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FORMULATION AND EVALUATION OF ORALLY DISINTEGRATION TABLET OF DOLASETRON MESYLATE

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ABSTRACT

The present study aimed to formulate and evaluate orally disintegrating tablets (ODTs) of dolasetron mesylate, a selective serotonin 5-HT3 receptor antagonist used for the prevention and treatment of nausea and vomiting associated with chemotherapy, radiotherapy and postoperative conditions. Conventional oral dosage forms may be difficult to administer in nauseated, pediatric, geriatric, dysphagic or bedridden patients, and they may delay onset because of the time required for disintegration and dissolution. Therefore, the study focused on developing a patient-friendly solid oral dosage form capable of rapid disintegration without water, adequate mechanical strength and improved dissolution performance. Dolasetron mesylate ODTs were prepared by the direct compression method using crospovidone, croscarmellose sodium and sodium starch glycolate as superdisintegrants, with mannitol and microcrystalline cellulose as diluent and compressibility-improving excipients. Preformulation studies confirmed that the drug was white to off-white, odorless, crystalline and freely soluble in water, methanol and 1N hydrochloric acid. UV spectrophotometry showed lambda max at 281 nm, and the calibration curve was linear over 2-10 µg/mL with the regression equation y = 0.0503x - 0.0035. FTIR and DSC compatibility studies showed retention of characteristic drug peaks and no evidence of significant drug-excipient interaction. A 3-level factorial design was applied to study the influence of crospovidone and croscarmellose sodium on disintegration time, tablet hardness, drug release and wetting time. The optimized formulation showed acceptable weight variation, friability below 1%, rapid disintegration, drug content of 98% and 95.33% cumulative drug release within 5 min. Stability data for three months indicated minimal changes in drug content, disintegration time, dissolution, hardness, wetting time and friability. The findings demonstrate that dolasetron mesylate can be successfully developed as an ODT using direct compression and optimized superdisintegrant concentrations.

KEYWORDS: Dolasetron mesylate; orally disintegrating tablet; superdisintegrant; direct compression; crospovidone; croscarmellose sodium; dissolution; antiemetic.

1. INTRODUCTION

Nausea and vomiting are clinically important symptoms associated with gastrointestinal infection, food poisoning, pregnancy, motion sickness, migraine, neurological disorders, metabolic disorders and drug therapy. In oncology and surgical practice, chemotherapy-induced nausea and vomiting and postoperative nausea and vomiting are among the most distressing adverse effects experienced by patients. Persistent emesis can lead to dehydration, electrolyte imbalance, malnutrition, weakness, aspiration and poor adherence to essential therapy. The vomiting reflex is coordinated by the vomiting center in the medulla and is influenced by signals from the gastrointestinal tract, vestibular system, higher cortical centers and the chemoreceptor trigger zone. Neurotransmitters such as serotonin, dopamine, histamine, acetylcholine and substance P contribute to emetic signaling.[1-5]

Dolasetron mesylate is a selective serotonin 5-hydroxytryptamine-3 (5-HT3) receptor antagonist used as an antiemetic for chemotherapy-induced, radiotherapy-induced and postoperative nausea and vomiting. After oral administration, dolasetron is absorbed and extensively metabolized to hydrodolasetron, the active metabolite. Its antiemetic activity is attributed to blockade of 5-HT3 receptors in the chemoreceptor trigger zone and the gastrointestinal tract, thereby reducing serotonin-mediated stimulation of the vomiting reflex.[6-9] Although the drug is therapeutically useful, conventional tablets may not always be ideal for patients who are actively nauseated, unable to swallow, dehydrated or without access to water.

Orally disintegrating tablets are solid dosage forms designed to disintegrate rapidly in the mouth after contact with saliva. They combine the dosing accuracy, portability and stability of tablets with the convenience of liquid-like administration. ODTs are particularly useful in pediatric, geriatric, dysphagic, bedridden and travelling patients, and in individuals experiencing nausea where swallowing a tablet with water can precipitate vomiting. Rapid disintegration can promote fast drug release, improve patient acceptance and potentially support quicker therapeutic onset.[10-15]

The performance of ODTs depends strongly on the type and concentration of superdisintegrants. Crospovidone acts mainly through capillary action and wicking, drawing saliva into the tablet matrix and promoting rapid breakup without excessive gel formation. Croscarmellose sodium and sodium starch glycolate act primarily through swelling and water uptake. Proper selection and optimization of these excipients is essential because excessive superdisintegrant can weaken mechanical strength, whereas insufficient levels can prolong disintegration and slow dissolution. The present study was designed to formulate and optimize dolasetron mesylate ODTs using direct compression and a factorial design approach.

