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Validated stability-indicating assay method for determination of ilaprazole in bulk drug and tablets by high performance liquid chromatography

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A validated stability-indicating HPLC method has been reported for the determination of ilaprazole in bulk drug and tablet. The drug was subjected to the various stress conditions as per the ICH guidelines. The degradation behavior of ilaprazole was studied under hydrolytic, oxidative, photolytic and thermal conditions and was found to be unstable in almost all conditions except under alkaline and photolytic conditions. The separation of drug and its degraded products was carried out on Kinetex C-18 100A (5 µ, 250×4.6 mm) column. The initial mobile phase composition used was acetonitrile and water in the ratio 50:70 v/v for 1 min then was changed to 70:30 v/v in next 6 min and finally equilibrated back to initial composition in 14 min. The method was applied for the determination of ilaprazole in marketed tablet formulation. The detection was carried at 305 nm using PDA detector with a flow rate of 1.0 ml/min and injection volume 20 µl. The validation of developed method was performed for linearity, accuracy, precision, selectivity and specificity and robustness.

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