Biomedical & Pharmacology Journal Vol. **1**(2), 479-480 (2008)

Spectrophotometric method for determination of Lercanidipine in tablets

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(Received: November 10, 2008; Accepted: December 17, 2008)

ABSTRACT

A simple, rapid, precise and accurate spectrophotometric method has been developed for estimation of Lercanidipine from tablet formulation. In ethanol, Lercanidipine showed absorbance at 239 nm. Linearity was observed in the concentration range of 2-28 µg/mL. The assay result was found to be in good agreement with label claim. The recovery studies were carried out at three different levels. The method was validated statistically and by recovery studies.

Key words: Lercanidipine, spectrophotometry, validation.

INTRODUCTION

Lercanidipine[1] is 2-{(3,3-diphenylpropyl) methylamine}-1,1-dimethylethyl, methyl-1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-3,5-pyridine dicarboxylic ester with molecular formula $C_{36}H_{41}N_3O_6$. It is a new third generation 1,4-dihydropyridine calcium channel antagonist used as antihypertensive[2]. Few methods[3-8] has been reported for the determination of Lercanidipine.

In the present study a simple, rapid economical UV-visible spectrophotometric method was developed for estimation of Lercanidipine from tablets. The method was validated as per ICH guidelines.

MATERIAL AND METHODS

Preparation of standard stock solution

Standard stock solution was prepared by dissolving 10mgs of Lercanidipine in 10ml of ethanol. Different aliquot was taken from stock solution to obtain series of concentrations. The solution was scanned on shimadzu UV-1601 spectrophotometer and the absorbance was recorded at λmax of 239 nm against ethanol as blank. The calibration curve was found to be linear in the concentration range of 2-28 µg/mL. The linear regression was found to be $r^2 = 0.9991$.

Preparation of sample solution

Twenty tablets were accurately weighed, their average weight determined, crushed to fine powder. An accurately weighed quantity of tablet powder equivalent to 10 mgs of Lercanidipine was transferred to 10 ml volumetric flask containing 5 ml ethanol, sonicated for 5 min, filtered and the filtrate was made upto 10 ml with ethanol. After appropriate dilution, the absorbance of the solution was recorded at 239 nm and the concentration of drug was determined.

Recovery studies

To check the accuracy of the proposed method, recovery studies were carried out at three different levels. To the preanalysed sample solution, the amount of bulk drug was added at 3 different levels and then reanalyzed.

RESULT AND DISCUSSION

Lercanidipine is calcium channel antagonist used as antihypertensive agent, it

Table 1: Result of Assay

Label claim mg/tablet	Amount found*	% Amount found	SD	% RSD
Lorez 10 mgs	9.939	99.39	0.043133	0.45935

*Average of six determinations

Table 2: Recovery studies

S. No.	Conc. of standard drug (µg/ml) (A)	Conc.of marketed sample (µg/ml) (B)	Total drug conc (µg/ml) (A+B)	Absorbance* at 239 nm	Total conc of lercanidipine from standard curve (µg/mll)	Amount of sample (µg/ml)	% Recovery
1	10	4	14	0.535	13.95	9.95	99.5
2	10	6	16	0.624	16.1	10.1	101.0
3	10	8	18	0.700	18.2	10.2	102.0

*Average of three readings.

showed maximum absorbance at 239 nm. Linearity was obeyed in concentration range of 2-28 µg/mL. The percentage label claim was found to be in good agreement. The % recovery was found to be in range of 99-102 % w/w. The % RSD (0.5913) less than 2 indicated that the method was accurate. The precision of the method was studied as an intra day, inter day, repeatability. The % RSD value less than 2 indicated that the method was precise. The method was found to sensitive with respect to sandells sensitivity.

The developed method was found to be simple, linear, accurate, sensitive and reproducible and hence can be used for routine analysis of Lercanidipine in bulk and tablet formulation.

Table 3: Summary of the method

λmax	239 nm
Linearity	2-28 µg/mL
% Recovery	99-102 %
Precision (% RSD)	
Inter day (n=3)	0.2255
Intra day (n=3)	0.7143
Repeatability (n=6)	0.2255
Sandells sensitivity mcg/cm^3/AU	0.0251

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