Research in Pharmaceutical Sciences, 2012;7(5)
School of Pharmacy and Pharmaceutical Sciences
Isfahan University of Medical Sciences

Formulation design and optimization of direct compressed tablets of cefuroxime axetil using experimental design

H. Valizadeh[1], P. Zakeri-Milani[2], S. Ghanbarzadeh[3,*], M. Mahboob[4]

[1]Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, Iran and Research Center for Pharmaceutical Nanotechnology, Tabriz University of Medical Sciences, Tabriz, Iran
[2]Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, Iran.and Liver and Gastrointestinal Diseases Research Center, Tabriz University of Medical Sciences, Tabriz, Iran.
[3]Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, Iran and. Drug Applied Research Center, Tabriz University of Medical Sciences, Tabriz, Iran.
[4]Student Research Committee, Tabriz University of Medical Sciences, Tabriz, Iran

Background and Aims: The purpose of this study was to apply design of experimental (DOE) methodology for development and optimization of tablet formulations containing 250 mg cefuroxime axetil and six different excipients, manufactured by direct compression.
Methods: Forty one formulations, screened by DOE method in Minitab software, were prepared with different proportions of Avicel, Lactose, Aerosil, Polyvinylpyrrolidone (PVP), AcDiSol and MgStearate. Statistical design helps for better understanding of the formulation factors effects on tablet characteristics. For systematical optimization of flowability and hardness, they were taken as responses and cefuroxime axetil and six excipients concentrations were considered as the independent variables. Results were analyzed using Minitab software and then were used for evaluation and comparing of the prediction power of three regression models. Response Surface Plots, Contour Plots, Overlaid Contour Plots and Optimization Plots were drawn using Minitab and optimum formulations were selected as well.
Results: Lactose, Avicel, AcDiSol and cefuroxime axetil increased the flow time but PVP, MgStearate and Aerosil improved the flowability. More over AcDiSol and MgStearate had the greatest effect on flowability. Avicel, PVP, Aerosil, AcDiSol and MgStearate increased the hardness of tablets, and Lactose and cefuroxime axetil decreased the hardness. Additionally Lactose and AcDiSol had the maximum effect on hardness. Although all prepared formulations released more than 60% of drug in 30 minutes, the desired formulations in the case of flowability and hardness were selected for dissolution test and all of them were passed USP 34 criteria. Among the regression methods used in this research, stepwise method was the most predictable method having the lowest percentage error in flowability and hardness parameters in both test and standard groups.
Conclusions: Using statistical methods can reduce the number of experiments by optimizing formulations during development and lead to significant save in time and cost.

Keywords: Cefuroxime axetil; Direct compression; Design of experiment