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Formulation and Evaluation of Mouth Dissolving Tablets of Ondansetron Hydrochloride Using *Plantago ovata* (Isapghula) Mucilage as Natural Super Disintegrating Agent

Sunidhi Mahant*, Shivali Singla, Sachin Goyal, Bhimi Kumari, Abhishek Soni

School of Pharmacy, Abhilashi University, Mandi, Himachal Pradesh, India

ABSTRACT

Mouth dissolving tablet is an innovative solid unit dosage form that overcome the problem of swallowing and provide rapid disintegration & dissolution to release the drug as soon as they come in contact with saliva, hence provide quick onset action. The aim of this study was to formulate & evaluate mouth dissolving tablets of Ondansetron hydrochloride using natural super disintegrating agent. Ondansetron hydrochloride is a serotonin receptor (5-HT_3) antagonist used to treat nausea and vomiting arises during chemotherapy and radiation therapy. Mouth dissolving tablets were prepared by direct compression method using natural super disintegrating agent (*Plantago ovata* mucilage). Prepared tablet were evaluated for Hardness, weight variation, friability, thickness, wetting time, dispersion time, water absorption ratio, disintegration & dissolution study. According to results of optimized batches it has been concluded that Formulation batch F6 was an ideal batch which contain 12% w/v concentration of *Plantago ovata* mucilage showed least disintegration time that is 7 seconds & maximum drug release of (98.57%) within 15 minutes and was best among all the formulations.

Keywords: Mouth dissolving tablets, Ondansetron hydrochloride, super disintegrating agent, formulations.

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***Corresponding author**: Ms. Sunidhi Mahant
Address: School of Pharmacy, Abhilashi University, Mandi, Himachal Pradesh, India
Tel.: +91-7831991404
E-mail ✉: sunidhimahant19@gmail.com
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INTRODUCTION

Oral drug delivery has been known for decades as the most preferred and widely used route of administration among all the routes that has been explored for the systemic delivery of drugs. Oral drug delivery received the gold standard in the pharmaceutical industry because of the more flexibility in the designing of dosage form & it is regarded as safest, more convenient and often painless, the medicament need not be sterile & provide highest patient compliance. Solid dosage forms are popular because of ease of administration, accurate dosage, self-

medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms being tablets and capsules; Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience difficulty in swallowing (dysphasia) conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis, during pregnancy. For these reasons, Mouth Dissolving Tablets that can rapidly dissolve or disintegrate in the oral cavity have played a great deal of attention. [1]

Difficulty in swallowing to conventional tablets and capsules is common among all age groups, especially in elderly and dysphagic patients. [2] The concept of Mouth Dissolving Tablets emerged with an objective to improve patient's compliance. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus obviating the need for water during administration, an attribute that makes them highly attractive for Paediatric and geriatric patients. Mouth Dissolving Tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. [3]

United States Food and Drug Administration (FDA) define orally disintegrating tablets as "A solid dosage form which contain a medicinal substance or active ingredient which disintegrates rapidly within few seconds when placed on a tongue. US Food and Drug Administration Center for Drug Evaluation and Research (CDER) defines, in the 'Orange Book', an MDT as "a solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". European Pharmacopoeia described orally disintegrating tablets as 'uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed' and as tablets which should disintegrate within 3 minutes. [4]

Orally disintegrating tablets are also known as quick disintegrating tablets, fast disintegrating, mouth dissolving, rapid melt, rapid dissolving or orodispersible tablets. These are novel types of tablets that disintegrate/dissolve/ disperse in saliva. These are solid unit dosage forms containing medicinal substances which disintegrate or dissolve rapidly in oral cavity usually within a few seconds even without the need of water. In such cases, bioavailability of drug is significantly enhanced by avoiding first pass hepatic metabolism than those observed with conventional tablets. [5-7]

