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Research Article

FORMULATION, DEVELOPMENT AND EVALUATION OF ORODISPERSIBLE TABLET OF GRANISETRON HYDROCHLORIDE

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Abstract:

The present work concerned with the formulation and evaluation of Orodispersible tablet of Granisetron Hydrochloride by using Natural Superdisintegrants Banana powder. Granisetron HCL is a novel serotonin 5-HT₃ receptor used as antiemetic to treat nausea and vomiting during cancer chemotherapy but its oral bioavailability is low due to extensive first pass metabolism in liver which makes it ideal candidates for orodispersible tablet. Banana Powder itself has Antiemetic properties which prevents the Nausea and Vomiting. Pre compression studies revealed good micrometric properties of powder blend. Various formulation of were prepared by direct compression method and were evaluated for their physio chemical properties, drug release and stability studies. FTIR and DSC show that there is no interaction with drug and other excipients. From this study, we can conclude that, a formulated tablet of Granisetron HCL containing Banana Powder is better and effective to meet the patient compliance. Reserchers have found that Banana powder treatment not only strengthens mucosal resistance against ulcerogens but it's also promotes healing by inducing cellular proliferation. Banana powder mainly used as natural superdisintegrants when compared to synthetic superdisintegrants. The hardness, friability, drug content and disintegration time of Orodispersible tablets were found uniform and reproducible. The main aim of the study was to develop orodispersible tablets of Granisetron hydrochloride a selective 5-HT₃ receptor antagonist (antiemetic agent) for improving patient compliance, especially those of paediatric and geriatric categories with difficulties in swallowing. From this study it is concluded that orodispersible tablets could be prepared by direct compression method using Natural superdisintegrants enhanced dissolution will lead to improved bioavailability, improved effectiveness of Granisetron. The present study comprises the various kinds of natural superdisintegrants which are being used in the formulation to provide the safest, effective drug delivery with patient's compliance. By using Banana powder, it shows good result in given formulation batch.

Key words: Orodispersible tablet, Granisetron HCL, Banana powder, Superdisintegrants, Antiemetic

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INTRODUCTION:

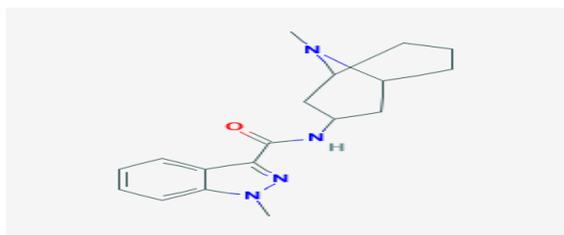
Orodispersible tablets disintegrate instantaneously when placed on tongue, releasing the drug that dissolve or disperse in the saliva. Cancer chemotherapy causes lots of adverse effect, of which nausea and vomiting is mainly prime once. This can be clearly seen with model anticancer drug cisplatin, mainly which is the first line drug in many types of cancers. Therefore, antiemetic drugs like Ondansetron, Granisetron are administered one hour prior to the administration of anticancer drug.

Granisetron HCL mainly its is novel serotonin 5-HT₃ receptor antagonist used as antiemetic to treat nausea and vomiting following chemotherapy.

Its main effects are to reduce the activity of the vagus nerve, which is a nerve that mainly activates the vomiting center in medulla oblongata. During chemotherapy induced vomiting mucosal enterochromaffin cells release serotonin, which stimulates 5-HT₃ receptors. The present study aimed to develop orodispersible tablet by using Banana powder as Natural Superdisintegrants to increase the Bioavailability of the drug.

Banana powder mainly having property of Antiemetic effect. Mainly it is used in Antiemetic (as source of energy and vitamins when patients feel nauseous and help replace potassium lost due to vomiting or diarrhea) Cancer (dietary fiber was found to be decrease the colorectal cancer risk.) Diabetes (low glycemic load).

Although oral tablet is the most widely used dosage form, patients often experience difficulty in swallowing conventional tablets when water is not available nearby. Pediatric and geriatric patients may also encounter inconvenience in swallowing tablets even taken with water. Other advantage of ODTs that have been investigated are their positional to increase the bioavailability of poorly water soluble drugs through enhancing the dissolution profiles.



Structure of Granisetron hydrochloride

In this study natural superdisintegrants utilized as Banana powder. Natural disintegrants are safe, more biodegradable, better compressible, easier to preparation and cheaper with no side effective no drug interaction and these advantages can boost the production of ODTs. Banana powder mainly disintegration property when compared to synthetic superdisintegrants. It also shows sweetening and flavouring agent.

