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Research Article

ESTIMATION OF LERCANIDIPINE BY FIRST DERIVATIVE UV SPECTROSCOPY

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ABSTRACT

A simple, accurate, economical, fast and reliable method for the determination of lercanidipine (LR) is highly desirable to support formulation screening and quality control. The method was developed for determination of LR in pure drug and tablet dosage form. Best results were shown in terms of linearity, accuracy, precision, LOD and LOQ for pure drug as well as for tablets. UV absorbance was measured at 332 nm. Excellent linearity (correlation coefficient (r^2) = 0.9970) found in the concentration range of 7.5-60 µg/ml. The LOD and LOQ were 1.0770 and 3.2638 µg/ml respectively and good recoveries were achieved (95.779%).

KEYWORDS: Lercanidipine, Methanol, Zero order spectra, First derivative zero crossing spectrophotomet

INTRODUCTION

Figure 1 is structure of Lercanidipine (LR), which is 2-[(3,3-diphenylpropyl)methylamine]-1,1-dimethylethylmethyl1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-3,5pyridinedicarboxylic ester and belongs to well-known pharmacological active compound series classified as 1,4-dihydropyridine calcium channel blockers. It is used as anti-hypertensive agent (1,2) as it has good specificity on the smooth vascular cells (3). The molecular weight of LR is 648.19 and melting point is 170-180 °C (4).

It is soluble in chloroform, methanol and acetonitrile and practically insoluble in water (5). LR exhibited high affinity for the dihydropyridine (DHP) subunit of the L-type calcium channel (6). The aim of the present work is to investigate utility of derivative spectrophotometry and to develop validated spectrophotometric procedures for determination of LR either in pure drug or in tablet dosage forms.

1. EXPERIMENTAL

1.1 Apparatus

Spectrophotometeric measurements were made on a Shimadzu 1700 double beam UV Visible spectrophotometer with a fix slit width of 1 nm coupled with computer loaded with Shimadzu UV PC software (UV probe) version 2.31.

1.2 Materials

1.2.1 pure samples

LR was kindly supplied by the Alembic pharmaceuticals Ltd. Vadodara, India.

1.2.2 Market samples

The marketed formulation of LR was obtained commercially from Sun Pharmaceuticals Ltd (Lotensyl-10 labeled 10 mg of pure drug, Batch Number-AD80120).

1.2.3 Chemical and reagents

AR grade methanol was used as a solvent for spectrophotometric work.

2.3 Preparation of standard and sample solutions

Stock solution of 1 mg/ml of pure LR and its formulation was freshly prepared in methanol. Test solution of LR was tested for stability in solution during the actual analysis. The behaviour of LR was found to be stable over the period of 24 hr from their preparation at room temperature.

2.4 Procedure

2.4.1 First derivative zero crossing spectrophotometry

The Zero order spectra of the LR were recorded between 200-400 nm against blank (AR grade methanol) using a 1.0 cm quartz cell. The zero order spectra of pure LR were stored individually within the 7.5-60 µg/ml concentration ranges and were derivatized in first order using delta lambda 4 and scaling factor 10. The first derivative amplitudes were recorded at 332 nm

3 Results and Discussion

It is observed from the absorption spectra of the LR that it has a good linearity in the range of 7.5-60 µg/ml. Figure 2 describes the 1st derivative spectra of LR. This method was validated; all the validation parameters were in limit as per the ICH guidelines (7). Table 1 exhibits the detailed validation parameters of the methods.

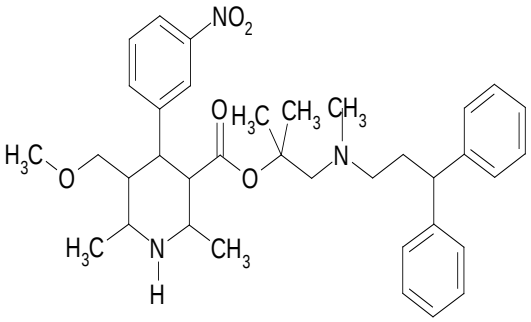

Figure 1. Structure of the LR.

Validation Parameters	Result
Absorption maxima, λ_{max} (nm)	332
Linearity range (µg/ml)	7.5-60
Coefficientof determination (r^2)	0.9970
Regression equation (Y^a)	Y=0.002X+0.003
Slope (b)	0.002
Intercept (a)	0.003
Limit of detection LOD, (µg/ml)	1.0770
Limit of quantitation LOQ (µg/ml)	3.2638
Accuracy (%)	95.779

Table 1. Validation parameters results obtained by the method

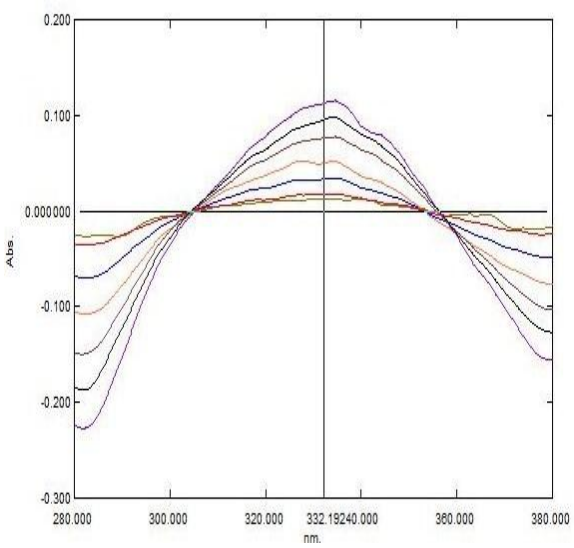

Figure 2. First order derivative spectra of LR.

4 Conclusion

The newly developed spectrophotometeric method for determination of LR is simple, specific, accurate, precise, rapid and economical which indicates its adequacy for routine Pharmaceutical analysis. It is concluded that derivative spectrophotometery is successfully utilized for the estimation of LR.

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REFERENCES

(1) McClellan KJ, Jarvis B. Lercanidipine: A Review of its Use in Hypertension. Ingenta connect,2000,60,1123-1140.
(2) Guarneri L, Angelico P, Ibba M, Poggesi E, Taddei C, Leonardi A, Testa R. In Vitro Calcium Antagonist Activity of Lercanidipine and Its Enantiomers. Journal of Cardiovascular Pharmacology,1997,29,S10-S18.
(3) Bianchi G, Passoni A, Griffini PL. Effects of a new calcium antagonist on cardiac contractility of conscious rabbits. Pharmacol Res,1989,21,193-200.
(4) Ambemethy, Schwartz JB. Calcium Antagonist Drugs. The New England Jounral of Medicine,1999, 341,1447-57.
(5) Mihaljica S, Radulovic D, Trbojevic J. Determination of Lercanidipine Hydrochloride and Its Impurities in Tablets. Chromatographia,2005,61,25–29.
(6) lvarez LA, Pujol S, Squella J, Nu´n˜ez VL. A selective HPLC method for determination of lercanidipine in tablets. Journal of pharmaceutical and biomedical analysis,2003,31,1-9.
(7) International Conference on Harmonization (ICH), Validation of Analytical Procedures: Methodology. (1996) Q2 B.

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