MATERIALS AND METHODS

Materials

Ondansetron hydrochloride was obtained as a gift sample from Morepen Pvt. Ltd. Parwanoo H.P. *Plantago ovata* seed (isapghula) was purchased from local market of Kullu (H.P.). Micro crystalline cellulose was taken from Pharmaceutics Laboratory and was purchased from Molychem Pvt. Ltd. Sodium saccharine was obtained from pharmaceutical chemistry laboratory and it was purchased from Loba Chemie Pvt. Ltd. India. Clove oil was obtained from Pharmacognosy Laboratory which was purchased from SDFCL. Povidone was taken from Pharmaceutics Laboratory and was purchased from Molychem Pvt. Ltd.

Method

The method used for preparation of mouth dissolving tablets of ondansetron hydrochloride was direct tablet compression method. It is the simplest and least expensive tableting process. Mouth dissolving tablets made by direct compression are robust and can be easily packaged and handled. For direct compression mouth dissolving tablet processes, sugar based excipients (mannitol, sorbitol, xylitol, maltose, etc.) are routinely used for their high water solubility, sweet taste, and pleasant mouth feel. In addition to taste and mouth feel, disintegration time is a primary concern. Some Mouth dissolving tablet technologies use effervescent couples alone or in combination with other disintegrants to achieve rapid dispersion. [8-9] The use of disintegrating agent, and especially the more modern super disintegrants, has made the advent of compression based Mouth Dissolving Tablets possible.

Formulation Development

Method of Formulations

Mouth Dissolving Tablets, Ondansetron hydrochloride was prepared by direct compression method with the addition of dried Plantago ovata mucilage as a natural super disintegrating agent and binding agent, along with other excipients. These were mixed in dry and clean mortar pestle. Then the blend was passed through sieve no. #60. The prepared powder were subjected to various pre compression evaluation parameters such as angle of repose, bulk density, tapped density, carr's index, hausner's ratio and compressed by twelve station Tablet Punching Machine and then post compression parameters such as Hardness, weight uniformity, friability, thickness, wetting time, dispersion time, water absorption ratio, disintegration & dissolution study were evaluated. Finally at different concentrations of natural super disintegrating agent the effect of Mouth dissolving tablets mainly in terms of disintegration time and dissolution rate were concluded.

Preformulation Study [10]

Angle of repose

The resistance forces in a free powder can be measured by the angle of repose (θ). Angle of Repose was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (*h*) was obtained. Radius of the heap (*r*) was measured and angle of repose (*θ*) was calculated using the formula.

$$\tan\theta = \frac{h}{r}; \quad \text{therefore; } \theta = \tan^{-1}\left(\frac{h}{r}\right)$$

Where, θ is Angle of Repose, h is height of Cone in cms & r is Radius of cone in cms.

Bulk Density

Density is defined as mass per unit volume. Bulk density, P_b is defined as the mass of the powder divided by the bulk volume and is expressed as g/cm^3. It depends upon particle size distribution, particle shape and the particles adhere together. Apparent bulk density (P_b) was determined by pouring the blend into a graduated cylinder the initial weight was noted. This initial volume is called the bulk volume. The bulk density was calculated using the formula.

$$\rho_b = \frac{M}{V_b}$$

Where, P_b is bulk density; V_b is bulk volume & M is the weight of the powder.

Tapped Density

The measuring cylinder containing a known mass of blend was tapped for a 100 times using density apparatus. The minimum volume (V_t) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density (P_t) was calculated using the formula.

$$\rho_t = \frac{M}{V_t}$$

Where, P_t is tapped density, V_t is tapped volume, M is weight of the powder.

Hausner's Ratio

Hausner ratio (HR) is an indirect index of ease of powder flow. It is calculated by the following formula.

$$HR = \frac{\rho_t}{\rho_b}$$

Where HR is Hausner's Ratio; ρ_t is tapped density; ρ_b is bulk density.

Lower Hausner's ratio (< 1.25) indicates better flow properties than higher ones (> 1.25).