Ideal Properties of Orodispersible Tablets: -

- Mainly it easily dissolves or disperses in saliva within a few seconds.
- It does not require water for oral administration.
- Mainly it has a pleasant mouth feel.
- Mainly it leave negligible or no residue in the mouth when administered.
- Cost effective
- It is portable and easy to transport.
- It should be compatible with taste masking.

Advantages of Orodispersible Tablets:

- Improved compliance
- Cost effective
- No water needed
- It improves stability
- Mainly suitable for controlled /sustained release activities
- Mainly it is suitable for patient with oesophageal problems and have difficulties of deglutition tablets.

Disadvantage of Orodispersible tablets: -

- Rapid disintegration tablet is hygroscopic in nature so must be kept in dry place.
- Sometime these tablets may leave unpleasant taste /or grittiness in mouth if not formulated properly.

Challenges to develop Orodispersible tablets:-

- Rapid Disintegration of tablets
- To avoid increase in tablet size
- Mainly minimum or no residue in mouth
- Good package design
- Compatible with taste masking technology.
- Not affected by drug properties

MATERIALS AND METHODS:

Granisetron hydrochloride was received as a gift sample from Swati Spentose pvt Ltd., Vapi. Banana powder were obtained as gifts from Varmora foods pvt ltd. Crosscarmellose Sodium were gifted from

Chemdy corporation Ahmedabad. Microcrystalline Cellulose and Magnesium Sterate and Aspartame were gifted from Finer Chemical pvt ltd. Ahmedabad.

Orodispersible tablets of Granisetron were prepared by direct compression method. All the ingredients were passed through 40-mesh separately. Then the ingredients were weighed and mixed in geometrical order and compressed into tablets of 100mg using 6mm round flat punches on tablet punching machine.

PREPARATION OF ORODISPERSIBLE TABLETS:

By Direct Compression Technique

PRELIMINARY BATCH FOR SELECTION OF SUPERDISINTEGRATES:

Ingredient's formulation code with quantity in mg												
Ingredients	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11	T12
Granisetron HCl	2	2	2	2	2	2	2	2	2	2	2	2
Banana powder	1	2	3	-	-	--	-	-	-	3	3	
C.C.S	-	-	-	1	2	3	-	-	--	2	-	3
S.S.G	-	-	-	-	-	-	1	2	3	-	2	2
Mg. sterate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Sucralose	4	4	4	4	4	4	4	4	4	4	4	4
Cherry flavour	3	3	3	3	3	3	3	3	3	3	3	3
MCC	85.5	84.5	83.5	85.5	84.5	83.5	85.5	84.5	83.5	80.5	80.5	80.5
Talc	3	3	3	3	3	3	3	3	3	3	3	3
Total weight	100 mg											

FORMULATION OF FACTORIAL BATCHES:

INGREDIENTS	FORMULATION CODE WITH QUANTITY IN mg								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
GSH	2	2	2	2	2	2	2	2	2
Banana Powder	1	2	3	1	2	3	1	2	3
C.C.S	1	1	1	2	2	2	3	3	3
Mg. sterate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Sucralose	4	4	4	4	4	4	4	4	4
MCC	85.5	84.5	83.5	85.5	84.5	83.5	85.5	84.5	83.5
Cherry flavour	3	3	3	3	3	3	3	3	3
Talc	3	3	3	3	3	3	3	3	3
Total weight	100 mg	100 mg	100 mg	100 Mg	100 mg	100 mg	100 mg	100 mg	100 mg

Evaluation of granules: -**Precompression parameters of orodispersible tablets:****Angle of repose**

The angle of repose of granules blend was determined by the fixed funnel method. The accurately weighed quantity of granules was taken in a funnel. The height of funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of the granules. The granules are allowed to flow through the funnel freely onto the surface. The diameter of powder cone was measured and angle of repose was calculated using the following equation,

$$\tan\theta = h/r$$

$$\theta = \tan^{-1}(h/r)$$

Where θ is the angle of repose, the height of cone in cm and r is the radius of the cone base in cm.

