

Formulation and optimization of pseudoephedrine and loratadine pellets using factorial design

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Background and Aims: The purpose of this study was to apply experimental design methodology (DOE) to the development and optimization of three stage release capsules containing loratadine and pseudoephedrine which have fast, intermediate and slow release pellets. Statistical design helped in better understanding on the effect of formulation factors important for designing formulations with desired characteristics.

Methods: Seventeen formulations, screened by DOE methodology in Minitab software, were produced with different proportions of excipients using Extrusion-spheronization method. Due to High solubility of pseudoephedrine in water, fast release pellets were prepared easily by this method.

Results: In preparation of slow release pellets statistical methods showed that in the early hours, the effectiveness of bees wax in the release rate decreasing was more than carnauba wax, and effect of carnauba wax became more during the time and effectiveness of HPMC was more than Avicel for the duration of the time. The amount of waxes and HPMC in intermediate release pellet was fewer than slow release pellets and Avicel was deleted from the intermediate release formulation. Overlaid Contour Plots were used to achieve desired results and it was found that one of the formulation results given by these plots was the same with the composition of one of the prepared formulation. Dissolution results in capsules containing three stage release pellets were acceptable according the USP criterion.

Conclusions: Due to the simplicity of this method and using statistical method, production of three stages pellets containing loratadine and pseudoephedrine is possible in the pharmaceutical industrial scale.

Keywords: Pseudoephedrine; Loratadine; Factorial Design; Extrusion-spheronization