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New Method for Spectrophotometric Determination of Lisinopril in Pure Form and in Pharmaceutical Formulations

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Abstract

An accurate, simple, fast and cheap spectrophotometric method has been developed for the determination of lisinopril in pharmaceutical pure and dosage forms. The method is based on the reaction of Alizarin with primary amine present in the lisinopril in the presence of 80% ethyl alcohol. This reaction produces a complex Red colored product which absorbs maximally at 434 nm. Beer's law was obeyed in the range of 4.415-300.23 µg/mL with molar absorptivity of 1.619×10^3 L $mole^{-1}cm^{-1}$ Sandell's sensitivity 0.272 $\mu g.cm^{-2}$. The effects of variables such as temperature, heating time, concentration of color producing reagent, and stability of color were investigated to optimize the procedure. The results are validated statistically. The proposed method was applied to commercially available tablets, and the results were Pharmaceutical formulations..

Keywords: Lisinopril; Alizarin; Spectrophotometry

Introduction

Lisinopril (S)-1-[N-[1-(ethoxycarbonyl)-3 phenylpropy1]-L-alanyl]-L-proline are Angiotensin-Converting Enzyme (ACE) has been widely used for the treatment of hypertension and heart failure. The analytical profiles of the drugs have been reviewed [1,2]. Enalapril maleate has been assayed by spectrophotometric [3-7], potentiometric [8,9], HPLC [10-14] and ^{1}H-NMR [15] methods. In tablets, lisinopril dihydrate has been determined by GC [16,17], spectrophotometric [18-21], colorimetric and fluorimetric [17] procedures. Capillary electrophoresis has been used to separate closely related ACE inhibitors and to quantities them in their pharmaceutical preparations [22,23] and stripping voltammetric method [24]. Quite a few researchers have dealt with the development of methods that quantify lisinopril in biological media. Methods that include Polarographic, spectrophotometric [25,26] even today because of its inherent simplicity, sensitivity, visible spectrophotometry is the technique of choice selectivity, accuracy, precision and cost-effectiveness. LNP in pharmaceuticals has been assayed based on reaction with N-bromosuccinimide and the charge transfer complexation reaction [27].

Sodium hypochlorite-phenyl hydrazine [7], 1-fluoro-2,4-dinitrobenzene [28] and ascorbic acid [29]. Most of these methods employ organic solvents as reaction medium, require longer heating times, use expensive reagents, and/or are less sensitive (Table 1). Of the various regents used in the assay of LNP in pharmaceuticals, ninhydrin has been employed by quite a few researchers. For example, Rehman et al. [29] used ninhydrin in DMF medium for kinetic spectrophotometric determination of LNP by initial rate and fixed-time procedures. Both methods showed linear response over 50 µg/mL LNP. The reagent in the same organic solvent medium (DMF) but involving heating was used by Raza et al. [30] to quantify LNP in 10-150 µg/mL range. Rajashekaran and Udayavani [31] assayed LNP in the 10-40 µg/mL range by measuring the coloured product formed between ninhydrin and LNP in acetone medium at elevated temperature. The common feature of all the three methods using ninhydrin [29-31] is the use of organic solvent as the reaction medium which quite often is undesirable.

Experimental

Reagents and apparatus

-Lisinopril (100.03% pure reference substance, produced by Lupin, India)

-Stock solution (1 mg/mL): 100 mg lisinopril was dissolved in 20% ml water and 80% ethyl alcohol in a 100 mL volumetric flask.

-Stock solution (1 mg/mL): 100 mg Alizarin was dissolved in 20% ml water and 80% ethyl alcohol in a 100 mL volumetric flask.

Buffer solution

Different buffer Solution used 0.2M Acetate buffer, 0.2M Ammonium buffer, 0.2M borate buffer and 0.2M (pH=2.0-12.0) universal Britton buffer solution.

-$FeCl_3$ Solution

Ferric chloride solution 1% dissolved in alkaline weak medium from -Ammonium hydroxide (1.0×10^{-4}M).

