ABSTRACT

The purpose of this research was to introduce and evaluate natural excipient that has versatile property in the oral disintegrant and immediate release formulations. This natural excipient was used as disintegrant, binder, and diluent in the formulation of orodispersible tablets of some model drugs such as Ondansetron HCl (OND), Propranolol (PNL) and Gabapentin (GP). Physicochemical studies such as swelling power and solubility, particle size distribution and some other physical evaluations was done on the natural excipient to ensure the suitability to incorporate for such formulation. Five formulations of each drug were formulated in different ratios of natural excipient and Crescaramellose (Superdisintegrant) and the final formulation of all drug used natural excipient alone as binder, diluent and disintegrant. All the formulations are subjected for in-vitro evaluations such as wetting time, water absorption ratio, in-vitro dispersion time and disintegration time, etc. Almost same results were obtained on formulations with or without the super disintegrant. Therefore, we conclude that the natural excipient proposed can be used as binder, diluent and disintegrant in oral disintegrating tablets and immediate release dosage forms. Mainly the natural excipient used is biocompatible, cost effective and provides as nutrition supplements.

Keywords: Natural excipient, Patient friendly dosage form, Diluent, Disintegrant, Binder, In vitro study.

INTRODUCTION

Recent advances in novel drug delivery systems aimed to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for ease of administration and to achieve better patient compliance. Oral drug delivery has been known for centuries as the traditional belief that by oral administration, the drug is as well absorbed as the food stuffs that are ingested daily. Rapid disintegrating Tablets (RDT) are gaining prominence as new drug delivery systems, that, these dosage forms dissolve or disintegrate in the oral cavity within a minute without the need of water or chewing. The RDTs are also called as orodispersible, mouth dissolving, oral disintegrating, fast melting, quick dissolving and freeze dried wafers. These are not only useful in administration of drugs in pediatric and geriatric patients but in patients suffering from dysphagia, leading to improved patient compliance. Often times people experience inconvenience in swallowing conventional tablets and capsules. In the case of motion sickness (kinetosis) and sudden continuation of cough during the common cold, allergic conditions and bronchitis, tablets which can rapidly dissolve or disintegrate in the oral cavity have attracted a great attention. In ODT formulations, the commonly used mixture of excipients comprising at least one disintegrant (1-1.5%), a diluent (10-85%), a binder (1-10%), a lubricant, and optionally, a swelling agent, a pellipulating agent, a sweetener and flavoring agents to achieve the effectiveness of the formulation.

No literature was found that a single natural excipient was tried and used as binder, diluents and disintegrant in the formulation development of ODTs. Instead of using synthetic excipients that are the foreign substances, if a natural excipient is opted for formulation of ODTs and immediate release formulations that have versatile properties which might reduce number of excipients used in formulations, unwanted toxic effects, economic to the patients and also provides nutritional supplements to the patients.

Banana fruit is economically one of the most important fruit produced and consumed in the world. In some parts of the world, banana is called plantain. The soft and sweet fruit of this tropical plant (not tree) is enjoyed by people from around the world. There is hundreds of variety of banana found growing in different parts of the world. Palayam kodan, Annaan, Ethan or nenthran (nenthra vazha), Morris or Robusta, Poovan, Kappa vazha (red banana), Monthan are few cultivars of banana in Kerala (all names in Malayalam). The DBP, which prepared from the banana especially from the variety called Ethan or nenthran (nenthra vazha), belongs to the family Musaceae which is a natural, commonly used as nutritional supplement as it contains many essential nutrients, including minerals and vitamins, and has a high energetic value in the range of 90–100 kcal per 100g edible portion. Fully ripe banana pulp contained 33.6% reducing sugars, 53.2% sucrose, 5.52% protein, 0.68% fat, 0.30% fiber, 2.58% starch and 4.09% ash. These results are in approximate agreement with those of other workers analyzing different bananas. It is considered to be good for the treatment of gastric ulcer and diarrhea because they contain vitamin A. Due to their high content of B6 vitamin, they help to reduce stress and anxiety, the high content of carbohydrates makes a very good source of energy, and potassium helps to better brain functioning. Therefore, the research is aimed to formulate Oral Disintegrant Tablet (ODT) of some highly water soluble drugs with the dose range from 10-100mg using a natural excipient i.e., dehydrated banana powder (DBP), which have versatile property. So that, the avoidance of many excipients in the ODTs formulations may be achieved. Moreover, super disintegrants, binders and diluents plays a main role in ODTs and immediate release formulations, hence, this research also mainly focused on the evaluation of the said properties.

