NEW APPROACH FOR ASSURING HIGHER QUALITY OF CALCIUM OROTATE BY ESTIMATING OROTIC ACID CONTENT USING STABILITY INDICATING RP-HPLC METHOD

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ABSTRACT

Calcium orotate is one of the highly prescribed calcium salts. The orotic acid content is crucial for exhibiting its high bioavailability. There are no methods available to estimate orotic acid content in calcium orotate. The primary objective of this study was to develop and validate a robust method for the estimation of orotic acid from the bulk calcium orotate. A stability indicating RP-HPLC method was developed using an isocratic condition of mobile phase comprising 20 mM of monobasic potassium phosphate in water (pH 2.5) with phosphoric acid at a flow rate of 1 mL min^{-1} over C-18 (ODS, 250 × 4.6 mm) column at ambient temperature with UV detection at 214 nm. It was validated with respect to accuracy, specificity, precision, linearity, range, robustness and system suitability. Real sample analysis was also performed to test the applicability for regular analysis of calcium orotate bulk samples to assure its quality.