

Formulation and Evaluation of Orodispersible Tablets of Granisetron Hydrochloride Using Agar as Natural Super disintegrants

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ABSTRACT

The main aim of the study was to develop orodispersible tablets of Granisetron hydrochloride a selective 5-HT₃ receptor antagonist (an antiemetic agent) for improving patient compliance, especially those of paediatric and geriatric categories with difficulties in swallowing. In the wet granulation method orodispersible (ORD) tablets were prepared using natural super disintegrants *Agar agar*. The prepared batches of tablets were evaluated for weight variation, hardness, friability, wetting time, *in vitro* dispersion time, drug content and *in vitro* dissolution studies. The tablet formulation batch F4 was considered as the overall best formulation (with an *in vitro* drug release study of 99.09%). Short term stability studies (at 40 ± 2°C/75 ± 5% RH) on the best formulation indicated that there no significant changes in drug content. From the FTIR study indicated that there are no drug

excipient interactions.

Key words: Granisetron hydrochloride, Orodispersible tablets, FTIR spectroscopy, Wetting time, *In vitro* drug release study, Stability studies.

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INTRODUCTION

The advances in novel drug delivery systems for designing dosage forms like orodispersible tablets^{1,2} for convenient to be manufactured and administered free side effects, offering immediate release and enhance bioavailability so as to achieve better patient compliance. Oral drug delivery systems preferably tablets are most widely used dosage forms for being compact offering uniform dose and painless delivery. But elderly and paediatrics patients suffer in dysphagia because physiological changes associated with those groups.^{3,4} Generally dysphagia is observed nearly 35% of population and associated with a number of conditions like parkinsonism, mental disabilities, motion sickness, unconsciousness, unavailability of water etc. To overcome such problems certain innovative drug delivery system^{5,6} like mouth dissolving tablets have been developed. These are novel dosage forms which dissolve in saliva within few seconds when put on tongue. The orally disintegrating tablets are also called as orodispersible tablets, quick disintegrating tablets, fast disintegrating tablets, porous tablets, rapimelts. The mouth dissolving tablets are absorbed from the mouth, pharynx and oesophagus as saliva passes down into the stomach.⁷ The solution containing active ingredients is absorbed through gastrointestinal epithelium to reach the target and produce desired effect. In these cases the bioavailability of drugs are significantly greater than those observed from conventional solid dosage forms such as tablets and capsules.⁸ Granisetron hydrochloride is a selective 5-HT₃ receptor antagonist which has effect on controlling nausea and vomiting. Granisetron hydrochloride undergoes hepatic first pass metabolism with a bioavailability of 60% and terminal elimination half life between 3 to 14 hrs after oral administration.⁹ In the present study orodispersible tablets of Granisetron hydrochloride were designed using wet granulation method using various excipients and *agar agar* as natural superdisintegrants with prime objective arriving of a cost effective product.¹⁰

MATERIALS AND METHODS

Materials

Granisetron hydrochloride was received as a gift sample from Suzikem Labs Pvt Ltd., cherlapally, A.P, Mannitol and Aerosil were obtained as gifts from Aurobindo labs Pvt Ltd, A.P. sodium saccharin, magnesium stearate, talc, micro crystalline cellulose, and potassium dihydrogen-o-phosphate were procured from SD fine chem. Ltd Mumbai. Sodium hydroxide, sodium lauryl sulphate and methanol were procured from Qualigens fine chemicals Mumbai.

Drug excipient studies

Fourier Transform Infrared Spectroscopy (FTIR)

Assessment of possible incompatibilities between an active drug substance and different excipients forms an important part of the preformulation stage during the development of a dosage form. The use of FTIR technique allows pointing out the implication of the different functional groups of drug and excipients by analyzing the significant changes in the shape and position of the absorbance bands. In this method individual samples as well as the mixture of drug and excipients were ground mixed thoroughly with potassium bromide (1:100) for 3-5 mins in a mortar and compressed into disc by applying pressure of 5 tons for 5 mins in hydraulic press. The pellet was kept in the sample holder and scanned from 4000 to 400 cm⁻¹ in FTIR spectrophotometer. Then the characteristics peaks were obtained of all sample as well as mixtures.

