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Derivatization of labetalol hydrochloride for its spectrofluorimetric and spectrophotometric determination inhuman plasma; Application to stability study

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Abstract:

Two simple, selective and accurate methods were developed for the determination of Labetalol hydrochloride in pure form and pharmaceutical tablets. Both methods are based on derivatization of the studied drug with 4-Chloro-7-nitrobenzo-2-oxa-1,3-diazole (NBD-Cl) in alkaline medium (pH 7.5).The reaction product was measured spectrofluorimetrically at 540 nm after excitation at 476 nm (method I) or spectrophotometrically at 480 nm (method II). The calibration graphs were rectilinear over the concentration ranges of 0.10–2.0 and 1.0–11.0 μg ml^{-1} for methods I and II, respectively. The proposed methods were successfully applied to the analysis of commercial tablets without interference from common excipients. Furthermore, the spectrofluorimetric method was utilized for the in vitro determination of labetalol in spiked human plasma, with a percent mean recovery (n =3) of 97.80 ± 1.29%. Moreover, the spectrofluorimetric method was extended to examine the stability study of LBT under different stress conditions such as alkaline, acidic, oxidative, photolytic and a thermal degradation.

Keywords: Labetalol hydrochloride; NBD-Cl; Spectrophotometry; Spectrofluorimetry; Stability study.

Introduction