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## FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF ONDANSETRON HYDROCHLORIDE

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### **Keywords:**

Ondansetron hydrochloride, Cross carmellose sodium, Cross povidone, Sodium starch glycolate

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**ABSTRACT:** Ondansetron hydrochloride (ONH) is an exceptionally harsh, powerful antiemetic drug utilized for the treatment and prophylaxis of chemotherapy or radiotherapy or postoperative prompted emesis. This investigation aims to detail and assesses taste-covered quick-dissolving tablets (FDTs) of ONH to expand patient consistence. ONH taste veiled granules were set up by a strong scattering procedure. Dissolvable dissipation techniques were utilized for such readiness. Totally taste veiling with zero arrival of medication in phosphate support pH 6.8 was acquired from granules arranged by dissolvable vanishing strategy utilizing drug: polymer proportion of 1:2, from which four equations pass a pre-pressure assessment and compacted to FDTs and assessed for their medication content, in-vitro breaking downtime, in-vivo deterioration time, wetting time and in-vitro drug discharge profile. It was tracked down that the tablet definitions F8 with cross carmellose sodium as super disintegrant showed the fast medication discharge when contrasted with unadulterated medication. T50 and DE 30% for the definition F8 was discovered to be in 7 min and 73.5%, Hence reasonable as quick-dissolving tablets.

**INTRODUCTION:** Oral course of Administration has been the most generally utilized innovation for many years since it is more advantageous medication conveyance framework for self-organization of different measurement forms <sup>1</sup>. In this oral organization, the downside is having a harsh taste and being incapable of swallowing by pediatric and geriatric patients. The sharpness of medication is totally veiled by different physical, synthetic, and physiological methods like lipophilic vehicles, coatings, incorporation complexation, particle trade, bubbly specialists, rheological change, bunch modification, and prodrug approach, freeze-drying measure, and nonstop multipurpose liquefy technology <sup>2</sup>.



Most pediatric and geriatric patients have an issue swallowing or trouble in the event of voyaging when there is no admittance to water in this way, to experience those issues Fast dissolving tablets are developed <sup>3-5</sup>. These tablets can deteriorate inside the space of seconds in the mouth in length, for example, 20 sec, and give fast remedial action <sup>6</sup>. Mouth dissolving tablets show better understanding consistency and acknowledgment with improved bioavailability, adequacy and biopharmaceutical properties <sup>7</sup>.

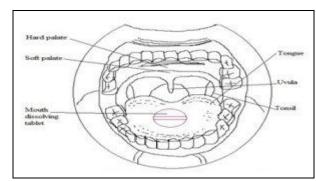


FIG. 1: ADMINISTRATION OF MOUTH DISSOLVING TABLETS

Mouth dissolving framework is a beneficial course forever threatening infections patients like anxious sickness, radioactivity treatment, Parkinson's illness, AIDS which face the dysphasia condition <sup>8</sup>. In this condition, ondansetron hydrochloride is the medication of choice <sup>3, 4</sup>. In the bio-drug characterization framework, ondansetron is delegated BCS class II medication because of its low water dissolvability and high porousness <sup>9</sup>.

Ondansetron hydrochloride is artificially 9-methyl-3-[(2-methyl1H – imidazol - 1-yl) methyl]-2, 3, 4, 9-tetrahydro-1H-carbazol-4-one hydrochloride particular serotonin receptor blocker (5 hydroxytryptamine type 3), which is utilized as an antiemetic in the malignancy chemotherapy <sup>10-11</sup>. To test the nature of item, assessment boundaries like hardness, friability, deterioration time, and disintegration contemplates are performed <sup>12-13</sup>.

A portion of the investigations showed ill-advised outcomes in post pressure boundaries among various showcased items containing the same dynamic drug fixings <sup>14-16</sup>.

In a few conditions, tablets with the same medication or medication substance may not be giving an equivalent remedial reaction, which might be because of the distinctive rate and degree of retention, shifting virtue of the medication, and utilizing different sorts of excipients *etc.* <sup>17-19</sup>.

