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Formulation and Evaluation of Natural Gum Based Fast Dissolving Tablet

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ABSTRACT

Current research is focused on formulation and evaluation of natural gum based fast dissolving tablet of aceclofenac by applying 3^2 factorial design. Direct compression method was used. Two factors as independent variable (x_1)okra gum (x_2) sodium saccharin glycol ate were taken with three level (+1, 0,-1) .The level two factors were selected on basis of preliminary experiments conducted and their effect on dependent variable (disintegration time ,in vitro drug release) was estimated formulated tablets were evaluated for parameters (hardness, thickness, weight variance, wetting time and water absorption ratio, disintegration time ,friability,% commutative drug release).the software design expert (11.0) was used for gee rating experimental design ,modeling the response surface and calculating the static evaluation .The tablet parameters tests of formulation (F1 TO F 10) were observed within prescribe limit. DT observed in the range of 51 sec to 9 min. % cumulative drug release 0.31 % to 107.97 %. Batch F10 was observed as promising batch with DT values 46 sec.

Keywords: Aceclofenac, Abelmoschus esculent us mucilage powder, Fast Dissolving tablets, pharmaceutical excipients.

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INTRODUCTION

A tablet is a pharmaceutical dosage form. Tablets may be defined as the solid unit dosage form of medicament or medicaments with or without suitable excipients and prepared either by molding or by compression.[1] Fast dissolving tablet is the most widely used dosage form because of its convenience in terms of self- administration, compactness, and ease in manufacturing. Beneficial in cases such as motion sickness, suede episodes of allergic attack or coughing, where an ultra-rapid onset of action required. increase bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.[2-3]Abelmoschusesculentus, commonly known as okra, a native plant from Africa, is known to grow in many other areas of the world. Okra gums are used as thickeners and flavoring for different foods. These polysaccharides, when extracted in water, can result in a highly viscose solution with slimy appearance.[4-5]

Method of extraction:

Okra was obtained from local market. Collected okra was carefully washed and dried under shade for 24 h, further dried at 30– 40°C until constant weight was obtained. Size was reduced through grinder. Powdered fruit passed through sieve no. #22 and stored it in air tight container for further use. Extraction of mucilage includes two steps

Step 1: Extraction of mucilage: powdered fruit kept in 500ml of distilled water. Heated with stirred continuous at 60°C for approximately 4h. Concentrated solution has filtrated through muslin. Cloth and cool at 4°C-6°C

Step 2: Isolation of Mucilage: Extracted gum has isolated in acetone. This allows filtration through muslin cloth. Washed with acetone and the mucilage filtrated through muslin cloth. Pressed mucilage was further dried to constant weight at 35–45°C in hot air oven. Hard mucilage cake was grinded and sieved through sieve # 22, stored in desiccators for further used .[6-7]

MATERIALS AND METHOD:

Characterization of okra gum:

Swelling ratio:

One gram of mucilage was placed into a 25ml glass Stoppard measuring cylinder. 25 ml of water was added into the cylinder containing mucilage and mixture was shaken thoroughly at intervals of

every 10 min for 1 h. The sample was allowed to stand for 3 hr. at room temperature and volume occupied by mucilage was measured. The mean value was calculated, related to 1 g of mucilage.[6]

Direct compression:

Direct compression method is the easiest way to manufacture tablets. Conversional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. The ingredients were weighted and passed through #60 mesh separately in these method drug with other excipient is mixed in mortal pestle geometrically and the mixture thus obtained is compressed into tablets through 6mm flat faced punch on pilot pressed 10 station machine tablets (Kalweka Eng. Ltd, Mehsana, India). The total weight of the formulation was maintained 200 mg.[3]

Factorial Design:

A 3^2 full factorial design was used. In this design 2 factors were evaluated, each at 3 levels and experimental trials were performed at all 9 possible combinations. The amount of okra gum (X_1) and the amount of SSG (X_2) was selected as independent variables. The disintegration time was selected as dependent variable. A polynomial term was used to evaluate the responses.

$Y = b0 + b1X_1 + b2X_2 + b11X_1X_1 + b22X_2X_2 + b12X_1$

Where, y is the dependent variable, b0 is the arithmetic mean response of the 9 runs, and b1 is the estimated coefficient for the factor X_1. The main effects (X_1 and X_2) represent the average result of changing 1 factor at a time from its low to high value. The interaction terms (X_1X_2) show how the response changes when 2 factors are simultaneously changed. The polynomial terms (X_1X_1 and X_2X_2) are included to investigate nonlinearity .[12]

Evaluation of Prepared Tablet

Hardness:

Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. It is done by using hardness tester like Pfizer hardness tester or Monsanto tablet hardness tester.

