Development of Ondansetron Tablets with Advanced Disintegrant Technology for Rapid Release and Improved Pharmacokinetics

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KEYWORDS

Ondansetron hydrochloride, Caitin, Cross povidone, Sodium starch glycolate

ABSTRACT

Ondansetron hydrochloride (ONH) is a potent antiemetic drug commonly used for managing nausea and vomiting induced by chemotherapy, radiotherapy, or postoperative conditions. The objective of this study was to develop and evaluate taste-masked fast-dissolving tablets (FDTs) of ONH to enhance patient adherence to treatment. Taste-masked granules of ONH were prepared using a solid dispersion technique, with a solvent evaporation method employed for granulation. The formulation aimed for complete taste masking and minimal drug release in a phosphate buffer (pH 6.8), achieved with a drug-to-polymer ratio of 1:2. Four formulations were selected based on pre-formulation testing and then compressed into FDTs for further evaluation. The tablets were analyzed for drug content uniformity, in-vitro disintegration time, wetting time, in-vivo dissolution profile, and the release rate of the drug. Among all the formulations, F8, which incorporated Caitin sodium as a superdisintegrant, exhibited the fastest drug release, outperforming the pure drug in terms of release speed. The time for 50% drug release (T50) and the drug release efficiency (DE 30%) for formulation F8 were determined to be 7 minutes and 73.5%, respectively, demonstrating its potential as a rapid-release tablet suitable for improving therapeutic outcomes.

INTRODUCTION

Oral administration remains the most widely used drug delivery system due to its convenience, allowing for easy self-administration of various dosage forms. However, one of the challenges associated with traditional oral dosage forms is the unpleasant taste of certain medications, which can make them difficult to take, particularly for pediatric and geriatric patients. To address this issue, various strategies are employed to mask the bitter taste of medications. These strategies include the use of lipophilic carriers, coatings, complexation, ion exchange resins, effervescence, rheological modifications, prodrug formulations, freeze-drying processes, and advanced technologies like continuous multi-purpose melt processing[1].

For many pediatric and geriatric patients, swallowing tablets can be problematic, especially in situations where water may not be readily available, such as while traveling. To overcome these challenges, fast-dissolving tablets (FDTs) have been developed. These tablets dissolve rapidly in the mouth, often within 20 seconds, offering quick therapeutic effects without the need for water. FDTs are particularly advantageous as they improve patient compliance, enhance bioavailability, and provide better efficacy and biopharmaceutical properties. The ease of administration and the convenience of

rapid disintegration make FDTs a promising solution for improving the treatment experience, especially for those who struggle with traditional oral dosage forms[2].

Mouth-Dissolving Tablets (MDTs) for Patients with Severe Medical Conditions

Mouth-dissolving tablets have proven to be highly beneficial for patients suffering from chronic and severe conditions such as anxiety disorders, cancer treatments like radiation therapy, Parkinson's disease, and HIV/AIDS, particularly those dealing with dysphagia (difficulty swallowing). In such cases, ondansetron hydrochloride is often the drug of choice due to its effective antiemetic properties. In the context of biopharmaceutical drug classification, ondansetron is categorized as a BCS (Biopharmaceutical Classification System) Class II drug, which indicates it has low water solubility but high permeability in the body. Chemically, ondansetron is a serotonin (5-HT3) receptor antagonist, specifically designed to prevent nausea and vomiting, particularly after chemotherapy treatments. To ensure the quality of mouth-dissolving tablets, various tests and parameters are essential, including assessments of tablet hardness, friability, disintegration time, and dissolution. These tests are crucial to compare products containing the same active pharmaceutical ingredient (API) but ensuring that their therapeutic efficacy is equivalent. Differences in absorption rates, the purity of the drug, or the excipients used in formulation may contribute to varying therapeutic responses, even when the same drug is used[3].