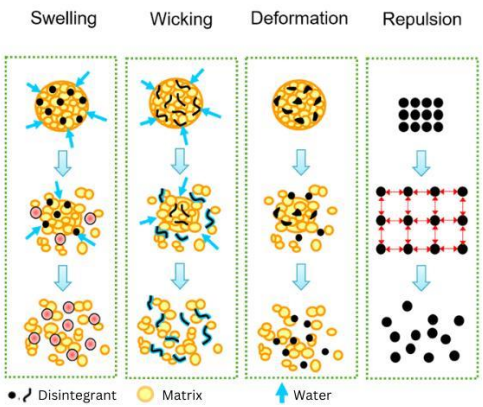

Figure 1: Mechanistic pathways involved in tablet disintegration by superdisintegrants.

2. MATERIALS AND METHODS

2.1 Materials

Dolasetron mesylate was used as the active pharmaceutical ingredient. Crospovidone, croscarmellose sodium and sodium starch glycolate were selected as superdisintegrants. Mannitol was used as diluent and mouthfeel-improving agent, microcrystalline cellulose (Avicel PH-102) as diluent/binder, aspartame as sweetener, magnesium stearate as lubricant and talc as glidant. The excipient selection was based on their common pharmaceutical use in ODTs, compatibility with direct compression and ability to support fast disintegration.

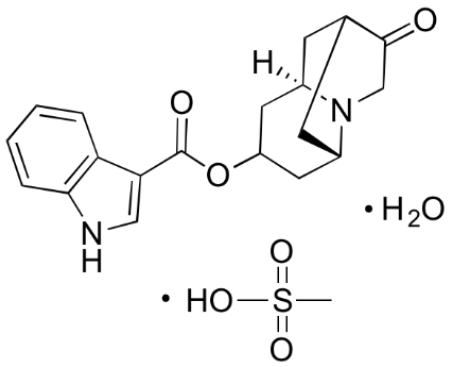

Figure 2: Chemical structure of dolasetron mesylate used in the formulation study.

2.2 Preformulation and Analytical Studies

The preformulation study included organoleptic evaluation, solubility profiling, melting point determination, UV-visible spectrophotometric analysis, FTIR spectroscopy and DSC analysis. The sample was evaluated for color, odor, appearance and texture. Solubility was checked in distilled water, methanol, 1N hydrochloric acid and ethanol to understand the suitability of the drug for fast-dissolving dosage form development.

The melting point was determined by capillary method and compared with the reported range for dolasetron mesylate. For UV analysis, standard solutions were prepared and scanned to identify the wavelength of maximum absorbance. A calibration curve was prepared using concentrations of 2, 4, 6, 8 and 10 µg/mL at 281 nm. The calibration equation was used for further analytical estimation of drug content and dissolution samples.

FTIR spectra of pure drug and drug-excipient physical mixture were recorded to identify characteristic functional groups and investigate possible interactions. DSC thermograms were recorded for pure dolasetron mesylate and its physical mixture with excipients to assess thermal behavior, melting endotherm retention and compatibility.

2.3 Experimental Design

A 3-level factorial design generated using Design-Expert version 13.0 was applied for formulation optimization. Crospovidone and croscarmellose sodium were selected as independent variables because of their direct influence on disintegration and drug release. The selected responses were disintegration time, tablet hardness, drug release response and wetting time. The design enabled evaluation of the main effects of both superdisintegrants and supported selection of an optimized formulation with desirable rapid disintegration, acceptable hardness and improved dissolution.

Table 2: Experimental design variables and responses.

