Egyptian Journal of Chemistry

http://ejchem.journals.ekb.eg/

Cathodic Stripping Voltammetric Determination of Lisinopril in Dosage Forms and Biological Fluids

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Abstract

Lisinopril (LSP) in pharmaceutical dosage forms and biological fluids was studied using the square wave cathodic stripping voltammetric method (SWCSV) at a carbon paste electrode (CPE). To maximize the method's circumstances, many parameters were defined. The linear concentration range of 3.53 – 44.17 ng/mL was effectively determined at ideal conditions of 0.08 M Britton-Robinson buffers (pH = 9.00) at accumulation times 15, 30 sec., and 2.64 – 44.17 ng/mL at 60 sec. With good results, the standard addition method was employed to determine LSP in pure solutions, tablets, and biological fluids. The proposed method is compared to the previously published standard method.

Keywords: Lisinopril, Cathodic Stripping Voltammetric, Dosage Forms; Biological Fluids.

1. Introduction

LSP was developed and discovered by the Dohme Research & Merck sharp laboratories [1]. It is a chemically known as an angiotensin-converting enzyme (ACE) inhibitor with the formula (a): (N- {N-[(S)-1-carboxy -3-phenypronyl) L -lysyl]-L- proline dehydrate. or (b): L- proline (N- [N- (1-carboxy -3-phenypronyl) L- lysyl dihydrate (S).

In both industrialized and developing countries, hypertension is a severe health issue [2], with cardiovascular disease, stroke, and renal failure are just a few of the consequences that can occur[3]. As a result, antihypertensive medication therapy is a critical area of medicine, and inhibitors of the angiotensin-converting enzyme are among the pharmaceuticals now in use (ACE). After a myocardial infarction, LSP is used to manage hypertension and prevent heart failure[4]. Various pharmacopeias have officially listed the medicine and its tablets[5-7], which suggests that they be quantified using the HPLC method at 50°C with phosphate solution/acetonitrile (96:4 v/v) as the mobile phase. Many analytical techniques such as HPLC[8-10], HPTLC[11, 12], GC [13, 14], micellar electrokinetic chromatography [15], capillary electrophoresis [16, 17], polarography [18, 19], chemiluminescence [20, 21], radioimmunoassay [22], fluorometry [23] and fluorimmunoassay [24] have been used to detect LSP in biological fluids and/or pharmaceutical formulations.

Many medicinal preparations may be determined using stripping voltammetry, which is a fairly sensitive approach. By integrating the accumulation process with voltage scanning measurements, it achieves low detection of traces of organic substances[25, 26]. Because of its appealing features, carbon paste electrodes are frequently utilized as working electrodes for voltammetric studies. In comparison to other solid electrodes, these electrodes have comparatively low background currents over a wide range of potentials from an analytical standpoint.

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Receive Date: 06 November 2021, Revise Date: 30 November 2021, Accept Date: 08 December 2021, First Publish Date: 08 December 2021
DOI: 10.21608/EJCHEM.2021.104642.4835

Furthermore, the new ability of their surface, as well as their great versatility and ease of modification [27, 28]. This work is a continuation of our drug analysis research employing mercury and modified carbon paste electrodes[29-31].

The goal was to use a paraffin oil bare carbon paste electrode CPE to study the square wave cathodic stripping voltammetric method for determining LSP in dosage forms (tablets) and biological fluids (spiked and genuine urine sample).

2. Experimental

2.1. Apparatus

EG, G Princeton Applied Research (PAR Princeton, NJ, USA) Model 273 was used for all voltammetric investigations. The model 270250 electrochemical software version 4.30 controls a potentiostat. A three-electrode cell was used, with a hand-made functioning carbon paste electrode created using this procedure[27], Using a Teflon-coated bar and a magnetic stirrer, an Ag/AgCl (saturated KCl) reference electrode and platinum wire were obtained at around 400 rpm (kikA Labortechinik, Germany).

2.2. Reagents and Materials

Lisinopril LSP (see Fig. 1) (Merck, 6 October City, Egypt) stock standard bidistilled water was prepared at 25ºC and maintained in a volumetric flask (brown). Serial dilution of stock standard solution yielded lisinopril working standard solutions every day

Pharmaceutical formulations: Zestril® protect tablet (SEDICO, 6 October City -Egypt). To contain 5 mg lisinopril (anhydrous) per tablet, Healthy participants who had previously taken the medication had their urine samples obtained.

