

# Formulation and Evaluation of Fast Disintegrating Tablets of Ondansetron Using Natural Superdisintegrants

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### ABSTRACT

**Background:** Fast disintegrating tablet (FDT) of ondansetron has better patient compliance as it is easy to swallow for the treatment of nausea and vomiting. Moreover, fast absorption, rapid onset, and enhanced bioavailability are making oral dispersible systems a better drug delivery system. This research was conducted with the objective to formulate and evaluate the oral FDT of ondansetron HCl using natural polymers.

**Methods:** The tablets were formulated employing the direct compression technique using different ratios of natural super disintegrants such as spray-dried banana powder, ispaghula husk powder, and combination of both. The developed powders were subjected to the pre-compression parameters and the were punched using a single-head rotatory compression machine. The formulated tablets were subjected to post-compression evaluation.

**Results:** The Fourier-transform infrared spectroscopy studies showed no chemical interaction between pure drugs, natural super disintegrants, and other excipients. Formulation F6 containing ispaghula husk powder in a 1:4 ratio demonstrated 98.60±0.003% of drug release within 10 minutes indicating the best formulation.

**Conclusion:** FDT of ondansetron was considered the best formulation in the drug delivery system which followed the Higuchi model with the Fickian release.

**Keywords:** Fast disintegrating tablet, Fourier- transform infrared spectroscopy, Ondansetron HCl, Polymers, Superdisintegrants

### INTRODUCTION

Ondansetron is a potent anti-emetic agent.<sup>1</sup> It is an odorless white to off-white crystalline powder and is soluble in water, methanol, ethanol, hydrochloric acid, and normal saline.<sup>2</sup> Though ondansetron is completely and rapidly absorbed from the gastrointestinal tract (GIT) after oral administration, first-pass metabolism reduces the bioavailability to 60%.<sup>3,4</sup>

Ondansetron is better used as an injection or a buccal tablet due to the low solubility and bioavailability.<sup>5,6</sup> Oral administration is the widely accepted, easy, and safest

medication delivery system.<sup>7,8</sup> As cutting-edge drug delivery techniques, Fast disintegrating tablets (FDTs) are now gaining favor. FDTs, also called mouth dissolving or oro-dispersible tablets are placed in the mouth, where these get dissolved or dispersed in the saliva sans the need for water and show rapid onset of action.<sup>9,10</sup> The disintegration plays a prime role in its action.<sup>11,12</sup> Such dosage forms have better compliance profiles especially in geriatric, pediatric, and semi-conscious patients as there is no difficulty in swallowing.<sup>13</sup> The rapid onset of action with fast absorption and enhanced bioavailability due to oral and pregastric absorption along with a reduction

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in first-pass effect is making the oral dispersible system a better drug delivery system.<sup>13</sup> Superdisintegrants are added to improve the efficacy of such dosage forms to decrease the disintegration time for enhancement of the drug dissolution rate.<sup>14,15</sup> Natural polymers get promptly dissolved in water. Therefore, the polymers such as spray-dried banana powder, ispaghula husk powder, and a combination of both can be used for the development of FDTs.<sup>16</sup> There are various techniques and approaches used in improving FDTs such as lyophilization, spray drying, sublimation, molding, mass extrusion, cotton candy process, melt granulation, phase transition process, effervescent method, floss blend, floss processing, floss chopping and conditioning, direct compression, nanonization, and fast dissolving films.<sup>17, 18</sup> Some other patented technologies used are Zydis technology, Durasolv technology, Wowtab technology, Flash dose technology, Orasolv technology, and Flashtab technology.<sup>19</sup>

This study was conducted with the objectives to improve patient compliance with an effective drug delivery system by formulating and evaluating the oral FDTs of ondansetron HCl using natural polymers.

## METHODS

### Materials

Ondansetron HCl was obtained from Yarrow Chem. Products, Mumbai-421 201. Spray Dried Banana and Ispaghula Husk Powder were collected from The Himalaya Drug Company, Bangalore. Microcrystalline Cellulose (PH 101) was brought from Indian Fine Chemicals, Mumbai. Sodium Saccharine and Mannitol were taken from Karnataka Fine Chemicals, Bangalore and Magnesium Stearate was acquired from Signet Chemical Corp. Pvt. Ltd.

