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An Overview of Analytical Determination of Captopril in Active Pharmaceutical Ingredients (API) Formulation and Biological Fluids

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Abstract

Present review article determine the analytical methods for the quantitative determinations of Captopril (ACE Inhibitor) by one of the spectroscopic technique (UV spectrophotometery) and separation technique such as High-Performance Liquid chromatography (HPLC). The clinical and pharmaceutical analysis of captopril requires effective analytical procedures for quality control, Pharmaceuticals dosage formulations and human serum. An extensive survey of the research articles published in various pharmaceutical, clinical and analytical chemistry related journals has been compiled in this paper. A synopsis of reported spectrophotometer and high-performance liquid chromatographic methods for captopril are integrated. This appraisal illustrate that majority of the HPLC methods reviewed are based on the quantitative analysis of drug in active Pharmaceutical ingredients (API) biological fluids such as serum and plasma and they are appropriate for therapeutic drug monitoring , pharmacokinetic purpose.

Keywords: HPLC; UV spectrophotometer; Active Pharmaceutical ingredients; Method development; Biological fluids

Introduction

The ACE inhibitors block the angiotensin converting enzyme that cleaves the terminal two peptides from angiotensin I (decapeptide) to form the potent vasoconstrictor angiotensin II (octapeptide) and lower the BP by reducing peripheral vascular resistance without increasing cardiac output rate and contractility.

ACE inhibitors are synthetic in nature and can be classified on the basis of their chemical structure. They can be grouped as sulfhydral containing (fentiapril, pivalopril, zofenopril and alacepril etc.), dicarboxyl containing (lisinopril, benazepril, quinapirl, perindopril, indopril, pentopril, indalapril, alazapril, moexipril, romipril and spirapril etc.), phosphorous - containing (fosinopril) [1] and naturally occurring casokinins and lactokinins that are breakdown products of casein and whey; they occur naturally after ingestion of milk products, especially sour milk, their role in blood pressure control is uncertain [2].

First demonstration of an orally active ACE inhibitor occurred on March 31, 1975 when they replaced the succinyl group with a derivative of cysteine, inhibitory potency was increased about 2,000-fold because sulfhydryl of cysteine bound with zinc more tightly than the carboxyl of succinyl. This resulted in captopril, having a dramatic effect on renal function and on hypertension [3].

Analytical determination of captopril

A number of assay methods have been developed like coulometric [4], conductometric and colorimetric for the quantitative determination of captopril [5]. Captopril is determined by using infrared spectroscopy [6,7], mass spectroscopy and nuclear magnetic resonance spectroscopy [8]. The UV absorption spectra of captopril were obtained which has a single band at 200 nm, while the CD spectrum consists of a single peak at 210 nm [9]. Alberto [10] determined captopril by spectrophotometric method and iron and copper complexation with captopril were also assayed [11] by UV spectrophotometer. Number of chromatographic methods as gas chromatography-mass spectrometry [12] was described for the determination of captopril. Stability-indicating HPLC methods for its determination are reported Ahmed et al. [13]. This method is used for the determination of captopril in the presence of its disulphide dimer in pure form and in pharmaceutical preparations, solution containing 0.025 % w/v of Pd(II) chloride in a mixture of acetonitrile-methanol-water containing 10 mm Britton-Robinson buffer [BRb] of pH 4.0 and 0.25 M KCl solution [1:4:5 v/v/v] was used as a mobile phase and method showed excellent linearity in the range 2-32 μgmL^{-1} with a limit of detection [S/N=2] of 0.18 μgmL^{-1}. Another HPLC method by Stulzer et al. [14] determined captopril in controlled release tablets and analyses was performed at room temperature on a reversed-phase Phenomenex Luna C_{18} column (250 mm × 4.6 mm), mobile phase water: methanol (45:55; v/v) and pH 2.5 at 1.0 $mLmin^{-1}$ and the response was linear in the range of 0.3–1.5 $mgmL^{-1}$ ($r^2 = 0.9983$). Validated RP–HPLC method for analysis of hydrochlorothiazide and captopril in tablets is reported by Ivanovic et al. [15]. Jankowski et al., determined captopril in blood by HPLC [16]. Recovery of captopril-adduct reached 93.1% and limit of detection was 15 $ngmL^{-1}$, while the quantitative limit was 30 $ngmL^{-1}$. Inter and intra-assay RSD was below 9%, but accuracy was below 8% found. Saleem et al. and Amini et al. [17,18] determined captopril in plasma. Number of assay methods has been developed for the quantitative determination of captopril by number of scientists using HPLC [19-21].