Bulk density

Bulk density was determined by pouring the granules into a graduated cylinder. The bulk volume (V_b) and mass (m) of the granules was determined. The bulk density was calculated by using the following formula

$$\text{Bulk density} = \frac{\text{Mass of granules (m)}}{\text{Bulk volume of granules (V}_b\text{)}}$$

Tapped density

The measuring cylinder containing known mass of granules blend was tapped 1000 times for a fixed time. The minimum volume occupied in the cylinder (V_t) and mass of the granules (m) was measured. The tapped density was measured by using the following formula.

$$\text{(Tapped density)} = \frac{\text{Mass of granules (m)}}{\text{Tapped volume of granules (V}_t\text{)}}$$

Compressibility index (Carr's index)

The compressibility index¹² determines the flow property characteristics of granules developed by Carr's. The percentage compressibility of granules is a direct measure of the potential powder arch and stability. The Carr's index can be calculated by the following formula

$$\% \text{ Carr's index} = \frac{e_t - e_b}{e_t} \times 100$$

Where e_t is the tapped density of granules and e_b is bulk density of granules

Hausner's ratio

Hausner's ratio is used for the determination of flow properties of granules. The ratio can be calculated by the taking the ratio of tapped density to the ratio of bulk density.

Post compression parameters of orodispersible tablets:-**Thickness**

The thickness of individual tablets is measured by using vernier caliper which gives the accurate measurement of thickness. It provides information of variation of thickness between tablets. Generally, the unit for thickness measurement is mm. The limit of the thickness deviation. of each tablet is 5%

Hardness

The hardness of prepared tablets was determined by using Monsanto hardness tester¹³ and measured in terms of kg/cm^2 . Test was done in triplicate.

Friability

The crushing strength test may not be the best measure of potential behavior during handling and packaging. The resistance to surface abrasion may be a more relevant parameter. A low friability value represents better tablet strength. Friability of each batch was measured in the Roche Friabilator. Ten pre-weighed tablets were rotated at 25 rpm for 4 min. The tablets were then re-weighed and the percentage of weight loss was calculated and limit should not more than 1% as per IP.

$$\% \text{ Friability} = \frac{\text{Initial Weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Weight Variation

To study weight variation, 20 tablets of each formulation were weighed using an electronic balance and test was performed according to Indian Pharmacopoeia (IP).

Table 5.4.4 Indian Pharmacopoeia limits for % weight variation: -

Average wt of tablet	% deviation
8mg or less	10
More than 80 mg but less than 250 mg	7.5
250 mg or more	5

Wetting time

Wetting time of dosage form is related with the contact angle. Wetting time of the ODT is an important parameter, which needs to be assessed to give an insight into the disintegration properties of the tablet. Lower wetting time implies a quicker disintegration of the tablet. A piece of tissue paper folded twice was placed in a petridish with 10 cm diameter. 10 ml of water (containing water soluble

dye Eosin) was added to the petridish. The time required for complete wetting was measured as the wetting time.

Water Absorption Ratio: -

A piece of tissue paper folded twice was kept in a Petri dish (internal diameter 6.5cm) containing 6 ml of purified water. The tablet was placed on the tissue paper and allowed to wet completely. The wetted tablet was removed and weighed. Water absorption ratio, R was determined according to the following equation.

$$R = \frac{(W_a - W_b)}{W_b} \times 100$$

Where W_a is the weight after water absorption W_b is the weight before water absorption.

Disintegration time:

The disintegration time is performed to find out that within how much time the tablet is disintegrated. Availability of drug depends upon solubility. The important step towards a solution is a breakdown of the tablet into small particles (disintegration).

***In-vitro* Disintegration time: -**

The assessment of the *in vitro* disintegration profile of ODT is very important in the evaluation and the development of such formulations. So far neither the US Pharmacopoeia nor the European Pharmacopoeia has defined a specific disintegration test for ODT. Currently, it is only possible to refer to the tests on dispersible or effervescent tablets for the evaluation of ODTs disintegration capacity. The disintegration test for ODT should mimic disintegration in mouth with in salivary contents. One tablet was placed in a beaker/petridish (10 cm diameter) containing 10 ml of pH 6.8 phosphate buffer at 37 ± 0.5 °C. The time required for complete dispersion of the tablet was measured. This method embraces physiological conditions of the oral cavity, as a screening tool for developing ODT products.

***In vitro* Drug release (Amount of drug release/Time): -**

Tablet Dissolution is a standardized method for measuring the rate of drug release from a dosage form. The principal function of the dissolution test may be summarized as follows:

- Optimization of therapeutic effectiveness in product development and stability

Assessment.

- Routine assessment of production quality to ensure uniformity between production lots. Assessment of the 'bioequivalence'.
- Prediction of *in-vivo* availability, i.e., bioavailability (where applicable).