### Method

#### Identification of pure drug by infrared spectroscopy

The Fourier-transform infrared spectroscopy (Jasco, FTIR 460 Plus, Hachioji, Tokyo, Japan) spectrum of the drug sample was compared with the standard FTIR spectra of the pure drug by scanning at a range of 400-4000  $\text{cm}^{-1}$ . The compatibility study was carried out employing Fourier-transform infrared spectroscopy (FTIR) spectroscopy to ascertain no interaction of the drug with the polymer or excipients and the shelf life of the formulations.<sup>5</sup>

#### Determination of the melting point

The open capillary method was applied to find out the melting point of ondansetron HCl. The drug sample was placed into a capillary fitted with a thermometer and positioned in an oil bath of liquid paraffin. The melting point was noted after heating the tube. This was performed thrice and the average value was calculated.<sup>20</sup>

#### Solubility analysis

Various common solvents were used for the solubility test of ondansetron HCl. It was tested in water, alcohol, methanol, acetone, and ethyl acetate at room temperature. The solubility was observed by visual inspection.<sup>21</sup>

#### Ultraviolet-visible (UV) spectrophotometric method for determination of ondansetron HCl

A solvent such as 0.1N HCl was selected to dissolve

ondansetron HCl for the preparation of a standard plot of ondansetron HCl for quantitative determination. (UV-117/ Systronics, Ahmedabad, Gujarat, India).

### Preparation of standard calibration curve of ondansetron HCl

#### Standard stock solution of ondansetron HCl

Accurately 100 mg of ondansetron HCl was taken. It was shifted into the 100 ml volumetric flask and the volume was made up to the mark with 0.1N HCl. Then, a 5 ml aliquot was withdrawn and transferred to a 100 ml volumetric flask. Then, it is diluted accordingly to produce a solution containing 50 micro g/ml concentration. Various solutions of concentration (2, 4, 6, 8, 10, 12, and 14) micro g/ml were prepared using 0.1N HCl as a medium from the standard stock solution containing 50 micro g/ml concentration.

#### Determination of wavelength of maximum absorbance ( $\lambda_{\text{max}}$ )

1 ml was pipetted out from the standard stock solution containing 50 micro g/ml concentration to the 10 ml volumetric flask and volume was maintained up to the mark with 0.1N HCl. The solution was then scanned from 200-800 nm to determine  $\lambda_{\text{max}}$ .<sup>5</sup>

#### Standard plot of ondansetron HCl

Various solutions of concentration of ondansetron drug solution were prepared as a stock solution containing 50 micro g/ml concentration, by pipetting out (1, 2, 3, 4, 5, 6, and 7) ml in a series. These were transferred to the 10 ml volumetric flask and prepared up to the level with 0.1N HCl as a medium. The absorbance was taken at 290 nm using a UV spectrophotometer. Then, the calibration curve was plotted with concentration and absorbance on the X- and Y-axis, respectively. The correlation coefficient ( $R^2$ ) was calculated from the obtained graph.<sup>22</sup> (Figure 1)

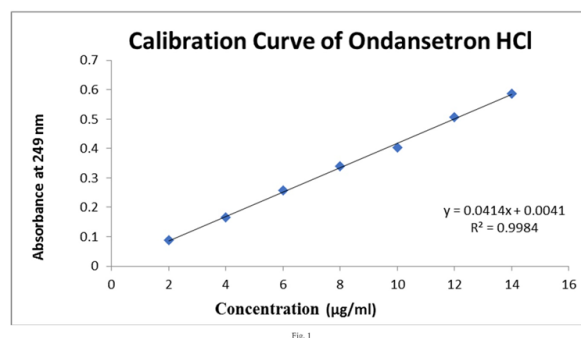


Figure 1: Standard calibration curve of ondansetron HCl

#### Drug content

The percentage of drug content in the prepared solution was determined by using the following formula:  
Percentage of drug content = [(The actual amount of drug in the tablet)/(The theoretical amount of drug in tablet)] $\times$ 100%