Several examinations using HPLC for determination of captopril in bulk drug substances and their formulations have been reported [22]. Direct Determination of Four ACE-Inhibitors Lisinopril, Enalapril, Captopril and Fosinopril in Pharmaceuticals and Serum by HPLC separation of the analysts was achieved by gradient RP-HPLC with the mobile phase composed as acetonitrile: water (60:40 v/v) adjusted to

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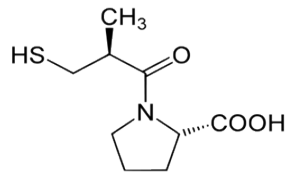

Figure1: Captpril.

pH 3.0 by ortho phosphoric acid [23].

Monitoring of *in vitro* interaction studies of captopril with hypoglycemic agents by LC-UV [24] and simultaneous LC determination of rosuvastatin, lisinopril, captopril, and enalapril in API, pharmaceutical dosage formulations, and human serum [25].

Another Facile and Manifest Liquid Chromatographic Method for the Simultaneous determination of captopril and NSAIDs in API and Pharmaceutical Formulations is reported and CAP was separated from NSAIDs using a Purospher STAR C18 column (250×4.6 mm, 5 µm) and a mobile phase consisting of methanol, water (80:20,v/v) [26] ACE inhibitor drugs do not respond sufficiently to reduce hypertension. Hence, these are used as combined dosage forms with other specific classes of drug compounds such as calcium channel blocker antihypertensive, diuretics; etc another method is reported of captopril with diuretic Hydrochlorothiazide and Furosemide in Active Pharmaceutical Ingredients, Pharmaceutical Dosage Forms and Human Serum [27]. Other methods of captopril with hypoglycemic, statins and H_2 receptor antagonist in bulk, formulations and human serum by RP-HPLC [28-32] are reported.

Conclusion

Patients diagnosed with hypertension are prescribed large number of medications for appropriate therapy which increasing the risk of side effects and drug interactions. But there are several electro analytical methods reported by Gupta et al. [33-40]. In this article UV and HPLC methods for the determination of captopril in active material, pharmaceutical formulations and biological specimens are reviewed alone or in combination with other drugs. HPLC methods generally required expensive equipment, provision for use and disposal of solvents, labor-intensive sample preparation procedure and personal skilled in chromatographic techniques. In addition, most of the HPLC methods reviewed have the potential application to clinical research of drug combination, multi-drug pharmacokinetics studies and interactions studies. Novelty of this method is these are less time consuming and very cheap solvents are used.