Compressibility index

The simplest way for measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility index (I) which is calculated as follows

$$I = \frac{t - b}{t} * 100$$

Where; I is compressibility index; t is Tapped Density & b is Bulk Density.

Post Compression Tests

Appearance

Twenty tablets of each formulation were taken to check any physical or surface roughness in the tablet formulation. [11]

Thickness

Tablet thickness is an important characteristic in reproducing appearance and also in counting by suing filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.

Uniformity of weight

IP procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be satisfactory method of determining the drug content uniformity. [11]

Hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet, the resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Monsanto Hardness Tester. [12]

Friability

Friability of the tablets was determined using Roche Friabilator. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inch in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were de dusted using a soft muslin cloth and reweighed. The friability (F %) is given by the formula.

$$F\% = \left(1 - \frac{W_o}{W}\right) * 100$$

Where, W_o is weight of the tablets before the test & W is the weight of the tablets after test. [12]

Wetting time

The wetting time of the tablets was measured using a simple procedure. Circular tissue paper of 10 cm diameter was placed in a Petri dish with a 10 cm diameter. Ten milliliters of water containing amaranth, a water-soluble dye, was added to the petri dish. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting time (The wetting time decreased with the increase in concentration of seed and mucilage powder). [13]

In-vitro disintegration time

The process of breakdown of a tablet into smaller particles is called as disintegration. The *in-vitro* disintegration time of a tablet was determined using disintegration test apparatus as per I.P. specifications. One tablet was placed in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using pH 6.8 (simulated saliva fluid) maintained at 37 ± 2°C as the immersion liquid. The assembly should be raised and lowered between 30 cycles per minute in the pH 6.8 maintained at 37 ± 2°C. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded. [14]

In-vitro dispersion time

The dispersion time was measured using a modified method. For this purpose, a petri dish (10 cm diameter) was filled with 10 ml of water. The tablet was carefully put in the center of the petri dish and the time for the

tablet to completely disintegrate into fine particles was noted. [15]

In-vitro dissolution study

The *in vitro* dissolution study was carried out in the USP dissolution test apparatus type 2 (paddle). 900 ml of the dissolution medium (saline phosphate buffer pH 6.8 solution) was taken in and the temperature was maintained at 37 ± 0.5°C. The speed of the paddle was maintained at 50 rpm. Sampling was done every one min interval. For each sample 5 ml of the dissolution medium was withdrawn and the same amount of dissolution medium was replenished to maintain sink condition. The samples withdrawn were analyzed in the UV spectrophotometer at 266 nm. [14]

Drug Content

Ten tablets from each batch were weighed and finely powdered. Powder equivalent to 8 mg of Ondansetron hydrochloride was transferred to 100 ml volumetric flask and shaken with 60 ml of phosphate buffer for 10 min. The volume of resulting solution was made to 1000 ml and contents were filtered. An aliquot of 1.0 ml from this solution was diluted to 100 ml with phosphate buffer in volumetric flask and then further 1 ml from this solution were diluted up to 10 ml with phosphate buffer in a 10 ml volumetric flask. A portion of the sample was analyzed by a UV spectrophotometer at 266 nm.

RESULTS AND DISCUSSION

Pre Formulations Studies

The results for characterization of blended powder are shown in Table 6**.** The bulk density of blend varied between 0.607-0.649g/cm^3. The tapped density was found in the range of 0.704-0.746 g/cm^3. By using these two density data, Hausner's ratio and compressibility index was calculated. The powder blends of all formulation had Hausner's ratio of less than 1.25 indicating good flow characteristics. Blends having value of compressibility index less than 25% were considered as free flowing ones. The values for compressibility index were found between 12.346-14.578. The flow ability of the powder was also evidenced by the angle of repose. The angle of repose below 35° ranges indicates good flow properties of powder. The angle of repose was found to be in range 25.793°.