### **Advantages of Mouth Dissolving Tablets:**

- ♦ Mouth dissolving tablets are absorbed by the pre gastric area *i.e.* pharynx, esophagus so it produces rapid onset of action <sup>20-21</sup>.
- ❖ This may enhance the bioavailability of an active pharmaceutical agent by dose minimization with low adverse effects <sup>22</sup>.
- ❖ Another comfort is to avoid blocking an oral route by using conventional dosage form <sup>23</sup>.

**Ideal Properties of Drug for Development of Mouth Dissolving Tablets:** In the development of MDTs various factors keeps for selecting the drug candidate.

 $\succ$  Those drugs are able to diffuse into epithelial of upper GIT (log P > 2).

> Short half-life drugs with frequent dosing.

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- > Drugs that produce toxic metabolites by first-pass metabolism.
- > Sustained and controlled release drugs are unsuitable for MDTs.
- ➤ Very bitter drugs with unacceptable taste are unsuitable for MDTs <sup>24</sup>.

**Mechanism of Superdisintegrants:** There are 4 major mechanisms for tablets disintegration, and they are as follows:

- ✓ Swelling.
- ✓ Porosity and Capillary action (Wicking).
- ✓ Disintegrating particle/particle repulsive forces.
- ✓ Deformation  $^{25-27}$ .

MATERIALS: Ondansetron Hydrochloride was obtained from Mylan Pharmaceuticals Ltd, Hyderabad. Stevia powder, Talc, Magnesium Stearate, Microcrystalline cellulose from S.D fine Chem Ltd, Mumbai. Superdisintegrants like Cross carmellose sodium, Sodium starch glycolate were purchased from Pellets Pharma Ltd, Hyderabad.

#### **METHODOLOGY:**

**Preformulation** Studies: Ondansetron Hydrochloride powder was evaluated Organoleptic properties (Colour, odour, appearance under the microscope), melting point, determination of solubility, UV Spectroscopy, determination of flow properties (Angle of repose, hausners ratio, Compressibility index)

### Calibration Curve of Ondansetron Hydrochloride:

**Preparation of Stock Solution:** 100 mg of Ondansetron Hydrochloride was weighed and dissolved in 100 ml of Methanol. The drug solution obtained was filtered into 100 ml volumetric flask and was further diluted to 100 ml with 6.8 pH phosphate buffer to get 1mg/ml stock solution.

**Preparation of Standard Dilutions:** Aliquots of Ondansetron Hydrochloride stock solution were transferred into 5 volumetric flasks and was further diluted with 6.8 pH phosphate buffer to get 2, 4, 6,

8and 10  $\mu$ g/ml of standard dilutions of Ondansetron Hydrochloride. The absorbance of the above dilutions was measured in UV-VIS spectro-

photometer at 310nm using 6.8 phosphate buffers as blank.

TABLE 1: COMPOSITION OF VARIOUS ONDANSETRON HYDROCHLORIDE FAST DISSOLVING TABLETS

Ingredients	Formulations							
(Mg/tab)	F1	F2	F3	F4	F5	F6	F7	F8
Ondansetron Hydrochloride	8	8	8	8	8	8	8	8
Sodium Starch Glycolate (SSG)	15	20	25	30	-	-	-	-
Cross carmellose sodium (CCS) (mg)	-	-	-	-	15	20	25	30
Microcrystalline cellulose powder	222.75	217.75	212.75	207.75	222.75	217.75	212.75	207.75
Stevia powder (mg)	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25
Talc (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Magnesium stearate (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Total Weight of Tablets(mg)	250	250	250	250	250	250	250	250

**Preparation of Fast Dissolving Tablets:** The tablets are prepared by using the direct compression technique. This technique can now be applied for the preparation of fast dissolving tablets because of the availability of improved excipients, especially polymers. The steps involved are:

Raw material →Weighing → Screening → Mixing →Lubrication→ Compression

Fast dissolving tablet formulations were developed for ondansetron by using various polymers. The tablet formulations consisted of drug, polymer, and diluent. The weights of all the tablet formulations were maintained uniformly by using microcrystalline cellulose (pH 102) as diluent. The compositions of various tablet formulations were given in **Table 1**.

