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

Chinmaya Keshari Sahoo1*, Nalini Kanta Sahoo2, Madhusmita Sahu2, Alok Kumar Moharana2, Deepak Kumar Sarangi2

ABSTRACT
The main aim of the study was to develop orodispersible tablets of Granisetron hydrochloride a selective 5-HT3 receptor antagonist (an antivomiting 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 tablets1-2 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 parkinosonism, mental disabilities, motion sickness, unconsciousness, unavailability of water etc. To overcome such problems certain innovative drug delivery system5-6 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, t alc, 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 minutes in 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 were 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 orodispensable tablets**

**Angle of repose**

The angle of repose\(^1\) 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,

\[
\tan \theta = \frac{h}{r}
\]

Where \( \theta \) 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.

\[
\text{Bulk density (} e_b \text{)} = \frac{\text{Mass of granules (m)}}{\text{Bulk volume of granules (} V_b \text{)}}
\]

**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.

\[
\text{Tapped density (} e_t \text{)} = \frac{\text{Mass of granules (m)}}{\text{Tapped volume of granules (} V_t \text{)}}
\]

**Compressibility index (Carr’s index)**

The compressibility index\(^2\)\(^-\)\(^4\) 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.

\[
\% \text{Carr’s index} = \frac{e_t - e_b}{e_t} \times 100
\]

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 orodispersable 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 tester\(^5\)\(^6\) and measured in terms of kg/cm\(^2\). Test was done in triplicate.

**Friability**

Friability\(^7\)\(^8\) 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.

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

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 ± 2°C. The time of disintegration of tablet was recorded. The average time and standard deviation were calculated. Three trials 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 filtered\(^17\) 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 for formulations were calculated using calibrated standard curve equation \( y=0.033x+0.018 \). The drug content was determined at \( \lambda_{max} 302 \text{ nm} \) by UV-spectrophotometer (ELICO164) against blank.
Table 1: Composition of Granisetron Hydrochloride orodispersible tablets containing natural superdisintegrants

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

Table 2: Relationship between powder flowability and angle of repose

<table>
<thead>
<tr>
<th>Angle of repose(°)</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25°</td>
<td>Free flowing granules</td>
</tr>
<tr>
<td>&gt;40°</td>
<td>Poorly flowing granules</td>
</tr>
</tbody>
</table>

Table 3: Relationship between powder flowability and % compressibility range

<table>
<thead>
<tr>
<th>%Compressibility index</th>
<th>Flow type</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-15</td>
<td>Excellent flow(free flowing granules)</td>
</tr>
<tr>
<td>12-16</td>
<td>Good</td>
</tr>
<tr>
<td>18-21</td>
<td>Fair(powdered granules)</td>
</tr>
<tr>
<td>23-28</td>
<td>Poor(very fluid powders)</td>
</tr>
<tr>
<td>28-35</td>
<td>Poor(fluid cohesive powders)</td>
</tr>
<tr>
<td>35-38</td>
<td>Very poor(fluid cohesive powders)</td>
</tr>
<tr>
<td>&gt;40</td>
<td>Extremely poor(cohesive powders)</td>
</tr>
</tbody>
</table>

Table 4: Relationship between powder flowability and Hausner’s ratio

<table>
<thead>
<tr>
<th>Hausner’s ratio</th>
<th>Flow type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>Free flowing granules</td>
</tr>
<tr>
<td>&gt;1.6</td>
<td>Poorly flowing granules</td>
</tr>
</tbody>
</table>