Advantages of Mouth-Dissolving Tablets[4, 5]:

1. **Rapid Onset of Action:** MDTs are rapidly absorbed in the pre-gastric area, such as the pharynx and oesophagus, leading to a quick onset of therapeutic effects.
2. **Enhanced Bioavailability:** These tablets can potentially improve bioavailability, meaning that the active pharmaceutical ingredient reaches the bloodstream more efficiently, allowing for dose minimization and reducing the chances of side effects.
3. **Convenience and Compliance:** MDTs provide an advantage in cases where conventional dosage forms may not be easily consumed, particularly when the oral route is obstructed, improving overall patient compliance.

Ideal Properties of Drugs for MDT Development[6, 7, 26]:

When developing mouth-dissolving tablets, selecting the right drug is crucial. Some important factors to consider include:

- **High Permeability:** Drugs that are easily absorbed across the epithelial layers of the upper gastrointestinal tract (log P > 2).
- **Short Half-Life:** Drugs that require frequent dosing are ideal candidates for MDT formulations.
- **First-Pass Metabolism:** Drugs that undergo significant metabolism in the liver, resulting in toxic metabolites, may benefit from MDT technology as it bypasses the first-pass effect.
- **Unsuitability for Sustained Release:** Drugs designed for sustained or controlled release should generally be avoided in MDT formulations.
- **Taste Considerations:** Drugs with an extremely bitter taste are generally unsuitable, as MDTs need to dissolve quickly in the mouth without causing an unpleasant experience.

Mechanisms of Super Disintegrants[8, 9, 27]:

The disintegration of MDTs is facilitated by various mechanisms of super disintegrants, including:

- **Swelling:** The super disintegrant absorbs water, causing the tablet to expand and break apart.
- **Porosity and Capillary Action (Wicking):** The porous nature of the tablet and the capillary action of the disintegrants help in the rapid breakdown of the tablet.
- **Repulsive Forces between Particles:** The internal forces between particles in the tablet repel each other upon hydration, leading to disintegration.
- **Deformation:** The physical deformation of the tablet structure under specific conditions contributes to its breakdown.

These mechanisms work together to ensure that mouth-dissolving tablets break down effectively in the mouth, allowing for fast absorption and rapid therapeutic action.

MATERIALS[10, 11, 28]:

Ondansetron Hydrochloride was obtained from Orchid Labs Ltd, Vijayawada. Stevia powder, Talc, Magnesium Stearate, Microcrystalline cellulose from S.D fine Chem Ltd, Mumbai. Superdisintegrants like Caitin, Sodium starch glycolate were purchased from RK Pharma Ltd, Guntur.

METHODOLOGY:

Preformulation Studies[12, 13, 29]:

The physical and chemical characteristics of Ondansetron Hydrochloride powder were assessed through various Preformulation studies. The powder was examined for its organoleptic properties, including color, odor, and appearance under a microscope. Additionally, the melting point was determined, and solubility was assessed. UV spectroscopy was used to analyze the substance, while the flow properties of the powder were evaluated using parameters like the angle of repose, Hausner's ratio, and compressibility index.

Calibration Curve of Ondansetron Hydrochloride[14, 15, 30]:

- **Preparation of Stock Solution:** A 100 mg quantity of Ondansetron Hydrochloride was precisely weighed and dissolved in 100 mL of methanol. The resulting solution was filtered and transferred into a 100 mL volumetric flask, where it was diluted with 6.8 pH phosphate buffer to achieve a final concentration of 1 mg/mL for the stock solution.
- **Preparation of Standard Dilutions[16, 17]:** Aliquots of the prepared stock solution of Ondansetron Hydrochloride were transferred into five separate volumetric flasks. Each flask was further diluted with the 6.8 pH phosphate buffer to create standard solutions with concentrations of 2, 4, 6, 8, and 10 µg/ml. The absorbance of each dilution was then measured using a UV-Vis spectrophotometer at a wavelength of 310 nm, with the 6.8 pH phosphate buffer used as the blank.

TABLE 1: COMPOSITION OF VARIOUS ONDANSETRON HYDROCHLORIDE FAST DISSOLVING TABLETS

Ingredients (Mg/tab)	Formulations							
	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	-	-	-	-
Caitin (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[18, 19, 31]:

Fast-dissolving tablets were formulated using the direct compression method. This technique has become viable for producing such tablets due to the availability of advanced excipients, particularly polymers.