The materials were individually weighed, passed through sieve no: 120, and blended for 15 minutes by using a double cone blender. The prepared mass was lubricated with 1% talc and magnesium stearate; the processing variables all batches of tablets were compressed under identical conditions. The compressed tablets were further evaluated for their physical parameters such as weight uniformity, hardness, friability, drug content, *invitro* dissolution.

### **Evaluation Parameters:**

**Angle of Repose:** The angle of repose of the powder blend was calculated by using the following formula<sup>28</sup>

Tan 
$$\theta = h / r \theta = tan-1 (h / r)$$

Where,  $\theta$  = Angle of repose h = Height of the pile. r = Radius of the pile

**Compressibility Index:** Calculated based on the following formula.

Compressibility index (%) =  $TD - BDTD \times 100$ 

Where, TD = Tapped density BD = Bulk density

**Hausner's Ratio:** Calculated based on the following formula.

Hausner's ratio = *Tappeddensity / Bulkdensity* 

The value was expressed in Kg/cm<sup>2</sup>.

**Thickness:** The thickness of the individual tablets was measured using Vernier caliper, and the average thickness was determined. The thickness was denoted in millimeters.

Weight Variation Test: Twenty tablets were selected at random, and their weight was noted, and from that, the mean weight of the tablets was calculated.

Not more than two of the individual weights deviate from the average weight by more than the percentage deviation shown in the table: 12 and none should deviate by more than twice that percentage. Table: Weight Variation of Tablets and Percentage Deviation Average Weight of Tablets(mg) in I.P Percentage Deviation (%) 130 or less  $\pm 10\ 130 - 324\ \pm 7.5$  More than  $324\ \pm 5\ 4.5.6.5$ .

**Friability:** Friability is the measure of tablet's ability to withstand both shock and abrasion without crumbling during manufacturing, packing, shipping and consumer use.

Tablets that tend to powder, chip and fragment when handled lack elegance and consumer acceptance.

The weight of 10 tablets was noted and placed in Roche friabilator. The device subjects the tablets to the combined effect of shock and abrasion by utilizing a plastic chamber that revolves at 25 rpm, rolling the tablets a distance of 6 inches with the revolution.

The tablets were removed after 100 revolutions, dedusted, and reweighed. Tablets that weigh less than 0.5 to 1 percent are generally acceptable. The percentage friability of the tablets was calculated by the formula <sup>30</sup>.

Percentage Friability = Initial Weight - Final Weight / Initial Weight x 100

**Disintegration Test:** The disintegration test was carried out at 37°C±2 0C in 900 ml of distilled water. The disintegration time of tablets from each formulation was determined using the disintegration test apparatus.

One tablet was placed in each of the six tubes of the apparatus containing distilled water. One disk was added to each tube.

The time taken in seconds for complete disintegration of the tablets with no palpable mass remaining in the apparatus was measured <sup>31</sup>.

*In-vitro* **Dispersion Time:** Tablet was placed in a small petri dish containing 10ml of water, and the time required for the complete dispersion of the tablet was determined.

The fineness of the dispersion test was done by using two tablets in 100ml of water and stirring gently until completely dispersed. The smooth dispersion obtained was passed through a sieve screen with a nominal mesh aperture of 710mm (Sieve #22) 32.

**Stability Studies:** Stability studies were carried out with optimized formulation at  $25 \pm 2^{\circ}\text{C}/60 \pm 5\%$  RH and  $40 \pm 2^{\circ}\text{C}/75\% \pm 5\%$  RH for (F-VII) for 3 months. The selected clear ALU-ALU packed formulations were stored at  $25 \pm 2^{\circ}\text{C}/60\% \pm 5\%$  RH and  $40 \pm 2^{\circ}\text{C}/75\% \pm 5\%$  RH for 3 months and their physical appearance, average weight, thickness, hardness, friability, disintegration test, *in-vitro* dispersion time, fineness of dispersion, assay and *in-vitro* drug release were evaluated at specified intervals of time(every month)  $^{33}$ .