Drug content uniformity:

10 tablets were weighed and triturated. The tablet triturate equivalent to 50 mg of the drug was weighed accurately, dissolved in 0.1N HCl and suitably diluted with 0.1 N hydrochloric acid (HCl) solution of pH 1.2. The content of granisetron hydrochloride was determined spectrophotometrically at 302 nm against blank using UV-visible spectrophotometer

Dissolution test

USP dissolution apparatus 1 and 2 can be used for tablet dosage form. But in case of USP 1 Basket apparatus, sometimes tablet fragments or disintegrated tablet Masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles. USP 2 Paddle apparatus is the most suitable and common choice for ODTs, with a paddle speed of 50 rpm. Typically, the dissolution of ODT is very fast when using USP monograph conditions; hence slower paddle speeds may be utilized to obtain a profile. USP Dissolution Test Apparatus Type II (Electro lab) was used with paddle stirred at 50 rpm using 900 ml of pH 6.8 phosphate buffer at 37 ± 0.5 °C, as the dissolution medium. Since the drug absorbance is found very low from the standard curve, UV method is not appropriate for determination of drug. so, RP-HPLC method was utilized for Dissolution study. Aliquots of dissolution medium were withdrawn at specified intervals of time and analyzed for drug content (i.e. amount of drug dissolved from tablet) measuring by RP-HPLC method. The volume withdrawn at each interval was replaced with fresh quantity of dissolution medium. And then Cumulative % of drug release was calculated. Although the tablet is fast disintegrating and the drug GRANISETRON HYDROCHLORIDE is potent (low dose) with water insoluble characteristics; because of the Kyron T-314 which is act as solubility improver, the drug release from tablets will also be very rapid, within few minutes. Absorbance of the solution was measured using RP-HPLC method using phosphate buffer and calculate the AUC.

RESULT AND DISCUSSION:

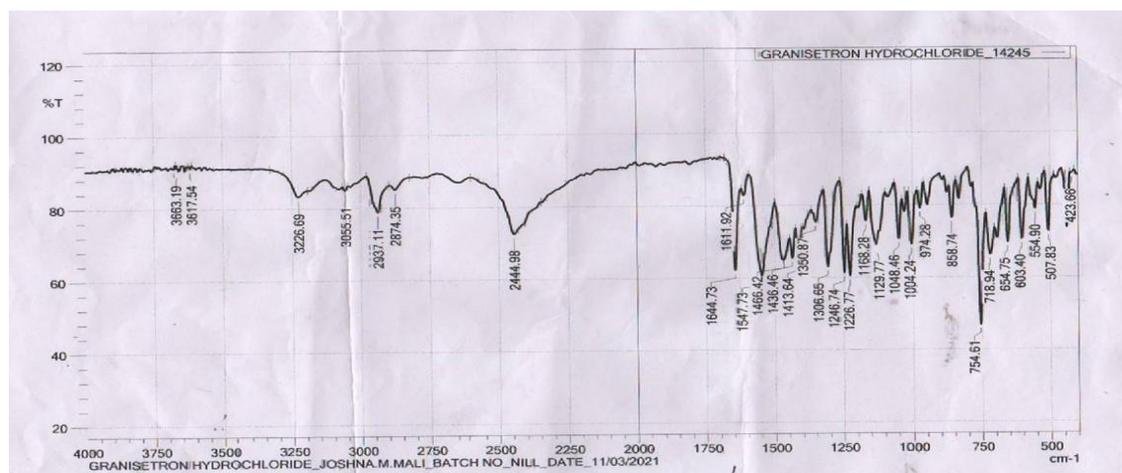


Figure 1:- FTIR of Granisetron Hydrochloride



Figure 2:-FTIR of Granisetron Hydrochloride +All excipients

Table 1 Pre -compression parameters of Granisetron HCL

Formulation code	Angle of repose (±SD), n=3	Bulk density (gm/ml) (±SD), n=3	Tapped density (gm/ml) (±SD), n=3	Carr's index (±SD), n=3	Hausner's ratio (±SD), n=3
F1	25.28±1.23	0.534±0.10	0.634±0.02	14.303±1.58	1.17±0.08
F2	26.0±0.13	0.58±0.14	0.66±0.02	12.12±0.01	1.13±0.01
F3	25.14±0.57	0.5137±0.007	0.6098±0.01	15.759±0.63	1.2±0.125
F4	24.19±0.69	0.509±0.01	0.5998±0.02	15.005±0.58	1.07±0.09
F5	26.41±1.20	0.543±0.09	0.640±0.03	15.044±0.60	1.09±0.11
F6	28.56±1.55	0.535±0.15	0.629±0.03	15.104±0.75	1.17±0.08
F7	25.71±1.42	0.5121±0.02	0.621±0.02	17.536±1.23	1.08±0.12
F8	26.01±0.13	0.5342±0.013	0.594±0.01	16.635±0.67	1.09±0.11
F9	27.01±1.21	0.5088±0.01	0.638±0.02	14.357±1.51	1.2±0.125