Table 5: Pre-compression parameters of ORD formulations

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Bulk density (gm/cc) ± S.D</th>
<th>Tapped density (gm/cc) ± S.D</th>
<th>Angle of repose (degree) ± S.D</th>
<th>Carr’s index (%) ± S.D</th>
<th>Hausner’s Ratio ± S.D</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>0.56 ± 0.02</td>
<td>0.66 ± 0.08</td>
<td>23.0 ± 0.03</td>
<td>15.15 ± 0.02</td>
<td>1.17 ± 0.08</td>
</tr>
<tr>
<td>F2</td>
<td>0.68 ± 0.11</td>
<td>0.74 ± 0.09</td>
<td>25.0 ± 0.12</td>
<td>8.1 ± 0.13</td>
<td>1.08 ± 0.12</td>
</tr>
<tr>
<td>F3</td>
<td>0.54 ± 0.13</td>
<td>0.68 ± 0.11</td>
<td>24.0 ± 0.11</td>
<td>20.58 ± 0.01</td>
<td>1.2 ± 0.125</td>
</tr>
<tr>
<td>F4</td>
<td>0.58 ± 0.14</td>
<td>0.66 ± 0.02</td>
<td>26.0 ± 0.13</td>
<td>12.12 ± 0.01</td>
<td>1.3 ± 0.01</td>
</tr>
<tr>
<td>F5</td>
<td>0.52 ± 0.15</td>
<td>0.56 ± 0.02</td>
<td>27.0 ± 0.01</td>
<td>7.1 ± 0.14</td>
<td>1.07 ± 0.09</td>
</tr>
<tr>
<td>F6</td>
<td>0.53 ± 0.11</td>
<td>0.58 ± 0.14</td>
<td>29.0 ± 0.09</td>
<td>8.62 ± 0.11</td>
<td>1.09 ± 0.11</td>
</tr>
</tbody>
</table>

Table 6: Post-compression parameters of ORD formulations

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Hardness(kg/cm²) ± S.D</th>
<th>Friability (%) ± S.D</th>
<th>%Drug content (mg) ± S.D</th>
<th>Average wt. of 1 tablet (mg) ± S.D</th>
<th>Thickness (mm) ± S.D</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>3.9 ± 0.02</td>
<td>0.49 ± 0.11</td>
<td>99.2 ± 0.01</td>
<td>191 ± 0.1</td>
<td>4 ± 0.10</td>
</tr>
<tr>
<td>F2</td>
<td>3.89 ± 0.01</td>
<td>0.52 ± 0.01</td>
<td>99.4 ± 0.02</td>
<td>190 ± 0.1</td>
<td>4 ± 0.11</td>
</tr>
<tr>
<td>F3</td>
<td>3.85 ± 0.02</td>
<td>0.57 ± 0.02</td>
<td>99.3 ± 0.03</td>
<td>190 ± 0.1</td>
<td>4 ± 0.14</td>
</tr>
<tr>
<td>F4</td>
<td>3.94 ± 0.05</td>
<td>0.51 ± 0.10</td>
<td>99.9 ± 0.04</td>
<td>189 ± 0.1</td>
<td>4 ± 0.13</td>
</tr>
<tr>
<td>F5</td>
<td>3.85 ± 0.01</td>
<td>0.52 ± 0.01</td>
<td>99.4 ± 0.02</td>
<td>190 ± 0.1</td>
<td>4 ± 0.10</td>
</tr>
<tr>
<td>F6</td>
<td>3.85 ± 0.02</td>
<td>0.53 ± 0.04</td>
<td>99.1 ± 0.02</td>
<td>189 ± 0.1</td>
<td>4 ± 0.10</td>
</tr>
</tbody>
</table>

Table 7: Post-compression parameters of ORD formulations

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

The release rate of Granisetron hydrochloride\textsuperscript{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 37º± 0.5ºC and 50 rpm. In specified time intervals (0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 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 \(\lambda_{	ext{max}}\) 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 dispersion\textsuperscript{19} 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\textsuperscript{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 ± 2ºC, 65 ± 5% RH and at 40 ± 2ºC, 75 ± 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 groups\textsuperscript{20} 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 orodispersible 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 ± 2oC/75 ± 5% RH for 3 mo) have 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 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 ± 2oC/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 orodispersible 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 orodispersible 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 orodispersible tablets will surely enhance the patient compliance providing rapid onset of action.

ACKNOWLEDGEMENT

The authors would like to acknowledge the contributions of Department of Pharmaceutics, Osmania University College of Technology, Osmania University, Hyderabad, Telangana, India for providing necessary facilities to carry out the research work.

CONFLICT OF INTEREST

There is no conflict of interest.

ABBREVIATION USED


REFERENCES

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 ± 2ºC/75 ± 5% RH) on the best formulation showing no significant changes in drug content.

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