Variable/response	Description	Levels/units
A	Crospovidone concentration	20, 45, 70 mg
B	Croscarmellose sodium concentration	10, 30, 50 mg
R1	Disintegration time	sec
R2	Tablet hardness	kg/cm²
R3	Drug release response	%
R4	Wetting time	sec

2.4 Formulation of ODTs

Dolasetron mesylate ODTs were prepared by the direct compression method. Accurately weighed quantities of drug, superdisintegrants, mannitol and microcrystalline cellulose were blended to obtain a uniform powder mixture.

Aspartame was incorporated to improve palatability. Talc and magnesium stearate were added toward the end of mixing to improve flow and compression performance. The final blends were compressed into tablets with a target weight of 200 mg.

Table 3: Formulation composition of dolasetron mesylate ODTs (mg/tablet).

Batch	Drug	CP	CCS	SSG	Mannitol	MCC	Aspartame	Mg stearate	Talc
F1	10	20	10	10	60	80	5	3	2
F2	10	20	30	15	55	70	5	3	2
F3	10	20	50	10	50	50	5	3	2
F4	10	45	10	15	50	60	5	3	2
F5	10	45	30	10	55	40	5	3	2
F6	10	45	50	15	50	20	5	3	2
F7	10	70	10	15	55	40	5	3	2
F8	10	70	30	10	40	30	5	3	2
F9	10	70	35	15	50	40	5	3	2
F9/Optimized	10	70	40	15	45	10	5	3	2

2.5 Evaluation of Powder Blends and Tablets

Pre-compression flow properties of powder blends were evaluated using bulk density, tapped density, angle of repose, Carr's compressibility index and Hausner's ratio. These tests were performed to judge the suitability of the blends for direct compression and to predict uniformity of die filling.

The prepared tablets were evaluated for appearance, weight variation, thickness, hardness, friability, in vitro disintegration time, wetting time, drug content and in vitro dissolution. Weight variation was determined by weighing individual tablets and comparing the values with the average weight. Thickness was measured using a digital vernier caliper. Hardness was measured using a hardness tester to ensure mechanical integrity. Friability was determined using a Roche friabilator at 25 rpm for 4 min, with a target friability below 1%.

In vitro disintegration was carried out using a USP disintegration apparatus. Dissolution testing was performed using USP Apparatus II in 900 mL phosphate buffer pH 6.8 maintained at 37 ± 0.5 °C. Samples were withdrawn at predetermined time intervals and analyzed spectrophotometrically at 281 nm after suitable dilution. Stability studies were conducted for the optimized formulation for up to three months, monitoring drug content, disintegration time, dissolution, hardness, wetting time and friability.

3. RESULTS AND DISCUSSION

3.1 Preformulation Findings

Dolasetron mesylate was observed as a white to off-white, odorless crystalline powder with fine and free-flowing texture. The drug was freely soluble in distilled water, methanol and 1N hydrochloric acid and soluble in ethanol, indicating favorable aqueous solubility for fast-dissolving oral dosage form development. The observed melting point of 275-278 °C was close to the reported value of approximately 278 °C, supporting identity and purity.

UV spectrophotometric scanning showed maximum absorbance at 281 nm in methanol. The calibration curve over the range 2-10 µg/mL showed a direct relationship between concentration and absorbance, with the regression equation y = 0.0503x - 0.0035 and R^2 = 0.9895. This confirmed that the method was sufficiently linear for routine estimation of dolasetron mesylate during drug content and dissolution analysis.

Table 3.1: Calibration curve observations for dolasetron mesylate.

Concentration (µg/mL)	Absorbance at 281 nm
2	0.103
4	0.205
6	0.270
8	0.412
10	0.503

