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ESTIMATION OF LOSARTAN POTASSIUM IN PHARMACEUTICAL FORMULATIONS: APPLICATION TO CONTENT UNIFORMITY TESTING

Nief Rahman Ahmed*[1], Mohammad Jassim Essa[2] and Muna Sobhi Abdullah[3]

[*1]Department of Environmental Technology, College of Environment, University of Mosul-Iraq.

[2]Nineveh Health Directorate, Oncology and Specialized Nuclear Medicine Hospital Mosul-Iraq.

[3]Department of Chemistry, College of Science, University of Mosul, Iraq.

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***Corresponding Author**
Nief Rahman Ahmed
Department of Environmental Technology, College of Environment, University of Mosul-Iraq.

ABSTRACT

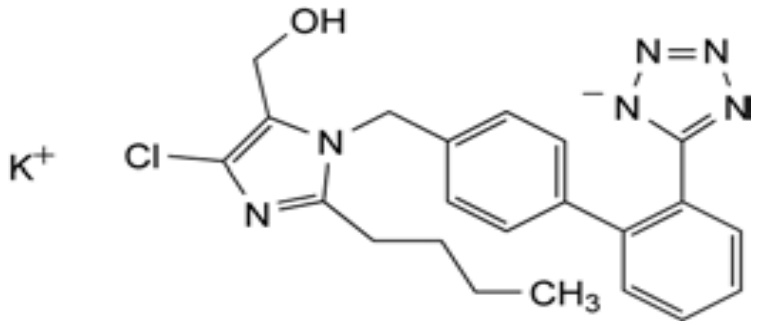
A simple, accurate, precise, rapid, economical and sensitive Uv spectrophotometric method has been developed for the estimation of losartan potassium in pharmaceutical preparations and environmental wastewater samples, which shows maximum absorbance at 230 nm in distilled water. Beer's law was obeyed in the range of 2-16 µg/ ml,with molar absorptivity of $2.706x10^4$ $L.mol^{-1}.cm^{-1}$, relative standard deviation of the method was less than 1.7%, and accuracy (average recovery %) was 100 ± 1.0. No interference was observed from common excipients and additives often accompany with losartan potassium in pharmaceutical preparations. The method was successfully applied to the estimation of losartan potassium in pharmaceutical formulations (tablets) and content uniformity testing. The proposed method was validated by sensitivity and precision which proves suitability for the routine analysis of losartan potassium in true samples.

KEYWORDS: losartan potassium, Estimation, Pharmaceutical Preparations, Content uniformity.

INTRODUCTION

Losartan potassium is chemically known as mono Potassium 5-[4′-[[2-butyl-4-chloro-5-(hydroxymethyl)-1H-imidazol-1-yl]methyl]biphenyl-2-yl]tetrazol-1-ide, as shown below

(Figure.1)[1] Losartan Potassium is an Angiotensin II (AT_1) receptor antagonist with a strong antihypertensive activity agent. It is used in the management of hypertension and heart failure.[2,3]



Molecular formula: $C_{22}H_{22}ClKN_6O$ 461.0

Figure 1: Chemical structure of losartan potassium.

Analytical procedures for the estimation of losartan potassium include titrimetric method,[1] various spectrophotometric methods,[4-7] HPLC,[8-11] differential pulse voltammetry,[12] LC-MS/MS[13] fluorometry method.[14] These methods are required expensive or sophisticated instruments and not simple for routine analysis. The present paper reports the development of a new UV method for estimation of losartan potassium in pharmaceutical formulations (tablets) and content uniformity testing

EXPERIMENTAL

Apparatus

Shimadzu UV- 1700 pharm aspect (double beam) spectrophotometer with 1.0 cm quartz cells was used for absorption measurement.

Reagents

All chemical used were of analytical or pharmaceutical grade and losartan potassium standard material and pharmaceutical preparations (tablets) was provided from pioneer company for pharmaceutical industries –Iraq. Distilled water was used as a solvent.

Losartan potassium standard solution 100ppm

This solution was prepared by dissolving 10mg of losartan potassium in 100ml of distilled water in calibrated flask.

