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Response Surface Methodology to Obtain Disopyramide Phosphate Loaded Controlled Release Ethyl Cellulose Microspheres

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Abstract : The present study deals with the preparation and optimization of ethyl cellulose-containing disopyramide phosphate loaded microspheres using solvent evaporation technique. A central composite design consisting of a two-level full factorial design superimposed on a star design was employed for optimizing the preparation microspheres. The drug:polymer ratio (X1) and speed of the stirrer (X2) were chosen as the independent variables. The cumulative release of the drug at a different time (2, 6, 10, 14, and 18 hr) was selected as the dependent variable. An optimum polynomial equation was generated for the prediction of the response variable at time 10 hr. Based on the results of multiple linear regression analysis and F statistics, it was concluded that sustained action can be obtained when X1 and X2 are kept at high levels. The X1X2 interaction was found to be statistically significant. The drug release pattern fitted the Higuchi model well. The data of a selected batch were subjected to an optimization study using Box-Behnken design, and an optimal formulation was fabricated. Good agreement was observed between the predicted and the observed dissolution profiles of the optimal formulation.

Keywords : disopyramide phosphate, ethyl cellulose, microspheres, controlled release, Box-Behnken design, factorial design
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