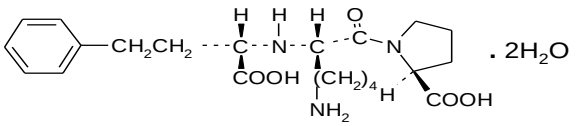

Fig. 1: Lisinopril Structure

2.3. General Analytical procedure:

The preconcentration step was completed by immersing the carbon paste electrode in stirring 15.0 ml sample solution for a period of time at a potential range of [– 0.5 – (-1.0V)], then stopping the stirring and waiting 10 seconds to settle the solution and reduce the background current before recording a square wave voltammogram in the negative potential direction. For each measurement, a fresh carbon paste surface was used.

30 mL urine sample (containing 0.883 ng mL of drug in spiked urine and an unknown amount of excreted drug in real urine samples) was added to 15.0 mL 0.08 M Britton – Robinson buffer pH = 9.0 to determine lisinopril in biological fluids (spiked and real urine samples). The square wave voltammogram was recorded while the solution was agitated at 400 rpm under open-circuit conditions. In addition, 10 medication tablets were weighed, ground, and thoroughly combined in a small dish. A quantity of 0.097 g was weighed, sonicated, and filtered in 100.0 ml of bidistilled water. The clear product solution was put into a calibrated flask and topped up with bi-distilled water to make it volume. The measurement cell was then filled with 30 liters of each solution. The square wave voltammogram was recorded in a negative potential direction in all tests. Table 1 shows the optimal operating parameters used for LSP determination by SWCSV using CPE.

Table 1 shows the optimal operating parameters chosen for determining LSP using SWCSV at CPE.

Parameter	Selected value
Accumulation potential	-0.5 V
Final potential	-1.0 V
Modulation time	10 S.
Frequency	50 HZ
Scan increment	2 mV
Accumulation time	Various
pH	9.0
Buffer type	0.08M Britton-Robinson universal buffer

3. Results and Discussion

3.1 Effect of buffer type, pH, and Ionic strength

The effect of buffers on the analytical signal was investigated (acetate, citrate, phosphate, HCl – sodium acetate, and Britton – Robinson universal). When deciding on the sort of buffer, both the peak height and peak form were taken into account. A study of the effect of medium ionic strength on the voltammetric peak indicated that 0.08 M Britton – Robinson buffer produced the lowest background current, the best curve, and the highest peak. The influence of pH on LSP reduction at CPEs was investigated using square wave voltammetry spanning the pH range 2.8–12.0 at a concentration of 8.83 ng mL LSP, as shown in Fig. 2. At pH = 2.8, a modest current was found, which steadily rose up to pH = 9.0, which was employed in

all measurements. With increasing the pH over 9.0, the cathodic potential of LSP shifts linearly towards fewer negative values. For a 30 s preconcentration time, the effect of ionic strength on the efficiency of accumulation 8.83 ng mL LSP was investigated (Fig. 3). The ionic strength varied depending on the pH (9.0) concentration, which ranged from 0.02 to 0.15 M in the specified buffer type. The findings revealed that increasing ionic strengths had a significant impact on the amount of accumulation. This demonstrated that the drug accumulating at the electrode surface was mostly an electrostatic mechanism.

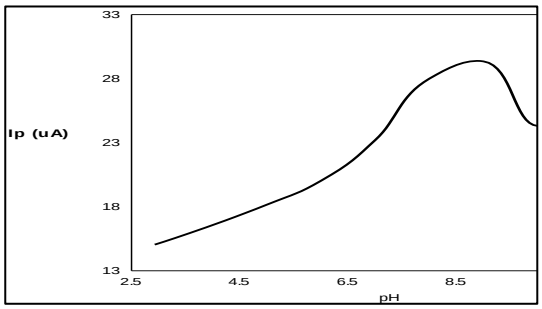

Fig.2. a plot of Ip versus different Britton -Robinson universal buffer solutions pH values at 8.83ng\mL of LSP.

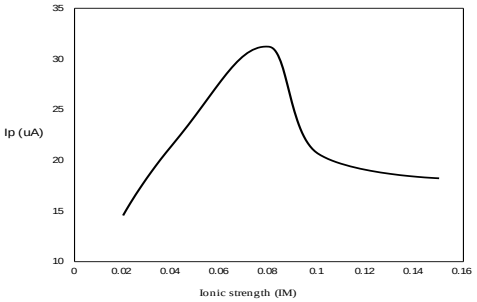

Fig.3. a plot of Ip versus different ionic strengths of pH = (9.0) at 8.83 ng\mL of LSP.