Preparation of orodispersible tablets

Accurately weighed quantities of ingredients mentioned in Table 1 were passed through sieve no. 12. and *agar agar* was passed through sieve no.20. All the ingredients lubricant magnesium stearate and talc

(glidant) were manually blended homogenous by way of geometric dilution. The mixture was moistened with aqueous solution and granulated with sieve no.20 and placed in hot air oven at 60°C for sufficient 3-4 hrs. Then dried granules passed through sieve no.12 and blended with magnesium stearate and talc. The homogenous mixture was placed into tablet punching machine(10 station rotary tablet machine Clint India) getting tablet weight 190 mg each using deep concave punch.

Evaluation of granules

Precompression parameters of orodispersible tablets

Angle of repose

The angle of repose¹¹ 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, h is the height of cone in cm and r is the radius of the cone base in cm.

Bulk density (e_b)

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.

$$\text{Bulk density } (e_b) = \text{Mass of granules}(m) / \text{Bulk volume of granules } (V_b)$$

Tapped density (e_t)

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.

$$\text{Tapped density } (e_t) = \text{Mass of granules } (m) / \text{Tapped volume of granules } (V_t)$$

Compressibility index (Carr's index)

The compressibility index¹² determines the flow property characteristics of granules developed by Carr. 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.

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

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 are 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/cm². Test was done in triplicate.

Friability

Friability¹⁴ of tablets was performed in a Roche friabilator. Ten tablets were initially weighed (W_0) together and then placed in the chamber. The friabilator was operated for 100 revolutions and the tablets were subjected to the combined effects of abrasion and shock because the Plastic chamber carrying the tablets drops them at a distance of six inches with every revolution. The tablets are then dusted and reweighed (W). The percentage of friability was calculated using the following equation.

$$\% \text{ Friability} = F = \left(1 - \frac{W_0}{W} \right) \times 100$$

Where, W_0 and W are the weight of the tablets before and after the test respectively. The limit for percentage of friability is between 0.5-1%.

Weight Variation

The weight variation test was done by weighing 20 tablets individually (Shimadzu digital balance), calculating the average weight and comparing the individual tablet weights to the average. The percentage weight deviation was calculated and then compared with USP specifications.

Disintegration test

Six tablets along disc were introduced in each tube of basket of disintegration test apparatus (Lab care instruments). The basket was positioned into a beaker containing 900 ml of distilled water and operated at $37 \pm 2^\circ \text{C}$. The time of disintegration of tablet was recorded. The average time and standard deviation were calculated. Three trails were performed.

Wetting time

The Wetting time of the tablets can be measured using a simple procedure. Five circular tissue papers of 10 cm diameter are placed in petri dish with a 10 cm diameter. Wetting time was measured by placing a tablet on a piece of tissue paper folded twice, and was placed in a small Petridish containing 6 ml of simulated saliva pH 6.8, and the time for complete wetting was measured. Five tablets from each batch were used.

Water Absorption Ratio

A piece of tissue paper folded twice was placed in a small Petri dish (internal diameter=6.5 cm) containing 5 ml of distilled water. A tablet was placed on the tissue paper. The wetted tablet was weighed. The test was done in triplicate. The water absorption ratio (R) was determined according to the following equation,

$$\text{Water absorption ratio} = \frac{W_a - W_b}{W_a} \times 100$$

Where, W_a is the weight of the tablets before the test and W_b is the weight of the tablet after water absorption.

Drug Content

Drug content for ORD tablet was done by the assay method.^{15,16} First the prepared tablet (2 mg API) was crushed and added to 10 ml of phosphate buffer pH 6.8. After 30 min the solution was filtered¹⁷ and from 10 ml solution 1ml solution was withdrawn diluted up to 20 ml with phosphate buffer pH 6.8(10 µg/ml). This solution concentration for the drug content of formulations were calculated using calibrated standard curve equation $y=0.033x+0.018$. The drug content was determined at λ_{max} 302 nm by UV-spectrophotometer (ELICO164) against blank.

Ingredients(mg)	F1	F 2	F 3	F 4	F 5	F 6
GSH	2	2	2	2	2	2
Agar	4	6	8	10	12	14
Micro Crystalline Cellulose	126	124	122	120	118	116
Mannitol	50	50	50	50	50	50
Aerosil	2	2	2	2	2	2
Sodium Saccharin	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2
Talc	2	2	2	2	2	2
Total weight(mg)	190	190	190	190	190	190

Angle of repose(θ)	Observation
<25 $^\circ$	Free flowing granules
>40 $^\circ$	Poorly flowing granules

%Compressibility index	Flow type
5-15	Excellent flow(free flowing granules)
12-16	Good
18-21	Fair(powdered granules)
23-28	Poor(very fluid powders)
28-35	Poor(fluid cohesive powders)
35-38	Very poor(fluid cohesive powders)
>40	Extremely poor(cohesive powders)

