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Quality by design approach for development of stability indicating method for determination of cefditoren pivoxil

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A hybrid development strategy of Quality by design (QbD) and one factor at time (OFAT) approaches was used to develop a stability indicating HPLC method for quantitative determination of cefditoren pivoxil (CTP) in bulk powder and pharmaceutical formulations. A forced degradation studies were performed under acid, alkaline, thermal and photolytic stress conditions. Chromatographic separation achieved in less than 10 min. using a RP C-18 column, mobile phase [methanol: acetate buffer pH 4.5 (55:45, v/v)], flow rate 1.5 mL min-1 and UV detection at 225 nm. Optimization of column, pH, and wavelength implemented according to OFAT approach, while elution temperature and methanol content in the mobile phase considering QbD approach. The method was validated to meet official requirements including specificity, linearity, precision, accuracy and robustness. The drug response was linear (r=0.9999) in range of 89-672 µg mL-1, the limit of detection (LOD) and limit of quantitation (LOQ) were 5.31 µg mL-1 and 16.1 µg mL-1, respectively. The intra- and inter-day precisions were 0.11%, 0.44% respectively. The proposed method was successfully applied for the determination of CTP in bulk and tablets with acceptable accuracy and precisions. The obtained results demonstrated that the proposed method has a great value for application in quality control labs and stability studies for CTP.

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Kinetic modelling, equilibrium and selectivity of heavy metal ions adsorption onto C-4-bromophenylcalix[4]resorcinarene

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Adsorption studies were performed on selected heavy metal ions ((Pb (II), Co (II), Cu (II), Mn (II) and Zn (II)) using synthetic adsorbent (C-4-bromophenylcalix[4]resorcinarene 3) to investigate the effect of different parameters such as adsorbate dose, agitation time, and pH. Selectivity of the adsorbents towards a mixture of heavy metals adsorbates was investigated. Results showed that optimum agitation time was 30 min at pH of 5.6 and initial concentration of 1ppm for all investigated heavy metals. Different kinetic models of Santosa first order, Lagergren pseudo first order and Ho pseudo second order were applied on the adsorption experimental data. Results proved that all adsorption processes were followed and adopted pseudo second order kinetic model. The adsorption capacity of C-4-bromophenylcalix[4]resorcinarene towards the selected heavy metal ions was 84.55%, 84.29%, 84.06%, 79.76%, 75%, for Cu (II), Pb (II), Zn(II), Mn (II) and Co (II), respectively. Selectivity of adsorption was tested on a mixture of Cu (II), Mn (II), Zn (II), Pb (II) and Co (II) with initial concentration of 1 ppm of each heavy metal and agitated time of 10 min with the adsorbent, removal percentage of each metal showed different values from each heavy metal alone as it was in decreasing order Cu (II) > Co (II) > Mn (II) > Pb (II) > Zn (II).

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