Development of RP-HPLC method for the analysis of levocetirizine. 2HCl and ambroxol. HCl in combination and its application

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ABSTRACT: A simple, sensitive isocratic and reproducible reversed phase High Performance Liquid Chromatographic (RP-HPLC) method was developed for the estimation of ambroxol hydrochloride (ABH) and levocetirizine dihydrochloride (LCD) in combination using PDA detector. The system consisted of RP-C18 column and the detection was performed at 230nm. The mobile phase was a mixture of acetonitrile : phosphate buffer solution (60:40) (pH 7.0) pumped at room temperature and a flow rate of 1 ml/min. ABH and LCD were eluted at 2.75 and 5.01 sec respectively. The mean absolute recoveries of ABH and LCD were about 98 % and 99 % respectively and the limit of detection of LCD and ABH in the mixture of given proportion is observed to be 0.1 µg/ml and 1.5 µg/ml and the limit of quantitation is 0.3 µg/ml and 4.5 µg/ml respectively. The calibration was linear over a concentration range of 4.5 µg/ml to 15.0 µg/ml with $r^2 > 0.997$ for ABH and 0.3 µg/ml to 1.0 µg/ml with $r^2 > 0.999$ for LCD. The intra (n = 5) and inter (n = 5) day assay variations in the linear range are < 4 % for ABH and < 6 % for LCD. Three pharmaceutical products containing this combination are analyzed to test the applicability of the new method. The percentage of ABH and LCD in three marketed capsule dosage form studied range from 99 to 102 % and 100 to 103 % and respectively to the claimed value.

KEYWORDS: Ambroxol hydrochloride; HPLC; Levocetirizine; PDA detection

Introduction

Levocetirizine (as levocetirizine 2HCl) is a third generation non-sedative antihistamine acts by blocking histamine receptors. It is used in the treatment of several allergic reactions, viz., allergic rhinitis, idiopathic urticaria, hay fever etc., (Pasquali et al., 2006; Grob and Lacapelle, 2008; Dubuske, 2007). Ambroxol (as ambroxol, HCl) is an active mucolytic agent works by the breakdown of acid mucopolysaccharide fibers, which makes the sputum thinner and less viscous and therefore more easily removed by coughing. It is used in the treatment of upper respiratory tract diseases (Nobata et al., 2006). LCD and ABH combination have been used clinically for their anti-allergic and expectorant properties. Earlier literature reveals analytical methods like UV, HPLC, and LC - MS (Shahed et al., 2008; Qi et al., 2004; Arayne et al., 2008; Morita et al., 2008) for the determination of these drugs individually and with other combinations. Lakshmana et al., reported an UV method for simultaneous determination of Levocetirizine and Ambroxol HCl in tablet dosage forms. To date there is no report available for the simultaneous determination of LCD and ABH by HPLC using diode array detection. This paper reports a simple, sensitive and reproducible HPLC method for the simultaneous determination of LCD and ABH and its application in the evaluation of three marketed capsule dosage forms.

Experimental

Materials and methods

Pure samples of LCD and ABH were gifted by Orchid Chemicals and Pharmaceutical Ltd., (Chennai, India). All the solvents were of HPLC and analytical grade purchased from Merck (Mumbai, India). Capsules of three brands, Airitis Plus (Brand 1; Nicholas Piramal India Ltd, Mumbai, India), Laveta – A (Brand 2; Alembic Ltd, Vadodara, India) and Levocet – Plus (Brand 3; Hetero Health Care Ltd, Hyderabad, India) were purchased from local market.