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Simultaneous estimation of losartan potassium and ramipril from tablets by first order derivative spectroscopy

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ABSTRACT

Losartan Potassium and Ramipril are used in combination for treatment of hypertension. The present work deals with simple spectrophotometric method development for simultaneous estimation of Losartan Potassium (LOS) and Ramipril (RAM) in two component tablet formulation. The method employed first order derivative spectroscopy. For determination of sampling wavelength 20 μ g/ml of each of LOS and RAM were scanned in 200-400 nm range and sampling wavelengths were 234 nm for LOS were RAM showed zero crossing point and 271 nm for RAM were LOS showed zero crossing point in first order derivative spectroscopy. For this method linearity observed in 10-90 μ g/ml for LOS and 2-18 μ g/ml for RAM. The recovery studies confirmed accuracy of proposed method and low values of standard deviation confirmed precision of method. The method is validated as per ICH guidelines. © 2012 Trade Science Inc. - INDIA

INTRODUCTION

Losartan Potassium is chemically described as [4(2hydroxy3isopropylaminopropoxy) phenylacetamide] and is competitive antagonist and inverse agonist of A-II, and ramipril is 2S-[1(R*{R*}), 2 α , 3 $\alpha\beta$, 6 $\alpha\beta$]-1-[2({1ethoxycarbonyl}-3-phenylpropyl) amino-1-oxopropyl] octahydrocyclopenta [b] pyrrole-2-carboxylic acid used as ACE inhibitor^[1-3]. In the chemical analysis of multicomponent dosage form one drug may interfere with estimation of other drug. Hence analytical methods are developing to estimate all the drugs simultaneously in multicomponent formulations^[1-11].

Many analytical methods like HPLC, HPTLC,

Losartan potassium; Ramipril;

KEYWORDS

Ramipril; Derivative spectroscopy; ICH guidelines; Validation.

electrochemical, radioimmunoassay were reported for determination of LOS^[12-15] and RAM^[16-19] alone and in combination with other antihypertensive drugs. The RP-HPLC method has been reported for simultaneous estimation of LOS and RAM^[20].

MATERIALS AND METHOD

Instrument

Spectrophotometric analysis was carried out on a JASCO UV-spectrophotometer V- 630 using a 1 cm quartz cell. The instrument settings were zero order and first derivative mode and band width of 2.0 nm in the range of 200–400 nm.

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Reagents and chemicals

Losartan Potassium and Ramipril supplied by Cipla Ltd. India. All solvents were spectrophotometric grade obtained from LOBA CHEM. Water purified by glass distillation apparatus.

Method

Stock solutions were prepared separately in water: methanol (50:50) to obtain 100 µg/ml of all drugs. The nine working mixed standard were prepared by dilution of stock solution in same solvent system in concentration range 10-90 µg/ml of LOS and 2-18 µg/ml for RAM. Losartan Potassium and Ramipril initially scanned for determining sampling wavelength in range 200-400 nm. Sampling wavelengths were 234 nm for LOS where RAM showed zero crossing point and 271 nm for RAM where LOS showed zero crossing point. Calibration graphs were constructed from the absorbances at respective wavelength.



Figure 1 : Overlain spectra of LOS and RAM.

ANALYSIS OF TABLET FORMULATION

Marketed tablet formulation containing LOS 50 mg and RAM 5 mg were analyzed using this method. From the contents of 20 tablets, an amount equivalent to 10 mg of LOS and 5mg of RAM was weighed and dissolved in 60 ml of solvent in 100 ml volumetric flask. The solution was filtered through Whatmann filter paper no. 41 and then final volume of the solution was made up to 1000 ml to get stock solution containing 100 μ g/ml of LOS and 50 μ g/ml of RAM. After appropriate dilutions, the absorbances were measured and the concentration of each analyte was determined with the equations generated from calibration curve for respective drugs^[9-10].

RESULTS AND DISCUSSION

Sampling wavelengths were determined from scan-

ning individual drug samples in 200-400 nm range. Sampling wavelengths were 271 nm and 234 nm for RAM and LOS respectively in first order derivative mode. For this method equations generated were Y=0.010x+0.011 (R²=0.998) and Y=0.005x+0.005 (R²=0.998) for LOS and RAM respectively. Linearity of proposed method was found to be 2-18 µg/ml for RAM and 10-90 µg/ml for LOS. Limits of detection were found to be 1.2563 and 1.0145µg/ml of LOS and RAM respectively. Limits of quantitation were found to be 3.8069 and 3.0742 µg/ml for LOS and RAM respectively. Results of tablet analysis were reported in Table 1, result of precision studies and recovery study reported in TABLE 2 and 3 respectively.

TABLE 1 : Results of analysis of commercial formulation.

Analyte	Label Claim (mg/cap)	%Label Claim Estimated* (Mean ± %R.S.D.)
LOS	50	101.30±0.7186
RAM	5	100.16±0.9815

*Average of nine determinations, R.S.D.: Relative standard deviation.

TABLE 2 : Results of precision studies.

Analyte	Label Claim (mg/cap)	%Label Claim Estimated* (Mean ± %R.S.D.)
LOS	50	100.18 ± 0.7170
RAM	5	99.06±0.7522

*Average of nine determinations, R.S.D.: Relative standard deviation.

TABLE 3 : Results of recovery studies.

Analyte	Label Claim (mg/cap)	%Recovery Estimated* (Mean ± %R.S.D.)
LOS	50	100.16±0.7157
RAM	5	99.04±0.5278

*Average of nine determinations, R.S.D.: Relative standard deviation

CONCLUSION

The method used is simple and rapid and does not involve the use of complex instrument, low value of standard deviation showed that the method is precise and high percentage of recovery of as shown in table shows that the method is accurate.

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