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Orally Disintegrating Tablets of Fa[illegible] Compression Method Using 3[illegible] Full Factorial Design

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Abstract and Key words Italic, Heading alignment and text should be justified, 12

ABSTRACT

Difficulty in swallowing (dysphagia) is common among all age groups, especially in elderly and pediatrics. Orally disintegrating tablets constitute an innovative dosage forms that overcome the problems of swallowing and provides a quick onset of action. The purpose of this study was to formulate and evaluate orally disintegrating tablet of Famotidine using croscarmellose sodium and sodium starch glycolate (S.S.G.) as a superdisintegrant.

Key words: *Orally disintegrating tablets, Famotidine, Crospovidone, 3^2 full factorial design*

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INTRODUCTION

Famotidine is a H_2 receptor antagonist. A thiazole ring containing H_2 blocker which binds tightly to H_2 receptors and exhibits longer duration of action despite an elimination [2]. Famotidine after oral administration has an onset of effect within 1 hr and inhibition of gastric secretion is present for the next 10-12 hrs. Elimination is by renal and metabolic route. It is therefore important to decrease the dose of the drug for patient with kidney or renal failure [1- 3]. Famotidine not only decrease both basal, food-stimulated acid secretion by 90% or more but also promotes healing of duodenal ulcer [4, 5]. Many patients find it difficult to swallow tablets and hard gelatin capsules and do not take their medicines as prescribed. The concept of mouth dissolving drug delivery system emerged from the desire to provide patient with more conventional means of taking their medications. Mouth dissolving tablets (MDT) disintegrate and are dissolving rapidly in the saliva with out the need of water. Disintegrants plays a major role in the disintegration and dissolution of MDT. Superdisintegrants provide quick disintegration due to combined effect of swelling and water absorption. Due to swelling of superdisintegrants, the wetted surface of the carrier increases, this promotes the wettability and dispersibility of the system thus enhancing the disintegration and dissolution [5].

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MATERIALS AND METHODS

Famotidine was obtained as gift sample from Cadila Pharmaceutical Ltd. Dholka (Ahemdabad), (SSG), Crospovidone, Avicel pH 102, obtained as gift samples from Signet Chemicals Mumbai. Sodium Saccharine and Mannitol from Ranbaxy Research Lab, Gurgaon .and other reagents were of analytical grade.

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3^2 FULL FACTORIAL DESIGNS

A 3^2 full factorial design was used in the present study. In this design 2 factors are evaluated, each at 3 levels, and experimental trials are performed at all 9 possible combinations. [7-8]. The amount of SSG (*X1*), and the amount of Crospovidone (*X2*), was selected as independent variables the disintegration time and wetting time were selected as dependent variables. The polynomial equation generated by this experimental design (using the software, Design Expert 8.04; State Ease Inc.) is as follows:

Polynomial equation

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$$Y = B_0 + B_1 X_1 + B_2 X_2 + B_{11} X^2 + B_{22} X^2 + B_{12} X_1 X_2$$

Where Y is the dependent variable; B_0 is the intercept; B_1 to B22 are the regression coefficients;
And X_1 and X_2 are the independent formulation variables [9].

Optimization

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The runs or formulations, which are designed based on 3^2 full factorial designs, are evaluated for the response variables. The response values are subjected to multiple regression analysis to find out the relationship between the factors used and the response values obtained. The response values subjected for these analyses are;

RESULTS

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Data Analysis

A response surface model factorial design with 2 independent variables at 3 different levels was used to study the e ll the batches of orally disintegrating tablets were evaluated for disin

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- Transformed values of all the batches along with their results are shown in Table 2. The dependent variables (DT, WT) obtained at various levels of the 2 independent variables (X1 and X2) were subjected to multiple regressions to yield a second-order polynomial equation, the obtained coefficients are shown in Table 3.
- The DT and WT values measured from different batches showed wide variation. These results clearly indicated that the DT and WT value is strongly affected by the variables selected for the study. This was also reflected by the wide range of values for coefficients of the terms of equation.
- The value of the correlation coefficient (R2) of polynomial regression equation was found to be greater than 0.99, indicating a good fit for all the dependent variables as shown in Table 4.

DISCUSSION

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Effect of formulation variables on

The Model F-value of 12.42 impl is only a 3.22% chance that a Model F-Value" this large could occur due to noise. Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case X1, X2 are significant model terms.

CONCLUSION

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Optimization of an orally disintegrating tablet is a complex process that necessitates one to consider a large number of variables and their interactions with each other. The present study conclusively demonstrates the use of a response surface design in the optimization of orally disintegrating tablet. The derived polynomial equations and contour plots aid in predicting the values of selected independent variables for preparation of optimum Famotidine orally disintegrating tablet with the desired properties.