Estimation of absorption maxima

The standard solution of losartan potassium (10µg/ml) was scanned in the range of 200-350 nm which shows maxima located at 230nm. Figure 2: Therefore, 230nm wavelength was selected for the construction of calibration curve.

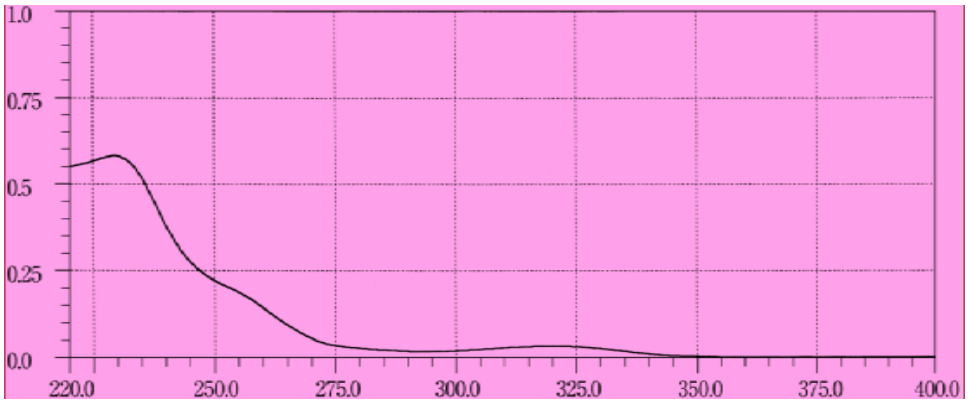


Figure 2: Absorption spectra of 10µg/ml losartan potassium against distilled water.

Recommended procedure

From the absorption maxima, calibration curve was prepared in the concentration range of 2-16 µg/ml. The absorbance was measured at 230 nm against distilled water as a blank. The concentration of the sample solution can be determined by using the calibration curve.

Procedures for pharmaceutical preparations (tablets):

To minimize a possible variation in the composition of the [Tablets 50mg/tab] were provided from pioneer company for pharmaceutical industries -Iraq. Ten tablets were weighed and amount of tablet powder equivalent to 10mg of losartan potassium was weighed accurately and dissolved in about 80 ml Distilled water, mixed well for 20min and then filtered. The filtrate was made up to 100mL with Distilled water. The final concentration is 0.1mg /ml. and aliquot of this solution was treated as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

RESULTS AND DISCUSSION

UV- Visible spectrophotometry is still considered to be a convenient and low cost method for the estimation of pharmaceuticals.[15-17] This method used for the estimation of losartan potassium in pharmaceutical preparations and environmental wastewater samples was found to be sensitive, simple, accurate, and reproducible. Beer s law was obeyed in the concentration range of 2-16 µg/ml Figure 3 with correlation coefficient of 0.9988, intercept

of 0.0159 and slope of 0.0587.The conditional molar absorptivity was found to be $2.706x10^4$ l/mol.cm.