**RESULTS AND DISCUSSION: Table 2** gives the calibration data of ondansetron using 6.8 pH phosphate buffer at 310 nm in the concentration range of 2-10 µg/ml.

**Fig. 2** reveals that the calibration curve has a regression of 0.9983 which is close to unity indicates that it follows beer's law. Hence these values are used for the *in-vitro* studies.

TABLE 2: CALIBRATION DATA FOR THE ESTIMATION OF ONDANSETRON HYDRO-CHLORIDE IS 6.8 pH PHOSPHATE BUFFER AT 310nm

S. no.	Concentration (µg/ml)	Absorbance( $X \pm SD$ )
1	0	0
2	2	$0.1408 \pm 0.0010$
3	4	$0.2589 \pm 0.0013$
4	6	$0.3894 \pm 0.0018$
5	8	$0.5460 \pm 0.0010$
6	10	$0.6684 \pm 0.0026$

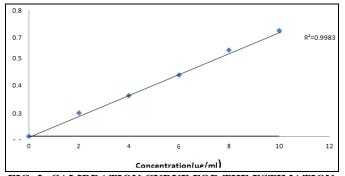


FIG. 2: CALIBRATION CURVE FOR THE ESTIMATION OF ONDANSETRON HYDROCHLORIDE IN 6.8PH PHOSPHATE BUFFER AT 310nm

TABLE 3: SATURATED SOLUBILITY STUDIES OF ONDANSETRON HYDROCHLORIDE IN DIFFERENT DISSOLUTION MEDIA

S. no.	Dissolution medium	Amount of ondansetron hydrochloride soluble (µg/ ml)
1	Distilled water	284.36
2	6.8 Ph phosphate buffer	667.35
3	7.2 pH phosphate buffer	436.22
4	0.1 N HCl	323.14

**Table 3** gives the data of saturation solubility of ondansetron and its solubility was more in 6.8 pH

Phosphate buffer compared to another dissolution medium.

TABLE 4: DISSOLUTION DATA OF ONDANSETRON HYDROCHLORIDE- FDTS FROM F1-F4

Time(min)	Cumulative % Drug Released					
	PD	<b>F</b> 1	F2	F3	F4	
0	0	0	0	0	0	
5	28.36	50.28	60.55	65.41	65.41	
10	36.88	71.69	79.52	89.44	90.33	
15	51.26	85.91	87.23	90.44	96.24	
20	57.88	91.89	93.56	95.34	97.11	
25	62.77	95.88	96.61	97.56	98.26	
30	70.87	97.59	98.00	98.24	98.44	

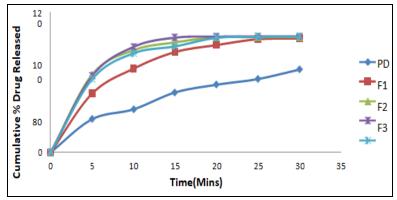


FIG. 3: DISSOLUTION PROFILE OF ONDANSETRON HYDROCHLORIDE-FDTS FROM F1-F4

**Table 4** and **Fig. 3** give the data of dissolution profile of Ondansetron Hydrochloride-FDTS from F1-F4, which reveals that pure drug has low dissolution compared to prepared FDTS

formulations. **Table 5** and **Fig. 4** show that FDTS F8 formulation has fast release within 15 min compared to other formulations and pure drugs.

TABLE 5: DISSOLUTION DATA OF ONDANSETRON HYDROCHLORIDE FDTS FROM F5-F8

Time (min)	Cumulative % Drug Released					
	PD	F5	F6	F7	F8	
0	0	0	0	0	0	
5	28.36	52.99	66.56	68.66	66.6	
10	36.88	74.88	88.84	89.66	91.76	
15	51.26	87.1	90.69	93.36	99.73	
20	57.88	92.99	97.55	98.88	-	
25	62.77	96.55	97.67	98.92	-	
30	70.87	97.77	98.12	98.96	-	