Post Compression Studies

Appearance

All the tablets were greyish white in color, flat in shape with smooth surface without any defects.

Uniformity of thickness

Thickness of all the formulations was found to be within the range of 2.03mm to 2.16 mm shown in Table 7 and graphical presented in Figure 1.The values were almost uniform in all the formulation.

Weight Uniformity

All the tablets passed weight variation test as the % weight variation was within the pharmacopoeial limits of ±7.5% given in Table 7. It was observed that all the batches were uniform in weight with no significance difference. It is related to tooling of the compression machine, head pressure, machine speed and flow properties of the powder. A graphical representation is shown in Figure 2.

Table 1: Angle of Repose for Powder Flow Properties

S. No.	Angle of Repose (θ)	Type of Flow
1	1 < 25	Excellent
2	25 – 30	Good
3	30 – 40	Passable
4	> 40	Very Poor

Table 2: Relationship between flow characters and Hausner's ratio

Flow Character	Hausner's Ratio
Excellent	1.00-1.11
Good	1.12-1.18
Fair	1.19-1.25
Passable	1.26-1.34
Poor	1.35-1.45
Very Poor	1.46-1.59
Very Very Poor	>1.60

Table 3: Relationship between % compressibility and flow ability

% Compressibility	Flow ability
5-12	Excellent
12-16	Good
18-21	Fair Passable
23-35	Poor
33-38	Very Poor
<40	Very Very Poor

Table 4: Weight variation limit

Average of tablets (mg)	Maximum % difference allowed
80 or less	10
80-250	7.5
More than 250	5