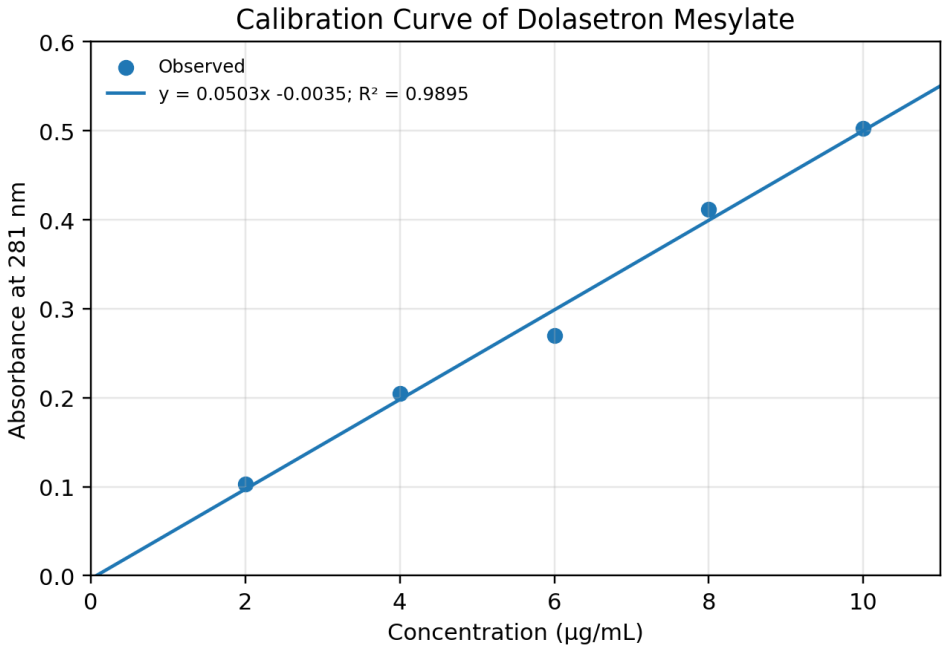

Figure 3.1: Calibration curve of dolasetron mesylate at 281 nm.

3.2 Drug-Excipient Compatibility

The FTIR spectrum of pure dolasetron mesylate showed characteristic peaks corresponding to N-H stretching at 3350 cm^{-1}, aromatic C-H stretching at 3010 cm^{-1}, aliphatic C-H stretching at 2925 cm^{-1}, C=O stretching at 1659 cm^{-1}, C-N stretching at 1191 cm^{-1} and S=O stretching at 1032 cm^{-1}. In the drug-excipient mixture, these principal peaks were retained without significant shifting, disappearance or formation of major new peaks. This indicated absence of chemical interaction between the drug and selected excipients.

DSC analysis of pure dolasetron mesylate showed a sharp endothermic peak at 277 °C, indicating crystalline nature and thermal purity. The physical mixture showed a broad but identifiable peak at 273 °C. The slight shift and reduction in enthalpy can be attributed to dilution and physical mixing effects, while preservation of the drug endotherm indicated compatibility.

Table 3.2: FTIR peak assignments of dolasetron mesylate.

Functional group	Peak (cm^{-1})	Interpretation
N-H stretching	3350	Amine group
Aromatic C-H stretching	3010	Aromatic ring
Aliphatic C-H stretching	2925	Alkyl groups
C=O stretching	1659	Carbonyl group
C-N stretching	1191	Amine linkage
S=O stretching	1032	Sulfonyl group

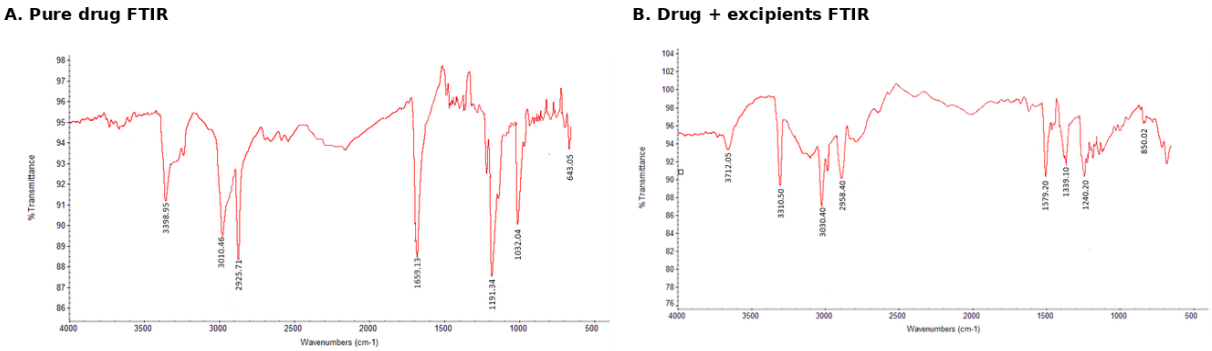

Figure 3.2: FTIR spectra of pure dolasetron mesylate and drug-excipient physical mixture.

