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Original Research Paper

Formulation, optimization & evaluation of mouth dissolving film of nifedipine by using design of experiment

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The oral mucosa is vascularized, drugs can be absorbed directly and can enter the systemic circulation without first-pass metabolism [1]. This advantage can be used in preparing products with increased oral bioavailability of molecules that undergo first pass metabolism. Thus oral mucosa is an attractive site for drug delivery [2,3].The objective of this research work is to formulate mouth dissolving film of nifedipine for enhanced bioavailability. nifedipine is used to treat hypertension and angina pectoris.

In the present investigation, an attempt was made to develop mouth dissolving films of nifedipine to achieve fast disintegration and dissolution characteristics with improved bioavailability by oral route. The drug & excipients were characterized as per IP 2014. Drug and excipients studies were conducted using FTIR. Oral films of nifedipine were formulated using HPMC E5, PVP polymer as a film forming agent and PEG-400 as plasticizer. The solvent casting method was used for the preparation of films. A central composite design using Design Expert Software was used to optimize and evaluate the main effects, interaction effects and quadratic effects of the formulation ingredients on the disintegration time & *in vitro* drug release. A 2-factor, 2-level design was observed to be the most suitable and appropriate for exploring quadratic response surfaces and constructing second-order polynomial models. nifedipine oral film was evaluated for folding endurance, thickness, weight variation test, surface pH, content uniformity, disintegration test, & *in vitro* dissolution. The stability studies of the films were performed for optimized batch as per ICH guideline.

No drug–excipients interaction was observed. The characterization studies depict the purity of drug & all the excipients used in the formulation. The IR spectrum of mixture of

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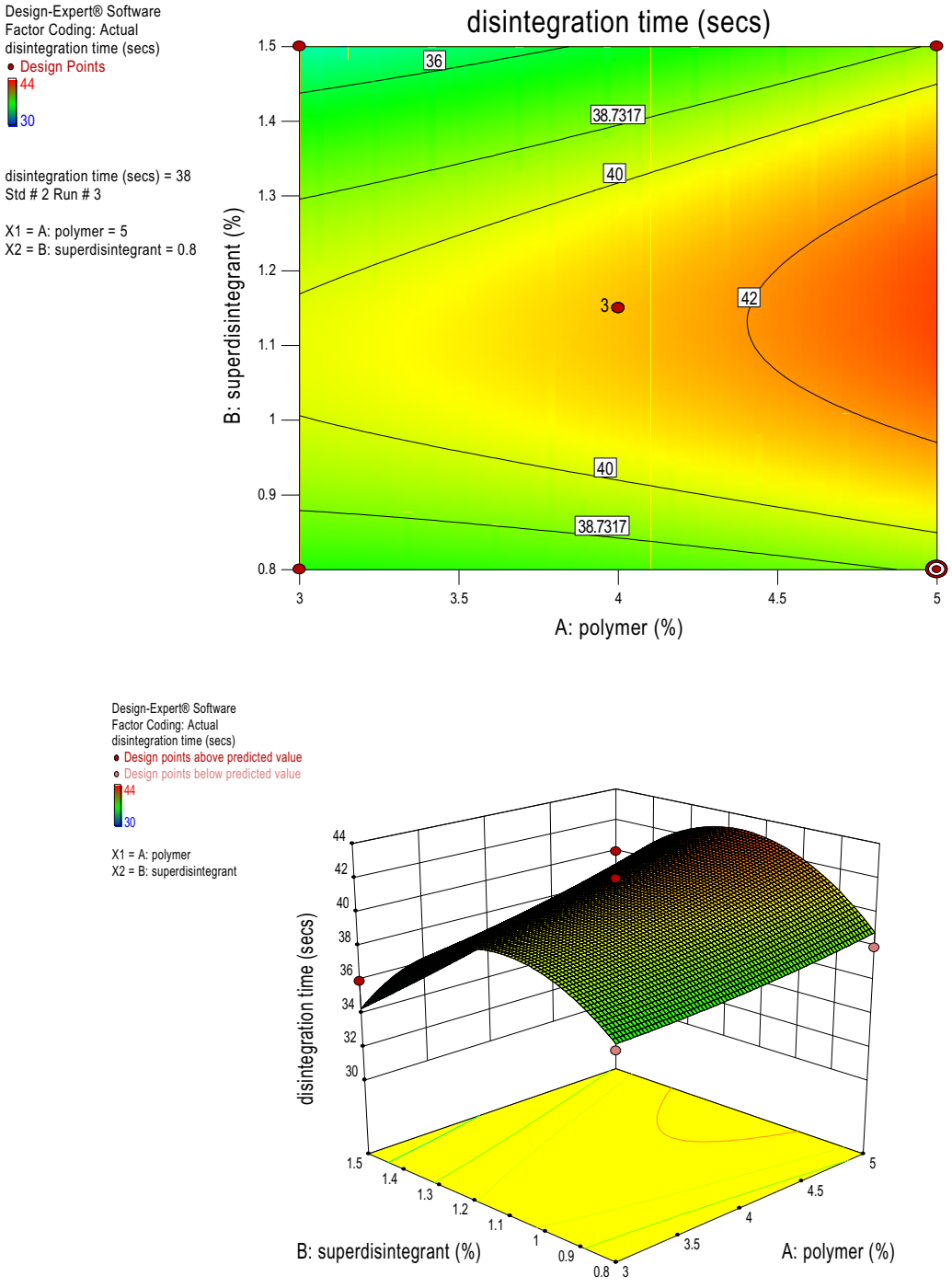

Fig. 1 – Contour plot (a) and 3D surface plot (b).

nifedipine with all other excipients does not show any changes which indicates its compatibility with other excipients. As per DOE 11 different formulation trials were carried out. The optimized batch showed a disintegration time of 30 seconds & maximum % drug release was within 60 seconds as shown in Fig. 1.

From the results, it can be concluded that the fast dissolving oral film of nifedipine showed fast disintegration dissolution of drugs in salivary pH. Thus the prepared fast dissolving films of nifedipine could be a better alternative for achieving rapid oral bioavailability in angina pectoris.

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