#### Bulk density and tapped density

Bulk density or loose bulk density, LBD =  $W/V_0$

Tapped bulk density, TBD =  $W/V_f$

Where;

W = Weight of the granules

$V_0$  = Untapped volume

$V_f$  = Tapped volume

**Hausner's ratio and compressibility index (Carr's Index)**

Hausner's Ratio = [Tapped bulk density (TBD)]/(Loose Bulk density (LBD))

Compressibility Index = [(TBD-LBD)/TBD] × 100

Angle of repose

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

Where;

h = Height of pile

r = Radius of the base of the pile

$\theta$  = Angle of repose

**Formulation development of oral FDT of ondansetron HCl**

Tablets containing 4 mg equivalent of ondansetron HCl were prepared by taking the pure drug by using natural superdisintegrants, diluents, sweetening agents, and other excipients. Dried banana powder and ispaghula husk powder as superdisintegrants, microcrystalline cellulose (pH: 101) as a binding agent, sodium saccharine as a sweetening agent, magnesium stearate as a lubricant, and mannitol as a diluent were used. (Table 1)

**Table 1:** Formulations of orally fast disintegrating tablet of ondansetron HCl in different ratios by direct compression method

Composition	Ratios		
Ondansetron HCl-Spray Dried Banana Powder	1 : 2 (F1)	1:3 (F2)	1:4 (F3)
Ondansetron HCl-Isapghula Husk Powder	1:2 (F4)	1:3 (F5)	1:4 (F6)
Ondansetron HCl- (Spray Dried Banana + Isapghula Husk) Powder	1:1:1 (F7)	1:1.5:1.5 (F8)	1:2:2 (F9)

Ondansetron HCl, microcrystalline cellulose, superdisintegrants, sweetening agent, and mannitol were passed through sieve #44 and mixed properly together for 15 minutes in an air-tight plastic container. Magnesium stearate was passed through sieve #60.

The powders obtained from step-1 and 2 were mixed for 15 minutes in an air-tight plastic container (tumbling).

The mixed ingredients were evaluated for pre-compression parameters, followed by direct compression. The weight of the tablet was adjusted to 200 mg using an 8mm punch in a single-headed 16 station tablet punching machine. After compression, the formulated tablets were evaluated for post-compression parameters.<sup>5</sup>

**Evaluation of tablets:** Tablets from different formulations were evaluated for post-compression parameters like physical appearance, hardness, thickness, weight uniformity, friability, drug content, disintegration time, and

in vitro dissolution test.

**Friability test:** The friability test was carried out and obtained by using following formula:

$$F = [(W_{\text{initial}} - W_{\text{final}})/W_{\text{initial}}] \times 100\%$$

**Drug content:** Ten tablets were selected randomly and weighed. The weighed tablets were crushed and powdered. The quantity of fine powder equivalent to ondansetron HCl 4mg was dissolved in 100 ml of 0.1N HCl and the solution was filtered, and diluted to a suitable concentration for absorbance. The absorbance of the final solution was measured at wavelength 249 nm with 0.1N HCl as blank using a UV spectrophotometer. The amount of the drug was determined by using the standard calibration curve of the drug. The study was done thrice for each batch of the formulation.<sup>23</sup>

**In vitro disintegration time:** The three tablets taken randomly were subjected to the disintegration apparatus. The test was carried out in 0.1 HCl at 37°C with a disc plate. The time taken to break down the tablets and pass through the mess was noted as disintegration time. The test was carried out thrice for each formulation.<sup>24</sup>

**In-vitro dissolution test:** The dissolution test was carried out in a dissolution USP type II apparatus. According to IP, 500 ml of 0.1N HCl was taken as medium and the temperature was maintained at 37.0°C.<sup>25</sup> The agitation rate was maintained at 50 rpm. The test was carried out for 15 min. About 5ml of each aliquot of dissolution medium was taken out after every minute. The fresh dissolution medium was replaced every time to maintain the sink condition.<sup>26</sup>

**Study of dissolution data using different release kinetic models****Zero-order kinetics**

$$Q_t = Q_0 + K_0 t$$

Where;  $Q_t$  = amount of drug dissolved in time t;  $Q_0$  = initial amount of drug in the solution;  $K_0$  = zero order release constant

If the zero-order drug release kinetic is obeyed, a plot of  $Q_t$  versus t will give a straight line with a slope of  $K_0$  and an intercept at  $Q_0$ .