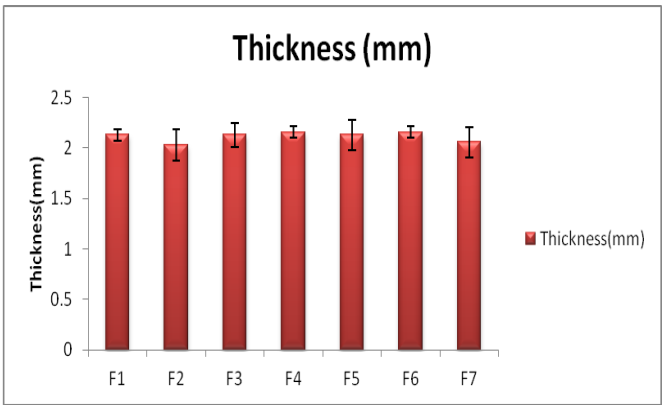

Fig. 1: Thickness of tablets

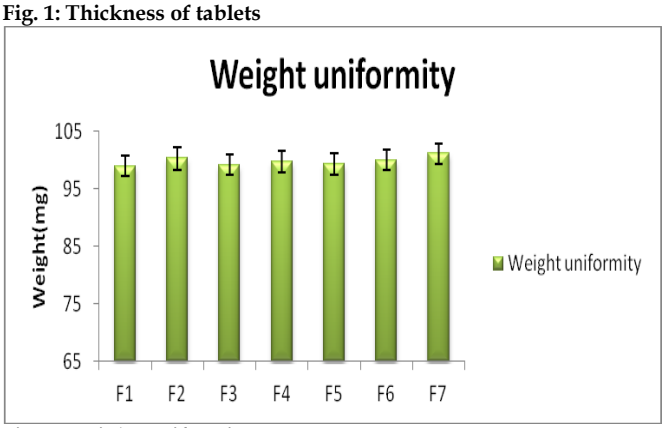

Fig. 2: Weight Uniformity

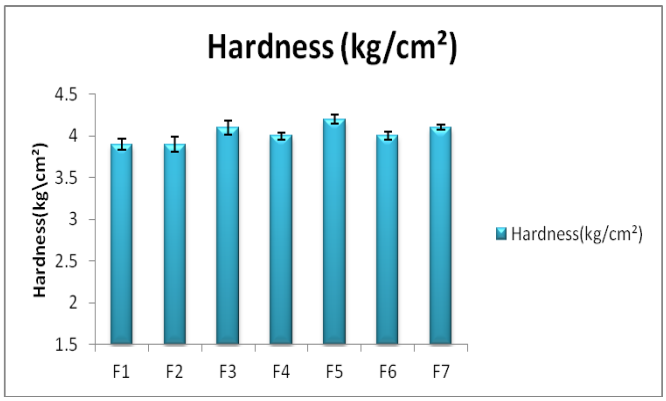

Fig. 3: Hardness of tablets

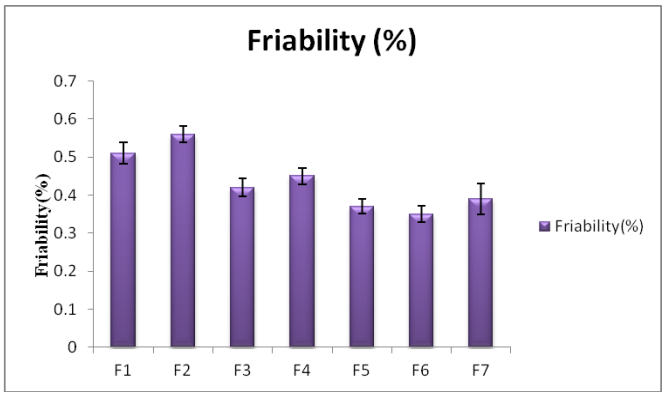

Fig. 4: Friability of tablets

Table 5: Composition of Ondansetron hydrochloride mouth dissolving tablets

S. No.	Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)
1.	Ondansetron hydrochloride	8	8	8	8	8	8	8
2.	Plantago ovata	2	4	6	8	10	12	14
3.	Micro crystalline cellulose	82	80	78	76	74	72	70
4.	Sodium saccharine	1	1	1	1	1	1	1
5.	Talc	3	3	3	3	3	3	3
6.	Clove oil	2	2	2	2	2	2	2
7.	Povidone	2	2	2	2	2	2	2
8.	Total weight (mg)	100	100	100	100	100	100	100

Table 6: Characterization of blended powder

Formulation code	Bulk density(gm/cm³)	Tapped density(gm/cm³)	Carr's Index (%)	Hausner's ratio (HR)	Angle of repose (⁰)
F1	0.632 ± 0.008	0.735 ± 0.010	13.925 ± 0.176	1.161 ± 0.002	28.063 ± 0.987
F2	0.649 ± 0.008	0.746 ± 0.011	12.988 ± 0.168	1.149 ± 0.002	28.066 ± 0.681
F3	0.625 ± 0.007	0.724 ± 0.010	13.751 ± 0.171	1.159 ± 0.002	28.363 ± 0.445
F4	0.630 ± 0.012	0.731 ± 0.016	13.868 ± 0.265	1.161 ± 0.003	29.533 ± 0.662
F5	0.607 ± 0.011	0.711 ± 0.015	14.578 ± 0.268	1.170 ± 0.003	28.666 ± 0.254
F6	0.617 ± 0.007	0.704 ± 0.009	12.346 ± 0.152	1.140 ± 0.001	25.793 ± 0.265
F7	0.632 ± 0.008	0.724 ± 0.010	12.651 ± 0.160	1.144 ± 0.002	25.943 ± 0.708

Results are in mean ± SD (n=3)

