

**Development and Validation of Analytical Method for Simultaneous Estimation of Pantoprazole Sodium Sesquihydrate and Diclofenac Sodium in bulk and its Dosage Form**

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**ABSTRACT**

A simple, specific, accurate and precise RP-HPLC method was developed and validated for simultaneous estimation of Diclofenac sodium and Pantoprazole sodium sesquihydrate in bulk and its Capsule dosage form. The RP-HPLC method has shown adequate separation of Diclofenac sodium and Pantoprazole sodium sesquihydrate in bulk and its dosage form. The separation was achieved on a BDS hypersil C<sub>18</sub>, (250mm X 4.6mm i.d., 5µm particle size) using Potassium dihydrogen phosphate buffer pH 3.5: ACN (60:40 v/v) as mobile phase. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 280nm. The retention time for Diclofenac sodium and Pantoprazole sodium sesquihydrate was obtained as 3.300 min and 6.613 min, respectively. The linearity of the proposed method was investigated in the range of 18.75-56.25 µg/ml and 5-15 µg/ml for Diclofenac sodium and Pantoprazole sodium

sesquihydrate, respectively. Regression coefficient was 0.998 for both drugs. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ, Robustness, specificity and the results were found to be satisfactory, thus the method is accurate, precise, rapid and simple for estimation of Diclofenac sodium and Pantoprazole sodium sesquihydrate.

**Key words:** Diclofenac sodium, Pantoprazole sodium sesquihydrate, RP-HPLC, Validation.