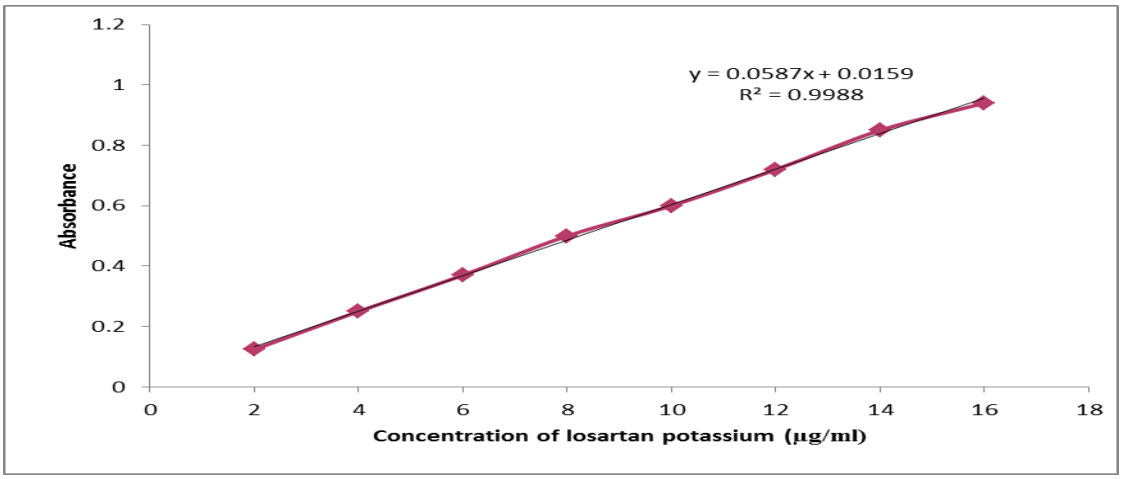


Figure 3: Calibration curve for losartan potassium.

The accuracy and precision of the method, a pure drug solution was analyzed at three different concentrations, each estimation being repeated six times. The relative error (%) and relative standard deviation values are summarized in (Table 1).From table 1 the values of standard deviation were satisfactory and the recovery studies were close to 100%,.The RSD% value is less than 1.6 indicative of accuracy of the method.

Table I: Accuracy and precision of the proposed method.

(Losartan potassium taken(µg/ml)	Er (%)[a]	RSD (%)
5	1.0	1.4
10	0.91	1.5
16	0.88	1.5

a: Mean of six estimations

The proposed method was compared with other reported UV spectrophotometric methods and found to be superior, (Table 2).

Table 2: Comparison of the existing UV spectrophotometric methods with the proposed method for losartan potassium.

Parameters	Method 1	Method 2	Method 3	Method 4
Ref	4	5	6	Proposed
λMax(nm)	208	227.4	240.8	230
Solvents	Distilled Water	0.01N HCl	Phosphate buffer of pH 7.4	H_2O
Linear range µg/ml	0.035-0.1	2.02-22.22	4-24	2-16
ε(l/mol.cm)	———	1.9235×10^4	2.199×10^4	2.706×10^4
RSD%	1.15	0.362	Less than 2	Less than 1.7
Application	Tablets	Tablets	Tablets	Tablets and content uniformity testing

Analytical application

The proposed method was satisfactorily applied to the estimation of losartan potassium in its pharmaceutical preparations Tablets. The results of the assay of the pharmaceutical preparations revels that there is close agreement between the results obtained by the proposed method and the label claim. as cited in Table 3.

Table 3: Estimation of losartan potassium formulations

Pharmaceutical formulations	Proposed method found*	Label amount	Recovery %
Losartan potassium tablet (Anglzaar-50)-Micro Labs Limited-India	49.6	50mg/tab	99.2

*Mean of ten estimations

Application of the proposed method to content uniformity[18-20]

Content uniformity or the Uniformity of dosage unit was defined as the degree of uniformity in the amount of active substance among dosage units. The risk assessment strategy underlying content uniformity testing is the assumption that some pre-specified limits exist where safety and efficacy outcomes may change if content uniformity fails. The proposed method proved to be suitable for the content uniformity test, where a great number of assays on individual tablets are required. Data presented in table 4 indicate that the proposed method cans accurately and precisely quantitative losartan potassium in its commercially available tablets. The mean percentage (with RSD) of the labeled claim found in ten tablets was 100.06(0.3132%) which fall within the content uniformity limits specified by the United State Pharmacopeia.[19]

Table 4: Content uniformity testing of tablets using the Proposed method.

Parameter	% of the label claim
Table No.1	100.5
Table No.2	99.7
Table No.3	100.4
Table No.4	100.3
Table No.5	99.6
Table No.6	100.1
Table No.7	99.8
Table No.8	100.2
Table No.9	100,2
Table N0.10	99.8
Mean(X)	100.06
%RSD	0.3132
Max. allowed unit value[19]	±15%

CONCLUSION

The developed method is found to be high sensitive, accurate, simple, precise and economical, and can be used for routine quality control analysis of losartan potassium in pure form, pharmaceutical formulations and application to content uniformity testing.

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