The drugs, such as Ondansetron HCl (OND), Propranolol (PNL), and Gabapentin (GP) are selected as model drugs to formulate as ODTs. Ondansetron HCl is a selective blocking agent of the serotonin 5-HT3 receptor type, primarily used to treat and prevent chemotherapy-induced nausea and vomiting, effective in controlling post-operative nausea and post-radiation vomiting and nausea, and is a possible therapy for nausea and vomiting due to acute or chronic medical illness or acute gastroenteritis. Propranolol, a synthetic beta-adrenergic receptor blocking agent, used to treat high blood pressure, irregular heartbeats, shaking (tremors), and other conditions. It is used after a heart attack to improve the chance of survival. It is also used to prevent migraine headaches and chest pain (angina). Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. Gabapentin is indicated for the management of post herpetic neuralgia in adults and it is indicated
as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 12 years of age with epilepsy.

MATERIALS AND METHODS

Ondansetron hydrochloride (Zydus Cadila, Ahmedabad, India), Propranolol (Shaaban Pharmaceuticals, Puducheri, India), and Gapentin (Aurbindo Pharma Ltd, Hydrabad, India) was chosen as model active principles incorporated for the study. Croscarmellose sodium (Karnataka Antibiotics, Karnataka, India) as gift sample, Dehydrated Banana Powder (Safety food Pvt Ltd, Kerala, India), colloidal silicum dioxide (Aerosil 200, Degussa, Frankfurt/M., Germany), and Magnesium stearate (LobaChem, Mumbai, India) were used as tablet excipients. The other ingredients were used of analytical grade.

Fourier Transform Infra Red (FTIR) analysis

The FTIR spectrum of DBP, OND, PNL, and GP was recorded between the scanning range of 4000 - 400 against wave number (cm⁻¹) and % Transmittance. Samples were prepared in KBr discs (2mg sample in 200mg KBr) with a hydrostatic press at a force of 5t cm⁻² for 5min and the resolution was 4 cm⁻¹. Experiments were duplicated to check the reproducibility.

Drug-excipients interaction study

Infra red spectrometry is a useful analytical technique utilized to check the chemical interaction between the drug and the other excipients used in the formulations. The samples (drugs blended with DBP and stored at room temperature for a week) were powdered and intimately mixed with dry powdered potassium bromide. The powdered mixture was taken in a diffuse reflectance sampler and the spectra recorded by scanning in the particular wavelength region (4000 – 400 cm⁻¹) using Shimadzu FTIR spectrometer. The IR spectrum of drug was compare with that of the physical mixture of the drug and excipients used to check for any possible drug-excipients interaction.

Dehydrated banana powder evaluations

a. Swelling of powder (SP) and solubility (S)

Swelling power (SW) and solubility (S) were measured according to a modified method of Schoch et al, Leach, H. W et al., and Leach, H.W and Schoch, T. J. A 0.1 g (dry basis) ground sample was placed in a centrifuge tube, make up the volume up to 10 ml using distilled water, and mixed by using a vortex mixer to get a suspension (1%w/v). The suspension was kept for 4h for complete swelling and wetting at room temperature. Thereafter, the suspension was heated at different temperatures such as 40, 60, 80 and 100°C for 30min individually using electric water bath and centrifuged at 3000xg for 15 min. The supernatant was decanted and dried in an oven for 3 h at 100°C ± 5°C. The residue obtained after drying the supernatant represents the amount of solubilized materials in water. The solubility was calculated as g per 100 g of sample on dry weight basis. All determinations were done in triplicate. The SW and S indices were determined by following the formulas;