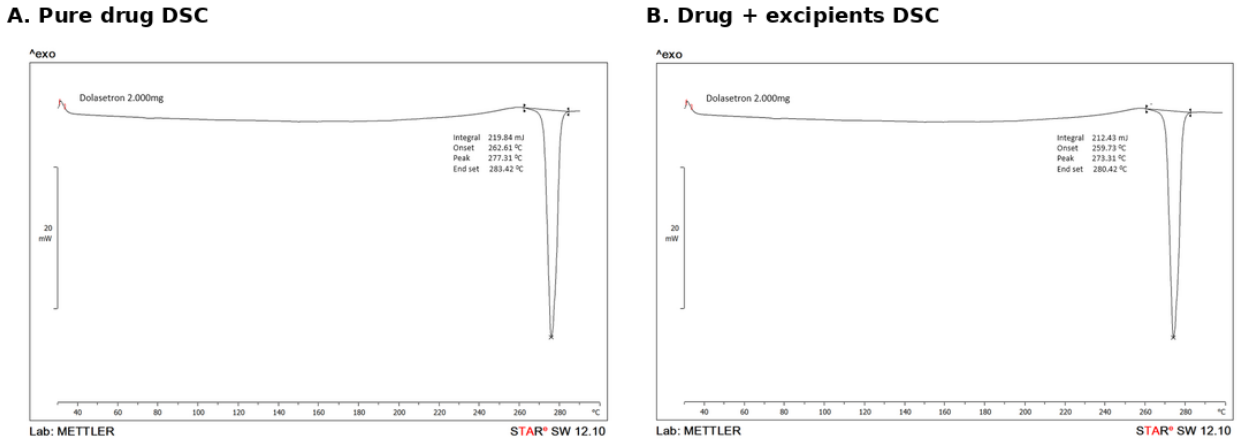

Figure 3.3: DSC thermograms of pure dolasetron mesylate and drug-excipient physical mixture.

3.3 Optimization by Factorial Design

The factorial design demonstrated that crospovidone and croscarmellose sodium significantly influenced disintegration time, tablet hardness, drug release and wetting time. For disintegration time, the model was significant, with the main effects of crospovidone and croscarmellose sodium showing negative coefficients. This indicates that increasing either superdisintegrant decreased disintegration time. Crospovidone produced a strong effect through wicking and capillary water uptake, while croscarmellose sodium supported tablet breakup by swelling and water absorption.

For tablet hardness, crospovidone showed a strong negative effect. This can be attributed to increased tablet porosity and reduced interparticulate bonding at higher concentrations. Croscarmellose sodium showed a comparatively smaller effect on hardness. Therefore, optimization required balancing rapid disintegration with adequate mechanical strength.

The drug release response increased with superdisintegrant concentration, particularly with croscarmellose sodium, because faster hydration and tablet breakup increased the available surface area for dissolution.

The desirability approach identified an optimized solution with crospovidone 67.744 mg and croscarmellose sodium 38.028 mg, predicting disintegration time of 28.565 sec, tablet hardness of 1.684 kg/cm², drug release response of 64.345% and wetting time of 11.990 sec with a desirability value of 1.000. The final optimized batch was marked as F9/Optimized in the formulation evaluation data.

Table 3.3: Desirability-based optimized solution from DOE.

Parameter	Optimized/predicted value
Crospovidone	67.744 mg
Croscarmellose sodium	38.028 mg
Disintegration time	28.565 sec
Tablet hardness	1.684 kg/cm²
Drug release response	64.345%
Wetting time	11.990 sec
Desirability	1.000

