

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 spectrophotometry) 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 sulfhydryl containing (fentiapril, pivalopril, zofenopril and alacepril etc.), dicarboxyl containing (lisinopril, benazepril, quinapril, perindopril, indopril, pentopril, indalaprill, 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 $\mu\text{g mL}^{-1}$ with a limit of detection [S/N=2] of 0.18 $\mu\text{g mL}^{-1}$. 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 C₁₈ 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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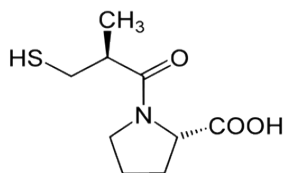


Figure1: Captopril.

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 H₂ 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.

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