\[
SW = \frac{\text{Weight of sediment}}{\text{weight of dry sample solids}}
\]

\[
S = \frac{\text{weight of dissolved solids in supernatant}}{\text{weight of dry sample solids in the original sample}} \times 100
\]

b. Powder characterization

The banana powder was evaluated for the parameters such as percent compressibility, Hausner ratio, moisture content, particle size distribution, etc. The compressibility index and Hausner ratio was calculated based on the untapped and tapped density results. Moisture loss was estimated by heating (at 105°C for 5min) the known quantity of the banana powder using moisture balance. The particle size distribution of the powder was determined by microscopic technique.

Preparation of orodispersible tablets by wet granulation method

Five formulations of OND (OF1 - OF5), PNL (PF1 - PF5) and GP (GF1 - GF5) were developed by varying concentration of super disintegrating agent (2.5% - 15%) and the final formulation of each drug (OF5, PF5, GF5) was formulated using DBP alone without addition of superdisintegrant. The presieved (# 60 mesh) drug and other excipients were mixed using planetary mixer (32 rpm) and then subjected to wet granulation by using purified warm water (60-70°C) as a granulating fluid. The cohesive mass is passed through sieve (#18 mesh) and dried until get the moisture content of 3-5%. Again the mass was passed through sieve (#10 mesh), lubricated using double cone blender at the rate of 16 rpm and compressed in to tablets using 8 station rotary tablet machine with 6mm punch. The formulations were made according to the formulas showed (Table 1).

Table 1: Formula for orodispersible tablets formulation of the drugs

<table>
<thead>
<tr>
<th>Formulations/ Ingredients</th>
<th>OND (mg)</th>
<th>PNL (mg)</th>
<th>GP (mg)</th>
<th>Banana powder (mg)</th>
<th>Croscara-melose sodium (mg)</th>
<th>Aerosil (%)</th>
<th>Magnesium stearate (%)</th>
<th>Purified water</th>
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<tbody>
<tr>
<td>OF1</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>72</td>
<td>15</td>
<td>2</td>
<td>1</td>
<td>Qs</td>
</tr>
<tr>
<td>OF2</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>77</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>Qs</td>
</tr>
<tr>
<td>OF3</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>82</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>Qs</td>
</tr>
<tr>
<td>OF4</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>84.5</td>
<td>2.5</td>
<td>2</td>
<td>1</td>
<td>qS</td>
</tr>
<tr>
<td>OF5</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>87</td>
<td>-</td>
<td>2</td>
<td>1</td>
<td>qS</td>
</tr>
<tr>
<td>PF1</td>
<td>-</td>
<td>40</td>
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<td>42</td>
<td>15</td>
<td>2</td>
<td>1</td>
<td>qS</td>
</tr>
<tr>
<td>PF2</td>
<td>-</td>
<td>40</td>
<td>-</td>
<td>47</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>qS</td>
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<tr>
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<td>-</td>
<td>40</td>
<td>-</td>
<td>52</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>qS</td>
</tr>
<tr>
<td>PF4</td>
<td>-</td>
<td>40</td>
<td>-</td>
<td>54.5</td>
<td>2.5</td>
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<td>-</td>
<td>57</td>
<td>-</td>
<td>2</td>
<td>1</td>
<td>qS</td>
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<tr>
<td>GF1</td>
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<td>-</td>
<td>10</td>
<td>72</td>
<td>15</td>
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<td>1</td>
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</tr>
<tr>
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<td>77</td>
<td>10</td>
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<td>82</td>
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<td>qS</td>
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<td>GF5</td>
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<td>-</td>
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<td>87</td>
<td>-</td>
<td>2</td>
<td>1</td>
<td>qS</td>
</tr>
</tbody>
</table>

Pre-compression parameters

The granules were evaluated for the parameters such as Angle of Repose, Bulk density, Carr's index, % compressibility, Hausner ratio for their suitability to execute further process.