Table 7: Evaluation parameters of Formulations

Formulation Code	Appearance	Thickness (mm)	Uniformity of Weight (mg)	Hardness (kg/cm²)	Friability (%)
F1	Greyish white	2.13 ± 0.057	98.90 ± 1.774	4.1 ± 0.07	0.51 ± 0.028
F2	Greyish white	2.03 ± 0.152	100.30 ± 1.976	3.9 ± 0.09	0.56 ± 0.021
F3	Greyish white	2.13 ± 0.115	99.20 ± 1.735	4.1 ± 0.08	0.42 ± 0.024
F4	Greyish white	2.16 ± 0.057	99.70 ± 1.838	4.0 ± 0.04	0.45 ± 0.022
F5	Greyish white	2.13 ± 0.152	99.35 ± 1.843	4.2 ± 0.05	0.37 ± 0.019
F6	Greyish white	2.16 ± 0.057	100.00 ± 1.716	3.9 ± 0.05	0.35 ± 0.022
F7	Greyish white	2.06 ± 0.152	101.10 ± 1.774	4.0 ± 0.03	0.39 ± 0.041

Results are in mean ± SD (n=3)

Table 8: Wetting time of Formulations

Formulation code	Time (sec)
F1	15.34 ± 0.012
F2	14.45 ± 0.014
F3	13.23 ± 0.023
F4	12.84 ± 0.016
F5	11.12 ± 0.019
F6	9.09 ± 0.010
F7	10.81 ± 0.019

Results are in mean ± SD (n=3)

Table 9: Water absorption ratio of Formulations

Formulation code	Percentage
F1	56 ± 0.039
F2	58 ± 0.123
F3	61 ± 0.135
F4	63 ± 0.211
F5	66 ± 0.121
F6	68 ± 0.118
F7	67 ± 0.287

Results are in mean ± SD (n=3)

Table 10: *In-vitro* Disintegration time

Formulation code	Time (seconds)
F1	13 ± 0.53
F2	12 ± 0.58
F3	11 ± 0.57
F4	10 ± 0.56
F5	9 ± 0.56
F6	7 ± 0.55
F7	8 ± 0.59

Results are in mean ± SD (n=3)

Table 11: Dispersion time of formulations

Formulation code	Time (seconds)
F1	14 ± 0.103
F2	12 ± 0.153
F3	11 ± 0.211
F4	10 ± 0.149
F5	9 ± 0.184
F6	7 ± 0.234
F7	8 ± 0.212

Results are in mean ± SD (n=3)

Hardness

In all the formulations, hardness test indicated good mechanical strength, as the hardness of the Mouth dissolving tablet was found in the range of 3.9 to 4.2 kg/cm² is given in Table 7 and Figure 3. High hardness values increase the disintegration time and reduced dissolution values.

Friability

Friability was observed less than 1% represented in Table 7 and graphically shown in Figure 4 indicated that Mouth Dissolving Tablets had a good mechanical resistance. It is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping.

Wetting time

The wetting time was rapid in all the formulations. Wetting is closely related to inner structure of tablets, this may be due to ability of swelling and also capacity of absorption of water. Among all the formulations F6 showed less wetting time. The result was shown in Table 8 and Figure 5.

Water absorption ratio: The capacity of disintegrants to swell in presence of little amount of water were found to be in the range of 56-68% is given in Table 9 and graphically represented in Figure 6. The water absorption ratio that is the up taking of water was very fast and the ratio was found higher.

***In-vitro* Disintegration time:** This rapid disintegration of the Mouth Dissolve in Tablets Ondansetron Hydrochloride was due to the penetration of saliva into the pores of the tablet, which lead to the swelling of super disintegrating agent (*Plantago ovata*) to create enough hydrodynamic pressure for quick and complete disintegration of the tablet. The disintegration time of all the formulations shown in Table 10, and graphically presented in Figure 7.