ACKNOWLEDGEMENTS

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For journal reference

Mukesh PR, Mohanta GP, Upadhyay L. Review on: Fast dissolving tablet. Journal of pharmacy research, 2009; 2(1): 5-12.

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For Book reference

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Tables, graph and figure seperet after References

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Table I: Factorial design batch

INGREDIENTS	R_1	R_2	R_3	R_4	R_5	R_6	R_7		
Famotidine	-	-	-	-	-	-	-	-	-
Avicel pH 102	-	-	-	-	-		-	-	-
Sodium Starch Glycolate	-	-	-	-	-	-	-	-	-
Cross Povidone	-	-	-	-	-	-	-	-	-
Pregelatinized Starch	-	-	-	-	-	-	-	-	-
Aspartame	-	-	-	-	-	-	-	-	-
Magnesium Stearate	=	-	-	-	-	-	-	-	-
Talc	-	-	-	-	-	-	-	-	-
TOTAL	-	-	-	-	-	-	-	-	-

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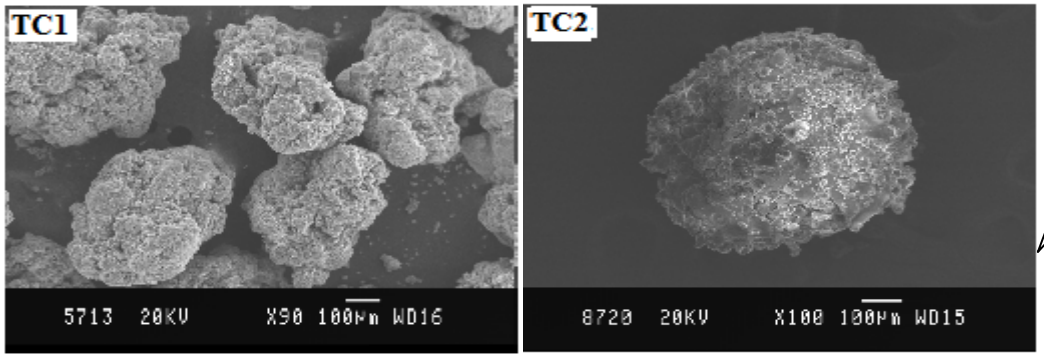

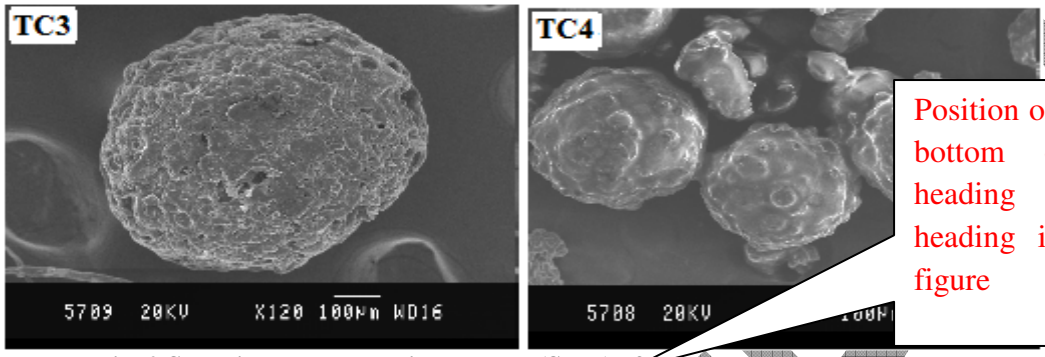

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Fig. 2.Scanning Electron Micrographs (SEM) of Tramadol

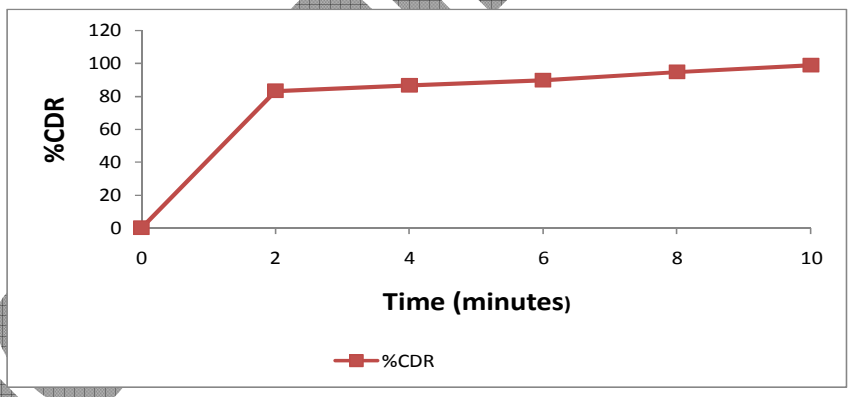

Fig.6: Dissolution profile of optimized formulation

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