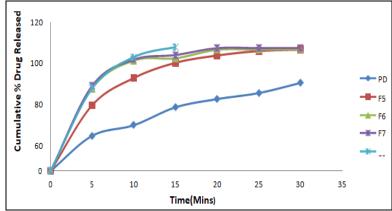


FIG. 4: DISSOLUTION PROFILE OF ONDANSETRON HYDROCHLORIDE-FDTS FROM F5-F8

TABLE 6: FLOW PROPERTIES OF ONDANSETRON HYDROCHLORIDE-FDTS FORMULATIONS

S. no.	<b>Tablet Formulations</b>	Compressibility Index (%)	Angle of repose	Hausner's ratio
1	F1	14.10±0.04	21.24±0.06	1.21±0.08
2	F2	15.25±0.01	$23.02 \pm 0.05$	1.21±0.04
3	F3	16.00±0.03	22.01±0.05	$1.21\pm0.04$
4	F4	$14.98 \pm 0.06$	$24.45 \pm 0.02$	$1.22\pm0.01$
5	F5	$12.28 \pm 0.07$	23.21±0.04	1.21±0.04
6	F6	$14.08 \pm 0.04$	$24.84 \pm 0.08$	$1.24\pm0.01$
7	F7	$15.94 \pm 0.01$	23.21±0.01	$1.22\pm0.02$
8	F8	16.01±0.06	26.45±0.07	1.23±0.02

**Table 6** revealed that the prepared FDTS of repose, and hausner's ration, which indicates formulations has good compressibility index, angle that the formulations has excellent flow properties.

TABLE 7: EVALUATION OF PHYSICAL PARAMETERS OF ONDANSETRON HYDROCHLORIDE-FDTS **FORMULATIONS** 

S. no.	Tablet	Weight uniformity	Friability loss	Hardness	Drug content	Wetting	Dispersion
	Formulation	(mg/tablet)	(% w/w)	(kg/cm <sup>2</sup> )	(mg)	time (Sec)	Time(Sec)
1	F1	284±4	0.68	3.5±0.1	7.5±0.2	28	Passed
2	F2	$247 \pm 1$	0.89	$3.4\pm0.5$	$7.7 \pm 0.3$	26	Passed
3	F3	246±2	0.90	$3.5\pm0.2$	$7.8 \pm 0.1$	20	Passed
4	F4	$249\pm4$	0.87	$3.5\pm0.4$	$7.8\pm0.2$	34	Passed
5	F5	248±3	0.75	$3.4\pm0.2$	$7.9 \pm 0.3$	28	Passed
6	F6	249±7	0.88	$3.5\pm0.3$	$7.6\pm0.3$	34	Passed
7	F7	$247 \pm 8$	0.74	$3.4\pm0.4$	$7.5\pm0.2$	27	Passed
8	F8	250±9	0.86	$3.5\pm0.4$	$8.0\pm0.5$	26	Passed

The Data given in **Table 7** revealed that the prepared tablet has weight uniformity in the range of 247±1 to 284±4. The friability of the prepared tablets was less than 1 and the hardness of tablets was in the range of 3.4±0.2 to 3.5±0.4 indicating that the prepared tablets have sufficient strength to

withstand abrasion. The drug content of the formulated tablets was in the range of 7.5±0.2 to  $8.0\pm0.5$ . Wetting time was in the range of 20 to 34. Dispersion of tablets was in seconds. It was revealed from the data given in Table 8, all the formulations follow first-order kinetics.

TABLE 8: DISSOLUTION PARAMETERS OF ONDANSETRON HYDROCHLORIDE-FDTS FORMULATIONS

S. no.	<b>Tablet formulations</b>	T <sub>50</sub> (min)	T <sub>90</sub> (min)	<b>DE 30%</b>	First order	
					K (min <sup>-1)</sup>	R
1	F1	22.5	>30	64.50	0.0267	0.967
2	F2	15	>30	64.4	0.0398	0.973
3	F3	10	29.5	65.6	0.0374	0.971
4	F4	9	16	70.5	0.0489	0.990
5	F5	15	18	67.8	0.0357	0.977
6	F6	14	17	70.0	0.3894	0.992
7	F7	11	15	71.5	0.3712	0.982
8	F8	7	10	73.5	0.3943	0.987

Accelerated **Stability Studies:** accelerated stability studies, which were shown in Table 9, revealed that the weight uniformity,

hardness, friability, drug content was not changed after storage in accelerated conditions.

