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 spectrophotometry

INTRODUCTION

Figure 1 is structure of Lercanidipine (LR), which is 2-[(3,3-diphenylpropyl)methylamino]-1,1-dimethylethylmethyl]-1,4-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

Spectrophotometric 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.
**Conclusion**

The newly developed spectrophotometric 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 spectrophotometry is successfully utilized for the estimation of LR.

**Acknowledgement**

The authors express their sincere thanks to Mr Bhagirath Patel, F & D Division, Alembic Pharmaceuticals Ltd. Vadodara, India for supplying gift samples of pure Lercanidipine and also I.S.F College of Pharmacy, Moga for providing facilities to carry out the research.

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**Table 1. Validation parameters results obtained by the method**

<table>
<thead>
<tr>
<th>Validation Parameters</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorption maxima, $\lambda_{	ext{max}}$ (nm)</td>
<td>332</td>
</tr>
<tr>
<td>Linearity range (µg/ml)</td>
<td>7.5-60</td>
</tr>
<tr>
<td>Coefficient of determination ($r^2$)</td>
<td>0.9970</td>
</tr>
<tr>
<td>Regression equation ($Y^2$)</td>
<td>$Y=0.002X+0.003$</td>
</tr>
<tr>
<td>Slope (b)</td>
<td>0.002</td>
</tr>
<tr>
<td>Intercept (a)</td>
<td>0.003</td>
</tr>
<tr>
<td>Limit of detection LOD, (µg/ml)</td>
<td>1.0770</td>
</tr>
<tr>
<td>Limit of quantitation LOQ (µg/ml)</td>
<td>3.2638</td>
</tr>
<tr>
<td>Accuracy (%)</td>
<td>95.779</td>
</tr>
</tbody>
</table>

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**Figure 1. Structure of the LR.**

**Figure 2. First order derivative spectra of LR.**
REFERENCES


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AUTHORS AFFILIATIONS AND ADDRESS FOR COMMUNICATION:

1Department of Pharmaceutical Analysis, I.S.F. Analytical Laboratory, I.S.F. College of Pharmacy, Ferozepur Road, Ghal Kalan, Moga 142001, PUNJAB
Phone: +91 1636 324200 324201, +91 9779300464
TeleFax: +91 1636 236564
*Email: artirthakkar@gmail.com