-Analytical balance

-UV-Vis Spectrophotometer Model SP3000 OpTMA from Korea

Principle of the method

We studied the best volume and concentration of the Lisinopril, Alizarin, universal Britton buffer at pH=8.0, Ferric chloride solutions on the formation red complex, and added 0.4 ml Ferric chloride solution 1% dissolved in weak NH_4OH determined at λ_{max}=434 nm.

Lisinopril-Alizarin method

To different aliquots of Alizarin solution corresponding to 0.5-7.0 ml^{-1} was transferred into a series of 10 ml volumetric flasks. 0.5-6.0 ml of Lisinopril solution and Universal buffer Britton solution pH=8.0 were added to each flask diluted to volume with 1:2 H_2O:C_2H_5OH. The solution was heated in a water bath at 40 ± 1°C (5 min), respectively. The mixtures were cooled and the volume was completed to 10 mL with mixture solvent measured after 10 min of mixing against reagent blank [32,33].

Analysis of pharmaceutical formulations

20 tablets were accurately weighted finely powdered and dissolved

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into sufficient volume of mixture solvent. The mixture was stirred well and filtered through Whatman filter paper No. 42 and the filtrate was diluted with mixture solvent added universal Britton buffer pH=8.0 and 0.4 ml $FeCl_3$ 1% in alkali weak medium from NH_4OH (1×10^{-4} M) in 10 ml volumetric flask. The mixtures were cooled and the volume was completed to 10 mL with mixture solvent and absorbance was measured after 7 min of mixing against reagent blank [34].

Results and Discussion

Preliminary investigations have been shown that Lisinopril react with Alizarin in buffer Britton solution 0.1M at pH=8.0 in presence catalytic reagent as ferric chloride 0.40 ml with Concentration (1×10^{-3}M) to give red coloured complex which absorbs at λ_{max}=434 nm as shown in Figure 1 [30,35].

The optimum reaction conditions for quantitative determination of the ion pair complexes were established via number of preliminary experiments. Several parameters such as amount of buffer added, reagent concentration, temperature, heating time, sequence of addition and color stability. It was observed that complete color development was attained at 40 ± 1°C (7 min) (Figure 2). The effect of Alizarin concentration on the color development was investigated 3 ml of Alizarin reagent produced maximum color intensity (Figure 3) [36].

Stoichiometric relationship

A series of solutions were prepared by mixing equimolecular proportions while keeping the total molar concentration constant in all cases and reagent concentration within range 100-800 µM or complex Lisinopril-Alizarin (LNP-ALZ) solutions changed the volume of Lisinopril (VLNP) and Volume of Alizarin was kept constant (VALZ) within range from (1.0-8.0 ml) and the total volume was kept constant in all these series are equal to (LNP+ALZ=9.0 ml) The absorbance values were then plotted against the mole fraction (VLNP)/(VLNP+VAZ) or VAZ/(VLNP+VAZ). The stoichiometry of the reaction between Lisinopril and Alizarin at selected conditions (Figure 4) was observed. The stoichiometry of the reaction between drugs and at the selected conditions was established by the molar ratio method. In this method 0.4 mL of 1% $FeCl_3$ in alkali weak from NH_4OH medium is and 0.05 ml buffer Universal Britton pH=8.0 kept constant and variable concentrations of drugs (5.0×10^{-4}M) were added [34,35]. The absorbance was measured at λ_{max} against blank solution prepared in the same manner. The absorbance values were then plotted against the molar ratio [Alizarine]/[Lisinopril] (Figure 5).

Developed color was stable up to 72 hours which was considered sufficient time for an analysis (Figure 6). Beer's law was obeyed in the range of 4.415-300.23 µg/ml. More than 99% recover of Lisinopril was obtained in the presence of possible excipients and ingredient in lisinopril formulations (Tables 1 and 2) [35].

Optical characteristics and statistical data for the regression equation of the proposed method are given in Table 1. Commercial formulation was successfully analyzed for the lisinopril by the proposed method and the results are compared with reference method (20) (Table 3) did not exceed the theoretical values, which indicates the absence of any difference between the methods compared. The proposed method gives good results for lisinopril in pure and pharmaceutical formulations [35,36].

