Thesis Title Determination of Tolperisone Hydrochloride in Pharmaceutical Preparations by High Performance Thin-layer Chromatography (HPTLC)

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Abstract

A high performance thin layer chromatographic(HPTLC) procedure for determining tolperisone hydrochloride with densitometric detection has been developed. Two solvent systems namely methanol and a mixture consisting of methanol:acetone:butanol(50:45:5 v/v) were found to be appropriate mobile phases. The detection limit for tolperisone hydrochloride with the former mobile phase was 20.12 nanogram. Linear calibration curves over the ranges of 0.02-0.1, 0.2-0.5, 0.5-5.0 and 5.0-25.0 microgram with correlation coefficients of 0.9998, 0.9915, 0.9929 and 0.9885 respectively were established. The percentage relative standard deviation and the percentage recovery were 0.66 and 99.18 respectively. When the latter mobile was used, a detection limit for toperisone hydrochloride was 4.0 nanogram was obtained. Calibration curves were linear over the ranges of 0.004-0.021, 0.03-0.41, 0.5-5.0 and 5.04-25.18 microgram with correlation coefficients of 0.9929, 0.9976, 0.9958 and 0.9955 respectively. The percentage relative standard deviation and the

percentage recovery were 0.74 and 99.49 respectively. The proposed method using both solvent systems as mobile phases have been applied to the determination of tolperisone hydrochloride in pharmaceutical preparations: they were Biocalm tablet, Mydocalm tablet, and Mydocalm injection. The percentage labelled amounts with the former mobile phase were 107.13, 104.43 and 92.10 with the percentage relative standard deviations of 1.25, 1.41 and 1.37 respectively. With respect to utilization of the latter mobile phase, it was found that the percentage labelled amounts were 107.58, 102.49 and 93.62 with the percentage relative standard deviations of 1.22, 1.09 and 1.37 respectively. A comparative determination of tolperisone hydrochloride by potentiometric titration was also carried out. Results obtained by both methods were rather different. The HPTLC method was superior to the potentiometric titration method in that less consumption of organic solvents, less time-consuming, more sensitive, accurate and reproducible.