Post-compression parameters

Hardness of six tablets at all compression force level was determined using a Pfizer type hardness tester. Friability of all the formulations was performed by using Roche Friablator with the
revolution speed at 30rpm on 10 tablets from each batch. Weight
variation test was performed with 20 tablets and mouth feel was
checked with the placebo tablets by following the conventional
method.

In-vitro dispersion and disintegration time

In vitro dispersion time was measured by dropping a tablet in a
measuring cylinder containing 10ml of simulated saliva fluid of pH
6.4. After dropping a tablet in the simulated saliva fluid, the tablet
started to swell quickly, broke and followed by dispersed. Another
method was also tried to determine the in vitro disintegration time, in
this method, the tablet was dropped in a beaker containing 50 ml of
Sorenson’s buffer pH 6.4. The time of breakdown of tablet followed
by dispersion was noted. Three tablets from each formulation were
randomly selected for this study and the in vitro disintegration time is
expressed in seconds.

In vitro disintegration time, modified dissolution apparatus was
used5, instead of the actual disintegration apparatus due to several
limitations and they do not suffice the measurement of very short
disintegration times (actual disintegration time that patience can
experience ranges from 5 to 30s. In this experiment, 900 ml of water
maintained at 37°C as the disintegration fluid and the paddle at 100
rpm as stirring element was used. Disintegration time was noted
when the tablet disintegrated and passed completely through the
screen of the sinker (3–3.5 mm in height, 2–2.5 mm in width and
having #10 mesh), immersed at a depth of 8.5cm from the top with
the help of a hook. This method was useful in providing
discrimination among batches which was not possible with the
conventional disintegration apparatus.

Wetting time

A conventional method was followed to measure wetting time and
capillarity of the orodispersible tablets. A pinch of amaranth powder
was placed at the upper surface of tablet and it was carefully placed
in a petri dish of 9.0cm in diameter, containing tissue paper which
was completely wet (10 ml of water) at room temperature. Tablet
absorbs water through tissue paper, penetrates inside the tablet and
moves quickly upward and after complete wetting, spreading of
colour occurs due to the presence of amaranth powder. The time for
time for complete wetting was recorded. To check for
reproducibility, the measurements were carried out six times and the
mean value calculated.

Water absorption ratio

Tablet was carefully placed in a petri dish of 9.0cm in diameter,
containing tissue paper which was completely wet (excess with 25
ml of water) and maintained at room temperature. Tablet absorbs
water through tissue paper, penetrates inside the tablet and loses its
integrity. Then, the tablet was carefully withdrawn from the surface
of the tissue paper with help of spatula and weighed. The water
absorption ration of the tablets was calculated using the following
formula;

\[
\frac{\text{Wt of the Tablet after studies} - \text{Wt of the Tablet before studies}}{\text{Wt of the Tablet before studies}} \times 100
\]

In-vitro dissolution studies

Dissolution study of OF1–OF5 formulations was performed using
USP II standard dissolution apparatus maintained at 37°C ± 1°C
using 500ml of 6.4 pH phosphate buffer as dissolution medium and
the paddle speed was maintained at 50 rpm. A 5ml of aliquate was
withdrawn every 5 min for 45min and replaced 5 ml of the fresh
medium every time and the absorbance was measured using double
beam UV-spectrophotometer at 250 nm.

Moisture uptake studies

Moisture uptake studies on the formulations conducted to assess the
stability of the formulation. Tablets of each batch were kept in at
room temperature and 60% RH and maintained for 2h. Tablets were
weighed and the percentage increase in weight was recorded.

Stability studies

The purpose of stability testing is to provide evidence on how the
quality of a drug substance or drug product varies with the time
under the influence of variety of environmental conditions such as
temperature, humidity and light. Stability studies of the formulations
were carried out at room temperature (25°C± 2°C and
60±5% RH) and refrigerated condition (2–5°C) for 3 month period.

RESULTS AND DISCUSSION

Orodispersible tablets belong to oral drug delivery system that are
capable of disintegrating in the oral cavity and thus rapidly releases
the drug. The dehydrated banana powder was evaluated for their
physicochemical properties such as Swelling power and Solubility,
moisture content, particle size and size distribution and some
powder characterisations.