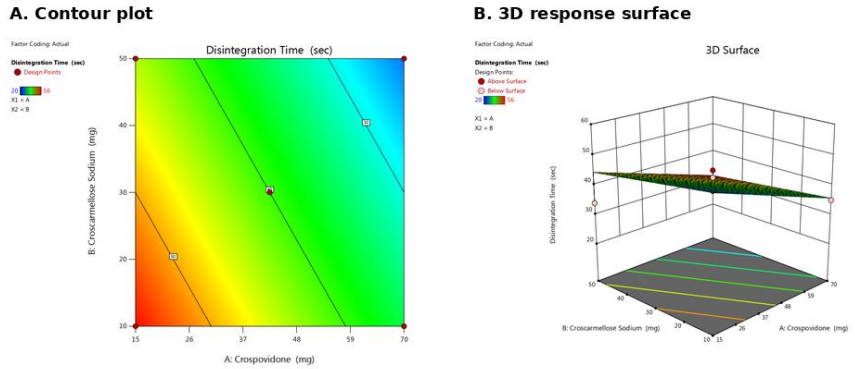

Figure 3.4: DOE contour and 3D response surface plots for disintegration time.

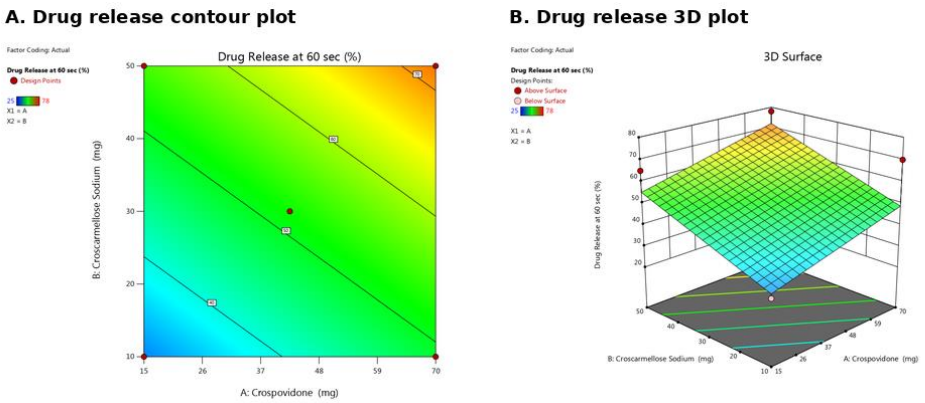

Figure 3.5: DOE contour and 3D response surface plots for drug release response.

3.4 Evaluation of Powder Blends

Powder blend evaluation showed bulk densities between 0.44 and 0.51 g/mL and tapped densities between 0.51 and 0.57 g/mL. Angle of repose ranged from 28° to 40°, indicating that some batches had fair flow while the optimized formulation showed improved flow behavior. Carr's index values were in the range of 20-25%, suggesting fair to passable compressibility, and Hausner's ratio values indicated that flow improvement by glidant and controlled mixing was important before compression. The optimized batch showed bulk density 0.51 g/mL, tapped density 0.57 g/mL, angle of repose 29°, Carr's index 20% and Hausner's ratio 1.32.

Table 3.4: Pre-compression flow properties of powder blends.

Formulation	Bulk Density (g/mL)	Tapped Density (g/mL)	Angle of Repose (°)	Carr's Index (%)	Hausner's Ratio
F1	0.45	0.52	35	22	1.22
F2	0.46	0.53	38	20	1.37
F3	0.44	0.51	40	25	1.42
F4	0.47	0.54	33	21	1.51
F5	0.48	0.55	33	23	1.23
F6	0.46	0.52	31	22	1.40
F7	0.49	0.56	30	20	1.80
F8	0.50	0.56	28	24	1.62
F9 / Optimized	0.51	0.57	29	20	1.32

3.5 Post-Compression Evaluation

All formulations were successfully compressed by direct compression. Tablet weight values ranged from 195 to 203 mg, indicating acceptable weight control around the target weight of 200 mg. Thickness ranged from 1.2 to 2.1 mm, and hardness ranged from 1.3 to 2.6 kg/cm². These values showed that the batches had sufficient mechanical strength while maintaining the ability to disintegrate rapidly.

Friability values were below 1% for all batches, confirming adequate resistance to abrasion and handling stress. The optimized formulation had friability of 0.60%, hardness of 2.4 kg/cm², disintegration time of 30 sec, drug content of 98% and 95.33% cumulative release within 5 min. The optimized batch therefore achieved a desirable balance between mechanical integrity, rapid disintegration and drug release.