The process involves the following steps:

- **Raw Materials → Weighing → Screening → Mixing → Lubrication → Compression**

For the development of ondansetron fast-dissolving tablet formulations, different polymers were incorporated into the tablet composition. The formulation generally included the active drug, polymer,

and a diluent. Microcrystalline cellulose (pH 102) was used as the diluent to ensure uniformity in tablet weight across all formulations. The composition of each formulation is presented in Table 1.

To begin the formulation, each ingredient was carefully weighed and sifted through sieve no. 120. The materials were then mixed for 15 minutes using a double cone blender. After blending, the mass was lubricated with 1% talc and magnesium stearate. The tablets from all batches were compressed under the same conditions. Subsequently, the physical properties of the compressed tablets were assessed, including weight uniformity, hardness, friability, drug content, and in-vitro dissolution performance.

Disintegration Test[20, 21, 22, 32]:

The disintegration test was performed at 37°C ± 2°C in 900 mL of distilled water. A single tablet from each formulation was placed into each of the six tubes of the disintegration apparatus, which contained distilled water. A disk was added to each tube. The time taken for the tablets to disintegrate completely, with no remaining palpable mass, was recorded.

In-vitro Dispersion Time:

To assess the dispersion time, a tablet was placed in a small petri dish containing 10 mL of water. The time required for the tablet to completely disperse was noted. For the dispersion fineness, two tablets were placed in 100 mL of water and stirred gently until fully dispersed. The resulting dispersion was then passed through a sieve screen with a nominal mesh size of 710 mm (Sieve #22) to evaluate the smoothness of the dispersion.

Stability Studies[23, 24, 25]:

Stability testing was conducted on the optimized formulation (F-VII) under two different environmental conditions: 25 ± 2°C/60 ± 5% RH and 40 ± 2°C/75 ± 5% RH for 3 months. The tablets, packaged in clear ALU-ALU blisters, were stored under these conditions. The physical appearance, average weight, thickness, hardness, friability, disintegration time, in-vitro dispersion time, dispersion fineness, assay, and in-vitro drug release were evaluated at regular intervals (every month) to monitor any changes over time.

RESULTS AND DISCUSSION:

Table 2 presents the calibration data for ondansetron, measured using a 6.8 pH phosphate buffer at a wavelength of 310 nm, within a concentration range of 2-10 µg/ml. **Figure 1** illustrates the calibration curve, which shows a regression value of 0.9983. This value, which is very close to 1, confirms that the drug adheres to Beer's Law. These calibration values were subsequently applied in the in-vitro studies.

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

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

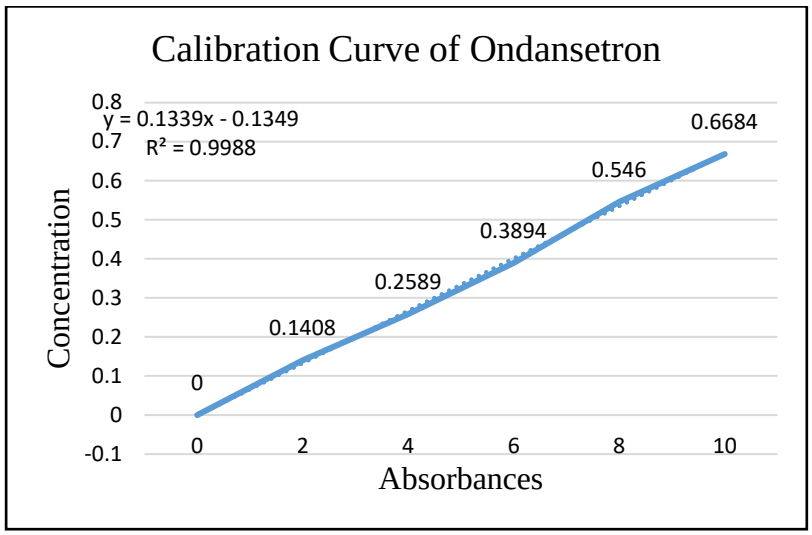

FIG. 1: CALIBRATION CURVE FOR THE ESTIMATION OF ONDANSETRON HYDROCHLORIDE IN 6.8PH PHOSPHATE BUFFER AT 310nm

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: SATURATED SOLUBILITY STUDIES OF ONDANSETRON HYDROCHLORIDE IN DIFFERENT DISSOLUTION MEDIA