**First order kinetics**

$$\log Q_t = \log Q_0 + K_1 t/2.303$$

Where;  $Q_t$  = amount of drug dissolved in time;  $Q_0$  = initial amount of drug in the solution;  $K_1$  = first order release constant

If the release pattern of the drug follows first-order kinetics, then a plot of  $\log (Q_0 - Q_t)$  versus t will be a straight line with a slope of  $K_1/2.303$  and an intercept at t = 0 of  $\log Q_0$ .

**Higuchi model**

$$M_t/M_\infty = K_H t^{1/2}$$

Where;  $M_t$  and  $M_\infty$  = cumulative amount of drug release at time t and infinite time;

$K_H$  = Higuchi dissolution constant reflection formulation characteristics.

If the Higuchi model of drug release is obeyed, then a plot of  $M_t/M_\infty$  versus  $t^{1/2}$  will be a straight line with a slope of  $K_H$ .

**Korsmeyer- peppas model**

$$M_t / M_\infty = K_t^n$$

Where;  $M_t$  = the amount of drug release at time t

$M_\infty$  = the amount of drug release at an infinite time.

$M_t / M_\infty$  = fraction of drug released at time t.

K= release constant

n= release exponent

Mechanism of drug release as per Korsmeyer equation/ Peppas's model is shown in **Table 2**.

**Table 2:** Mechanism of drug release as per Korsmeyer equation/ Peppas's model

Release exponent (n)	Drug transport mechanism	Rate as a function of time
< 0.45	Fickian diffusion	$t^{-0.5}$
0.45 < n < 0.89	Non-Fickian transport	$t^{n-1}$
0.89	Case II transport	Zero-order release
>0.89	Super case II transport	$t^{n-1}$

**RESULTS**

**Physiochemical parameter**

The solubility test was determined for ondansetron and it was found to be sparingly soluble in water (23.9 mg/ml) and ethanol (31.5 mg/ml), soluble in methanol (97 mg/ml), and freely soluble in 0.1 N HCl (1291.39 mg/ml). The melting point of the oral FDT was found to be 232.9°C. The  $\lambda_{max}$  of the ondansetron HCl was reported as 249 nm in 0.1N HCl. Standard calibration curve for absorbance versus concentration (2-14) of ondansetron HCl in 0.1N HCl showed a linear relationship with correlation coefficient ( $R^2$ ) 0.998 and regression equation. The FTIR spectrum of the obtained sample of ondansetron HCl recorded by FTIR spectrometer was compared with standard functional group frequencies of ondansetron HCl. The functional group frequencies of the obtained sample of the drug

were in the reported range. (**Figure 2**)

