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HPLC method for analysis of Lercanidipine Hydrochloride in Tablets

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ABSTRACT

A reverse phase HPLC method was developed for quantitative determination of Lercanidipine hydrochloride in tablets. The separation was achieved by using 250 X 4.6mm Wakosil C_{18} (5µm) column with a mixture of methanol: acetonitrile (70:30) as a mobile phase, at a flow rate of 1.0ml/min. The detection was carried out at 219nm, and the retention time was found to be 4.10min. Linearity was observed in the concentration range of 10-60µg/ml. The mean recoveries obtained for lercanidipine HCl ranged from 96.38 to 101.23 %. The LOD and LOQ was found to be 0.03µg/ml and 0.04µg/ml respectively. The developed method was found to be accurate, precise and rapid for analysis of Lercanidipine HCl in tablets.

KEYWORDS

HPLC, Methanol, Acetonitrile, Lercanidipine Hydrochloride, Validation.

INTRODUCTION

Lercanidipine hydrochloride[1] (±)2-)[(3, 3-diphenylpropyl)methylamino]-1, 1- dimethylethyl, methyl -2, 6-dimethyl -4- (3- nitrophenyl)- 1,4-dihydro pyridine -3,5-dicarboxylate monohydrochloride with molecular formula $C_{36}H_{41}N_3O_6$. This is used in the treatment of mild to moderate hypertension . Lercanidipine hydrochloride is not an official drug in IP , BP and USP.

Literature survey revealed that many spectrophotometric methods [2-6] and a HPLC[7,8] method has been reported for determination of lercanidipine hydrochloride in bulk and in biological fluids. The present work describes the

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development of precise and accurate HPLC method for determination of Lercanidipine HCl in tablets.

MATERIALS AND METHODS

The pure drug sample of Lercanidipine HCl was obtained as a gift sample from Glen Mark Pharmaceutical Limited, Mumbai, India and Lercanidipine HCl tablets (Lerka= 10mg) were obtained from local market (Sun Pharmaceutical Limited, Silvassa, India). Qualigens fine chemicals, Mumbai supplied HPLC grade acetonitrile and methanol. An isocratic HPLC Shimadzu LC-10ATVP liquid chromatograph was used. The column used was a RP Wakosil C_{18} , 250 X4.6mm , particle size 5µm. A mixture of methanol and Acetonitrile in ratio of 70:30 V/V was used as mobile phase and was filtered before use through 0.45µ membrane filter. The flow rate of mobile phase was maintained at 1.0ml/min and UV detection was carried out at 219nm.

Standard stock solution of Lercanidipine HCl(1mg/ml) was prepared in mobile phase. The standard solution was further diluted with mobile phase to get concentration of 10µg/ml. Twenty tablets of Lerka (Sun pharmaceuticals, India) containing 10mg of Lercanidipine HCl were weighed and finely powered. A quantity of powder equivalent to 10mg was weighed and transferred to 10ml volumetric flask, extracted with 5ml of mobile phase and the extract was made up to the volume of 10ml with mobile phase, then the dilutions were made to get concentration of 8 , 10, 12µg/ml of Lercanidipine HCl. The solution was filtered through 0.45µ membrane filter . An aliquot of 100µl of both standard and sample solutions were injected separately and chromatograms were recorded.

RESULTS AND DISCUSSION

The retention time was found to be 4.10min. A typical chromatogram of sample solution is shown in fig.1 .The proposed method was validated as per the standard analytical procedures [9]. Table (1) gives the data obtained for all the validation parameters performed. Each of the sample solution was injected six times and the retention time was observed in all the cases. Linearity experiments were performed and the response was found to be in concentration range of 10-60µg/ml for Lercanidipine HCl. Linearity graph was plotted by peak area versus concentration and the correlation coefficient R^2 was found to be 0.9987. The %RSD for precision of the proposed method was found to be 0.8752%, the low %RSD value indicated that the method had good precision. The proposed method was found to be robust as the %RSD calculated with respect to change in flow rate, mobile phase, column was found to be not more than 2%. The accuracy of the method was determined by recovery studies at three different levels. Standard drug solution containing Lercanidipine HCl in range of 8, 10, 12µg/ml was added to previously analysed test solution. Amount of drug recovered at each level was calculated and was found to be 98.27, 101.23, 96.38 % (Table2) which was in good agreement with label claim. The high percentage recovery showed that the method was free from interference of the excipients used in tablet formulation. The results

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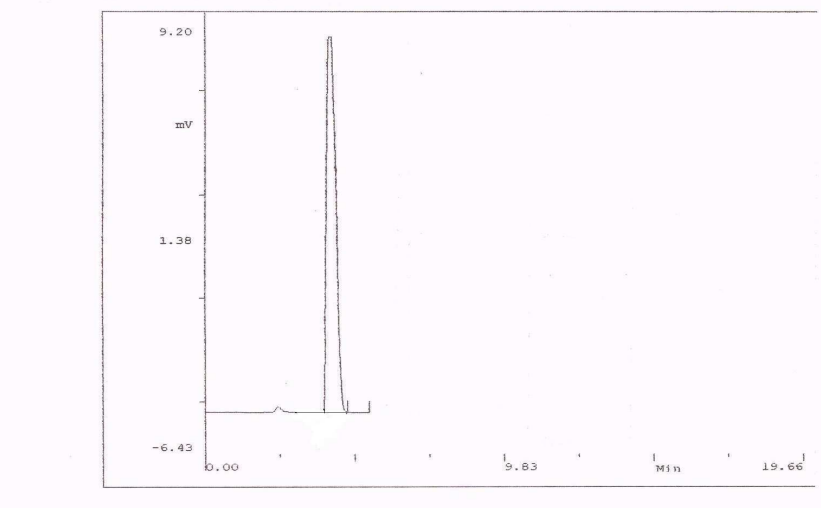
of the study indicated that the proposed method is simple accurate, precise and less time consuming and can be useful for determination of Lercanidipine HCl in tablets.

Fig: 1

Typical chromatogram of sample solution



Chromatogram showing sample solution of Lercanidipine Hydrochloride at concentration of 10µg/ml.

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Table 1

Validation parameters for the proposed method:

Parameters	lercanidipine
Regression equation Regression coefficient	Y=323586X + 398533 0.9987
Limit of Detection	0.03µg/ml
Limit of Quantitation	0.04µg/ml

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Precision (%RSD)	
Method precision	0.8752
System precision	0.9762
Inter-day precision	0.7309
Intra –day precision	0.6249
Accuracy (% Recovery)n=3	96.38 to101.23%

Table 2

Recovery studies of Lercanidipine hydrochloride

Drug	Amount added(µg/ml)	Amount* recovered (µg/ml) n=3	%Recovery
Lercanidipine HCl	8	7.93	99.2%
		7.702	96.2%
		7.957	99.42%
	10	10.05	100.5%
		10.14	101.4%
		10.18	101.8%
	12	11.46	95.5%
		11.55	96.25%
		11.69	97.41%

**Average of 3 readings. Table showing % recovery of Lercanidipine hydrochloride at three different levels.*

CONCLUSION

The data obtained indicated that the proposed method is simple accurate, precise and less time consuming and can be useful for routine determination of Lercanidipine HCl in tablets.

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