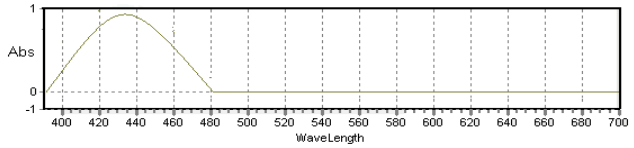

Figure 1: Absorption spectrum of lisinopril-alizarin formation.

Conclusion

The proposed method for the estimation of Lisinopril using

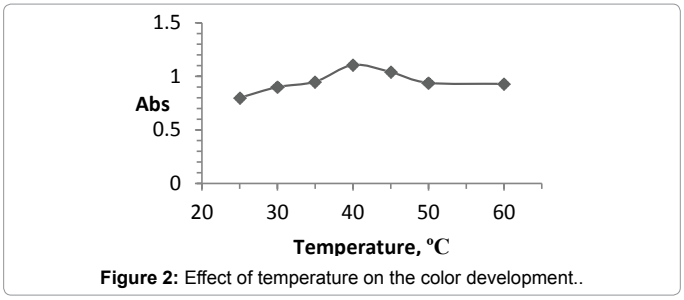

Figure 2: Effect of temperature on the color development..

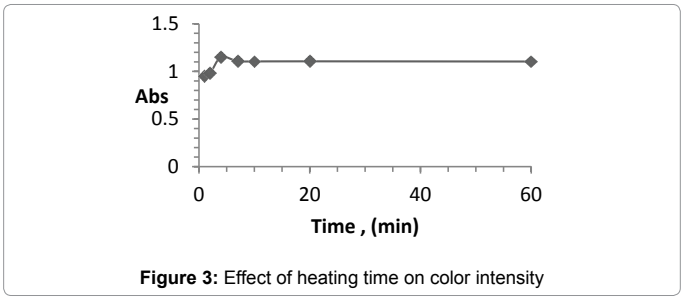

Figure 3: Effect of heating time on color intensity

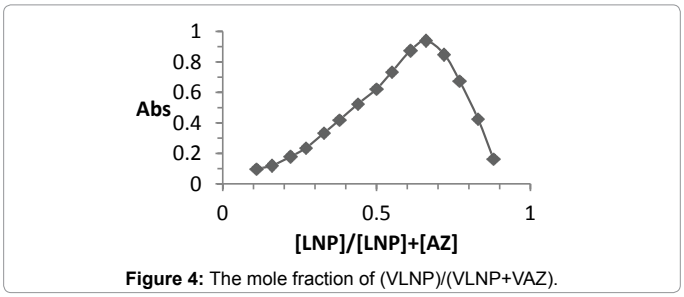

Figure 4: The mole fraction of (VLNP)/(VLNP+VAZ).

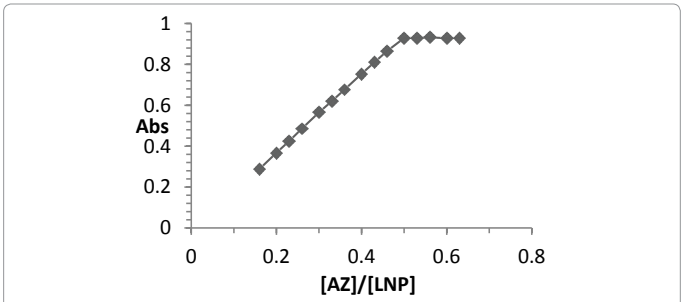

Figure 5: The molar ratio of [Alizarin]/[Lisinopril].

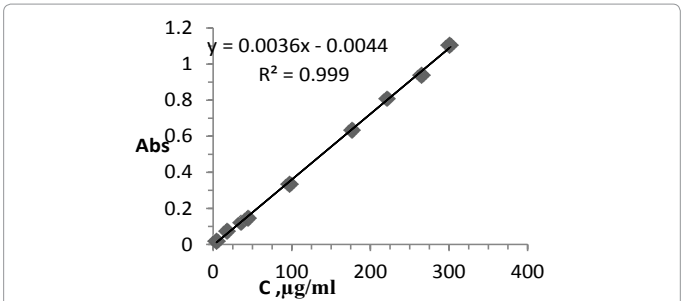

Figure 6: The molar ratio of [Alizarin]/[Lisinopril].

