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Identification, Isolation and Characterization of Unknown Degradation Products of Cefprozil Monohydrate by HPTLC

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Abstract : The present research work was aimed to determine stability of cefprozil monohydrate (CEFZ) as per various stress degradation conditions recommended by International Conference on Harmonization (ICH) guideline Q1A (R2). Forced degradation studies were carried out for hydrolytic, oxidative, photolytic and thermal stress conditions. The drug was found susceptible for degradation under all stress conditions. Separation was carried out by using High Performance Thin Layer Chromatographic System (HPTLC). Aluminum plates pre-coated with silica gel 60F254 were used as the stationary phase. The mobile phase consisted of ethyl acetate: acetone: methanol: water: glacial acetic acid (7.5:2.5:2.5:1.5:0.5v/v). Densitometric analysis was carried out at 280 nm. The system was found to give compact spot for cefprozil monohydrate (0.45 Rf). The linear regression analysis data showed good linear relationship in the concentration range 200-5.000 ng/band for cefprozil monohydrate. Percent recovery for the drug was found to be in the range of 98.78-101.24. Method was found to be reproducible with % relative standard deviation (%RSD) for intra- and inter-day precision to be < 1.5% over the said concentration range. The method was validated for precision, accuracy, specificity and robustness. The method has been successfully applied in the analysis of drug in tablet dosage form. Three unknown degradation products formed under various stress conditions were isolated by preparative HPTLC and characterized by mass spectroscopic studies.

Keywords : cefprozil monohydrate, degradation products, HPTLC, stress study, stability indicating method
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