Hausner's ratio	Flow type
1.2	Free flowing granules
>1.6	Poorly flowing granules

Formulation code	Bulk density (gm/cc) \pm S.D	Tapped density (gm/cc) \pm S.D	Angle of repose (degree) \pm S.D	Carr's index (%) \pm S.D	Hausner's Ratio \pm S.D
F1	0.56 \pm 0.02	0.66 \pm 0.08	23.0 \pm 0.03	15.15 \pm 0.02	1.17 \pm 0.08
F 2	0.68 \pm 0.11	0.74 \pm 0.09	25.0 \pm 0.12	8.1 \pm 0.13	1.08 \pm 0.12
F 3	0.54 \pm 0.13	0.68 \pm 0.11	24.0 \pm 0.11	20.58 \pm 0.01	1.2 \pm 0.125
F 4	0.58 \pm 0.14	0.66 \pm 0.02	26.0 \pm 0.13	12.12 \pm 0.01	1.13 \pm 0.01
F5	0.52 \pm 0.15	0.56 \pm 0.02	27.0 \pm 0.01	7.1 \pm 0.14	1.07 \pm 0.09
F6	0.53 \pm 0.11	0.58 \pm 0.14	29.0 \pm 0.09	8.62 \pm 0.11	1.09 \pm 0.11

Formulation code	Hardness(kg/cm 2) \pm S.D	Friability (%) \pm S.D	%Drug content \pm S.D	Average wt. of 1 tablet (mg) \pm S.D	Thickness(mm) \pm S.D
F1	3.9 \pm 0.02	0.49 \pm 0.11	99.2 \pm 0.01	191 \pm 0.1	4 \pm 0.10
F2	3.89 \pm 0.01	0.52 \pm 0.01	99.4 \pm 0.02	190 \pm 0.1	4 \pm 0.11
F3	3.85 \pm 0.02	0.57 \pm 0.02	99.3 \pm 0.03	190 \pm 0.1	4 \pm 0.14
F4	3.94 \pm 0.05	0.51 \pm 0.10	99.9 \pm 0.04	189 \pm 0.1	4 \pm 0.13
F5	3.85 \pm 0.01	0.52 \pm 0.01	99.4 \pm 0.02	190 \pm 0.1	4 \pm 0.10
F6	3.85 \pm 0.02	0.53 \pm 0.04	99.1 \pm 0.02	189 \pm 0.1	4 \pm 0.10

Formulation code	Disintegration time(s) \pm S.D	<i>In vitro</i> dispersion time(s) \pm S.D	Wetting time(sec) \pm S.D	Water absorption ratio \pm S.D
F1	31 \pm 1.01	36 \pm 1.02	24 \pm 1.1	68.23. \pm 1.3
F2	26 \pm 1.05	33 \pm 1.02	20 \pm 1.02	69.50 \pm 1.8
F3	24 \pm 1.11	29 \pm 1.02	17 \pm 1.06	71.51. \pm 1.2
F4	19 \pm 1.23	26 \pm 1.02	14 \pm 1.07	76.48 \pm 1.6
F5	22 \pm 1.12	28 \pm 1.01	22 \pm 1.02	72.50 \pm 1.8
F6	24 \pm 1.04	30 \pm 1.02	19 \pm 1.02	56.23. \pm 1.3

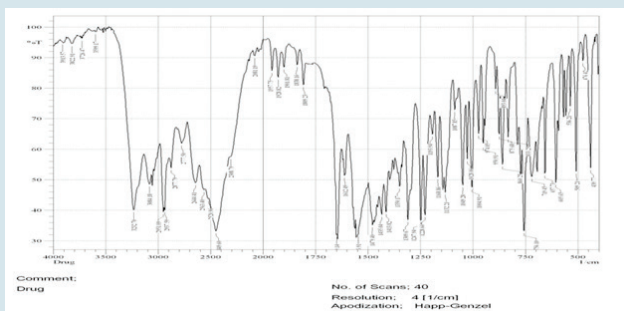


Figure 1: FTIR spectrum of Granisetron HCl pure drug.

