

Spectrophotometric Determination of Losartan Potassium and its Dosage Form by Bromothymol Blue and Phosphate Buffer

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Abstract: Simple, rapid and accurate, spectrophotometric method for the determination of losartan potassium by using bromothymol blue as a chromogen and phosphate buffer solution (pH 3-4) as a diluting agent was developed. The developed colour shows maximum absorbance at 620 nm and it was observed that the absorbance of different dilution from the plots the calibration curve between the concentrations in x-axis, absorbance at y-axis. The recovery studies were also carried out to ensure the reproducibility and repeatability. This recovery studies shows between 96.82-100.08% for the different formulation. Hence, it was concluded that the developed simple, precise and accurate method can be effectively used for the routine analysis of losartan potassium.

Keywords: Losartan potassium, Bromothymol blue, Phosphate buffer.

Introduction

Losartan potassium is an angiotensin II antagonist, chemically known as 2-butyl-4-chloro-1-(*p*-(*o*-1*H*-tetrazole-5-yl-phenyl)-benzyl)-imidazole-5-methanol monopotassium salt and it has the molecular weight of 460.01. Losartan potassium was previously assed by costly and complicated analysis technique like high equilibrium dialysis, HPLC, modulated scanning colorimetric and analysis the inhibitory effect of DUB 753 EXP 3174 on response to angiotensin II. It has less adverse effect when compared to other antihypertensive drugs, which blocking the action of angiotensin II of rennin angiotensin-aldosteron system. At presents there is no specific method for the estimation of losartan potassium by, spectrophotometric method.

Analytical chemistry is a branch of chemistry that deals with the separation, identification and determination of components in a sample. It is the science of making quantitative measurements, which requires background knowledge of chemical and physical concepts^{1,2}. Analytical instrumentation plays an important role in the production and evaluation of new products and in the protection of consumers and the environment. This instrumentation provides the lower detection limits required to assure safe foods, drugs, water and air³.

Pharmaceutical analysis techniques are applied mainly in two areas⁴ *i.e* qualitative and quantitative analysis. Specific technologies and instrumentation in the recent and past are spectroscopic, electrochemical, chromatographic techniques *etc*. Many new techniques have been developed and at the same time the classic spectroscopic techniques have been modified to suit newer methods for the analysis of active principles.

UV-Visible spectrophotometry

The absorption of light by analytes is due to the presence of chromophores in their molecules, which are specific portions of molecules that can absorb radiant energy in the visible region. This method of analysis is based on measuring the absorption of monochromatic light by colored compounds in the visible path of the spectrum (380- 800 nm). If the analytes are colorless, they are converted into colored compounds by reaction with a suitable chromogenic reagent. They must be stable and have a constant compositions and high color intensity. The photometric methods of analysis are based on Bouguer-Lambert-Beer's Law, which establishes, the absorbance by a solution is directly proportional to the concentration of the analyte.

Experimental

Losartan potassium was received as a gift sample from Dr.Reddy's laboratory, Hyderabad. All other chemicals used were of analytical grade. Bromothymol blue, phosphate buffer were bought from Sd-fine chemicals. Dematerialized water was used throughout the work. Digital balance, systronics-117, UV-spectrometer, Jasco-410 FTIR spectrometer were used for this project.

Preparation of standard solution

Phosphate buffer solution (pH:3.4) was prepared by dissolving 5.04 g of disodium hydrogen phosphate and 3.01 g of potassium dihydrogen phosphate in water and made upto 1000 mL.

Stock solution (1 mg/1 mL)

100 mg of pure losartan potassium was accurately weighed and transferred into 100 mL volumetric standard flask and added phosphate buffer to dissolve the drug and made up to 100 mL with phosphate buffer.

Bromothymol blue solution

50 mg of bromothymol blue was dissolved in 4 mL of 0.02 M NaOH and 20 mL of ethanol (95%). After solution is effected, sufficient water was added and made upto 100 mL.

Absorption spectra for drug in bromothymol blue

From the stock solution, 10 mL was taken and added with 1 mL of bromothymol blue and it was diluted with 500 mL of phosphate buffer to make the concentration 200 µg/mL. The absorbance of the solution was measured between 400-800 nm.

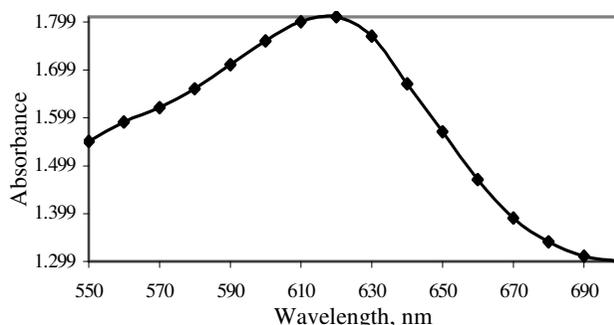


Figure 1. Absorbance obtained from different wavelength.