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-F8

Time (Min)	Cumulative % Drug Released								
	PD	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0	0
5	28.36	50.28	60.55	65.41	65.41	52.99	66.56	68.66	66.6
10	36.88	71.69	79.52	89.44	90.33	74.88	88.84	89.66	91.76
15	51.26	85.91	87.23	90.44	96.24	87.1	90.69	93.36	99.73
20	57.88	91.89	93.56	95.34	97.11	92.99	97.55	98.88	-
25	62.77	95.88	96.61	97.56	98.26	96.55	97.67	98.92	-
30	70.87	97.59	98.00	98.24	98.44	97.77	98.12	98.96	-

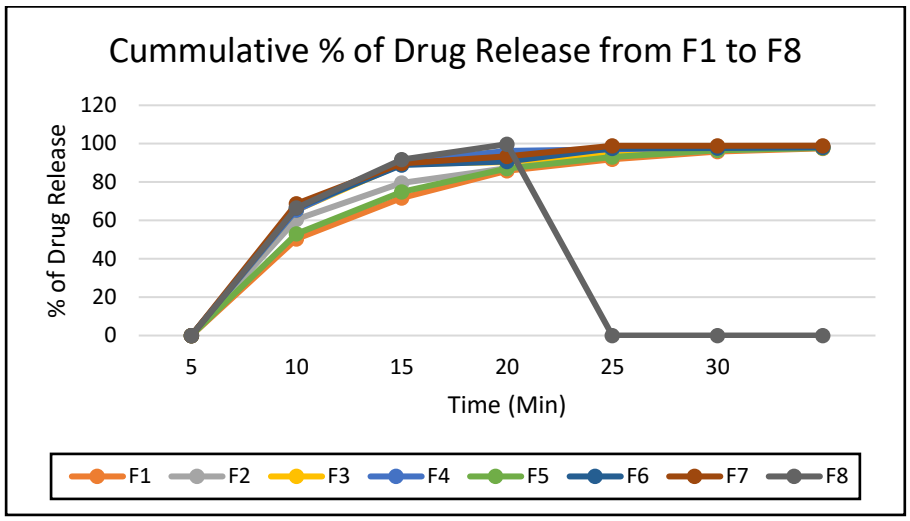

FIG. 2: DISSOLUTION PROFILE OF ONDANSETRON HYDROCHLORIDE-FDTS FROM F1-F8

Fig. 2 give the data of dissolution profile of Ondansetron Hydrochloride-FDTS from F1-F8, which reveals that pure drug has low dissolution compared to prepared FDTS formulations show that FDTS F8 formulation has fast release within 15 min compared to other formulations and pure drugs.

TABLE 5: FLOW PROPERTIES OF ONDANSETRON HYDROCHLORIDE-FDTS FORMULATIONS

S. no.	Tablet Formulations	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±0.05	1.21±0.04
3	F3	16.00±0.03	22.01±0.05	1.21±0.04
4	F4	14.98±0.06	24.45±0.02	1.22±0.01
5	F5	12.28±0.07	23.21±0.04	1.21±0.04
6	F6	14.08±0.04	24.84±0.08	1.24±0.01
7	F7	15.94±0.01	23.21±0.01	1.22±0.02
8	F8	16.01±0.06	26.45±0.07	1.23±0.02

Table 5 revealed that the prepared FDTS formulations has good compressibility index, angle of repose, and Hausner's ration, which indicates that the formulations has excellent flow properties.