In FTIR study, DBP showed some characteristic bands between 4000
– 400 cm−1 range like the broad band between 3390 – 3429, sharp
peak between 2940 – 2910, 2380 – 2330, 1650 – 1630, and 1635 –
1615, which identifies the presence of free –OH, C=H Stretching, C=O
Stretching, and N-H bending respectively. OND showed broad peak between 4000 – 2700 and sharp peak between 3500 – 3200 identifies the presence of amine group and H-N
Stretching. The sharp peaks at 2960, 1710, and 1180 identifies the
presence of C=C Stretching, C=O Stretching, and C-N Stretching
respectively. PNL showed broad peak between 3800 – 2700, sharp
peak between 3360 – 3380, 2830 – 2815, and 2350 – 2340 which
identifies the presence of free hydroxyl group, N-H Stretching, C-H
Stretching of ether linkage, and C-N Stretching respectively. GP showed sharp peak between 2960 – 2940, 2880 – 2860, 2350 –
2340, 1650 – 1630, and 1635 – 1615 which identifies the presence
of C-H Stretching, N-H Stretching, C-N Stretching, and C=O Stretching respectively and the presence of broad peak between 4000 – 2500
indicated the presence of free –OH and amine group.

FTIR spectra of the physical mixture of all the drugs with DBP exhibited all the characteristic bands as in the spectrum of the individual DP, OND, PNL, and GP excluding the possibility of any
interaction, chemical and functional group change during the
processing of the formulation of ODTS.

In particle size evaluation, almost uniform, round and oval shape
particles ranged from 5 to 25 μm was observed. Moisture content
was found to be approximately 2% which states that it is not a
hygroscopic powder which may results good stability to the
formulations. The poor compressibility (28.04%) was found in the
powder of DBP and required to go for granulation to improve the
flow and better compression during the process.

Swelling and solubility study, at 40°C, swelling power and percent
solubility was in the range from 2.4 – 29 fold and 82 – 9.4 %
respectively, and in addition, DBP exhibits rapid increases in
swelling power from 9.2 – 96 fold and percent solubility from 22.4–
24.17% when the temperature increased to 80 and 100°C. This may
be due to the deformation and surface cracking of the starch which
is present in the DBP and thus making DBP useful for the
formulation with various properties. The Swelling and solubility
study profile of DBP is showed (Figure 1).

The lubricated granules of Ondensetron, Propranolol, and
Gabapentin were evaluated for their suitability to compress in to
tablets. In this study, almost all the formulations showed the angle of
repose less than 30°, which reveals good flow property. The loose
bulk density and tapped bulk density of all the formulation granules
varied from 0.410 gm/cm3 to 0.450 gm/cm3 and 0.410 gm/cm3 to
0.530 gm/cm3 respectively. The results of Carr’s consolidation index
In post compression evaluation, hardness values ranged between 2.5 to 3.5 kg/cm² for all formulations which is almost acceptable range for ODTs and the tablet hardness is not as absolute strength. The entire tablet passes weight variation test as the average percentage weight variation was within the pharmacopoeia limit of 10%. It was found to be 97.0 ± 0.70 mg to 101.0 ± 0.45 mg. Moreover, weight of all the tablets was found to be uniform with low standard deviation. The friability values were found to be within the limit (0.1 – 0.9%). These evaluation parameters reveal there is no significant difference between the formulation batches. The results are showed (Table 3).

Wetting time is closely related to the inner structure of tablet. This experiment mimics the action of saliva in contact with the tablet to illustrate the water uptake and subsequent wetting of tablet. This study showed the wetting process was very rapid, almost in all the formulations which may be due to the ability of swelling followed by breaking and also capacity of water absorption causes swelling. It was found to be in the range of 10 sec to 20 sec. The wetting time of formulation using DBP alone is better when compared to formulations used superdisintegrant. The in vitro dispersion and disintegration time was found to be in the range between 15sec to 25 sec and 20sec to 35 sec of almost all the batches respectively. The results showed that the in vitro dispersion and disintegration time of formulations with DBP alone is almost equal and better than the formulations along with superdisintegrant. The in vitro dispersion and disintegration time of all the formulations is showed (Table 4).

