Thesis Title

Development of High-Performance Liquid Chromatographic

Method (HPLC) for the Determination of Mebendazole in Tablets.

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Abstract

High-Performance Liquid Chromatographic method (HPLC) has been developed and validated for the determination of mebendazole in tablets. Optimum conditions for quantitation of mebendazole were investigated. Chromatographic separation was carried out on the Lichrosorp 10 RP-18 column at room temperature using a mixture consisting of acetonitrile: methanol: water (45:45:10) as mobile phase with a flow rate of 1.7 millilitre per minute. Measurements were made by UV detector at 300 nanometre., using tinidazole as internal standard. The resulting chromatograms showed good resolution (R = 2.53) with a short retention time (2.0 minute) and no interfering peak was found. The proposed method provided a wide range of linearity (5 - 1000 ppm.) and standard curves were linear in the concentration range from 50-250 ppm. (R-square > 0.999). The percentage recoveries at 3 levels of concentration for 2 commercially available preparations; Fugacar® and Benda® were 99.17, 99.50, 99.98 % and 100.39, 100.04, 100.08 % respectively and % relative standard deviation (%RSD) were less than 1.1 %. The detection limit was 0.05 ppm. Mebendazole and tinidazole were found to be stable in the mobile phase at 24 hours. The proposed method was applied to the determination of mebendazole in tablets compared with the USP's method. By using the USP's method, the percentage recoveries for Fugacar® and Benda® were 86.71 % and 88.55 % respectively and % relative standard deviation (%RSD) were less than 0.5 %, which indicated that this method was very accurate and precise and moreover, less time consuming.