TABLE 6: EVALUATION OF PHYSICAL PARAMETERS OF ONDANSETRON HYDROCHLORIDE-FDTS FORMULATIONS

S. no.	Tablet Formulation	Weight uniformity (mg/tablet)	Friability loss (% w/w)	Hardness (kg/cm^2)	Drug content (mg)	Wetting time (Sec)	Dispersion Time(Sec)
1	F1	284±4	0.68	3.5±0.1	7.5±0.2	28	Passed
2	F2	247±1	0.89	3.4±0.5	7.7±0.3	26	Passed
3	F3	246±2	0.90	3.5±0.2	7.8±0.1	20	Passed
4	F4	249±4	0.87	3.5±0.4	7.8±0.2	34	Passed
5	F5	248±3	0.75	3.4±0.2	7.9±0.3	28	Passed
6	F6	249±7	0.88	3.5±0.3	7.6±0.3	34	Passed
7	F7	247±8	0.74	3.4±0.4	7.5±0.2	27	Passed
8	F8	250±9	0.86	3.5±0.4	8.0±0.5	26	Passed

Table 6 shows that the weight uniformity of the prepared tablets ranged from 247±1 mg to 284±4 mg. The friability of the tablets was found to be below 1%, indicating good tablet integrity. The hardness of the tablets varied between 3.4±0.2 and 3.5±0.4, which suggests they possess sufficient strength to resist mechanical stress. The drug content in the tablets ranged from 7.5±0.2 to 8.0±0.5. The wetting time was between 20 and 34 seconds, while the dispersion time of the tablets was measured in seconds. According to the data in **Table 7**, all formulations followed first-order kinetics.

TABLE 7: DISSOLUTION PARAMETERS OF ONDANSETRON HYDROCHLORIDE-FDTS FORMULATIONS

S. no.	Tablet formulations	T_{50} (min)	T_{90} (min)	DE 30%	First order K (min$^{-1)}$	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: From the accelerated stability studies, which were shown in **Table 8**, revealed that the weight uniformity, hardness, friability, drug content was not changed after storage in accelerated conditions.**TABLE 8: PHYSICAL PARAMETERS OF ONDANSETRON HYDROCHLORIDE F8 BEFORE AND AFTER STORAGE AT DIFFERENT CONDITIONS**

Storage conditions	Weight Uniformity (mg)	Hardness (kg/cm^2)	Friability (%)	Drug content (mg/tablet)
Before storage				
25° ± 2°C	250±9	3.5±0.4	0.86	8.0±0.5
60%±5% RH	249±7	3.5±0.2	0.77	7.8±0.4
40°±2°C	249±5	3.5±0.5	0.74	7.8±0.2
75% ±5%				

TABLE 9: RELEASE OF ONDANSETRON HYDROCHLORIDE (F8) BEFORE AND AFTER STORAGE AT DIFFERENT CONDITIONS

Time Min	Storage Conditions	% Drug released	
	Before Storage	25° ± 2°C 60%±5% 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