Preparation of standard graph

According to Beer's law, the graph was drawn by measuring the absorbance of various concentration of drug solution against the blank from stock solution (1 mg/mL) of various concentrations 0.5 mL, 1 mL, 1.5 mL, 2 mL, and 2.5 mL were pipette out and transferred into 100 mL of volumetric flask and make up with phosphate buffer. The drug concentration in each flask was 5 μ /mL, 10 μ /mL, 15 μ /mL, 20 μ /mL and 25 μ /mL respectively. Absorbance of each solution was observed and the calibration graph was drawn by plotting the concentration against absorbance (Figure 2).

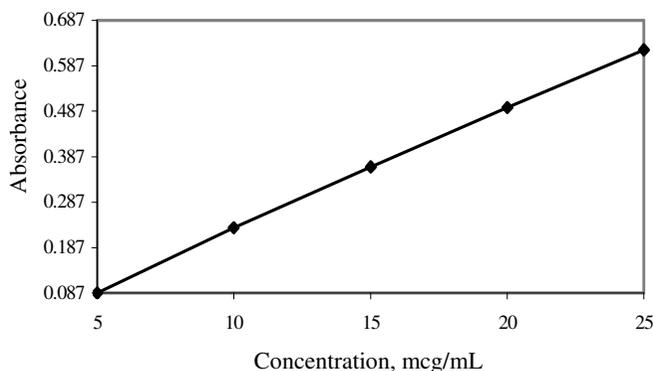


Figure 2. Calibration curve for losartan potassium using phosphate buffer as a blank.

Effect of reagent concentration

The effect of reagent concentration was done by using different reagent concentration and this 1 mL of 1N bromothymol blue was found to be the minimum effect concentration. The concentration less than 1N bromothymol blue and less than 1 mL of reagent give the deviation in the curve.

Stability of colour

The colour changes from yellowish orange to green shows the completion of reaction with bromothymol blue. Then the stability of colour was studied by measuring the absorbance for every 10 minutes and it has no colour changes and no change in the absorbance up to 1 h.

Analysis of formulation and recovery studies

Three different brands of losartan potassium tablets were taken for analysis. They are covance-25 mg, losar-50 mg and repace-25 mg and the tablets were powdered gently in a glass mortar. The tablet powder equivalent to 10 mg of losartan potassium was weighed and transferred to 100 mL volumetric flask. Then phosphate buffer was added as a solvent to dissolve the drug content and made up to 100 mL.

The solution was filtered by using whattmann filter paper. From that 1 mL of filtrate was pipette out and transferred into a 100 mL volumetric flask along with 1 mL of bromothymol blue and made up to 100 mL with phosphate buffer. The absorbance was measured at 620 nm against mixture of bromothymol blue and phosphate buffer for each brand of tablet. The amount of drug present in the solution was calculated and shown in Table 1

Table 1. Analysis of losartan potassium in formulation.

S.No	Name of formulation	Labeled amount mg/tablet	Amount found*, mg	Percentage label claim, %
1	Covance	25	24.86±0.05	99.44±0.24
2	Losar	25	25.08±0.01	100.37±0.06
3	Reopace	25	24.77±0.03	99.08±0.86

The recovery studies experiments were performed for the same three brands of tablets (Covance, Losar and Repace) and calculated recovery studies by the following formula,

$$\text{Percentage of recovery} = [b-a/c] \times 100$$

Where, a = Amount of sample drug

b = Amount of sample drug + standard drug

c = Amount of sample drug added.

The results of the recovery studies are shown in Table 2.

Table 2. Analysis of losartan potassium in recovery studies.

S.no	Name of formulation	Labeled amount mg/tablet	Amount found*, mg	Percentage of recovery studies, %
1	Ovance	25	25.02±0.01	100.08±0.06
2	Losar	25	24.20±0.05	96.80±0.42
3	Eopace	25	24.68±0.02	98.60±0.70

Results and Discussion

A simple, rapid and accurate spectrophotometric method was developed for the estimation of losartan potassium using bromothymol blue. The wavelength selected for analysis was 620 nm where the absorbance for the drug is maximum. The spectra and calibration curve were obtained for losartan potassium in the range of 5-25 µg/mL. The recovery studies were also carried out to ensure the reproducibility and repeatability of the method of adding known amount of standard drug solution. The reports of formulation and recovery studies are given in Table 2.

Conclusion

The method is specific and there were no interference from additives and impurities and the low standard deviation values ensure the reliability of the method. The amount of drug obtained is in good agreement with labeled claim. Hence it is concluded that the developed simple, precise and accurate method can be effectively used for the routine analysis of losartan potassium.

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