Table 2 post compression parameters of GRANISETRON HCL

Formulation code	Weight variation (%) (\pm), (n=3)	Thickness (mm) (\pm SD), (n=3)	Hardness (kg /cm ²)	Friability
F1	99 \pm 0.61	3.26 \pm 0.09	3.5 \pm 0.11	0.49 \pm 0.11
F2	98 \pm 0.13	3.78 \pm 0.10	4.4.0 \pm 0.10	0.51 \pm 0.10
F3	101 \pm 0.47	3.37 \pm 0.20	3.6 \pm 0.15	0.52 \pm 0.01
F4	102 \pm 1.25	3.43 \pm 0.21	4.0 \pm 0.21	0.57 \pm 0.02
F5	101 \pm 1.37	3.28 \pm 0.28	3.0 \pm 1.20	0.53 \pm 0.04
F6	100 \pm 0.61	3.29 \pm 0.12	4.0 \pm 1.05	0.52 \pm 0.01
F7	98 \pm 0.42	3.27 \pm 0.17	3.5 \pm 1.19	0.57 \pm 0.02
F8	99 \pm 1.45	3.40 \pm 0.10	3.0 \pm 1.35	0.49 \pm 0.11
F9	97 \pm 1.05	3.27 \pm 0.15	3.1 \pm 1.31	0.53 \pm 0.04

Table 3 Disintegration, wetting time absorption ration and drug content of granisetron HCL

Formulation code	In -vitro dispersion time (sec) ,(n=3)	Wetting time (sec) (\pm SD) ,(n=3)	Water absorption ratio (\pm SD), (n=3)	Drug content (\pm SD), (n=3)
F1	30 \pm 1.50	41 \pm 1.0	69 \pm 1.20	99.01 \pm 0.85
F2	17 \pm 1.23	17 \pm 1.42	80 \pm 1.05	99.9 \pm 0.04
F3	20 \pm 1.70	22 \pm 1.89	67 \pm 1.19	98.52 \pm 1.40
F4	28 \pm 1.00	41 \pm 1.0	71 \pm 1.35	99.13 \pm 1.31
F5	80 \pm 1.45	92 \pm 1.12	57 \pm 1.31	100.01 \pm 1.11
F6	60 \pm 1.28	73 \pm 1.35	48 \pm 1.73	99.63 \pm 0.95
F7	52 \pm 2.15	64 \pm 1.79	52 \pm 1.23	99.41 \pm 1.33
F8	43 \pm 1.55	54 \pm 1.41	63 \pm 1.37	99.91 \pm 1.81
F9	42 \pm 1.21	55 \pm 1.25	61 \pm 1.41	99.46 \pm 0.93