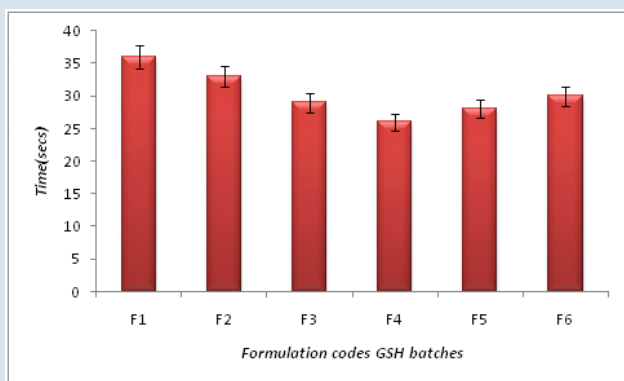


Figure 2: *In vitro* dispersion time of orodispersible tablets.

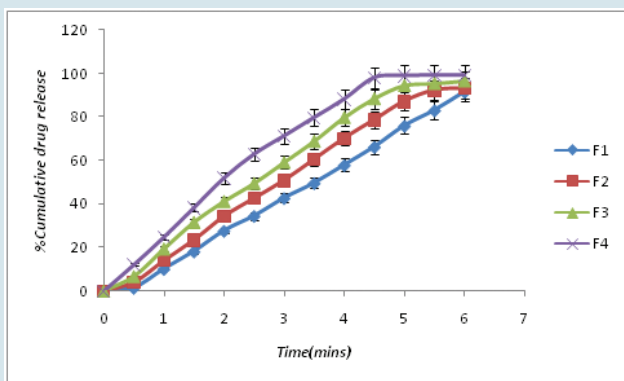


Figure 3: Comparative *in vitro* drug release study of GSH batches.

In vitro dissolution studies

The release rate of Granisetron hydrochloride^{11,18} Orodispersible tablets was determined using United States Pharmacopoeia (USP) dissolution testing apparatus type 2 (paddle method). The dissolution test was performed using 900 ml of Phosphate buffer pH 6.8, at $37 \pm 0.5^\circ\text{C}$ and 50 rpm. In specified time intervals (0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5.5, 6 min) an aliquot of 5 ml samples of the solution were withdrawn from the dissolution apparatus and with replacement of fresh fluid to dissolution medium. The samples were filtered through filter paper of 0.45 μm . Absorbance of these solutions were measured at λ_{max} 302 nm using a UV/Visible Spectrophotometer (ELICO164). The drug release

was plotted against time to determine the release profile of various batches.

In vitro dispersion time

This test is performed to ensure disintegration of tablets in the salivary fluid, if it is to be used as an orodispersible tablet. *In vitro* dispersion¹⁹ time was measured by dropping a tablet in a measuring cylinder containing 6 ml of simulated salivary fluid of pH 6.8. Three tablets from each formulation were randomly selected and *in vitro* dispersion time was measured.

Stability studies

The purpose of stability study is to provide evidence on the quality^{4,5} 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. The formulation was subjected to accelerated stability studies as per ICH (The International Conference of Harmonization) guidelines. The packed tablets were placed in stability chambers maintained at $30 \pm 2^\circ\text{C}$, $65 \pm 5\%$ RH and at $40 \pm 2^\circ\text{C}$, $75 \pm 5\%$ RH for 3 months. In a stability chamber. Tablets were periodically removed and evaluated for physical characteristics, drug content, *in-vitro* drug release etc.

RESULTS AND DISCUSSION

Drug excipient studies

The IR allows identification of functional groups²⁰ in various chemicals as well as incompatibilities between the drug and excipients. From the IR study the major peak (Figure 1) of GSH were found to 3240 cm^{-1} (NH of CONH), 3060 cm^{-1} (Aromatic C-H Stretching), 2860 cm^{-1} (C-H Stretching of CH_2), 2960 cm^{-1} (C-H Stretching of CH_3 Groups), 1660 cm^{-1} (C=O of CONH), 1610 cm^{-1} (C=N Stretching), 1560, 1480, 1450 cm^{-1} (C=C Ring stretching), 1410 cm^{-1} (C-N Stretching). The major peaks of agar was found to at 3342 cm^{-1} which is associated with O-H stretching, 1635 cm^{-1} (stretching of conjugated bond by amide of C=O group), 1367 cm^{-1} (C-C bending) and at 1041 cm^{-1} (C-O stretching). In the formulation of orodispersible tablets (F4) peak at 3342 cm^{-1} was due to presence of the disintegrant agar peak at 3061 cm^{-1} and 1453 cm^{-1} was due to the presence of drug GSH in the formulation. So from the study it can be concluded that the major peaks of drug (2960 cm^{-1} , 1410 cm^{-1}) remains intact and no interaction was found between the drug and disintegrants.

