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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 pH4.5 (55:45, v/v)], flow rate 1.5 mL min<sup>-1</sup> 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 including specificity, linearity, precision, accuracy and robustness. The drug response was linear ( $r=0.9999$ ) in range of 89-672  $\mu\text{g mL}^{-1}$ , the limit of detection (LOD) and limit of quantitation (LOQ) were 5.31  $\mu\text{g mL}^{-1}$  and 16.1  $\mu\text{g mL}^{-1}$ , 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 results demonstrated that the method would have a great value when applied in quality control and stability studies for CTP.

### Biography

Sawsan Mohamed Amer has completed her PhD from Cairo University and Postdoctoral studies from the same University, Faculty of Pharmacy. She is the Professor of Analytical Chemistry since 2003 and as Head of Analytical Chemistry Department, Faculty of Pharmacy, Cairo University from 2010 to till date. She has published more than 50 papers in reputed journals and has been serving as a Reviewer and Editorial Board Member of many journals. She supervised more than 10 Master degree and more than 10 PhD degrees. She has contributed as an external examiner in more than 12 thesis discussion.

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