In moisture uptake study, there was no significant variation of the tablets weighed before and after the moisture uptake studies was found to be almost equal.

The in vitro dispersion and disintegration time was found to be in the range between 15sec to 25 sec and 20sec to 35 sec of almost all the batches respectively. The results showed that the in vitro dispersion and disintegration time of formulations with DBP alone is almost equal and better than the formulations along with superdisintegrant. The in vitro dispersion and disintegration time of all the formulations is showed (Table 4).

In moisture uptake study, there was no significant variation of the tablets weighed before and after the moisture uptake studies was found to be almost equal.

Fig. 1: Swelling and solubility profile of DBP.

<table>
<thead>
<tr>
<th>Formulations/Parameters</th>
<th>Angle of repose (°)</th>
<th>Bulk density gm/cm³</th>
<th>Tapped density gm/cm³</th>
<th>Compressibility Index (%)</th>
<th>Hausner ratio</th>
</tr>
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<tbody>
<tr>
<td>GF5</td>
<td>28.58 ± 0.34</td>
<td>0.449 ± 0.29</td>
<td>0.510 ± 0.32</td>
<td>12.0 ± 0.14</td>
<td>1.136 ± 0.15</td>
</tr>
<tr>
<td>GF4</td>
<td>27.24 ± 0.65</td>
<td>0.432 ± 0.45</td>
<td>0.515 ± 0.51</td>
<td>16.0 ± 0.19</td>
<td>1.190 ± 0.18</td>
</tr>
<tr>
<td>GF3</td>
<td>30.34 ± 0.47</td>
<td>0.422 ± 0.36</td>
<td>0.502 ± 0.22</td>
<td>16.0 ± 0.23</td>
<td>1.903 ± 0.12</td>
</tr>
<tr>
<td>GF2</td>
<td>26.01 ± 0.32</td>
<td>0.420 ± 0.15</td>
<td>0.500 ± 0.24</td>
<td>16.0 ± 0.31</td>
<td>1.904 ± 0.12</td>
</tr>
<tr>
<td>GF1</td>
<td>27.42 ± 0.44</td>
<td>0.414 ± 0.32</td>
<td>0.518 ± 0.39</td>
<td>20.0 ± 0.37</td>
<td>1.250 ± 0.17</td>
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<tr>
<td>PF1</td>
<td>24.12 ± 0.12</td>
<td>0.359 ± 0.22</td>
<td>0.424 ± 0.12</td>
<td>15.3 ± 0.12</td>
<td>1.181 ± 0.12</td>
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<tr>
<td>PF2</td>
<td>22.23 ± 0.24</td>
<td>0.452 ± 0.35</td>
<td>0.516 ± 0.42</td>
<td>12.0 ± 0.38</td>
<td>1.141 ± 0.20</td>
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<td>PF3</td>
<td>25.36 ± 0.18</td>
<td>0.352 ± 0.38</td>
<td>0.404 ± 0.26</td>
<td>15.3 ± 0.24</td>
<td>1.147 ± 0.14</td>
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<td>PF4</td>
<td>26.26 ± 0.34</td>
<td>0.420 ± 0.19</td>
<td>0.522 ± 0.32</td>
<td>19.5 ± 0.16</td>
<td>1.242 ± 0.19</td>
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<td>PF5</td>
<td>24.24 ± 0.29</td>
<td>0.432 ± 0.42</td>
<td>0.532 ± 0.22</td>
<td>18.7 ± 0.12</td>
<td>1.231 ± 0.16</td>
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<tr>
<td>GF1</td>
<td>32.12 ± 0.52</td>
<td>0.349 ± 0.19</td>
<td>0.412 ± 0.32</td>
<td>15.29 ± 0.24</td>
<td>1.180 ± 0.18</td>
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<td>GF2</td>
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<td>0.402 ± 0.25</td>
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<td>GF4</td>
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<td>0.410 ± 0.18</td>
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<td>GF5</td>
<td>30.23 ± 0.42</td>
<td>0.412 ± 0.32</td>
<td>0.488 ± 0.39</td>
<td>15.57 ± 0.17</td>
<td>1.184 ± 0.17</td>
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</table>

