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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 p^H4.5 (55:45v/v)], flow rate 1.5mLmin⁻¹ and UV detection at 225nm. Optimization of column, p^H, 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 89-672µgmL⁻¹, the Limit Of Detection (LOD) and Limit Of Quantitation (LOQ) were 5.31µgmL⁻¹ and 16.1µgmL⁻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.

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Pharmacoeconomics: A tool in formulary development

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Essential medicines list is the concept that satisfies the priority of healthcare needs and promotes rational use of medicines. The drugs which are present in the list should address the disease burden based on its prevalence at all levels of health care. It also serves as basis of drug formulary. Increased drug utilization, increased drug price, availability of number of drugs to single indication and limited budgets shows the need of formulary. Formulary is a continuous revised compilation of pharmaceuticals and related products started as simple list of available drugs, and then they evolved into a dynamic guide for an effective management of drug therapy by health care professionals in clinical applications. Decisions about drug selection are complex and are influenced not just by evidenced based criteria but also take into account of economical and therapeutic aspects of drug, and political, social and ethical values of community to which the decisions apply. Thus pharmacoeconomics (PE) can serve as one of the tool in drug selection process for an effective development of formulary, but it may require strong co-ordination between pharmacoeconomic expertise and health care professionals. Literatures also reported that use of PE information in creating formulary is limited due to various barriers. However, it must be used to manage limited health resources in the best way. Therefore more educational programs to the decision makers should be conducted to facilitate the use of such tool in developing formulary. Because current evidence suggests that pharmacoeconomic information is not widely used worldwide.

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