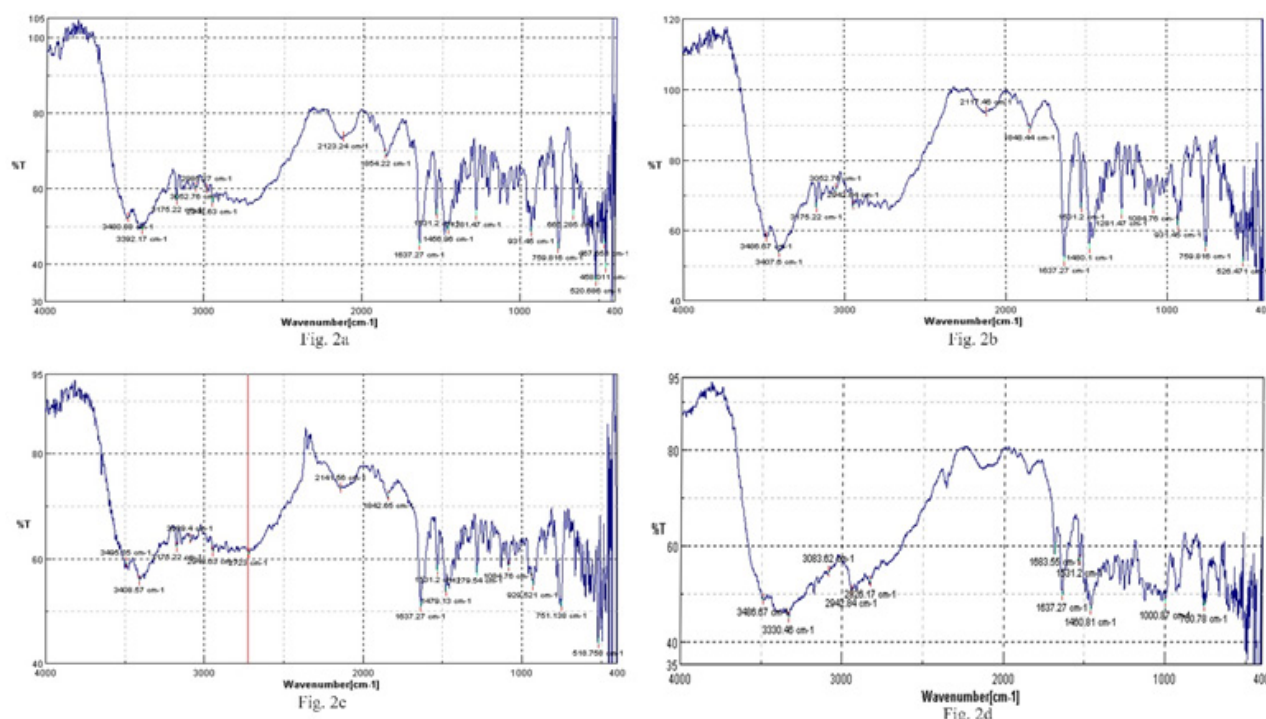
The compatibility studies of ondansetron HCl, spray-dried banana powder, and ispaghula husk powder were done by FTIR. The typical peaks of ondansetron HCl existed in a spectrum of the physical mixture, therefore, no interaction in such a case was seen.

**Pharmaceutical parameter**

The drug content of all the formulated oral FDTs was evaluated for uniformity and was found to be between  $96.17 \pm 0.04$  and  $98.43 \pm 0.01$ .

The micrometric study of various pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose was performed which has a vital role in improving the flow properties of pharmaceutical formulations. For all the formulations (F1-F9), the angle of repose was reported to be between  $23.81^\circ \pm 0.95$  to  $27.07^\circ \pm 0.22$ . Formulation F2 demonstrated excellent; formulations F1, F3, F4, F5, F6, F7, and F9 demonstrated good; and formulation F8 demonstrated fair flow properties. For all formulations, bulk density was found in the range of  $(0.338 \pm 0.00$  to  $0.358 \pm 0.017)$  gm/ml, tapped density in the range of  $(0.392 \pm 0.021$  to  $0.405 \pm 0.00)$  gm/ml, Carr's index in the range  $(8.80 \pm 0.370$  to  $16.74 \pm 0.00)$  %, and Hausner's ration in the range  $(1.095 \pm 0.003$  to  $1.201 \pm 0.00)$ . (**Table 3**)

The thickness of the formulated tablets was evaluated with a Vernier caliper. The thicknesses of all the formulations were found to be within  $2.8 \pm 0.05$  to  $3.0 \pm 0.00$ mm. The hardness of the formulated oral FDTs was evaluated using a Monsanto hardness tester. The hardness of the formulated tablets ranged from  $3.0 \pm 0.00$  to  $3.5 \pm 0.00$  kg/cm<sup>2</sup>. The friability of all the formulations ranged from  $0.11 \pm 0.005$  to  $0.25 \pm 0.025$ %. The disintegration time of the formulated tablet ranged from  $18.48 \pm 0.011$  to  $58.58 \pm 0.005$  seconds. (**Table 4**)