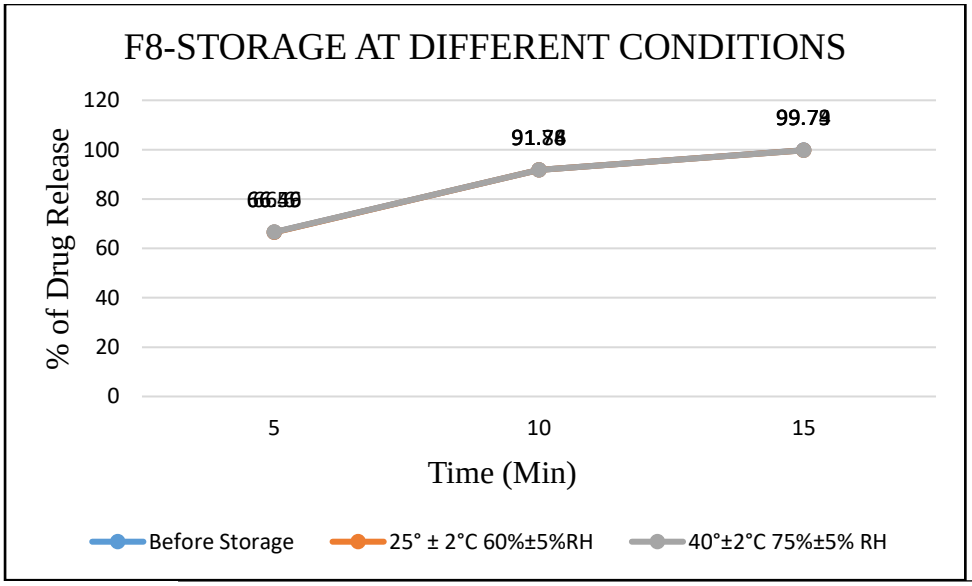

FIG. 3: RELEASE OF ONDANSETRON HYDROCHLORIDE F8 BEFORE AND AFTER STORAGE

From the data given in **Table 9** and **Fig. 3**, 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 analysis was conducted to investigate any potential interactions between pure ondansetron, super disintegrants, and the combination of the drug with the highest proportion of super disintegrants. The study was performed using an IR spectrometer (SHIMADZU). The results are presented in **Figures 4** and **Tables 10**. A comparison of the FTIR

spectra of the drug and super disintegrants is provided in the corresponding table. **14.**

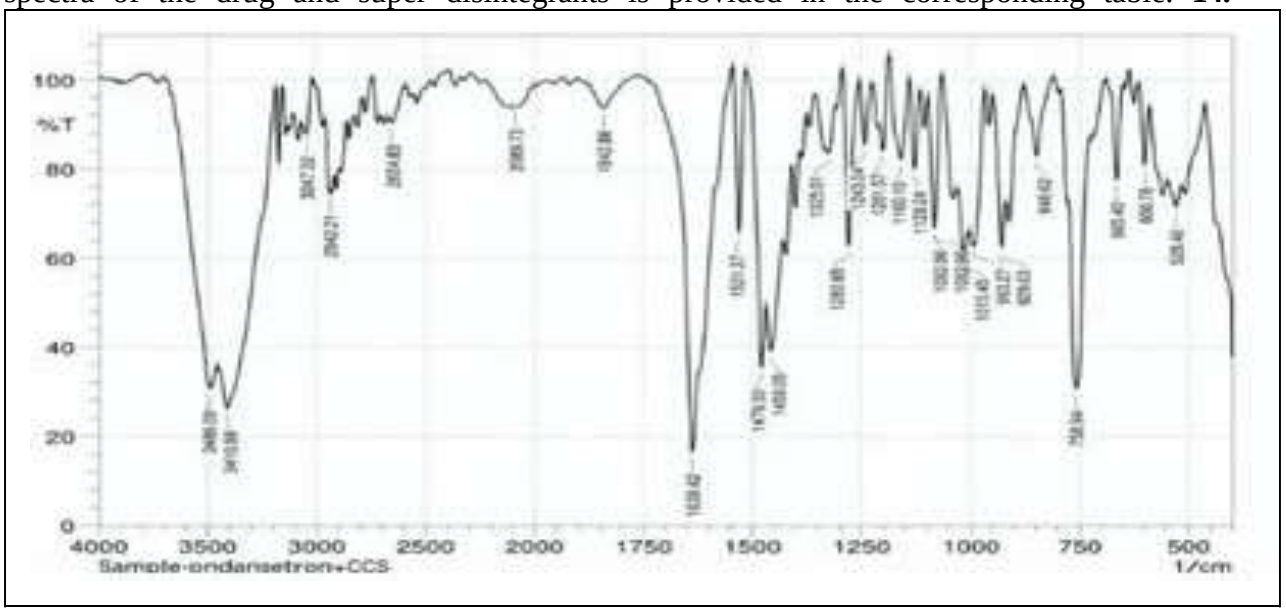

FIG. 4: FT-IR SPECTRUM OF ONDANSETRON HYDROCHLORIDE + CAITIN SODIUM

TABLE 10: FT-IR SPECTRAL DATA OF ONDANSETRON HYDROCHLORIDE AND CAITIN

S. no.	Wave Number (cm^{-1})	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_3 group

TABLE: 11 COMPARATIVE FT-IR SPECTRAL DATA OF DRUG AND SUPERDISINTEGRANTS

Compounds	Functional Groups				
	OH (cm^{-1})	C=O (cm^{-1})	C=C (cm^{-1})	C-O (cm^{-1})	Aliphatic CH_3 (cm^{-1})
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 presented in **Figure 6** and **Table 10**, it is clear that there is no interaction between the drug and the polymers. The peaks in the functional group regions are consistent with the individual components, showing no signs of interaction with the polymers.

