

DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR ESTIMATION OF ILAPRAZOLE IN ITS TABLET DOSAGE FORM

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ABSTRACT

The present work involves the development and validation of a simple, accurate and precise UV spectrophotometric method and RP-HPLC Method for the assay of Ilaprazole. Simple, specific, accurate, precise and reproducible method have been developed and validated for the estimation of Ilaprazole in its tablet dosage form.

UV- spectrophotometric method was a determined at 306nm over the concentration range 5-50 μ g/ml for Ilaprazole in 0.1 N NaOH. The % recovery of the drug (in sample preparation) was found to be 99.52-100.82%.

The RP-HPLC method was developed and validated for Ilaprazole in its tablet dosage Form. The method was performed on a Hypersil BDS C₁₈ (250mm X 4.6 mm i.d., 5 μ m particle size) with a gradient system of (Water: Acetonitrile) in the ratio of (30:70 v/v). The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20 μ l and wavelength of detection used was 306nm. The retention time for Ilaprazole was obtained as 4.957min. The linearity of the proposed method was investigated in the range of 5-25 μ g/ml.

Correlation coefficient was 0.9983 for Ilaprazole. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Ilaprazole. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in tablets.

Key words: Ilaprazole, UV Spectrophotometric Method, RP-HPLC Method, Analytical Method Validation.