DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF FEBUXOSTAT AND DICLOFENAC POTASSIUM 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 Simultaneous Equation Method UV-spectroscopy and RP-HPLC Method for the assay of Febuxostat and Diclofenac Potassium.

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 Simultaneous Equation Method UV-spectroscopy at 314 nm and 277nm over the concentration range 4-14 µg/ml for Febuxostat and 10-35 µg/ml for Diclfoenac Potassium in 0.1 N NaOH respectively. The % recoveries of the both the drugs (in sample preparation) were found to be 100.67-101.5 % for Febuxostat and 100.15-101.9 % for Diclofenac Potassium respectively. The % recoveries of the both the drugs (in bulk preparation) were found to be 99.87-100.83 % and 99.84-100.67% respectively.

THE RP-HPLC METHOD has shown adequate separation of Febuxostat And Diclofenac Potassium in bulk and it's tablet dosage Form. The separation was achieved on a Enable C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with a gradient system of ACN: Methanol: water (30:30:40) pH 5 adjusted with O-phosphoric acid and TEA. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 280 nm. The retention time Febuxostat and Diclofenac Potassium for was obtained as 3.0±0.1min and 4.4±0.1min, respectively. The linearity of the proposed method was investigated in the range of 4-24 µg/ml and 10-60 µg/ml for Febuxostat and Diclofenac Potassium, respectively. Correlation coefficient was 0.998 and 0.998 for Febuxostat and Diclofenac Potassium 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 Febuxostat and Diclofenac Potassium. 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: Febuxostat, Diclofenac Potassium, Simultaneous Equation Method UV-spectroscopy, RP-HPLC Method, Analytical Method Validation.