Pre-compression parameters of ORD formulations

All the compressible excipients (Table 1) with drug by wet granulation method was prepared using agar agar along with magnesium stearate and talc.

The bulk density of pre-compression blends was found to be in the range of 0.52 to 0.68 gm/cc, tapped density in the range of 0.56 to 0.74 gm/cc, the Carr's index values were in the range of 12 to 20% within limit expressed in (Table 2), angle of repose in the ranges from 23 to 29 degrees was in the specified limit expressed in (Table 3) and the hausner's ratio was in the range between 1.07 to 1.17 was within limit expressed in (Table 4). The pre-compression parameters of granules were evaluated such as bulk density, tapped density, angle of repose and Carr's index have expressed in (Table 5).

Post-compression parameters of ORD formulations

The post compression parameters such as hardness, weight variation, drug content uniformity, friability and thickness have given below (Table 6). The other parameters such as wetting time, disintegration time and *in vitro* dispersion time have given below (Table 7).

The hardness of the tablet formulations was found to be in the range of 3.85 to 3.94 kg/cm². The friability values were found to be in the range of 0.49 to 0.57%. The weight of all the tablets was found to be uniform with low values of standard deviation and within the prescribed USP limits. The average weight of one tablet was found to be in range 189 to 190 mg. The percent drug content of all the tablets was found to be in the range of 99.1 to 99.9% of the expected drug content, which was within the acceptable limits.

The disintegration time was in range 19 to 31 secs, wetting time was found be in range 14 to 24 sec, *in vitro* dispersion time was in range 26 to 36 secs and the water absorption ratio was between 56.23 to 76.48. The results are shown in Table 7.

In vitro dispersion time

This test was performed to ensure disintegration of tablets in the salivary fluid, if it is to be used as an orodispensible tablet. Among all formulations F4 formulation was found to be best. The dispersion time was found to be 26 s (Figure 2).

In vitro drug release study

In vitro drug release studies were performed in pH 6.8 phosphate buffer, on the above promising formulation (F4) gives maximum amount of drug release comparing to other formulations. The Percentage of drug release of F4 was best giving 99.09% in 6 mins comparing to other batches F1(91.51%), F2(93.1%), F3(96.31), F5(95.21%) and F6(93.34%). The dissolution profiles of the above formulations are depicted in Figure 3.

Short-term stability studies

Short-term stability studies on the above promising formulation (at 40 ± 2°/75 ± 5% RH for 3 mo) have shown no significant changes in physical appearance, drug content and *in vitro* dispersion time.²¹ Statistical analysis (*t*-test) of drug content data gives *t* value of 1.9 for F4 formulation which is much less compared to the table value of 4.3 (*p*<0.05). There are no appreciable changes in *in vitro* dispersion time up on storage at 40 ± 2°/75 ± 5% RH for 3 months period. The IR spectrum of the pure drug with excipients exhibits no interactions in all ORD formulations.

CONCLUSION

The study clearly demonstrates that orodispensible tablets of Granisetron hydrochloride could be successfully prepared by wet granulation method in a cost effective manner employing plantago ovate. It was evident from the results that rate of drug release can be optimized using disintegrants for orodispensible formulations. From the developed formulations the release of Granisetron hydrochloride was best in F4 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 orodispensible tablets will surely enhance the patient compliance providing rapid onset of action.

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CONFLICT OF INTEREST

There is no conflict of interest.

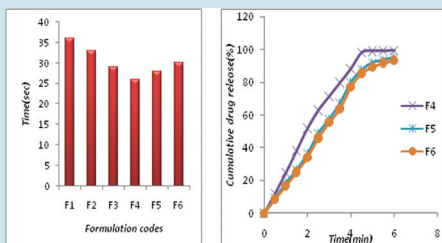
ABBREVIATION USED

ORD: Orodispensible; **FTIR:** Fourier Transform Infrared Spectroscopy; **GSH:** Granisetron hydrochloride; **S.D:** Standard deviation; **USP:** United States of Pharmacopoeia; **ICH:** The International Conference of Harmonization.

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PICTORIAL ABSTRACT



SUMMARY

- The main aim of the study was to develop orodispersible tablets of Granisetron hydrochloride using natural super disintegrants *Agar agar*. The tablet formulation batch F4 was considered as the overall best formulation (with an *in vitro* drug release study of 99.09 %). Short term stability studies (at $40 \pm 2^\circ\text{C}/75 \pm 5\% \text{ RH}$) on the best formulation showing no significant changes in drug content.

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