Determination of cetirizine dihydrochloride, related impurities and preservatives in oral solution and tablet dosage forms using HPLC. Jaber A M Y; Al Sherife H A; Al Omari M M; Badwan A A Chemistry Department, King Fahid University of Petroleum and Minerals, Dhahran 31261, Saudi Arabia. amjaber@kfupm.edu.sa Journal of pharmaceutical and biomedical analysis (2004), 36(2), 341-50. Journal code: 8309336. ISSN:0731-7085. Journal; Article; (JOURNAL ARTICLE); (RESEARCH SUPPORT, NON-U.S. GOV'T) written in English. PubMed ID 15496327 AN 2004594700 MEDLINE (Copyright (C) 2008 U.S. National Library of Medicine on SciFinder (R))

Abstract

An HPLC method was developed and validated for the determination of cetirizine dihydrochloride (CZ) as well as its related impurities in commercial oral solution and tablet formulations. Furthermore, two preservatives associated with the drug formulations, namely, propyl (PP) and butylparabens (BP) were successfully determined by this method. The chromatographic system used was equipped with a Hypersil BDS C18, 5 microm column (4.6 x 250 mm) and a detector set at 230 nm in conjunction with a mobile phase of 0.05 M dihydrogen phosphate:acetonitrile:methanol:tetrahydrofuran (12:5:2:1, v/v/v/v) at a pH of 5.5 and a flow rate of 1 ml min(-1). The calibration curves were linear within the target concentration ranges studied, namely, 2 x 10(2) - 8 x 10(2) microg ml(-1) and 1-4 microg ml(-1) for CZ, 20-100 microg ml(-1) for preservatives and 1-4 microg ml(-1) for CZ related impurities. The limits of detection (LOD) and quantitation (LOQ) for CZ were, respectively, 0.10 and 0.34 microg ml(-1) and for CZ related impurities were in the ranges of 0.08-0.26 microg ml(-1) and 0.28-0.86 microg ml(-1), respectively. The method proved to be specific, stability indicating, accurate, precise, robust and could be used as an alternative to the European pharmacopoeial method set for CZ and its related impurities.