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Research Article

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC ASSAY METHOD FOR SIMULTANEOUS ESTIMATION OF RABEPRAZOLE SODIUM AND ACECLOFENAC IN CAPSULE DOSAGE FORM

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ABSTRACT

A simple, rapid, and precise Reverse Phase HPLC method has been developed for determination of Rabeprazole Sodium (RBP sodium) and Aceclofenac (ACE) in combined Dosage form. The RP-HPLC method carried out on Hypersil BDS C18 (150 mm x 4.6 mm, 5µm) as stationary phase by using mobile phase consisting of 0.02M Phosphate buffer (pH 6with orthophosphoric acid) : acetonitrile (67:33). Mobile phase was maintained at a flow rate 1.0 ml/min. The UV detector was operated at 280nm. Retention time was found to be 4.3min for RBP Sodium and 5.6 min for Aceclofenac. The specificity studies shows that the analyte peaks were well resolved from the intermediates. Developed method was found to be linear over the range of 100-300µg/ml and 10-30µg/ml for Aceclofenac and Rabeprazole Sodium respectively; the correlation coefficient was found to be 0.9995 and 0.9995 for Aceclofenac and Rabeprazole Sodium. The precision study showed that the percentage relative standard deviation was within the range of acceptable limits, and the mean recovery was found to be 100.45 % and 99.63 % for Aceclofenac and Rabeprazole Sodium respectively. Statistical analysis proves that the method is reproducible & selective for the estimation of said drug, as the method could effectively separate the drug from its degradation product.

Key words: RP-HPLC, Rabeprazole Sodium, UV detector, Aceclofenac