TABLE 9: PHYSICAL PARAMETERS OF ONDANSETRON HYDROCHLORIDE F8 BEFORE AND AFTER STORAGE AT DIFFERENT CONDITIONS

Storage conditions	Weight Uniformity (mg)	Hardness (kg/cm <sup>2</sup> )	Friability (%)	Drug content (mg/tablet)
Before storage	250±9	3.5±0.4	0.86	8.0±0.5
$25^{\circ} \pm 2^{\circ}\text{C }60\%$	249±7	$3.5\pm0.2$	0.77	$7.8 \pm 0.4$
±5% RH				
40°±2°C	249±5	$3.5 \pm 0.5$	0.74	$7.8 \pm 0.2$
$75\% \pm 5\%$				

TABLE 10: RELEASE OF ONDANSETRON HYDROCHLORIDE (F8) BEFORE AND AFTER STORAGE AT DIFFERENT CONDITIONS

Time Min	Storage Conditions	% drug released	
	Before Storage	$25^{\circ} \pm 2^{\circ}\text{C } 60\% \pm 5\%\text{RH}$	40°±2°C 75%±5% RH
5	66.56	66.49	66.6
10	91.84	91.78	91.76
15	99.79	99.74	99.73

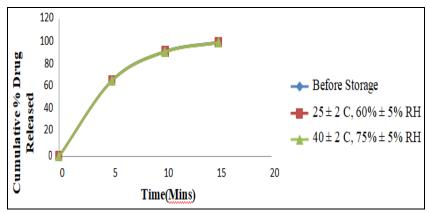


FIG. 5: RELEASE OF ONDANSETRON HYDROCHLORIDE F8 BEFORE AND AFTER STORAGE

From the data given in **Table 10** and **Fig. 5**, it was evident that there is no difference in the percentage drug release of ondansetron hydrochloride tablets before and after storage which indicates that the prepared tablets were stable.

FTIR Studies: FTIR studies of the pure ondansetron, super disintegrants, and combination of drug and super disintegrants containing the

highest proportion were carried out to find any interaction between drug and excipients used in the formulation. FT-IR study was performed using IR spectroscopy (SHIMADZU).

The results were shown in **Fig. 6** to **8** and in **Table 11** to **13**. The comparison of FT-IR spectral data of drugs with super disintegrants was given in **Table 14**.

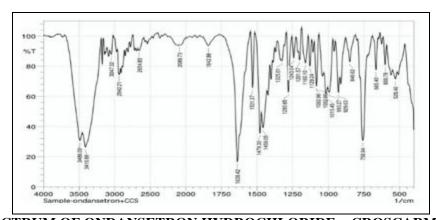


FIG. 6: FT-IR SPECTRUM OF ONDANSETRON HYDROCHLORIDE + CROSCARMELLOSE SODIUM

TABLE 11: FT-IR SPECTRAL DATA OF ONDANSETRON HYDROCHLORIDE AND CROSSCARMELLOSE SODIUM

S. no.	Wave Number(cm <sup>-1</sup> )	Functional Group
1	3486	OH stretching
2	3047	Aromatic C-H
3	2942	Aliphatic C-H
4	1638	C=O stretching
5	1531	Aromatic C=C
6	1082	C-N bending
7	993	C-O stretching
8	758	CH <sub>3</sub> group