3.2. Influence of accumulation potential:

The effect of accumulation potential on peak current was also explored at 30 s preconcentration time 8.83 ng/mL of LSP solution (pH = 9.0) in a potential range of 0.0 to -5.0 V. Experiments have shown that when the beginning potential is shifted negatively from -0.3 to -0.5 V, the peak current of LSP increases, and when the starting potential is shifted negatively from -0.5 to -1.0V, the peak current decreases. At the starting potential - 0.5 V - the peak current reaches its greatest value, which was employed in the subsequent testing of different decencies.

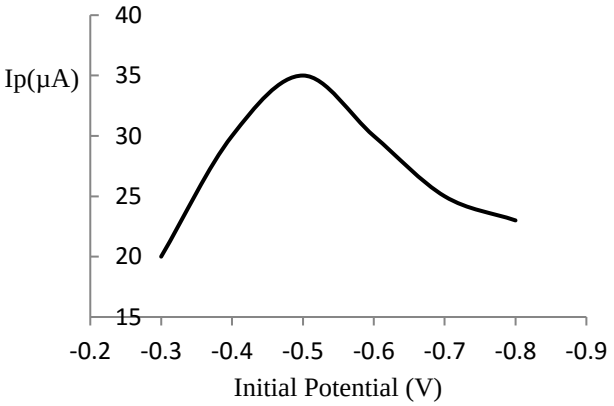

Fig.4. plot of Ip versus different initial potentials at 8.83 ng\mL of LSP.

3.3. Accumulation Time and Reproducibility Effects:

For five levels of LSP concentration (0.0883, 0.883, 8.83, 88.3, and 883.04 ng/mL), the relationship between peak current and accumulation time was investigated. For all concentrations, the stripping signal increased linearly with increasing accumulation time up to 90 s. Fig.5. The adsorption process was shown to be repeatable after three trials with 8.83 ng/mL and accumulation times of 60 seconds.

Table 2. The linear regression of calibration curves for lisinopril is characterized in 0.08 M Britton-Robinson buffer (pH= 9.0) using SWCS at different deposition times.

Deposition time (s)	Linearity range (ng/mL)	Correlation coefficient	Slope (µA/ (ng mL^{-1}) ± SD	Intercept (µA) ± SD
15	3.53 – 44.15	0.9973	11.50 ± 1.85	19.05 ± 1.51
30	3.53 – 44.15	0.9994	11.47 ± 1.38	22.78 ± 1.68
60	2.65 – 44.15	0.9995	11.73 ± 1.33	26.56 ± 1.23

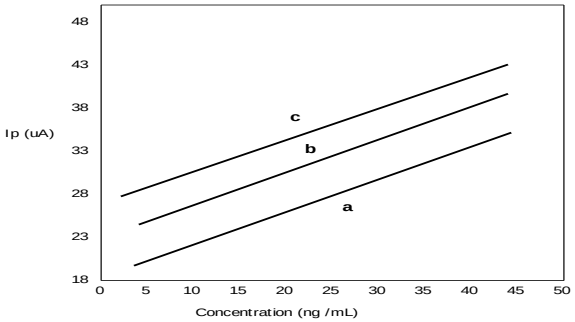

Fig.5. Current - time plot at different concentration s of LSP at optimum condition
(a) 0.0883 ng /mL, (b) 0.883 ng/mL (c) 8.83 ng/mL (d) 88.3ng/mL and (e) 883 ng /mL of LSP

3.4. Concentration and Detection Limit Effects

Using the SWCSV approach, the square wave cathodic stripping peak for LSP produces a well–defined concentration dependence. The effects of varied preconcentration durations on calibration plots over the LSP concentration range were explored. However, with the stirring at – 0.5 V, the concentration range was 3.532 – 44.17 ng/mL at 15, 30, and 2.64 – 44.17 at 60s; the data are given in Fig.6. On increasing the LSP concentration, one peak was seen at (- 672 mV), as shown in Fig. 7. The linearity ranges, on the other hand, are shown in Table 3.The detection limits were estimated as 3σ/b where b is the slope and σ = standard deviation (SD) of the intercept [27, 30, 31], 10/ b was used to calculate quantitative limitations. The results reveal that LSP can be detected at concentrations of 210–10 M (0.0883ng/ml) using the suggested approach, with a relative standard deviation of 0.01 percent and a correlation coefficient of 0.9933 (n = 5) at accumulation time of 60 seconds. Table 4 shows a comparison of the suggested Electrode and other published techniques.