References

1. Goodman, Gilman s (1996) The Pharmacological Basis of Therapeutic. (9thedn), McGraw-Hill Press.
2. FitzGerald RJ, Murray BA, Walsh DJ (2004) Hypotensive peptides from milk proteins. J Nutr 134: 980S-8S.
3. Cushman DW, Ondetti MA, Gordon EM, Natarajan S, Karanewsky DS, et al. (1987) Rational design and biochemical utility of specific inhibitors of angiotensin-converting enzyme. J CardiovascPharmacol 10 Suppl 7: S17-30.
4. Goldnik A, Gajewska M, Ostaszewska B (1991) Acta Pol Pharm 48: 5-7.
5. El- Kerdawy M, Mustafa MA, EL-Ashry SM, El-Waseef R (1993) J Pharm Sci 9: 191-203.
6. Atzei D, Rossi A, Sadun C (2000) Synthesis and characterization of a cobalt(III) complex with 1-(D-3-mercapto-2-methylpropionyl)-L-proline. SpectrochimActaAMolBiomolSpectrosc 56A: 1875-1886.
7. Atzei D, Sadun C, Pandolfi L (2000) X-ray photoelectron spectra of complexes with 1-(D-3-mercapto-2-methylpropionyl)-L-proline and Ni(II), Cd(II) and Cu(I): synthesis and LAXS study of Cu(I) derivative. SpectrochimActa A MolBiomolSpectrosc 56: 531-540.
8. Casy AF, Dewar GH (1994) Captopril and its probable contaminants: NMR and MS features of analytical value. J Pharm Biomed Anal 12: 855-861.
9. Brittain HG, Kadin H (1990) Ultraviolet (UV) absorption and circular dichroism (CD) spectra of captopril. Pharm Res 7: 1082-1085.
10. Albero MI, Sánchez-Petreño C, García MS, Ródenas V (1993) Determination of captopril in pharmaceutical samples by flow injection analysis. J Pharm Biomed Anal 11: 887-891.
11. Frnandez M, Silva MM, Mira L, Florencio MH, Gill A et al. (1998) Iron and copper complexation by angiotensin-converting enzyme inhibitors. A study by ultraviolet spectroscopy and electrospray mass spectrometry. J Inorg Biochem 71: 93-98.
12. Franklin ME, Addison RS, Baker PV, Hooper WD (1998) Improved analytical procedure for the measurement of captopril in human plasma by gas chromatography--mass spectrometry and its application to pharmacokinetic studies. J Chromatogr B Biomed SciAppl 705: 47-54.
13. Ahmed S, Rizk M ,Belal F, Ibrahim F, Sheribah ZA (2006) Stability-Indicating HPLC method for captopril through Pre-Column derivatization with Pd(II). Journal of Liquid Chromatography & Related Technologies 29: 521-532.
14. Stulzer HK, Tagliari MP, Kuminek G, Oliveira PR, Bertol CD et al. (2009) Development and validation of stability indicating LC method to quantify captopril in tablets of controlled release. Chromatographia 69: 123-128.
15. Ivanovic D, Medenica M, Malenovic A, Jancic B (2004) Validation of the RP-HPLC method for analysis of hydrochlorothiazide and captopril in tablets, Accreditation and Quality Assurance, Journal for Quality. Comparability and Reliability in Chemical Measurement 9: 76-81.
16. Jankowski A, Skorek A, KrzyÅ›ko K, Zarzycki PK, Ochocka RJ, et al. (1995) Captopril: determination in blood and pharmacokinetics after single oral dose. J Pharm Biomed Anal 13: 655-660.
17. Salem II, Saif WA, Jmeian Y, Al Tamimi JI (2005) A selective and rapid method for the quantification of captopril in human plasma using liquid chromatography/ selected reaction monitoring mass spectrometry. J Pharm Biomed Anal 37: 1073-1080.
18. Amini M, Zarghi A, Vatanpour H (1999) Sensitive high-performance liquid chromatographic method for determination of captopril in plasma. Pharm ActaHelv 73: 303-306.
19. Meiju Du (2007) Determination of captopril in human plasma by liquid chromatography/Tandem mass spectrometry. Analytical Letters 40: 3245-3255.
20. Huang T, He Z, Yang B, Shao L, Zheng X, et al. (2006) Simultaneous determination of captopril and hydrochlorothiazide in human plasma by reverse-phase HPLC from linear gradient elution. J Pharm Biomed Anal 41: 644-648.
21. Alnajjar AO (2008) Simultaneous determination of captopril and indapamide in pharmaceuticals and human plasma. J Pharm Biomed Anal 68: 437-442.
22. Pérez-Ruiz T, Martínez-Lozano C, Galera R (2006) Development and validation of a capillary electrophoresis method with laser-induced fluorescence detection for the determination of captopril in human urine and pharmaceutical preparations. Electrophoresis 27: 2310-2316.
23. Safila Naveed, Najma Sultana b, M SaeedArayne (2013) Method for the Determination of Captopril in Bulk Pharmaceutical Formulations and Serum by HPLC using two different System. American Based Research Journal 2: 8-14.
24. Sultana N, Naveed S, Arayne MS (2013) Direct Determination of Four ACE-Inhibitors Lisinopril, Enalapril, Captopril and Fosinopril in Pharmaceuticals and Serum by HPLC. J Chromat Separation Techniq 4: 179.
25. Sultana N, Naveed S, Arayne MS (2013) Development and Validation of a Simple and Efficient RPLC Method for Analysis of Captopril,Metformin, Pioglitazone and Glibenclamide in API, Formulations and Human Serum. Pharm Anal Acta 4: 257.
26. M Saeed Arayne,Najma Sultana,Arman Tabassum,Saeeda Nadir Ali,Safila Naveed (2012) Simultaneous LC Determination of Rosuvastatin, Lisinopril, Captopril, and Enalapril in API, Pharmaceutical Dosage Formulations, and Human Serum. Med Chem Res 21: 4542-4548.