Table 3: Physical evaluations of the ODTs formulations

<table>
<thead>
<tr>
<th>Formulations/Parameters</th>
<th>Hardness kg/cm²</th>
<th>Weight variation (n=20) (mg)</th>
<th>% Friability</th>
<th>Wetting time (sec) (n=3)</th>
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<tbody>
<tr>
<td>OF1</td>
<td>2.8 ± 0.20</td>
<td>1.00 ± 0.45</td>
<td>0.609</td>
<td>14.52 ± 1.48</td>
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<tr>
<td>OF2</td>
<td>3.2 ± 0.34</td>
<td>97.1 ± 0.70</td>
<td>0.407</td>
<td>17.04 ± 1.14</td>
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<tr>
<td>OF3</td>
<td>2.5 ± 0.19</td>
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<td>0.309</td>
<td>13.00 ± 2.04</td>
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<td>OF4</td>
<td>2.8 ± 0.22</td>
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<td>0.551</td>
<td>18.42 ± 2.36</td>
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<td>3.0 ± 0.14</td>
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<td>0.85</td>
<td>13.40 ± 1.16</td>
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<td>14.52 ±1.24</td>
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<tr>
<td>GF2</td>
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<td>0.551</td>
<td>18.42 ± 1.26</td>
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<tr>
<td>GF5</td>
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<td>0.85</td>
<td>13.40 ± 2.12</td>
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</table>
and disintegrant in the conventional oral dosage form especially contain superdisintegrant (crocaramellose). Swelling and Solubility dispersion time and percent drug release with the formulation study showed that the DBP have enough swelling and solubility properties and from the results obtained from the formulations indicated that the DBP can be incorporated alone as binder, diluent and disintegrant in the conventional oral dosage form especially ODTs. The hardness of the tablets were increased when warm water (60-80°C) was used as granulating fluid due to more swelling of the DBP. The DBP is "effective" than the other commonly used excipients to achieve the drug release and ODTs formulations respectively. The DBP is "cost effective" due to the cost associated with the DBP. The DBP was used as granulating fluid in the wet granulation method. The % drug release of OF5 was almost equal to OF1 to OF4 in 45 min. The dissolution profile is showed (Figure 2).

## CONCLUSION

The OF5, PF5, and GF5 batches were formulated using DBP alone which showed almost equal and better results in terms of the evaluations such as wetting time, water absorption ratio, in vitro dispersion time and percent drug release with the formulation contain superdisintegrant (crocaramellose). Swelling and Solubility study showed that the DBP have enough swelling and solubility properties and from the results obtained from the formulations indicated that the DBP can be incorporated alone as binder, diluent and disintegrant in the conventional oral dosage form especially ODTs. The hardness of the tablets were increased when warm water (60-80°C) was used as granulating fluid due to more swelling of the DBP which showed good binding property. Therefore, warm and normal water could be used as granulation fluid for immediate release and ODTs formulations respectively. The DBP is "cost effective" than the other commonly used excipients to achieve the dissolution profile.

## ACKNOWLEDGEMENT

The authors gratefully acknowledge the Management, Karpagam University, and Principal, Karpagam College of Pharmacy for providing technical assistance and facilities to carry out the research. Furthermore, this work was supported by providing gift samples of Ondesetron HCl, Propranolol, Gapapentin, and Croscaramellose sodium by Zydus Cadila, Shashan Pharmaceuticals, Aurbindo Pharma Ltd and Karnataka Antibiotics respectively.

## REFERENCES


## Table 4: In vitro dispersion time and water absorption time of ODTs

<table>
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<tr>
<th>Formulations</th>
<th>Dispersion time (sec)</th>
<th>Disintegration time (sec)</th>
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