Statistical Analysis of 3² Factorial Designs: -

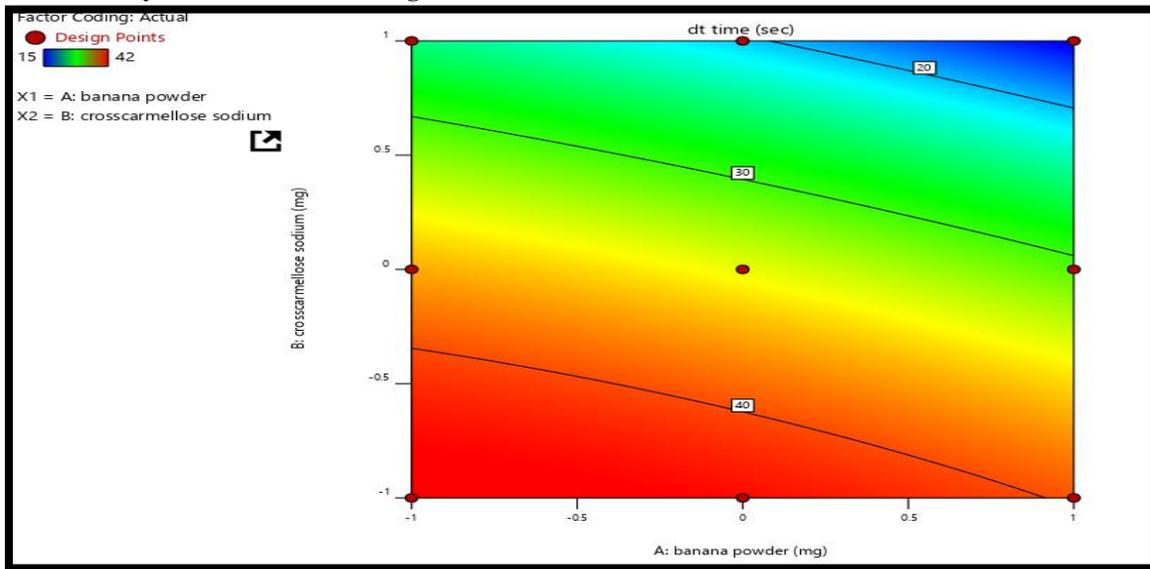


Figure 3 Two-Dimensional Response Surface Curve for Disintegration Time

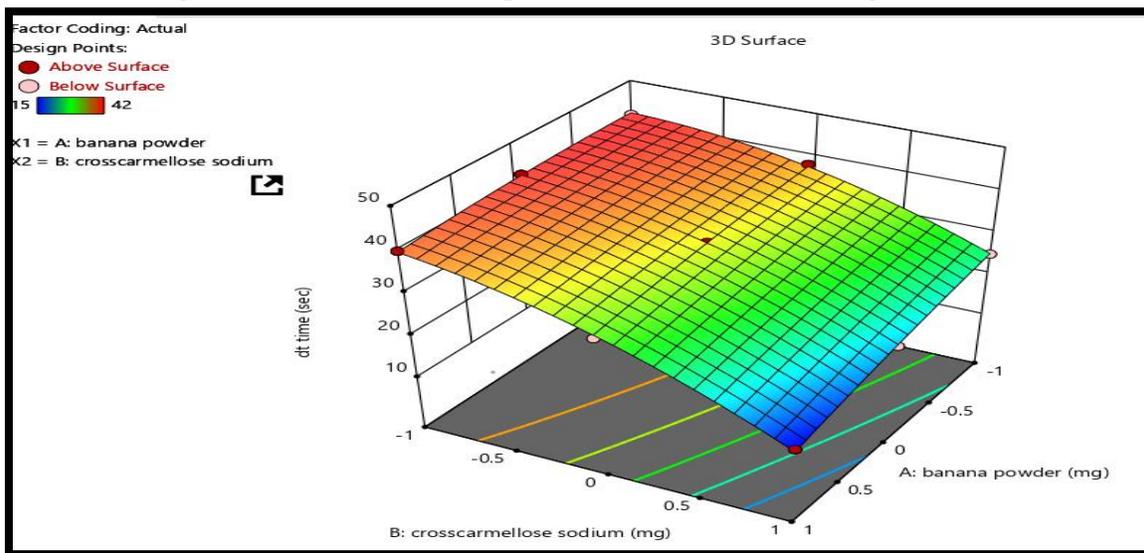


Figure 4 Three-Dimensional Response Surface Curve for Disintegration Time

Table 4 for ANOVA for disintegration time :-

ANOVA for Quadratic model						
Response 1: dt time						
Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	793.11	5	158.62	267.68	0.0004	significant
A-banana powder	66.67	1	66.67	112.50	0.0018	
B-crosscarmellose sodium	682.67	1	682.67	1152.00	< 0.0001	
AB	16.00	1	16.00	27.00	0.0138	
A ²	0.8889	1	0.8889	1.50	0.3081	
B ²	26.89	1	26.89	45.38	0.0067	
Residual	1.78	3	0.5926			
Cor Total	794.89	8				

Table 5 Fit Statistic for disintegration time:-

Fit Statistics				
Std. Dev.	0.7698		R²	0.9978
Mean	31.89		Adjusted R²	0.9940
C.V. %	2.41		Predicted R²	0.9734
			Adeq Precision	44.5477

The **Predicted R²** of 0.9734 is in reasonable agreement with the **Adjusted R²** of 0.9940; i.e. the difference is less than 0.2.