27. Sultana N, Arayne MS, SafilaNaveed (2010) Simultaneous Quantitation of Captopril and NSAIDs in API, Dosage Formulations and Human Serum by RP-HPLC. J Chin Chem Soc 57: 62-67.

28. Sultana N, Arayne MS, SafilaNaveed (2011) RP-HPLC Method for Simultaneous Determination of Captopril and Diuretics: Application in Pharmaceutical Dosage Forms and Human Serum. Chromatography Separation Sciences 2:109.

29. Sultana N, Naveed S, Arayne MS (2013) Development and Validation of a Simple and Efficient RPLC Method for Analysis of Captopril, Metformin, Pioglitazone and Glibenclamide in API, Formulations and Human Serum. Pharm Anal Acta 4: 257.

30. Sultana N, Arayne MS, Naveed S (2010) Simultaneous Determination of Captopril and Statins in API, Pharmaceutical Formulations and in Human Serum by RP-HPLC. J Chin Chem Soc 57: 378-383.

31. Sultan N, Naveed S, Arayne MS (2013) RP-HPLC Method for the Simultaneous Determination of Captopril and H2-Receptor Antagonist:Application to Interaction Studies. Med chem 3: 183-187.

32. Naveed S, Sultana N, Arayne MS, Akhtar M (2013) *In vivo* interaction studies of captopril with flurbiprofen and ibuprofen on carrageenan induced inflammation. J Bioequiv Availab.

33. Sultana N, Naveed S, Arayne MS (2013) Simultaneous Quantitation of Three ACE Inhibitors and Four Statins Using RP-HPLC Technique. Biomed chr.

34. Gupta VK, Chandra S, Lang H (2005) A highly selective mercury electrode based on a diamine donor ligand. Talanta 66: 575-580.

35. Gupta VK, Singh AK, Mehtab S, Gupta B (2006) A cobalt (II)-selective PVC membrane based on a Schiff base complex of N,N'-bis(salicylidene)-3,4-diaminotoluene. Analytica Chimica Acta 566: 5-10.

36. Goyal RN, Gupta VK, Bachheti N (2007) Fullerene-C60-modified electrode as a sensitive voltammetric sensor for detection of nandrolone--an anabolic steroid used in doping. Anal ChimActa 597: 82-89.

37. Gupta VK, Singh AK, Al Khayat M, Gupta B (2007) Neutral carriers based polymeric membrane electrodes for selective determination of mercury (II). Anal ChimActa 590: 81-90.

38. Gupta VK, Al Khayat M, Singh AK, Pal MK (2009) Nano level detection of Cd(II) using poly(vinyl chloride) based membranes of Schiff bases. Anal ChimActa 634: 36-43.

39. Gupta VK, Rastogi A (2008) Biosorption of lead(II) from aqueous solutions by non-living algal biomass Oedogonium sp. and Nostoc sp.--a comparative study. Colloids Surf B Biointerfaces 64: 170-178.

40. Gupta VK, Rastogi A (2008) Equilibrium and kinetic modelling of cadmium(II) biosorption by nonliving algal biomass Oedogonium sp. from aqueous phase. J Hazard Mater 153: 759-766.

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