel LCMS Method for Simultaneous Determination of Irbesartan and Hydrochlorothiazide in Human plasma	**Column:** Ace 5 C18 column **Mobile phase:** methanol:0.1% formic acid in water (70:30) **Flow rate:** 1.0 mL/min **Sample volume:** 5µg/mL **Linearity:** 1-500 ng/mL	**28**

3.ANALYTICAL METHODS FOR COMBINATION OF DRUGS (LISINOPRIL AND HYDROCHLOROTHIAZIDE)

The main purpose of analytical method development and validation is to prove that the proposed analytical method is accurate, specific, precise, and robust for the particular drugs.

3.1 UV/Vis spectrophotometric method

Sr. No.	Title	Description	Reference
1	Development and validation of UV spectrophotometric method for simultaneous estimation of Hydrochlorothiazide and	**λmax:** Lisinopril :215 nm Hydrochlorothiazide :274.5 nm	**29**

	Lisinopril in bulk drug and it's formulation.	**Linearity:** Lisinopril: 1-10 µg/ml Hydrochlorothiazide: 5-20 µg/ml **Solvent**: 0.01M sodium hydroxide	
2	Two smart spectrophotometric methods for simultaneous determination of Lisinopril and Hydrochlorothiazide in binary mixtures	**λmax:** Lisinopril :211 nm Hydrochlorothiazide :270 nm **Linearity:** Lisinopril: 5.0-30.0 µg mL-1 Hydrochlorothiazide: 1.0 – 20.0 µg mL-1 **Solvent**: Methanol	**30**

3.2 High performance thin layer liquid chromatography (HPTLC)

Sr. No.	Title	Description	Reference
1	A novel validated stability indicating analytical hptlc method for quantitation of hydrochlorothiazide and lisinopril in tablet formulation.	**Stationary phase**: silica gel 60 F254 HPTLC plate **Mobile phase**: chloroform: methanol: ethyl acetate: acetic acid (7:2:1.0:0.2; V/V/V/V) **Detection**: UV detection **Rf**: **Hydrochlorothiazide**:0.43 **Lisinopril:** 0.75 **λmax**: 218 nm	**31**
2	Spectrophotometric and HPTLC-densitometric determination of lisinopril and hydrochlorothiazide in binary mixtures	**Stationary phase**: Merck HPTLC aluminum plates of silica gel 60 F_{254} **Mobile phase**: chloroform–ethylacetate–acetic acid (10:3:2 by vol.) **Detection**: UV-Visible spectrophotometer detection **Rf**: **Hydrochlorothiazide**:0.81 **Lisinopril:** 0.63 **λmax**: **Hydrochlorothiazide**:272 nm **Lisinopril:** 215nm	**32**

3.3 High performance liquid chromatography (HPLC)

Sr. No.	Title	Description	Reference
1	Method development and validation of Lisinopril and Hydrochlorothiazide in combined dosage form by RP-HPLC.	**Column**: reversed phase C18 column **Particle size:** 10µm **Detector**: UV detector **λmax**: 225 nm **Mobile Phase**: sodium phosphate buffer solution: methanol (70:30 v/v) **Flow Rate**: 1 ml/ min **Retention Time:** **Lisinopril:**7.0667 min **Hydrochlorothiazide:**5.1000 min **Linearity:** **Lisinopril:**80-120 µg/ml	**33**

		Hydrochlorothiazide:200-300 µg/ml	
2	RP – HPLC Method for the Simultaneous Determination of Lisinopril and Hydrochlorothiazide in Pharmaceutical Formulation.	**Column**: Reverse phase C18 column **Particle size:** 10µm **Detector**: UV detector **λmax**: 215 nm **Mobile Phase:** potassium dihydrogen phosphate buffer solution:acetonitrile ,30:70 v/v **Flow Rate**: 1.5 ml/ min **Retention Time:** **Lisinopril:** 3.4 min **Hydrochlorothiazide:** 6.9 min **Linearity:** **Lisinopril:** 50-400 µg/ml **Hydrochlorothiazide:** 25-250 µg/ml	**34**
3	Simultaneous estimation of lisinopril and hydrochlorothiazide in bulk, pharmaceutical dosage forms and in dissolution samples by RP-HPLC-PDA method	**Column:** Inertsil ODS 3 column **Particle size:** 5µm **Detector**: PDA detector **λmax**: 220 nm **Mobile Phase:** 10mM Ammonium acetate: Acetonitrile (80:20% v/v) **Flow Rate**: 1 ml/min **Retention Time:** **Lisinopril:** 3.7min **Hydrochlorothiazide:** 7.6min **Linearity:** **Lisinopril:** 2-10µg/mL **Hydrochlorothiazide:** 5-25ug/mL	**35**

3.4 LC-MS/MS

Sr. No.	Title	Description	Reference
1	Fast and sensitive LC–MS/MS method for the simultaneous determination of lisinopril and hydrochlorothiazide in human plasma.	**Column:** Hypersil Gold C_{18} column. **Mobile phase:** acetonitrile- ammonium formate, (85:15, v/v). **Flow rate**: 2.4 L/min **Sample volume:** 100 µL **Linearity:** 0.50–250.0 ng/mL.	**36**

3.5 Liquid chromatography (LC)

Sr. No.	Title	Description	Reference
1	Stability-Indicating LC Method for the Simultaneous Determination of Lisinopril and Hydrochlorothiazide	**Column:** RP-18 column **Mobile phase:** methanol, acetonitrile and phosphate buffer (pH 7.1; 0.05 M) (15:15:70, v/v/v) **Flow rate**: 0.8 mL min-1 **Sample volume:** 1000 µL	**37**

		Linearity: **Lisinopril:** 40–200 mg mL-1 **Hydrochlorothiazide:** 25–175 mg mL-1	

CONCLUSION

The current study shows that several analytical approaches, including spectrophotometry chromatography techniques and mass spectroscopic techniques can be used to determine Lisinopril and Hydrochlorothiazide individually as well as in combination. The current review will be very beneficial to researchers in analytical chemistry that develop and validate methods for Lisinopril and Hydrochlorothiazide.

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