Comparative Dissolution Study of Marketed Formulation and Optimized Formulation (F-8): The dissolution profile of the optimized formulation (F-8) was compared with a marketed ondansetron Hcl orally disintegrating tablet. The comparative drug release profiles are shown in **Table 12** and **Figure 5**. According to the data in **Table 12** and **Figure 5**, both the prepared formulation (F-8) and the marketed formulation exhibit nearly complete drug release, with

percentages of 99.73% and 97.25%, respectively, after 15 minutes. This indicates that both formulations release almost all of the drug; however, the F-8 formulation demonstrates a slightly higher drug release compared to the marketed product.

TABLE 12: COMPARATIVE IN VITRO RELEASE DATA OF ONDANSETRON HCL MARKETED TABLET AND OPTIMIZED FORMULATION (F-8)

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

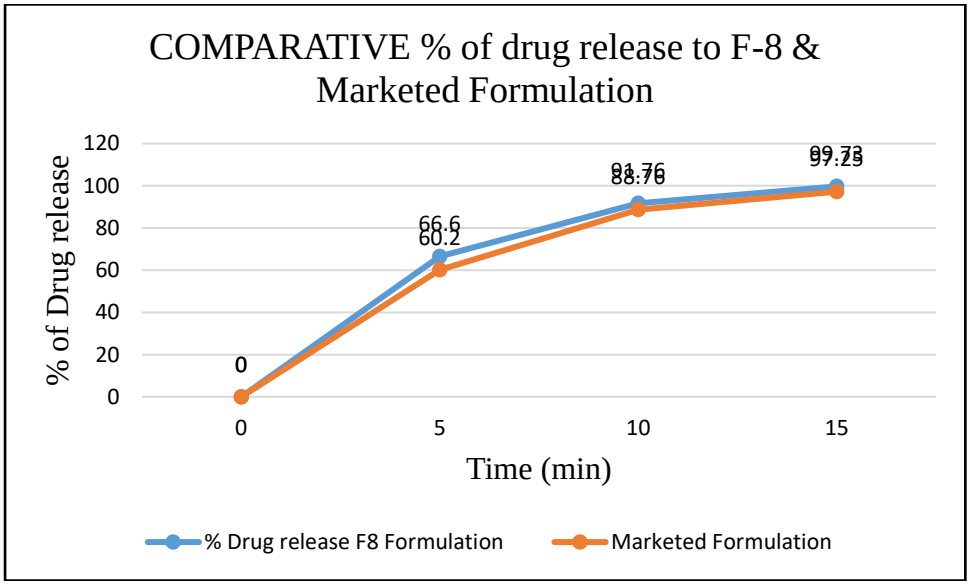

FIG. 5: COMPARATIVE DISSOLUTION DATA FOR THE F8 ONDANSETRON FORMULATION AND MARKETED FORMULATION

CONCLUSION

In this study, ondansetron hydrochloride orally disintegrating tablets (ODTs) were successfully formulated using the direct compression method. The incorporation of Caitin as a super disintegrant significantly improved the dissolution properties of the tablets. The formulation F-8, which utilized crosslinked povidone as the super disintegrant, demonstrated the best performance, exhibiting faster disintegration, superior drug release, and meeting the required criteria for ODTs. The optimized formulation showed a higher percentage of drug release (99.73%) within 15 minutes compared to the marketed formulation (97.25%). Additionally, the ODTs were found to bypass the first-pass effect, providing rapid drug absorption and enhanced therapeutic effectiveness. These results suggest that ondansetron ODTs formulated with Caitin and crosslinked povidone can provide an effective, patient-friendly alternative to conventional tablet forms, improving compliance and addressing issues like difficulty in swallowing, bitter taste, and choking risk. The promising characteristics of the F-8 formulation highlight its potential for use in treating nausea and vomiting induced by cytotoxic agents.

ACKNOWLEDGEMENT: **Nil**

CONFLICT OF INTEREST: No conflict of interest.

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