Table 6 Summary of coefficient in terms of coded factors: -

Coefficients in Terms of Coded Factors						
Factor	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	34.78	1	0.5738	32.95	36.60	
A-banana powder	-3.33	1	0.3143	-4.33	-2.33	1.0000
B-crosscarmellose sodium	-10.67	1	0.3143	-11.67	-9.67	1.0000
AB	-2.00	1	0.3849	-3.22	-0.7751	1.0000
A ²	-0.6667	1	0.5443	-2.40	1.07	1.0000
B ²	-3.67	1	0.5443	-5.40	-1.93	1.0000

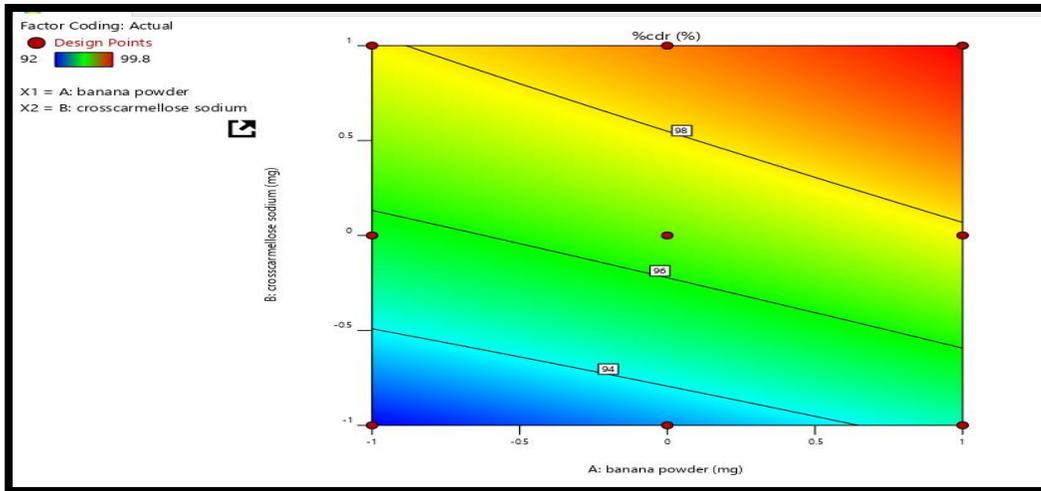


Figure 5 Two-Dimensional Response Surface Curve for Drug release

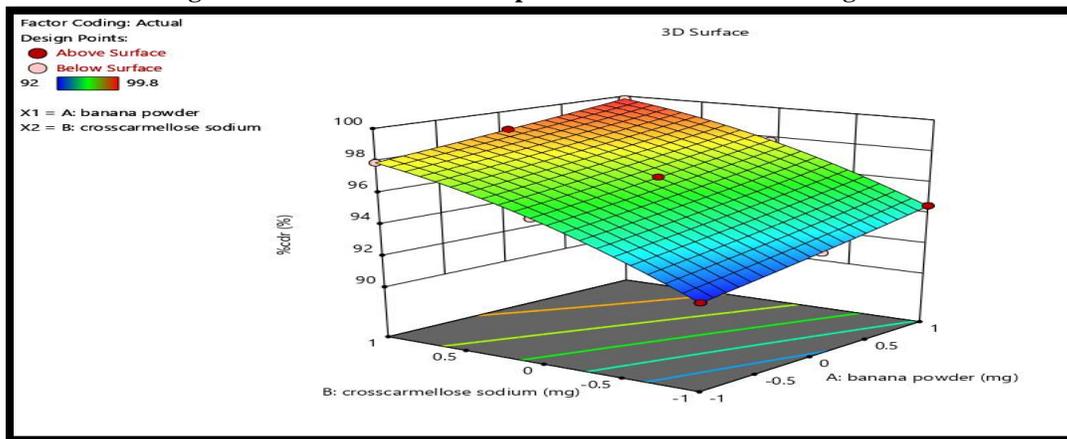


Figure 6 Three -Dimensional Response surface curve for Drug release

Table 7 ANOVA for drug release:-

ANOVA for Quadratic model

Response 2: %cdr

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	55.77	5	11.15	5836.51	< 0.0001	significant
A-banana powder	7.26	1	7.26	3798.84	< 0.0001	
B-crosscarmellose sodium	47.49	1	47.49	24848.93	< 0.0001	
AB	0.0900	1	0.0900	47.09	0.0063	
A ²	0.0072	1	0.0072	3.77	0.1476	
B ²	0.9248	1	0.9248	483.91	0.0002	
Residual	0.0057	3	0.0019			
Cor Total	55.78	8				

Table 8 Fit Statistic for drug release: -

Fit Statistics				
Std. Dev.	0.0437		R ²	0.9999
Mean	96.25		Adjusted R ²	0.9997
C.V. %	0.0454		Predicted R ²	0.9991
			Adeq Precision	219.2701

The **Predicted R²** of 0.9991 is in reasonable agreement with the **Adjusted R²** of 0.9997; i.e. the difference is less than 0.2.

