# DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF EPERISONE HYDROCHLORIDE AND DICLOFENAC SODIUM IN BULK AND SOLID DOSAGE FORM

Submitted By

**Bhatt Divyangkumar Jyotindrakumar**

**[Enrollment No: 112140813003]**

Supervised By

**Dr. Jawed Akhtar**

M. Pharm., Ph.D.

Associate Professor, Dept. of Quality Assurance

**Parul Institute of Pharmacy & Research**

Limda, Ta. Waghodia, Dist. Vadodara- 391 760

## ABSTRACT

A simple, accurate and precise UV Spectrophotometric methods and RP-HPLC method was developed and validated for simultaneous estimation of Eperisone Hydrochloride and Diclofenac Sodium in bulk and solid dosage form. In Q-absorbance ratio method determination was carried out at 256 nm $\lambda_{max}$ of Eperisone Hydrochloride and 269 nm an Isobestic point of both the drug. The linearity range was observed between 2-20 µg/ml for both Eperisone hydrochloride and Diclofenac Sodium at their respective wavelengths for both methods. Both the drugs were found in good agreement with the labelled claim in the marketed formulation. In capsule dosage form Eperisone Hydrochloride and Diclofenac Sodium were estimated 101.44 ±0.55 & 101.31±0.97 %. respectively. Second developed UV method was Area under Curve. The method involved the measurement of area at selected analytical wavelength ranges and performing the analysis using “Cramer’s Rule”. Two analytical wavelength ranges selected were

261-251 nm and 286-276 nm for estimation of Eperisone Hydrochloride and Diclofenac Sodium respectively. In capsule dosage form Eperisone Hydrochloride and Diclofenac Sodium were estimated 100.65±0.55 and 100.86±0.62 respectively. Both UV methods were statistically validated for its linearity, accuracy and precision. Both intraday and interday variation was found to be showing acceptable % relative standard deviation value. A simple, specific, accurate and precise reversed phase high performance liquid chromatographic method was developed for the simultaneous estimation of Eperisone Hydrochloride and Diclofenac Sodium in capsule dosage form. The determination was carried out by Waters C18 (250mm x 4.6 mm x 5µm) column using a mobile phase of Methanol: Water (90:10 v/v) at a flow rate of 1 mL/minute. Detection was carried out at 269 nm with UV-visible detector. Calibration curves were linear with correlation coefficient ($r^2$) 0.999 over a concentration range of 15-90 µg/mL for Eperisone Hydrochloride and 0.999 over a concentration range of 10-60 µg/mL for Diclofenac Sodium. The retention time for Eperisone Hydrochloride and Diclofenac Sodium was found to be 4.33 and 2.99 minutes, respectively. The mean recoveries were found 100.95±0.94 and 100.73±0.38 for EPE and DICLO respectively. The % relative standard deviation was found to be less than 2.0 % for both drugs. In capsule dosage form Eperisone Hydrochloride and Diclofenac Sodium were estimated 100.22±0.50 and 100.90±0.16 respectively. Finally all the three developed methods were compared statistically by ANOVA. $F_{calculated}$ value was less than $_{Ftabulated}$ at 95% confidence limit, which proved that all three developed methods were comparable with one another.

**Keywords:** Eperisone hydrochloride, Diclofenac Sodium, Q-Absorbance ratio method, Area under curve method, % relative standard deviation, Recovery, RP-HPLC.