

**Development and Validation of Analytical Methods for  
Simultaneous Estimation of Cyclobenzaprine Hydrochloride  
and Aceclofenac in Tablet Dosage form**

Submitted By

**Soida Sanketkumar Bharatsinh**

Supervised By

**Ms. Jignasa Modi**

M.Pharm.,

Assistant Professor, Department of Quality Assurance

**Parul Institute of Pharmacy & Research**

Limda, Ta. Waghodia, Dist. Vadodara 391760

**ABSTRACT**

A First order derivative spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Cyclobenzaprine Hydrochloride and Aceclofenac tablet dosage form. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous quantification of Cyclobenzaprine Hydrochloride and Aceclofenac. The method employed First order derivative method based on the measurement of absorbance at two wavelengths, 248.8 and 266 nm, ZCP of Cyclobenzaprine Hydrochloride and Aceclofenac respectively. The calibration curve was linear in a concentration range of 0.5-4.0 µg/ml for Cyclobenzaprine Hydrochloride and 6.65-53.2 µg/ml for Aceclofenac. The

RP-HPLC method has shown adequate separation of Cyclobenzaprine Hydrochloride and Aceclofenac in Tablet dosage form. The separation was achieved on a Hypersil BDS C18 (250mm X 4.6 mm i.d., 5 µm particle size) with a gradient system of Buffer: Acetonitrile in the ratio of 70:30 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 223nm. The retention time for Cyclobenzaprine Hydrochloride and Aceclofenac was obtained as 4.047 min and 6.083 min, respectively. The linearity of the proposed method was investigated in the range of 2.5-7.5µg/ml and 33.25-99.75µg/ml for Cyclobenzaprine Hydrochloride and Aceclofenac, respectively. Correlation coefficient was 0.9984 and 0.9989 for Cyclobenzaprine Hydrochloride and Aceclofenac, respectively. 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 Cyclobenzaprine Hydrochloride and Aceclofenac. 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:** Cyclobenzaprine Hydrochloride, Aceclofenac, First order derivative method, RP-HPLC method, Validation.