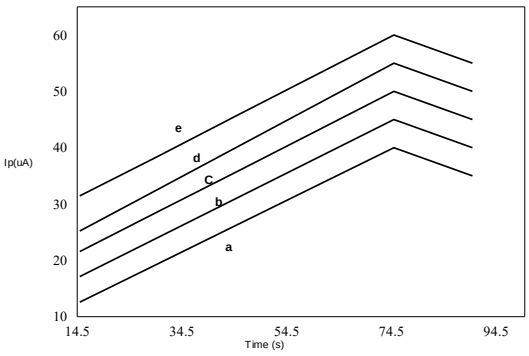

Fig.6. Plot of Ip versus concentrations of LSP using 0.08 M of Britton - Robinson buffer (pH = 9.0) at different accumulation times :(a) 15 s (b) 30 s (c) 60

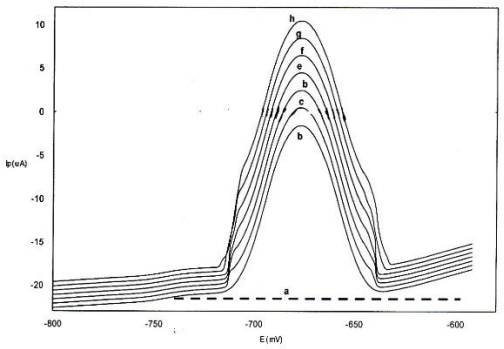

Fig7. Typical SWCS voltammograms of Lisinopril under optimum experimental condition at 30s. (a): residual current, (b) 3.53 ng/mL, (c): 4.42 ng/mL, (d): 8.83 ng/mL, (e) 22.07ng/mL, f)30.91 ng/mL, (g): 39.73 ng/mL and (h): 44.51 ng/mL.

Table 3. Comparison of proposed Electrode and other reported methods

No.	Electrode	Detection Limit	Method
This work	Carbon paste electrode	**2×10^{-10} M (0.08 ng/ml)**	*Square wave stripping voltammetry*
[32]	*PANI-CeO_2 coated gold sensor*	*36*$\times10^{-10}$ M	*Square wave stripping voltammetry*
[33]	modified glassy carbon electrode (β-CD/GO-SO_3H/GCE)	11×10^{-6}M	*Square wave stripping voltammetry*
[34]	(HMDE) Hanging mercury Dropping Electrode	21.5×10^{-10} M	differential pulse anodic stripping voltammetry
[35]	Hanging mercury Electrode (HMG)	4.54×10^{-8} M	Polarography

Table4. The collected data for effect of interference on peak of 1x10-6 mol dm3 lisinopril.

Interferent	Concentration mol dm^{-3}	Effect.
Glycine	1×10^{-6} $1x10^{-5}$	18.54 % 20.14%
DL-alannine	$1\ x10^{-6}$ $1x10^{-5}$	No effect.
DL- Valine	$1\ x10^{-6}$ $1x10^{-5}$	No effect 5.94 %
Ascorbic acid	$1x10^{-6}$ 1x10-5	No effect 8.87%
Urea	$1\ x10^{-6}$ $1x10^{-5}$	4.28 % 9.38 %
Fe (III)	$1x10^{-6}$ $1x10^{-5}$	7.72 % 20.31%
Cu (II)	١x10^{-6} ١x10^{-5}	No effect.
Cd (II)	١x10^{-6} ١x10^{-5}	No effect.

3.5. Effect of Interferences:

To test the efficiency and selectivity of the proposed analytical method for Pharmaceutical formulation, a synthetic solution containing a fixed amount of LSP (110 -6 mol dm-3) was spiked with an excess amount of some common excipients and additives (10:1) used in Pharmaceutical preparation (e.g., Glycine, DL-alanine, DL-valine (amino acids), Ascorbic acid, Urea, Fe (III), Cu(II (II).

3.5.1. Effect of Some Amino Acids:

Different concentrations of DL- valine, DL-alanine, and Urea ranged from $1x10^{-6}$ - 1×10^{-5} mol dm^{-3} were added to $1x10^{-6}$ LSP, and then the voltammograms were recorded. The results showed no interference. The addition of 1×10^{-6} - 1×10^{-5} mol dm^{-3} from Glycine on LSP showed an increase in the current peak by about 18.54 -20.14 %.

3.5.2 Effect of Ascorbic acid

In the presence of Ascorbic acid, there is no significant interference in the peak current response of LSP.

3.5.3. Effect of Metal ions:

The effects of some metal ions such as Fe (III), Cu (II), and Cd (II) on the peak response of $1x10^{-6}$ mol dm^{-3} of LSP were studied. Different concentrations of Fe (III), Cu (II), and Cd (II) ranged from 1×10^{-6} - 1×10^{-5} mol dm^{-3} were added. In Fe (III), the peak current response decreases by 7.72 - 20.31 %. But in the case of Cu (II) and Cd (II), no significant interference on the peak current response of LSP was observed. The results are shown in Table 5.

