RESEARCH PAPER International Journal of Medical Sciences (October, 2009 to March, 2010) Vol. 2 Issue 2 : 110-111

Development of New UV Spectrophotometric Method For Estimation of Losartan Potasium in Bulk and Tablet Dosage Form

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ABSTRACT

A new, simple, specific, precise and accurate spectrophotometric method has been developed for determination of losartan potassium in bulk and tablet dosage form. The drug shows absorption maxima at 228 nm. The method was statistically validated according to I.C.H.Guidelines. Percentage mean recovery obtained was 99.62%; coefficient of variance was found to be less than 2% and linearity coefficient was 0.9995. Linear response obtained for losartan potassium was in the concentration range of 2-18 «g/ml. The limit of detection and limit of quantification for Losartan was found to be 0.086 «g/ml and 0.259 «g/ml, respectively.

Key words : Losartan Potassium, Spectrophotometric, Validation

Accepted : May, 2009

Losartan potassium is chemically 1H-imidazole-5-methanol, 2-butyl-4chloro-1-[[2'(1H-tetrazol-5-yl)-[1,1'-biphenyl]-4-yl] methyl]-, potassium salt[1]. It is a newer angiotensin II receptor (type AT1) antagonist[2] used in mild to moderate hypertension. The drug is not official in any pharmacopoeia. Several methods such as High Performance Liquid Chromatography (HPLC)[3,4,5,6] methods have been reported for the estimation of losartan potassium. In this communication, a new simple, specific, accurate spectroscopic method is reported for the determination of losartan potassium in bulk and tablet dosage form.

MATERIALS AND METHODS

Instrumentation:

A Systronics UV-visible spectrophotometer with 1 cm matched quartz cells was used for all absorbance measurements.

Reagents:

Sodium hydroxide AR grade was procured from Loba Chemie Ltd., Mumbai. Double distilled water was used for preparing 1N sodium hydroxide solution. Losartan Potassium used as API was gift sample from M/s Intas Pharmaceuticals Ltd., Matoda, Ahemdabad, India. Different brands of losartan potassium were procured from the local market.

Preparation of calibration curve:

Losartan potasium (10 mg) was accurately weighed and dissolved in 1N sodium hydroxide solution to prepare stock solution having concentration of 100 μg/ml. From this stock solution, working standard solution of drug was prepared by appropriate dilution.

Working standard solution was scanned in entire UV range to determine λ-max. The μ-max. for losartan potassium was found to be 228 nm. Standard solutions were prepared having concentration 2, 4, 6, 8, 10, 12, 14, 16 and 18 μg/ml using working standard solution. The absorbances of these standard solutions were measured at 228 nm and calibration curve was plotted at this wavelength-using 1N sodium hydroxide solution as blank.

Estimation of drugs from pharmaceutical dosage forms:

Twenty tablets of three different pharmaceutical companies were accurately weighed and powdered. The powder equivalent to 20 mg of losartan potassium was transferred into 100 ml volumetric flask, it was dissolved and diluted with 1N sodium hydroxide solution and filtered through Whatman Filter Paper No. 40. Further suitable dilutions were made with

same solvent to get concentration within the range of Beer's law limits and the concentration of losartan potassium present in dosage forms was determined from respective calibration curve.

Recovery studies and validation of the method as per I.C.H Guidelines[7] :

Precision of the method was studied by carrying out Interday, Intraday analysis and expressed as % C.V. Specificity was determined by taking absorbance of a sample before adding excipients and after adding excipients and variation in concentration was observed. Limit of detection and limit of quantitation were studied based on standard deviation of the response and the slope. Recovery studies were carried out by addition of standard drug solution.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, molar extinction coefficient, Sandell's sensitivity, correlation coefficient, slope and intercept of regression equation are summarized in Table 1. The recovery studies for determination of losartan potassium in different pharmaceutical formulations (tablets) by proposed method are summarized in Table 2. The limit of detection (L.O.D.) and limit of quantitation (L.O.Q.) were found to be 0.086 μg/ml and 0.259 μg/ml, respectively. The proposed method was found to be specific as there was no shown sign of interference due to the presence of excipients.

Table 1 : Optical parameters along with validation parameters

Parameter	At λ-max. = 228 nm
Beer's law limit (μg/ml)	2 - 18
Molar extinction coefficient (l $mole^{-1}cm^{-1}$)	$2.0942 * 10^4$
Sandell's sensitivity (mg/cm^2/. 001 absorbance unit)	$2.2 * 10^{-2}$
Correlation coefficient	0.9995
Regression equation (y= a + bc)	
Slope (b)	0.0451
Intercept (a)	0.004
Precision (% CV)	
a. Repeatability (n= 6)	0.541
b. Intra-day (n=3)	0.784
c. Inter-day (n=3)	0.823
% Recovery	99.4 - 99.7
Limit of detection (μg / ml)	0.086
Limit of quantification (μg / ml)	0.259

Table 2: Estimation of losartan potassium in tablets

Tablet sample	Label claim (mg/tab)	Label claim estimated (mg/tab)	% Recovery
A	25	24.84	99.37
B	25	24.79	99.15
C	25	24.74	98.97

Conclusion:

The proposed spectrophotometric method was simple, sensitive, accurate, specific and reproducible and can be used for routine determination of losartan potassium in bulk as well as in tablets.

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REFERENCES

Gennaro, A.R. (2000). Instrumental method of analysis, In : *Remington : The Science and Practice of Pharmacy*. 20th Ed.,Vol.II, Indian Ed., Lippincott Williams and Wilkins: 618-19, 1280-1282.

Hardman, J.G., Limbird, L.E. Goodman and Gilman's (2001). The Pharmacological Basis of Therapeutics. 10th Ed. (International Ed.), McGraw Hill: 829- 832.

Gonzalez, L., Lopez, J.A., Alonso, R.M. and Jimenez, R.M. (2002). Fast screening method for the determination of angiotensin II receptor antagonists in human plasma by high-performance liquid chromatography with fluorimetric detection. *J. Chromatogr. A.*, **949** (1-2) : 49-60.

Yeung, P.K., Jamieson, A., Smith, G.J., Fice, D. and Pollak, P.T. (2000). Determination of plasma concentrations of losartan in patients by HPLC using solid phase extraction and UV detection. *Internat. J. Pharm.*, **204**(1-2) : 17-22.

McCarthy, K.E., Wang, Q., Tsai, E.W., Gilbert, R.E. and Brooks, M.A. (1998). Determination of losartan and its degradates in COZAAR tablets by reversed-phase high-performance thin-layer chromatography. *J. Pharm. Biomed Anal.*, **17**(4-5) : 671-7.

Furtek, C.I. and Lo, M.W. (1992). Simultaneous determination of a novel angiotensin II receptor blocking agent, losartan, and its metabolite in human plasma and urine by high-performance liquid chromatography. *J. Chromatogr,* **573**(2) : 295-301.

Text on Validation of Analytical Procedures Q2B In; I.C.H. Harmonised Tripartite Guidelines; Nov.1996.

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