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, Saudi Arabia. Journal of Pharmaceutical and Biomedical Analysis (2004), 36(2), 341-350. Publisher: Elsevier B.V., CODEN: JPBADA ISSN: 0731-7085. Journal written in English. CAN 141:401096 AN 2004:889271 CAPLUS (Copyright (C) 2008 ACS on SciFinder (R))

Abstract

An HPLC method was developed and validated for the detn. of cetirizine dihydrochloride (CZ) as well as its related impurities in com. oral soln. and tablet formulations. Furthermore, 2 preservatives assocd. with the drug formulations, namely, Pr (PP) and butylparabens (BP) were successfully detd. by this method. The chromatog. system used was equipped with a Hypersil BDS C18, 5 μm column (4.6 × 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, vol./vol./vol./vol.) at a pH of 5.5 and a flow rate of 1 mL min-1. The calibration curves were linear within the target concn. ranges studied, namely, 2×102-8×102 μg ml-1 and 1-4 μg ml-1 for CZ, 20-100 μg ml-1 for preservatives and 1-4 μg ml-1 for CZ related impurities. The limits of detection (LOD) and quantitation (LOQ) for CZ were, resp., 0.10 and 0.34 μg ml-1 and for CZ related impurities were in the ranges of 0.08-0.26 μg ml-1 and 0.28-0.86 μg ml-1, resp. 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.