**Figure 2:** FTIR spectra (Figure 2a. Ondansetron HCl pure drug; Figure 2b. Ondansetron + spray-dried banana powder; Figure 2c. Ondansetron + ispaghula husk powder; Figure 2d. Ondansetron + spray dried banana powder + ispaghula husk powder)

**Table 3:** Pre-compression evaluation of powder blend

S N	Formulation Code	Loose Bulk Density (g/ml)	Tapped Bulk Density (g/ml)	Angle Of Repose (θ)	Hausner's Ratio	Compressibility Index (%)
1	F1	0.348±0.017	0.405±0.0005	23.81°±0.95	1.167±0.058	14.19±4.405
2	F2	0.357±0.017	0.392±0.021	24.16°±0.85	1.097±0.004	8.89±0.409
3	F3	0.358±0.017	0.393±0.020	26.72°±0.72	1.095±0.003	8.80±0.370
4	F4	0.338±0.00	0.393±0.021	25.13°±0.92	1.164±0.063	13.96±4.815
5	F5	0.348±0.017	0.405±0.00	26.90°±0.20	1.165±0.056	14.07±4.278
6	F6	0.348±0.017	0.405±0.0005	26.74°±0.79	1.167±0.058	14.19±4.405
7	F7	0.338±0.0005	0.393±0.021	27.07°±0.22	1.130±0.061	11.41±4.623
8	F8	0.338±0.00	0.405±0.0005	26.34°±0.77	1.201±0.00	16.74±0.00
9	F9	0.338±0.00	0.393±0.021	25.30°±0.83	1.164±0.063	13.96±4.815

For the determination of the in-vitro drug release of formulation, all the formulated oral FDTs were evaluated for in vitro dissolution as described in the methodology section. The optimized formulation F6 showed the best drug release of 98.60±0.003. In vitro dissolution, studies reported the formulation containing ispaghula husk powder in the ratio of 1:4 demonstrated the best release of the drug at the end of 10 minutes. (Figure 3)

Drug release kinetic was done to understand the mechanism of optimized formulation, the data acquired from the in vitro dissolution studies were fitted to the mathematical model viz. zero order, first order, Higuchi, and Korsmeyer-Peppas equation and reported to the formulation follow the Korsmeyer-Peppas equation based on their R<sup>2</sup> value. The release coefficient of the optimized formulation F6 was found to be 1.565. (Figure 4)

The short-term stability study of the formulation F6 was conducted for 90 days at 40±2°C. There was no

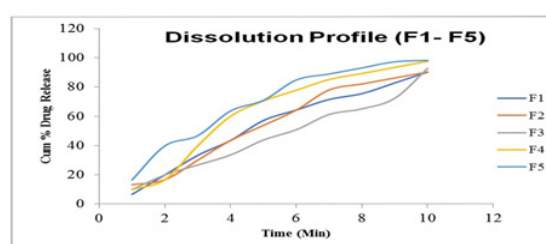


Fig. 3a

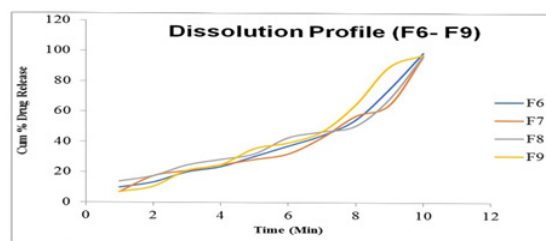


Fig. 3b

**Figure 3:** In-vitro dissolution studies (Figures 3a: Dissolution profile of F1-F5) and 3b: Dissolution profile of F6-F9)

