



RESEARCH ARTICLE

ECO-FRIENDLY QUANTITATIVE ESTIMATION OF LERCANIDIPINE HYDROCHLORIDE: A NOVEL APPROACH USING HYDROTROPIC SOLUBILIZATION TECHNIQUE

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Hydrotropic solution may be a proper choice to preclude the use of organic solvents so that, a simple, accurate, novel, safe and precise method could be developed for estimation of poorly water soluble drug, lercanidipine hydrochloride. Solubility of lercanidipine hydrochloride (LER) is increased by using 2M citric acid as hydrotropic agent. There was more than 61 fold solubility enhancement in hydrotropic solution as compared with distilled water. LER showed the maximum absorbance at 363 nm. At this wavelength, hydrotropic agent and other tablet excipients did not show any significant interference in the spectrophotometric assay. The developed method was found to be linear in the range of 50-250 µg/ml with correlation coefficient (r^2) of 0.9997. The mean percent label claims of tablets of LER in formulation-I and formulation-II estimated by the proposed method were found to be 98.63 ± 0.73 to 98.93 ± 0.57 respectively. The developed methods were validated according to ICH guidelines and values of accuracy, precision and other statistical parameters were found to be in good accordance with the prescribed values. As hydrotropic agent was used in the proposed method, this method is ecofriendly and it can be used in routine quantitative analysis of drug in bulk drug and dosage form in industries.

Key words: Lercanidipine hydrochloride, Citric acid, Hydrotropic solubilization technique.

INTRODUCTION

Lercanidipine hydrochloride (LER) is chemically 2-[(3,3-diphenylpropyl) (methyl) amino]-1,1-dimethylethyl methyl 2,6-dimethyl-4-(3-nitrophenyl) - 1,4-dihydropyridine-3,5-dicarboxylate monohydrochloride (**Figure 1**) and used in the treatment of mild to moderate hypertension, management of angina pectoris and Raynaud's syndrome (Sweetman, 1999; O'Neil *et al* 2001). Lercanidipine hydrochloride is not an official drug in IP, BP and USP. Literature survey revealed that many spectrophotometric methods (Eswar *et al* 2004; Mubeen *et al* 2009; Sastry and Ramakrishna, 2009) and HPLC (Alvarez-Lueje *et al* 2003; Vijaya *et al* 2004), LC-ESI-MS/MS

(Fiori *et al* 2006; Salem *et al* 2004) and voltametric method (Ozturk *et al* 2011; Alvarez-

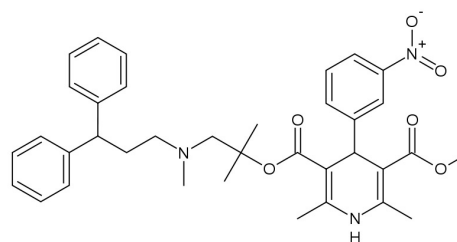


Fig. 1. Chemical structure of LER

Lueje *et al* 2002) has been reported for determination of lercanidipine hydrochloride in bulk drug and in biological fluids. Considering