3.6 Analytical applications

Lisinopril was successfully determined in pharmaceutical preparations, spiked urine samples, and genuine urine samples using the proposed approach.

3.6.1. Pharmaceutical Preparations

The tablet sample's square wave voltammogram was recorded after preconcentration for 15, 30, and 60 seconds in 0.08 M Britton-Robinson buffer pH (9.0). The conventional addition method [36] was used to determine the tablet's content in the cell. The peak current was increased linearly from 0.883 to 4.41ng/mL at 15 s and 0.883 to 3.53 ng/mL at 30, 60 s, fitting equations Y= 0.76x+ 20.05 with correlation coefficient 0.9937, Y= 0.66x +21.26 with correlation coefficient 0.9944, and Y= 0.71x+ 20.73 with correlation coefficient 0.9962 at 15, 30, and 60 s, respectively. The acquired values were statistically compared to the official technique using the researched t-test for accuracy and the f-test for precision. [28, 37] .

3.6.2. Real urine samples:

The proposed method was also used to determine LSP in human urine samples from healthy volunteers who were given a single oral dose of Zestril® pill of 5 mg. Individual urine samples were taken up to 24 hours after the tablet was administered, and urinary volumes were measured. Excipients did not interfere with the separation of LSP from organic components [50]. Table 6 summarizes the findings, which reveal that only a small portion of an administered dose is eliminated in the urine. Furthermore, the results revealed a high correlation coefficient ($r > 0.9992$) and a high correlation coefficient ($r > 0.9992$). Also, the results of the suggested voltammetric approach, in which an unmodified oral dose is eliminated in human urine in the first 24 hours[38].

3.6.3. Accuracy and Repeatability:

Using the proposed method for the analysis of LSP in dosage forms, the correlation coefficient of spiked and real urine samples in tables (5, 6) was 0.9962, 0.9937, and 0.9985 percent at 60 s, the standard deviation of both slopes was 0.01, 0.91, and 0.03 percent at 60 s, and the intercept was 20.73, 34.22, and 45.30 at 60 s, indicating adequate precision.

Table 5: Analysis of lisinopril in dosage from (Zestril® tablet)

Sample	Accumul -ation Time (s)	Detection limits (ng/mL)	Linearity range (ng/mL)	Slope (µA/ ng mL^{-1}) ± SD	Intercept (ng/mL) ± SD	Correlation coefficient
Zestril® tablet [a]	15	0.35	0.883 – 4.41	0.76 ± 0.04	20.05 ± 0.43	0.9937
	30	0.12	0.883 – 3.53	0.66 ± 0.02	21.26 ± 0.36	0.9944
	60	0.24	0.883 – 3.53	0.71 ± 0.07	20.73 ± 0.31	0.9962

Table 6 Analysis of lisinopril spiked and real urine samples:

Sample	Accumulation Time (s)	Detection limits (ng/mL)	Linearity range (ng/mL)	Slope (µA/ ng mL^{-1}) ± SD	Intercept (ng/mL) ± SD	Correlation coefficient
Spiked urine sample	15	0.04	0.088 – 0.44	24.39 ± 0.33	30.19 ± 0.23	0.9972
	30	0.03	0.088– 0.35	22.18 ± 0.83	28.76 ± 0.20	0.9984
	60	0.02	0.088 – 0.35	33.20 ± 0.91	34.22 ± 0.18	0.9937
Real urine sample after 12h	15	0.34	8.83 – 20.76	0.32 ± 0.06	32.78 ± 0.08	0.9999
	30	0.32	8.83 – 32.45	0.41 ± 0.03	36.24 ± 0.09	0.9990
	60	0.31	8.83 – 44.15	0.52 ± 0.03	45.30 ± 0.11	0.9985
Real urine sample after 24 h	15	0.65	0.883 – 0.83	0.472 ± 0.04	40.20 ± 0.18	0.9987
	30	0.46	0.883 – 2.50	0.581± 0.01	44.51 ± 0.20	0.9985
	60	0.43	0.883 – 4.16	0.846 ± 0.05	42.24 ± 0.28	0.9961

4. Conclusion

In dosage forms and biological fluids, the SWCSV method with carbon paste electrode for the quantitative detection of LSP proved straightforward and extremely sensitive (spiked and real urine samples). In pure solution, a detection limit of 2x10-10 M (0.08 ng/mL) was obtained at 60 s accumulation time with a standard deviation of 1.33 percent. As a result, it has certain notable advantages over existing approaches in terms of sensitivity, speed, and detectability. Furthermore, it can be used to determine LSP in urine without the need for extraction.

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