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Develop and validate stability indicating HPLC method for simultaneous estimation of Epalrestat and Methylcobalamin in tablet dosage forms

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Having a purpose of reducing analysis time, increasing reliability via higher resolution with very high pressure due to smaller particles, sensitivity and selectivity as well as producing economical method by reducing solvent consumption, HPLC is most promising advancement in a world of chromatography. In this research work, a new reverse phase HPLC method was developed for the Epalrestat and Methylcobalamin in its tablet dosage form. Forced degradation study was carried out and a newly developed method is applicable to degradation analysis of drug. A chromatographic separation of drug as well as its degradants was achieved using spherisorb CNRP, 4.6 × 250mm, 5µm C 18 column with Mobile phase of Acetonitrile: 0.05 M Potassium Dihydrogen Phosphate Buffer pH 4.0 adjusted with ortho Phosphoric acid (60: 40, V/V). Drug and degradants were monitored at detection wavelength of 292nm, the flow rate was 1 ml/min, injection volume was 20 µl. Retention time of Epalrestat and Methylcobalamin were about 3.26 min and 4.92 min respectively. Both the drugs were subjected to acid, alkali, oxidation, thermal and photo degradation. The degradation studies indicated, Epalrestat to be more susceptible to acid hydrolysis while Methylcobalamin to be more susceptible to photo hydrolysis. The degradation products were well resolved from the pure drug with significant differences in their retention time values. A developed method was validated as per ICH guideline using validation parameters like specificity, precision, accuracy, robustness, solution stability, linearity and range. Forced degradation studies demonstrated the stability indicating power of the HPLC method.

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