Table 12: Drug content of Mouth dissolving tablets

Formulation code	Drug content (%)
F1	98.1 ± 0.43
F2	98.3 ± 0.49
F3	98.2 ± 0.72
F4	98.5 ± 0.69
F5	98.8 ± 0.67
F6	99.3 ± 0.64
F7	98.5 ± 0.58

Results are in mean ± SD (n=3)

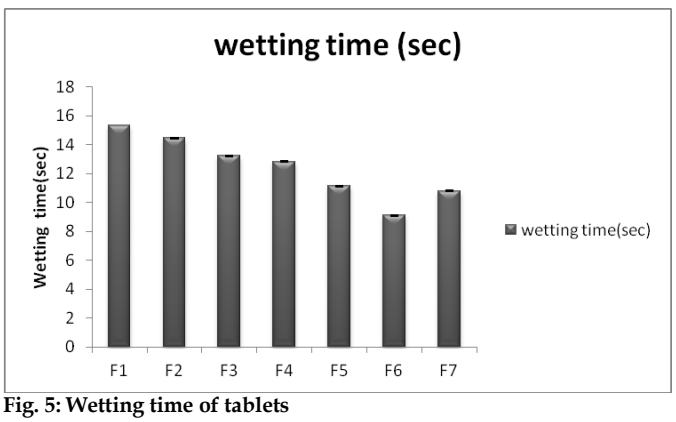

Fig. 5: Wetting time of tablets

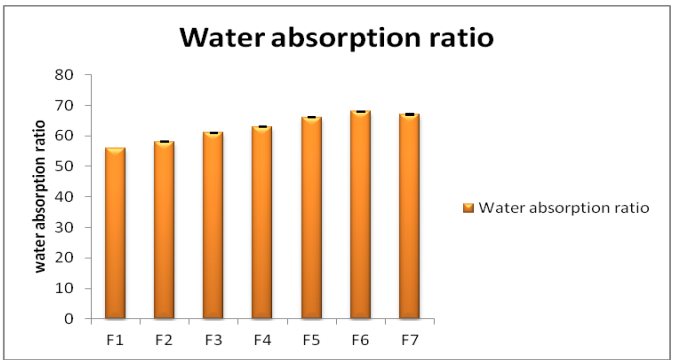

Fig. 6: Water absorption ratio of tablets

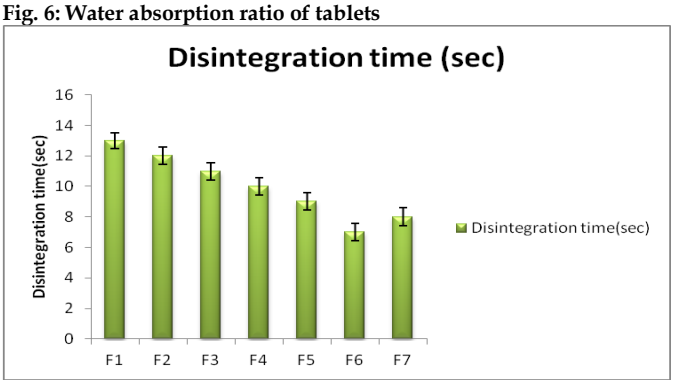

Fig. 7: *In vitro* disintegration time

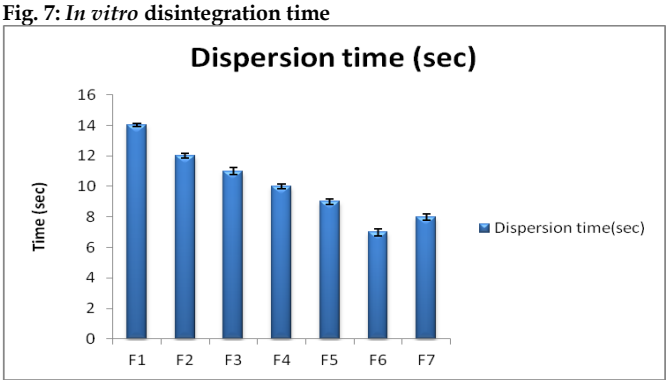

Fig. 8: Dispersion time of tablets

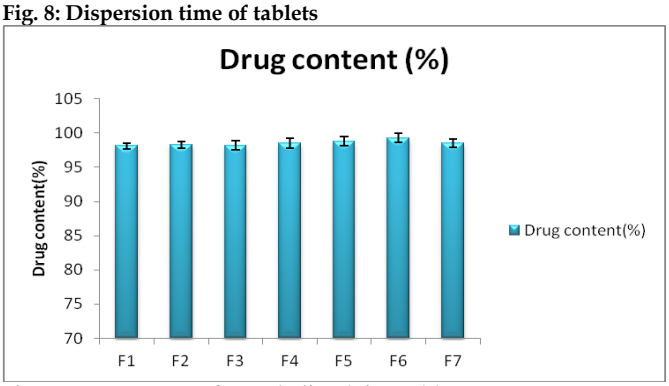

Fig. 9: Drug content of mouth dissolving tablets

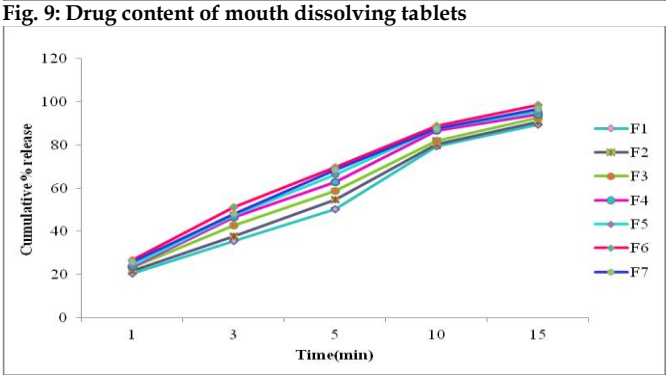

Fig. 10. *In vitro* drug release

Table 13: ***In vitro*** **Drug Release**

Time(min)	F1	F2	F3	F4	F5	F6	F7
1	20.56 ± 0.64	21.89 ± 0.65	23.22 ± 0.89	23.68 ± 0.72	24.15 ± 0.42	26.88 ± 0.43	25.91 ± 0.23
3	35.67 ± 0.43	37.75 ± 0.71	42.87 ± 0.91	46.39 ± 0.82	47.58 ± 0.37	51.09 ± 0.54	48.20 ± 0.38
5	50.23 ± 0.37	54.65 ± 0.89	58.65 ± 0.98	62.76 ± 0.49	66.24 ± 0.73	69.71 ± 0.87	68.56 ± 0.36
10	79.47 ± 0.62	80.45 ± 0.94	82.09 ± 1.02	87.74 ± 0.31	87.66 ± 0.31	88.96 ± 0.29	87.59 ± 0.77
15	89.54 ± 0.98	90.65 ± 1.25	92.32 ± 0.32	94.32 ± 0.35	95.34 ± 0.24	98.57 ± 0.72	96.82 ± 0.35

In-vitro **dispersion time:** The dispersion time decreases with increase in the concentration of super disintegrating agent. The result was given in Table 11 and Figure 8.

Drug content: The drug content was found to be within the range of 98.1 to 98.9 indicating uniform distribution of drug in the formulated tablets as per pharmacopeia specification, represented in Table 12 and Figure 9.

In vitro **drug release studies:** The *in vitro* drug release study of various formulation trials (F1-F7) were carried out represented in Table 13 and Figure 10 with different concentration of natural super disintegrating agent (2%-14%). The rate and extent of in vitro drug release was found to be in the order F1< F2< F3<F4<F5< F7< F6. From the various formulations F6 batch showed maximum drug release that is 98.57% within 15 minutes.

Mouth dissolving tablets of ondansetron hydrochloride were prepared by using natural super disintegrating agent (*Plantago ovata* mucilage). Different concentration of disintegrating agent was evaluated for a lot of parameters. It was concluded that batch F6 contain 12% w/v concentration of *Plantago ovata* mucilage showed least disintegration time that is 7 seconds and maximum drug release in 15 minutes. Also this was showed promising results in pre formulation and post formulation studies. Further preclinical studies can be done for future prospective to make the formulation marketable.

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