

UV-spectrophotometric determination of lercanidipine hydrochloride in bulk and tablet

ATUL A. SHIRKHEDKAR*, PRAFULLA V. DEORE and SANJAY J. SURANA

R.C. Patel College of Pharmacy, Karwand Naka, Shirpur, Dhule - 425 405 (India)

(Received: August 25, 2007; Accepted: October 08, 2007)

ABSTRACT

A simple, rapid, sensitive and accurate UV- Spectrophotometric method has been developed for estimation of lercanidipine hydrochloride from pharmaceutical formulations. In (50% v/v) acetonitrile, lercanidipine hydrochloride showed absorbance maxima at 237 nm. Linearity was observed the concentration range of 4 - 24 µg/mL ($r^2= 0.9999$). The amount of drug estimated from the formulation was found to be in the good agreement with the label claim. The recovery studies were carried out at three different levels i.e. at 80%, 100%, and 120%. The mean percentage recovery was found to be in the range of 99.55 -100.05. The method was validated statistically.

Keywords: UV-spectrophotometric method Lercanidipine hydrochloride

INTRODUCTION

Lercanidipine hydrochloride, 2-[(3, 3-diphenylpropyl) methylamine]-1, 1-dimethyl-ethylmethyl 1, 4-dihydro-2, 6-dimethyl-4-(3-nitrophenyl)-3, 5 pyridinedicarboxylic ester, HCl is dihydropyridine calcium channel blocker used in the treatment of hypertension¹. Literature survey revealed spectrophotometric² and few chromatographic³⁻⁶ methods estimation of lercanidipine hydrochloride in bulk, pharmaceutical formulations and biological fluids. Lercanidipine hydrochloride is not official in IP, BP and USP.

Present work deals with UV-spectrophotometric method for estimation of lercanidipine hydrochloride from tablets.

MATERIAL AND METHOD

All the reagents were used of analytical grades Preparation of standard stock solution

Standard stock solution was prepared by dissolving 10 mg of lercanidipine hydrochloride in 100 ml of (50% v/v) acetonitrile to get concentration

of 100 µg/ml. Different aliquots were taken from the stock solution and diluted to 10 ml mark with same solvent to obtain series of concentrations. The solutions were scanned on Spectrophotometer-2450 (Shimadzu) in the UV range 200-400 nm and absorbances were recorded at 237 nm against blank. The calibration curve was found to be linear in the concentration range 4 - 24 µg/ml. ($Y = 0.03995X + 0.00415$; $r^2= 0.9999$)

Preparation of Sample Solution

For analysis of commercial formulation; twenty tablets were weighed, average weight determined and crushed into fine powder. A quantity of tablet powder equivalent to 10 mg of lercanidipine hydrochloride was transferred into 100 ml volumetric flask containing 30 ml acetonitrile (50% v/v), shaken manually for 15 min., volume was adjusted to mark with same solvent and filtered through whatmann filter paper no. 41. After appropriate dilutions, absorbance of the sample solution was recorded at 237 nm and the concentration of the drug was calculated from linear regression equation; results are shown in Table 1.

Table 1: Results of assay

Label claim	*Amount found \pm SD	Amount found [%]	%RSD
10 mg of lercinidipine hydrochloride	10.01 \pm 0.23	100.02	0.242

* mean of five estimations

Recovery studies

To study the accuracy of the proposed method, recovery experiments were carried out by adding a known amount of drug to preanalysed sample at three levels and the percentage recoveries were calculated; the results are summarized in Table 2.

RESULTS AND DISCUSSION

The λ_{max} of lercanidipine hydrochloride

Table 2: Summary of validation

Parameters	Results
Linearity and range (μ g/ml)	4 – 24
LOD	0.0914
LOQ	0.277
Accuracy (%Recovery *)	99.55 - 100.05 %
%RSD	0.280
Precision (%RSD)	
Intra-day (n=3)	0.31 - 1.46
Inter-day (n=3)	0.41 - 1.35
Repeatability (n=6)	0.344
Ruggedness	
Analyst –I	100.04 (%RSD = 0.515)
Analyst –II	100.02 (%RSD = 0.230)

*mean of three estimation at each levels

in 50% v/v acetonitrile was found to be 237 nm. The drug follows linearity in the concentration range of 4 - 24 μ g/ml. The analysis of tablet formulation by proposed method was in good agreement with label claim. The recovery studies were carried out at three different levels i.e. 80%, 100% and 120%. The mean percentage recoveries were found to be in the range of 99.55 - 100.05%; the low values of %RSD are indicative of the accuracy of the method. The precision of the method was studied as an intra-day and inter-day precision and repeatability. The % RSD value less than 2 indicate that the method is precise. Ruggedness of the proposed method was studied with the help of two analysts. The %RSD value lies in the range of 0.230 and 0.515. The results from validation⁷ studies are shown in Table 2.

Conclusion

The proposed method is simple, rapid, accurate and economical and useful for the routine analysis of lercanidipine hydrochloride from marketed formulation.

ACKNOWLEDGMENT

The authors are thankful to R.C. Patel College of Pharmacy, Shirpur, for providing facilities to carry out this work.

REFERENCES

- Maryadele J.O. Neil. Eds, The Merck Index In, fourteenth Ed., Published by Merck and Co White House Station, NJ, USA, 942 (2006).
- Vijaya saradhi, S., Himabindu, V. and Devala Rao, G., *Asian J. of chem.*, **18**(2): 1551-1553(2006).
- Baranda Ana. B, Jimenez Rosa. M, Alonso Rosa.M., *J. of Chrom.* **1031**: 275-280 (2004).
- Alvarez-Lueje.A, Pujol.S, Squella J.A, Nunez-Vergara L.J., *J. of Pharm. and Bio. Ana.*, **31**:1-9 (2003).
- Kumar M.V. and Muley P.R., *Indian Drug.*, **41**: 24-27 (2004).
- Isam ismail Salem, Jafer Idrees, Jaafer I .Al tamimi, Pierluigi farina., *J. of Chrom.*, **803B**, 201- 207 (2004).
- United States Pharmacopeia, 28th edn, United States Pharmacopoeial Convention . Inc., Rockville, 2749 (2005).