Determinaton of sildenafil citrate and related substances in the commercial products and tablet dosage form using HPLC. Daraghmeh, N.; Al-Omari, M.; Badwan, A. A.; Jaber, A. M. Y.. The Jordanian Pharmaceutical Manufacturing and Medical Equipment Co. Ltd, Naor, Jordan. Journal of Pharmaceutical and Biomedical Analysis (2001), 25(3-4), 483-492. Publisher: Elsevier Science B.V., CODEN: JPBADA ISSN: 0731-7085. Journal written in English. CAN 135:322800 AN 2001:373648 CAPLUS (Copyright (C) 2008 ACS on SciFinder (R))

Abstract

This study aimed at developing and validating a HPLC method for the detn. of sildenafil citrate and its related substances that might coexist in the drug com. products and in tablets as impurities that originate from synthesis processes or degrdn. A chromatog. system comprising a μBondapak C18 (10 μm) column, a mobile phase of pH 7.0 0.2M NH4OAc-MeCN (1:1), a flow rate of 1 mL/min and a UV detector set at 240 nm showed good chromatog. sepn. for sildenafil and other related substances. The degree of linearity of the calibration curves, the percent recoveries of sildenafil and related substances, the limit of detection, LOD, and limit of quantitation, LOQ for the HPLC method were detd. The HPLC method under study was specific, precise, accurate, reproducible indicating stability and robust.