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NOTE

Spectrophotometric Determination of Lercanidipine in Pharmaceutical Formulations

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A simple and sensitive spectrophotometric method is developed for the determination of lercanidipine in bulk and in pharmaceutical formulations. The method is based on diazotization of reduced lercanidipine followed by addition of ammonia solution. The absorbance of the yellow colour solution developed was measured at 445 nm. Beer's law is obeyed in the concentration range of 5–25 µg/mL. Results of analysis were validated statistically and by recovery studies. The method is successfully employed for the determination of Lercanidipine in various pharmaceutical preparations.

Key Words: Lercanidipine, Spectrophotometry, Beer's Law.

Lercanidipine (LCD) is 1,4-dihydro-2,6-dimethyl-4-(3-nitrophenyl)-3,5-pyridine dicarboxylic acid 2-[(3,3-diphenyl propyl)methyl amine]-1,1-dimethyl ethyl methyl ester, which is used in the treatment of hypertension[1]. A very few methods appeared in literature for the determination of LCD in biological fluids and pharmaceutical formulations. The techniques used in this connection include HPLC[2,3], differential pulse polarography[4], extractive spectrophotometry[5] and visible spectrophotometry[6]. This paper describes the development of a simple, sensitive spectrophotometric method for the routine quality control analysis of pharmaceutical formulations containing LCD. The NO_2 group present in LCD is reduced to primary aromatic (amine) NH_2 group with zinc dust and hydrochloric acid.

In this method, the reduced LCD was treated with sodium nitrite in acidic medium at 0–5°C for diazotization. After diazotization, the drug was treated with ammonia-water (1 : 10) solution. The yellow colour formed was measured at 445 nm against the reagent blank prepared in a similar manner omitting drug solution.

Instrumentation: Spectral and absorbance measurements are made with Systronics UV-Visible double beam spectophotometer model 2201. All the chemicals used were of AnalaR grade. All the solutions were freshly prepared with double

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distilled water. Aqueous solutions of hydrochloric acid (5 N), sodium nitrite (0.1%) and 1 : 10 ammonia were prepared in the usual manner.

Standard and sample solution of lercanidipine

About 100 mg of LCD (bulk or formulation) was dissolved in 20 mL of methanol and treated with 5 N HCl and 5 g of zinc dust. After standing for 1 h at room temperature the solution was filtered through cotton wool. The residue was washed with 3 × 10 mL portions of distilled water and the total volume was brought to 100 mL with distilled water to give a concentration of 1 mg/mL. The final concentration of LCD was brought to 100 μg/mL.

Assay Procedure

To a series of 10 mL volumetric flasks, aliquot samples of reduced LCD ranging from 0.5--2.5 mL (1 mL = 100 μg/mL) and aqueous solutions of hydrochloric acid (5 N, 1 mL) and sodium nitrite (0.1%, 1 mL) were added and kept aside for 5 min at 0–5°C. Then 1 mL of 1 : 10 ammonia-water solution was added to each flask. The solution was made up to the mark with distilled water and after 5 min the absorbance of the yellow coloured solution was measured at 445 nm against the corresponding reagent blank. The amount of LCD was computed from the corresponding calibration curve.

The proposed method was based on the diazotization reaction followed by addition of mild alkali to develop the colour. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table-1. The regression analysis using the method of least squares for the slope (a), intercept (b) and correlation coefficient (γ) obtained from different concentrations is summarized in Table-1. The precision and accuracy were found by analyzing six replicate samples containing known amounts of the drug and the results are summarized in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS, PRECISION AND ACCURACY OF THE PROPOSED METHOD

λ_{max} (nm)	445
Beer's law limit (μg/mL)	5–25
Sandell's sensitivity (μg/cm^2/0.001 abs. unit)	0.166
Molar absorptivity (L mol^{-1} cm^{-1})	0.3932×10^4
Correlation coefficient (γ)	0.9997
Regression equation (Y)*	
Slope (a)	0.0004
Intercept (b)	0.0012
% RSD†	1.02
% Range of errors	
0.05 significance level	±0.852
0.01 significance level	±1.260

*Y = a + bx, where 'Y' is the absorbance and x is the concentration of LCD in μg/mL
†For six replicates.

The accuracy of the method was ascertained by comparing the results obtained with the proposed and reference methods in the case of formulations and are presented in Table-2. As an additional check on the accuracy of the method, recovery experiments were performed by adding known amounts of pure drug to pre-analyzed formulations and percent recovery values obtained are also listed in Table-2.

TABLE-2
ESTIMATION OF LERCANIDIPINE IN PHARMACEUTICAL FORMULATIONS

Formulations	Label claim (mg/tablet)	Amount found (mg) by		Recovery (%)
		Proposed method	Reported method	
Tablet-1	10	10.1	9.9	99.8
Tablet-2	10	10.2	9.8	99.9
Tablet-3	10	9.8	10.2	100.2

Thus, the proposed method is simple and sensitive with reasonable precision and accuracy. This can be used for the routine determination of lercanidipine in quality control analysis.

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