**Table 4:** Post-compression evaluation of formulated orally fast-disintegrating tablet of ondansetron HCl

Formulation Code	Thickness (mm)	Hardness (kg/cm <sup>2</sup> )	Friability (%)	Weight Variation (mg)	Disintegration Time (sec)	Drug Content (%)
F1	2.9±0.11	3.0±0.00	0.11±0.005	201.13±0.56	58.58±0.005	96.17±0.04
F2	2.9±0.05	3.3±0.28	0.14±0.011	201.48±0.93	56.27±0.015	96.92±0.02
F3	2.8±0.11	3.5±0.00	0.25±0.025	200.65±0.58	57.17±0.01	97.06±0.01
F4	3.0±0.00	3.1±0.28	0.23±0.045	200.18±0.98	29.36±0.03	98.03±0.02
F5	2.9±0.05	3.1±0.28	0.10±0.005	201.12±0.75	20.40±0.02	98.19±0.03
F6	3.0±0.00	3.0±0.00	0.11±0.011	200.66±0.83	18.48±0.011	98.43±0.01
F7	2.8±0.05	3.3±0.28	0.11±0.015	200.07±0.67	57.30±0.02	97.60±0.05
F8	2.9±0.05	3.5±0.00	0.13±0.026	200.73±0.93	48.52±0.036	97.10±0.01
F9	2.9±0.11	3.1±0.28	0.16±0.025	201.9±0.51	47.38±0.068	97.85±0.04

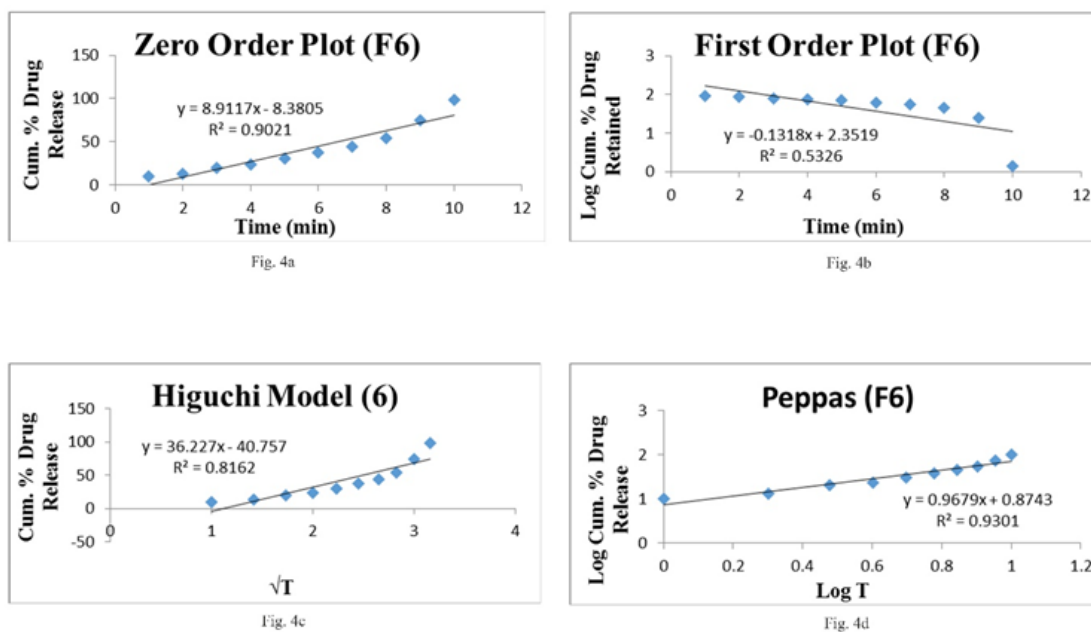
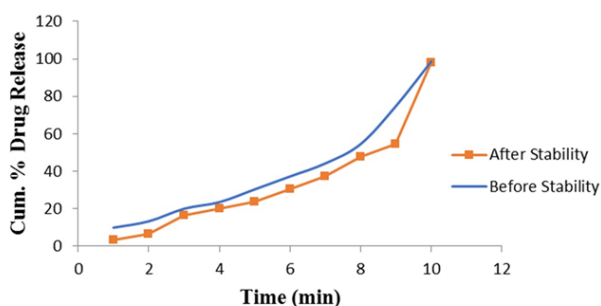


Figure 4: Drug release kinetics plot (F6)



**Figure 5:** In-vitro drug release of F6 before stability and after stability at  $40^\circ\pm C$

significant change in color and odor, hardness, drug content, and % cumulative drug release. Also, there was no significant degradation of the drug in 90 days of stability studies. (**Figure 5**)

