ABSTRACT

VALIDATION OF STABILITY-INDICATING HPLC METHOD FOR RANITIDINE HYDROCHLORIDE TABLET

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A stability-indicating HPLC method has been developed and validated for the determination of ranitidine HCl in tablets. Chromatographic separation was achieved on a NH_2 column using methanol-0.1 M aqueous ammonium acetate buffer pH 6.7 (85:15) as mobile phase. Ranitidine HCl was exposed to acid, alkali, oxidation, thermal and photolytic stress conditions. The stressed samples were analysed by the proposed method. Validation steps involved measurement of selectivity, linearity, accuracy, precision, robustness, and system suitability. The validated method has been demonstrated to be reliable for the determination of ranitidine HCl. The validation of this method indicated that it could be effectively used to monitor the stability of ranitidine HCl tablets.

Keywords: Ranitidine hydrochloride, HPLC, Stability-indicating method, Validation