Determination of terbutaline sulfate and its degradation products in pharmaceutical formulations using LC. Daraghmeh N; Al-Omari M M; Sara Z; Badwan A A; Jaber A M Y The Jordanian Pharmaceutical Manufacturing and Medical Equipment Co. Ltd, PO Box 94, 11710, Naor, Jordan Journal of pharmaceutical and biomedical analysis (2002), 29(5), 927-37. Journal code: 8309336. ISSN:0731-7085. Journal; Article; (JOURNAL ARTICLE); (RESEARCH SUPPORT, NON-U.S. GOV'T); (VALIDATION STUDIES) written in English. PubMed ID 12093527 AN 2002418840 MEDLINE (Copyright (C) 2008 U.S. National Library of Medicine on SciFinder (R))

Abstract

There is a lack of information concerning analysis of terbutaline sulfate and quantification of its related substances particularly in the liquid dosage forms. This work aimed at developing and validating an HPLC method for determination of terbutaline sulfate and its possible degradation products, namely, 3,5-dihydroxybenzoic acid, 3,5 dihydroxybenzaldehyde and 1-(3,5-dihydroxyphenyl)-2-[(1,1-dimethylethyl) amino]-ethanone that might appear as impurities in the starting material as well as in the solid and liquid formulations. The chromatographic system used consisted a Hypersil 100 C(18,) 150 x 4.6 mm (5 microm) column, a mobile phase of ammonium acetate (0.15 M) and glacial acetic acid (pH of 4.0, 96:4 v/v) with a flow rate of 2 ml min(-1) and a UV detector set at 270 nm. The degree of linearity and the characteristic statistical parameters of the calibration curves including the limit of detection (LOD) and limit of quantitation (LOQ) were estimated for terbutaline sulfate and its degradation products. The method was found to be specific, stability indicating, accurate, precise and robust.