Drug samples (µg/ml) Amount taken	Found (µg/ml)	Stander devation SD	R.S.D %	Detection limit (µg/ml)	Analytical Error SD/ $(n)^{1/2}$	Relative Recovery (%) R
4.415	4.503	0.155	3.44	4.503 ± 0.191	0.069	101.99
17.666	17.723	0.150	0.84	17.723 ± 0.185	0.067	100.32
35.321	35.414	0.164	0.46	35.414 ± 0.202	0.073	100.26
44.152	44.240	0.174	0.39	44.240 ± 0.213	0.077	100.19
97.134	97.276	0.217	0.22	97.276 ± 0.269	0.097	100.14
176.608	176.801	0.272	0.15	176.801 ± 0.335	0.121	100.10
220.760	220.602	0.281	0.12	220.602 ± 0.347	0. 125	99.92
264.912	264.802	0.275	0.10	264.802 ± 0.338	0.122	99.95
300.233	300.116	0.277	0.09	300.116 ± 0.341	0.123	99.96

Five independent analyses

Table 1: Test of precision and accuracy of the proposed method.

Parameter	Value
λmax	432 nm
Beer's law limit (µg/mL)	4.415-300.233
Molar abs orptivity (L $mole^{-1}$ cm^{-1})	1.619×10^3
Sandell's s ens itivity (µg/mL per 0.001 A)	0.273
Regres s ion equation (Y*)	
Slope (m)	0.003
Intercept (c)	0.004
Correlation coefficient	0.999
Relative Standard Deviation**	3.44
Limit of Detection (µg/mL)***	2.08
Limit of quantitation (µg/ml)	6.94

*Y=mx+C; Where x is the concentration of analyte (µg/mL) and Y is absorbance unit; **: Calculated from six determinations; ***: Calculated as per ICH guidelines

Table 2: Optical characteristics and statistical data for the regression equation of the proposed method.

S. No.	Reagents	λ_{max}	Linear Dynamic µg mL^{-1}	Reaction time	Molar absorptivity (ε)$Lmol^{-1}cm^{-1}$	LOD	LQP	References
1	Alizarine	432	4.415-300.23	7 min at 40°C	1.619×10^3	-	-	This Work
2	Dichlone	580	40-120	10 min at rt	2.6×10^3	-	-	[20]
3	Acetylacetone + Formaldehyde	356	6.0-42.0	10 min at 100°C	9.62×10^3	-	-	[20]
4	2,4- dinitrofluorobenzene	400	8.0-120.0	30 min at 80°C	-	1.16	3.87	[28]
5	Phenylhydraizine	362	40-200	20 min at 85°C	-	-	-	[8]
6	7-chloro-4-nitrobenzo-2-oxa-1, 3-diazole	470	20.0-560	30 min at 70°C	-	0.27	0.891	[36]
7	Ninhydrin	410	10-40	10 min at 100°C	1.845×10^3	-	-	[31]
8	As corbic acid method	530	5-50	15 min at 100°C	4.548×10^3	0.349	1.152	[29]
9	Ninhydin kinetic method							
a)	Initial rate method	595	10-50	Immed iately after mixing the reagent at rt	-	0.118	0.389	[29]
b)	Rate cons tant method	595	10-40	-do-	-	2.839	9.369	[29]
c)	Fixed time method	595	5-50	10 min at rt	4.70×10^3	1.03	3.399	[29]

rt: Room temperature

Table 3: Comparision of the proposed methods with existing spectrophotometric methods for the assay of lisinopril in pharmaceutical formulations.

Alizarin is advantages over many of the reported methods. The methods are rapid, simple and have good sensitivity and accuracy. Proposed method makes use of simple reagent, which an ordinary analytical laboratory can afford. The high recovery percentage and low relative Standard deviations reflect the high accuracy and precision of the proposed method. The method are easy, applicable to a wide range of concentration, besides being less time consuming and depend on simple reagent which are available, thus offering economic and acceptable method for the routine determination of Lisinopril in its formulations.

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