## DISCUSSION

The solubility plays an essential role in formulation of FDTs. In case of low solubility, the pharmacokinetic and pharmacodynamic properties will be unfavorably affected.<sup>8</sup> It was found that the drug was sparingly soluble in water and ethanol, soluble in methanol, and freely soluble in 0.1 N HCl.<sup>27</sup> Generally, a melting point test is conducted for certain solid materials under normal conditions before their storage and transport. The melting point of the oral FDT complied with the standard monograph that indicated the purity of the drug.<sup>28</sup>

Upon FTIR analysis, the functional group frequencies of the obtained sample of the drug indicated that the sample of ondansetron HCl was pure. No interaction in physical mixture (drug-polymer) compatibility studies indicated

the compatibility between drug and polymer mixture.<sup>28</sup> To attain rapid disintegration, natural superdisintegrants like spray-dried banana powder, ispaghula husk powder, and a combination of both were used. The study aimed

to develop FDTs by using natural superdisintegrants which get disintegrate rapidly and dissolve to enhance a greater therapeutic effect within a few minutes. The direct compression method was used to enhance stability and quick dissolution during the formulation.<sup>29</sup> To improve the content uniformity, the active ingredient and excipients were mixed properly before proceeding for direct compression.

Various pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose were performed which has a vital role in improving the flow properties of pharmaceutical formulations. All the data obtained were found to be within the limit as prescribed by the pharmacopeia.<sup>20</sup>

Since, the thickness, hardness, weight variation, friability, etc. can alter the therapeutic effectiveness of the tablets to deliver drugs.<sup>21</sup> All those post-compression parameters tests showed sufficient results to develop a therapeutically effective FDTs of ondansetron HCl.

The thicknesses of all the formulations were found to be within the accepted limit of deviation upon evaluation by the vernier caliper. Similarly, the hardness of the tablets was also found within the limit, while tested by the Monsanto hardness tester, as excess hardness is not suitable for oral FDTs. In the same manner, the friability of all the formulations was also found to be within the pharmacopeial limit of less than 1%.<sup>22</sup>

The disintegration time of the formulated tablet was within the pharmacopeial limits. Upon in vitro dissolution evaluation, the optimized formulation F6 showed the best drug release characteristics.<sup>30,31</sup> The formulation containing ispaghula husk powder in a ratio of 1:4 demonstrated the best release of the drug at the end of 10 minutes. The drug release kinetics study demonstrated that the release

coefficient of the optimized formulation F6 followed super case-II transport release.

It was reported that there was no significant change in color and odor, hardness, drug content, and percentage cumulative drug release upon stability testing. No significant degradation of the drug in 90 days of stability studies indicated the stable product.

#### Limitation

The research was conducted at the pharmaceuticals lab of the academic institution. High-scale preparation of such medicines in the sophisticated labs of the pharmaceutical industry utilizing expertise in the related field will contribute highly to the healthcare delivery system.

#### CONCLUSION

The fast disintegrating tablets of ondansetron HCl were formulated by the direct compression technique using spray-dried banana powder, ispaghula husk powder, and a combination of both. The formulation F6 containing ispaghula husk powder in the ratio of 1:4 was concluded to be stable and retained the original properties during the study period.

#### Authors' Contributions

AM: Concept, Design, Experimental studies, and Manuscript preparation; HK: Design, Literature search, Manuscript editing and Review; GSK: Literature search, Manuscript editing and Review, and Guarantor SFR: Literature search, Experimental studies, Data Acquisition, and Analysis; RKM: Literature search, Manuscript preparation, Editing, and Review SK: Definition of intellectual content, Editing, and Review Acknowledgements: We are highly grateful to all the staff of the Department of Pharmaceutics, Mallige College of Pharmacy, Rajiv Gandhi University of Health Sciences, Bangalore, Karnataka, India

**Data Availability:** Data will be available from corresponding author upon reasonable request.

**Source of Funding/support:** None

**Conflict of Interest:** None declared

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