Thickness:

Thickness of tablets is determined using Vernier caliper. An average value is calculated by using tablets in triplicate and then the mean ± standard deviation values of thickness are notified

Weight Variance:

According to I.P. procedure for uniformity of weight, twenty tablets are taken and their weight is determined individually and collectively on an electronic weighing balance. The average weight of

one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

Wetting Time:

A piece of tissue paper folded twice is placed in a small Petri dish containing 6ml. of distilled water. A tablet is carefully placed on the surface of the paper and the time required for water to reach the upper surface of the tablet is noted as the wetting time. Less is the wetting time, indicates more porous the tablet.

Water Absorption Ratio:

To measure Water absorption ratio of the Tablet, a piece of Tissue paper folded twice was placed in a small Petri dish (Internal Diameter is= 6.5 cm) containing 5 ml of Distilled water. A Tablet placed on the paper, and the time for complete wetting of the tablet was measured in seconds

Water absorption ratio "R" was determined using the equation:

$$\mathbf{R=100\ \frac{Wb-Wa}{Wa}}$$

Where,

Wa is weight of tablet before water absorption and *Wb* is weight of tablet after water absorption

Disintegration Time:

The test is carried out using the disintegration apparatus. Distilled water is used as a disintegration media and the time taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus is measured

Friability:

Friability is measured of mechanical strength of tablets. Roche friabilator is used to determine the friability by following procedure. A reweighed tablet is placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping the tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for 4 minutes for 100 revolutions. At the end of test, tablets are reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as;

$$\mathbf{\%\ Friability = \frac{Loss\ in\ weight}{Initial\ weight}\ x\ 100}$$

In Vitro Drug Release Studies:

The in vitro drug release is studied using USP dissolution apparatus II (paddle type) at 50 rpm in 900 ml of phosphate buffer (pH 6.8) at37±0.5ºC. At different time intervals, 10 ml of sample is withdrawn and filtered. An equal volume of the medium is introduced into the container after each withdrawal to maintain a constant volume. The absorbance of the samples is determined by UV

Spectrophotometer at given max. The mean values of drug released are plotted as cumulative % drug release vs. time .[1-1]

RESULTS AND DISCUSSION

Preparation of fast dissolving tablet using drug Aceclofenac. The super disintegrates and gum in different ratios were used to prepare the tablets. All the ingredients were shown in Table 1 were passed through sieve no. 60.The total 10 formulations (F1–F10) were prepared using different concentrations of okra gum and sodium starch Glycol ate to study its effect on disintegration time.

Preparation of Factorial formulation with the corresponding formulation is outlined in Table 2 and 3. The effect of the independent variables, viz., Okra gum (X_1) and SSG (X_2) on the dependent variable.

Preparation of fast dissolving tablet the superdisintegrants and gum in different ratios were used to prepare the tablets. All the evaluation were shown in Table 4 The total 10 formulations (F1–F10) were prepared using different concentrations of okra gum and sodium starch Glycolate to study its effect on, **Hardness (kg/cm^2)** 2.1 to 2.6, **Friability (%)** 0.25 to 0.69, **Weight variation (mg)** 182 to 196, **Thickness of tablet (mm)** 2.229 to2.296, **Wetting time (second)** 58 sec to1 min 8 sec, **Water absorption ratio** 0.1628to 0.2439, **Disintegration time range** 51 sec to 9 min. The value of **%cumulative drug release** range 0.31 % to 107.97 %.

Preparation of Factorial formulation with the corresponding formulation is outlined in **Table** 5. The effect of the independent variables, viz., Okra gum (X_1) and SSG (X_2) on the dependent variable, Disintegration time range 11 to 58 sec.