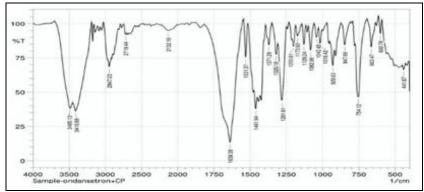


FIG. 7: FT-IR SPECTRUM OF ONDANSETRON HYDROCHLORIDE + CROSPOVIDONE

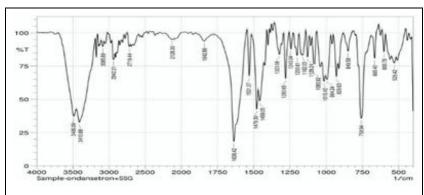


FIG: 8: FT- IR SPECTRUM OF ONDANSETRON HCL AND SODIUM STARCH GLYCOLATE

TABLE 12: FT-IR SPECTRAL DATA OF ONDANSETRON HCL AND CROSSPOVIDONE

S. no.	Wave Number(cm <sup>-1</sup> )	Functional Group
S. 110.	wave Number (cm )	runcuonai Group
1	3642	Aromatic C-H
2	3485	OH bending
3	2947	Aliphatic C-H
4	1639	C=O stretching
5	1531	C=C stretching
6	1461	C=N stretching
7	1082	C-N stretching
8	1042	C-O stretching

TABLE 13: FT- IR SPECTRAL DATA OF ONDANSETRON HCL AND SODIUM STARCH GLYCOLATE

S. no.	Wave Number(cm <sup>-1</sup> )	Functional Group
1	3486	OH bending
2	3085	CH aromatic
3	2942	Aliphatic CH
4	1638	C=O stretching
5	1531	C=C stretching
6	1459	CH <sub>2</sub> group
7	1015	C-O stretching
8	758	Aliphatic CH <sub>3</sub>

TABLE: 14 COMPARATIVE FT-IR SPECTRAL DATA OF DRUG AND SUPERDISINTEGRANTS

Compounds	Functional Groups				
	OH (cm <sup>-1</sup> )	C=O (cm <sup>-1</sup> )	C=C (cm <sup>-1</sup> )	C-O (cm <sup>-1</sup> )	Aliphatic CH <sub>3</sub> (cm <sup>-1</sup> )
Drug (Ondansetron Hydrochloride)	3408	1637	1420	1040	754
Drug + CCS	3486	1638	1531	993	758
Drug + CP	3485	1639	1531	1042	758
Drug + SSG	3486	1638	1531	1015	758

From the data given in **Fig. 6** to **8** and **Table 11** to 13, it was evident that there is no interaction of drug with polymers as peaks are present in the functional group range without any interaction with the polymers

Comparative Dissolution Study of Marketed Formulation and Optimized Formulation (F-8): The dissolution profile of optimized formulation (F-8) was compared with marketing. Ondansetron HCl orally disintegrating tablet.

Table 17 and Fig. 9. From the data given in Table 15 and Fig. 9, it was revealed that the prepared formulation and marketed formulation has a percentage drug release of 99.73 and 97.25 respectively at 15 min which indicates that both formulations have almost maximum drug release.

The F8 formulation has more drug release compared to marketed formulation.

TABLE 15: COMPARATIVE IN VITRO RELEASE DATA OF ONDANSETRON HCL MARKETED TABLET AND OPTIMIZED FORMULATION (F-VII)

Time	% Drug release	Marketed		
	F8 Formulation	Formulation		
0	0	0		
5	66.6	60.2		
10	91.76	88.76		
15	99.73	97.25		

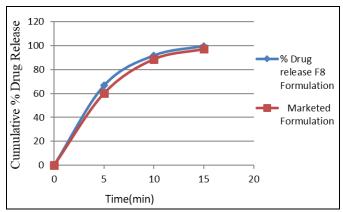


FIG. 9: COMPARATIVE DISSOLUTION DATA FOR THE F8 ONDANSETRON FORMULATION AND MARKETED FORMULATION

CONCLUSION: From the overall results, the study concluded that orally disintegrating tablets of Ondansetron hydrochloride could be successfully formulated by direct compression method using cross povidone as a super disintegrant, which could be a promising formulation to effectively treat nausea and vomiting caused by a cytotoxic agent, thereby preventing inherent drawbacks associated with conventional tablets such as the risk of choking, bitter taste and difficulty in swallowing, also providing faster disintegration, rapid release, bypassing first-pass effect, improve patient compliance and therapeutic effectiveness. From all the above observations, it was concluded that the formulation F-8 containing cross povidone as super disintegrant was better than the other formulations and satisfied the criteria for orally disintegrating tablets.

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