Table 9 Summary of coefficient in terms of coded factors:-

Coefficients in Terms of Coded Factors							
Factor	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF	
Intercept	96.66	1	0.0326	96.56	96.76		
A-banana powder	1.10	1	0.0178	1.04	1.16	1.0000	
B-crosscarmellose sodium	2.81	1	0.0178	2.76	2.87	1.0000	
AB	-0.1500	1	0.0219	-0.2196	-0.0804	1.0000	
A ²	0.0600	1	0.0309	-0.0384	0.1584	1.0000	
B ²	-0.6800	1	0.0309	-0.7784	-0.5816	1.0000	

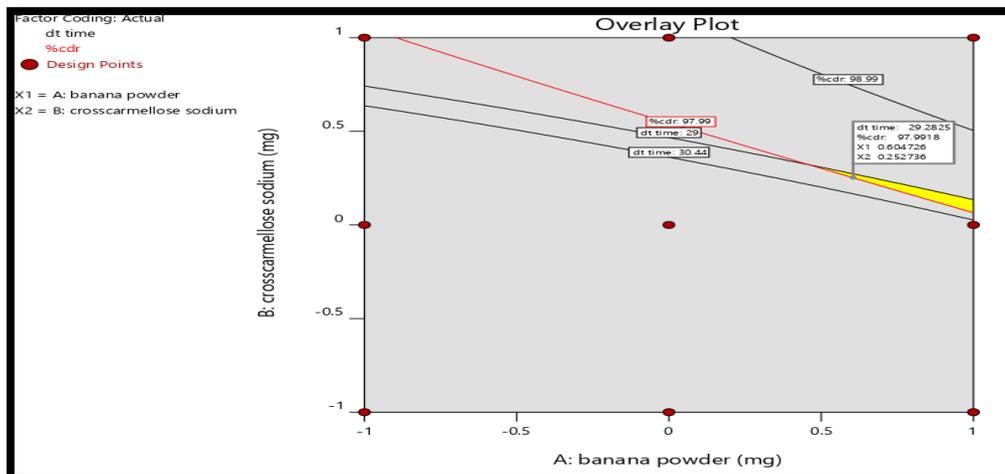


Figure 7 Overlay Plot of Response Variable

Short time Stability studies: -

The purpose of stability study is to provide evidence on the quality of a drug substance or drug product which varies with time under the influence of a variety of environmental factors such as temperature, humidity and light. Short-term stability studies on the above given formulation (at $40 \pm 2^{\circ}/75 \pm 5\%$ RH for 3 month) it has shown no significant changes in physical appearance, drug content and in vitro dispersion time. Statistical analysis ('t'-test) of drug content data gives 't' value of 1.9 for F2 formulation which is much less compared to the table value of 4.3 ($p < 0.05$). There are no appreciable changes in invitro dispersion time up on storage at $40 \pm 2^{\circ}/75 \pm 5\%$ RH for 3 months period. The FTIR spectrum of the pure drug with excipients exhibits no interactions in all Orodispersible tablets formulations.

CONCLUSION:

The study clearly demonstrates that orodispersible tablets of Granisetron hydrochloride could be successfully prepared by direct compression method in a cost-effective manner employing Banana powder. It was evident from the results that rate of drug release can be optimized using disintegrants for orodispersible formulations. From the developed formulations the release of Granisetron hydrochloride was best in F2 formulation i.e in-vitro study and in vitro dispersion time study. From the FTIR study, it was confirmed that the drug and excipients in the formulations were compatible with each other. Hence the availability of various technologies and the manifold advantages of orodispersible tablets will surely enhance the patient compliance providing rapid onset of action.

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ABBREVIATION

ORD: Orodispersible

FTIR: Fourier Transform Infrared Spectroscopy

GSH: Granisetron hydrochloride

S.D: Standard deviation

USP: United States of Pharmacopoeia

ICH: The International Conference of Harmonization.

DT:-Disintegration time

5HT3 :-Hydrxoytryptamine.

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