Data Analysis by Design Expert Software A 3^2 full factorial design was used. In this design 2 factors were evaluated, each at 3 levels and experimental trials were performed at all 9 possible combinations. The amount of okra gum (X_1) and the amount of SSG (X_2) was selected as independent variables. The disintegration time was selected as dependent variable. A polynomial term was used to evaluate the responses.

$$Y = b0 + b1X_1 + b2X_2 + b11X_1X_1 + b22X_2X_2 + b12X_1$$

Where, y is the dependent variable, b0 is the arithmetic mean response of the 9 runs, and b1 is the estimated coefficient for the factor X_1. The main effects (X_1 and X_2) represent the average result of changing 1 factor at a time from its low to high value. The interaction terms (X_1X_2) show how the response changes when 2 factors are simultaneously changed. The polynomial terms (X_1X_1 and X_2X_2) are included to investigate nonlinearity.

Final Equations in Terms of Coded Factors.

$DT = -0.00111 + 0.148333\ X_1 - 0.19833 X_2 - 0.255(X_1X_2) + 0.351667(X_1)2 + 0.361667\ (X_2)^2$

Final equations in Terms of Actual Factors.

DT = -0.00111+ 0.148333 Gum -0.19833 SSG -0.255 Gum * SSG 0.351667 (Gum)² 0.361667 (SSG)²

The above equation revealed the effect of independent variables on the desired response. The regression coefficient values are the estimates of the model fitting. The r^2 was high indicating the adequate fitting of the quadratic model. The polynomial equations can also be used to draw conclusions considering the magnitude of co-efficient and the mathematical sign it carries; i.e. positive or negative

The positive coefficient of variable X_1 i.e. Okra Gum, the response of disintegration time showed an increase in the A1 and A9 value with the increase in the gum concentration.

The second variable X_2 i.e. SSG, responses showed positive coefficient for response A1 and A2, respectively.

ANOVA for the dependent variables A1 and A 9, respectively are shown in table 3. ANOVA and Multiple regression analysis were done using Stat-Ease Design Expert 11.0 software. The response surface plot of the Okra Gum and SSG are shown in fig1.

The main effect of A and B represents the average result of changing variables at a time from its low level to high level. The interaction terms (AB, A^2, B^2) reveal the A1 and A10 changes when the two variables are simultaneously changed. The negative coefficient for the independent variable (B, B^2), (B, AB, A^2, B^2) and (B, B^2), (B, AB) indicate unfavorable effects on the Fast Dissolving Tablet (A1 and A9) , respectively. The independent variables exhibit positive interaction which indicates the favorable effect on the Fast Dissolving Tablet (A1 and A9), respectively.

The variance Inflation Factor (VIF) measures how much the variance of that model coefficient is inflated by the lack of orthogonality in the design and calculated for fast dissolving tablet (A 1 and A 9) and), respectively, which is found to be 1 indicating good estimation of coefficients. Similarly, Ri-squared is near to zero which is leading to good model. The model F value calculated for fast dissolving tablet (A1 and A9) respectively, are found to be 2.53, and there are only 5-10% chance of large lack of fit F value which could be due to noise and non-significant lack of fit F value is good fit of model. In all cases “Pred R-squared” values are in reasonable agreement with the “Adj R-squared” values. The Adeq-Precision is the measures of the signal to noise ratio. A ratio> 4 is desirable. In the case of Fast Dissolving Tablet, the Adeq-Precision value is in range of 5.3670 which indicates an adequate signal.

Table 1: Preparation of Fast Dissolving Tablet.

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Aceclofenac	100	100	100	100	100	100	100	100	100	100
Gum	1	2	3	4	5	6	7	8	9	10
Sodium Starch Glycolate	10	9	8	7	6	5	4	3	2	1
Magnesium Stearate	5	5	5	5	5	5	5	5	5	5
Mannitol	10	10	10	10	10	10	10	10	10	10
Talc	5	5	5	5	5	5	5	5	5	5
Meglumine	2	2	2	2	2	2	2	2	2	2
MCC	67	67	67	67	67	67	67	67	67	67
Total Weight	200	200	200	200	200	200	200	200	200	200

Table 2: Variable with coded value in factorial design.

Coded factor	Level	Factor Factor(x_1)(%w/w)	Factor(x_2)(%w/w)
-1	Low	3	0.5
0	Intermediate	4	1.5
+1	High	15	2.5

Table 3: Preparation of Factorial Formulation.

Ingredients (mg)	A1	A2	A3	A4	A5	A6	A7	A8	A9
Aceclofenac	100	100	100	100	100	100	100	100	100
Gum	6	6	6	8	8	8	10	10	10
Sodium Starch Glycolate	1	3	5	1	3	5	1	3	5
Magnesium Stearate	5	5	5	5	5	5	5	5	5
Mannitol	10	10	10	10	10	10	10	10	10
Talc	5	5	5	5	5	5	5	5	5
Meglumine	2	2	2	2	2	2	2	2	2
MCC	71	69	67	69	67	65	67	65	63
Total Weight	200	200	200	200	200	200	200	200	200

Table 4: Preparation of Fast Dissolving Tablet.

Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
Hardness (kg/cm^2)	2.2	2.2	2.6	2.1	2.5	2.1	2.3	2.2	2.4	2.4
Friability (%)	0.61	0.68	0.59	0.53	0.63	0.25	0.64	0.58	0.67	0.56
Weight variation (mg)	196	186	184	188	183	184	187	182	185	184
Thickness of tablet(mm)	2.294	2.228	2.295	2.239	2.249	2.227	2.283	2.296	2.285	2.296
Wetting time (second)	1min 3sec	1min4sec	58 sec	1min6sec	1min8sec	1min	59 Sec	58 Sec	1min	1min4sec
Water absorption ratio	0.2436	0.2433	0.2251	0.2224	0.2223	0.2439	0.2228	0.2224	0.02235	0.1628
Disintegration time(sec.)	6min	8 min	9min	5min	7min	56sec	3min	9min	6min	41sec
%cumulative drug release	0.76	2.15	3.97	0.31	4.40	107.97	7.26	3.09	3.10	52.00

Table 5: Preparation of Factorial Formulation.

Formulation	**A1**	**A2**	**A3**	**A4**	**A5**	**A6**	**A7**	**A8**	**A9**
Hardness (kg/cm^2)	2.2	2.6	2.1	2.5	2.3	2.2	2.4	2.2	2.1
Friability (%)	0.40	0.35	0.34	0.25	0.35	0.30	0.45	0.24	0.35
Weight variation(mg)	199.31	195.12	196.53	199.31	196.45	199.32	199.45	197.32	195.11
Thickness of tablet (mm)	2.229	2.236	2.254	2.244	2.284	2.276	2.214	2.234	2.248
Wetting time (second)	1.6	0.23	0.52	0.39	0.23	0.26	1.26	0.39	0.51
Water absorption ratio	0.154	0.123	0.154	0.215	0.184	0.154	0.184	0.153	0.153
Disintegration time (sec)	0.56	0.19	0.58	0.32	0.29	0.11	1.5	0.22	0.50
%cumulative drug release	12.39	81.27	102.1	8.99	82.54	98.11	7.98	9.52	11.47

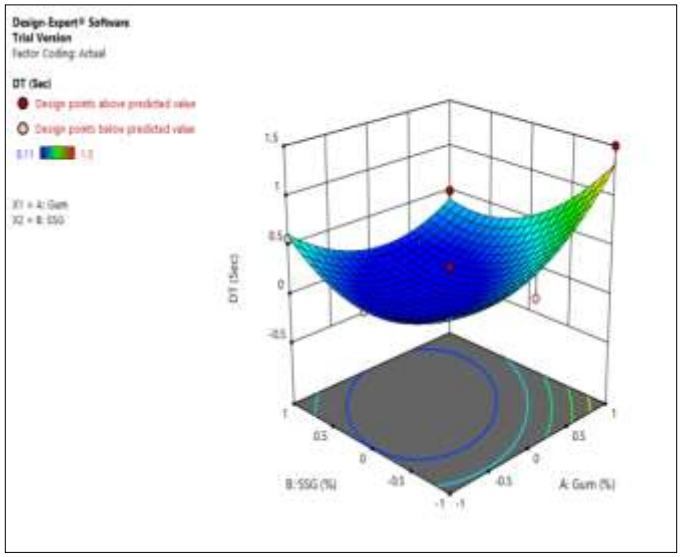

Figure. 1 Response surface plot of FDT on DT

CONCLUSION

From the present study, it can be concluded that natural super disintegrates like Abelmoschus esculent us mucilage powder showed better disintegrating property than the most widely used synthetic super disintegrates like SSG in the formulations of FDTs and may be used as disintegrate in tablet formulations The effect of different amount of complex and surfactant is used in different batches and the blending time for powder is also different for every batch. From these parameters the evaluation of tablet batches performed like wetting time, water absorption ratio, disintegration time ,percent drug release. From table no 1 it was found that batch F6 and F10 was good disintegration time. The factorial design conclusively demonstrated use of response surface design of FDT on DT.

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