DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF CAMYLOFIN DIHYDROCHLORIDE AND MEFENAMIC ACID COMBINATION IN BULK AND IN ITS TABLET DOSAGE FORM

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ABSTRACT

The present work involves the development and validation of a simple, accurate and precise Solvent Extraction spectrophotometric method and RP-HPLC Method for the assay of Camylofin Dihydrochloride and Mefenamic Acid.

Simple, specific, accurate, precise and reproducible method have been developed and validated for the simultaneous estimation of both drugs in their combined dosage form.

UV- spectrophotometric method was a determination using the solvent extraction method at 262nm and 285nm over the concentration range 200-700µg/ml and 5-30µg/ml for Camylofin Dihydrochloride in 0.1 N HCl and Mefenamic Acid in 0.1 N NaOH respectively. The % recoveries of the both the drugs (in sample preparation) were found to be 98.1-98.4% and 98.05-98.08% respectively. The % recoveries of the both the drugs (in bulk preparation) were found to be 98.3-98.5% and 98.20-98.28% respectively.

The RP-HPLC method has shown adequate separation of Camylofin Dihydrochloride and Mefenamic Acid in bulk and its tablet dosage Form. The separation was achieved on a

Hypersil BDS C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with a gradient system of (Water: Acetonitrile)in the ratio of (45:55 v/v), pH adjusted 3.5 with Ortho-Phosphoric acid. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 264nm. The retention time for Camylofin Dihydrochloride and Mefenamic Acid was obtained as 2.59±0.1min and 7.8±0.1min, respectively. The linearity of the proposed method was investigated in the range of 100-300µg/ml and 500-1500µg/ml for Camylofin Dihydrochloride and Mefenamic Acid, respectively. Correlation coefficient was 0.9964 and 0.9965 for Camylofin Dihydrochloride and Mefenamic Acid, 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 Camylofin Dihydrochloride and Mefenamic Acid. 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: Camylofin Dihydrochloride, Mefenamic Acid, UV-Solvent Extraction Spectrophotometric Method, RP-HPLC Method, Analytical Method Validation.