The dissolution profile showed that all batches released drug progressively over 5 min, but the optimized batch showed the highest and fastest release. At 0.5 min, F9/Optimized released 20% drug compared with lower values for the other batches. At 3 min, F9/Optimized reached 80% release, and at 5 min it reached 95.33%. This improvement can be explained by the high level of superdisintegrants, which promoted rapid water penetration, tablet breakup and surface area generation for dissolution.

Table 3.5: Post-compression evaluation and final drug release performance.

Batch	Weight (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	DT (sec)	Drug content (%)	Release at 5 min (%)
F1	200	1.9	1.8	0.82	35	93	79.00
F2	201	1.6	2.2	0.79	40	94	60.00
F3	196	1.8	2.1	0.76	45	92	82.00
F4	203	1.4	1.3	0.73	20	95	79.00
F5	200	1.3	2.6	0.70	56	91	83.00
F6	202	1.2	2.3	0.68	34	96	86.00
F7	195	2.1	1.6	0.65	25	95	87.00

F8	201	2.0	2.3	0.62	50	93	85.00
F9 / Optimized	195	1.5	2.4	0.60	30	98	95.33

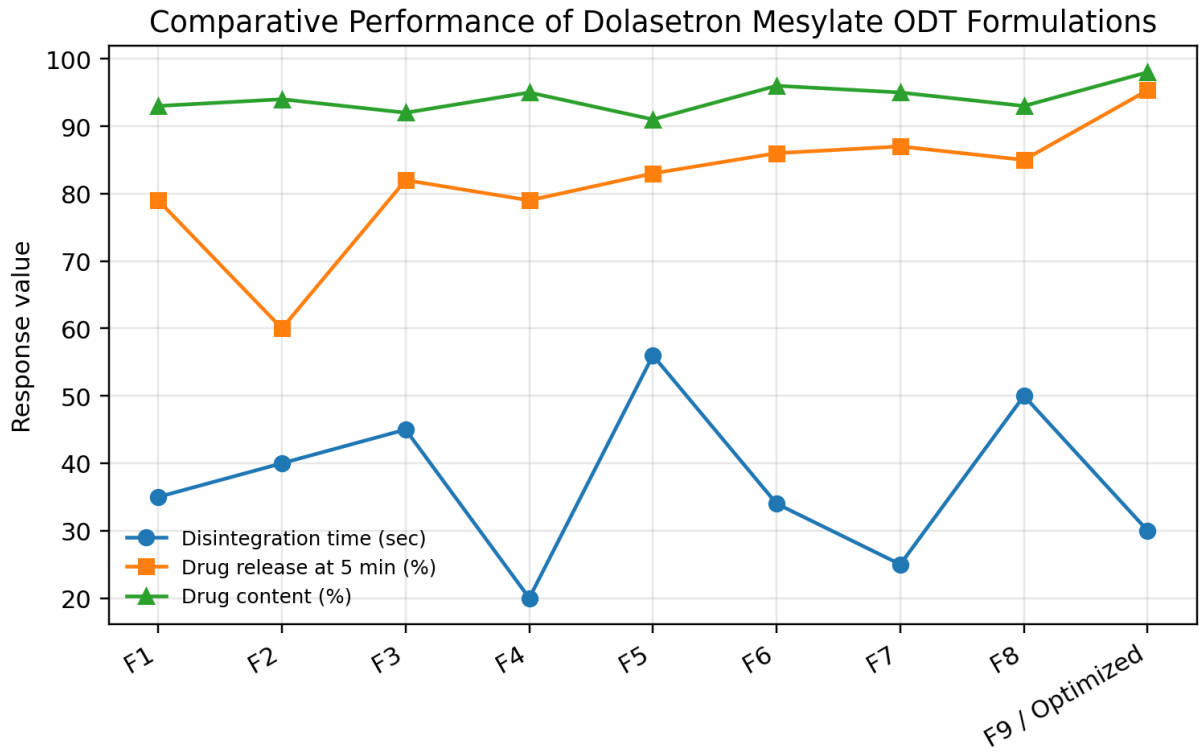

Figure 3.6: Comparative performance summary of dolasetron mesylate ODT formulations.

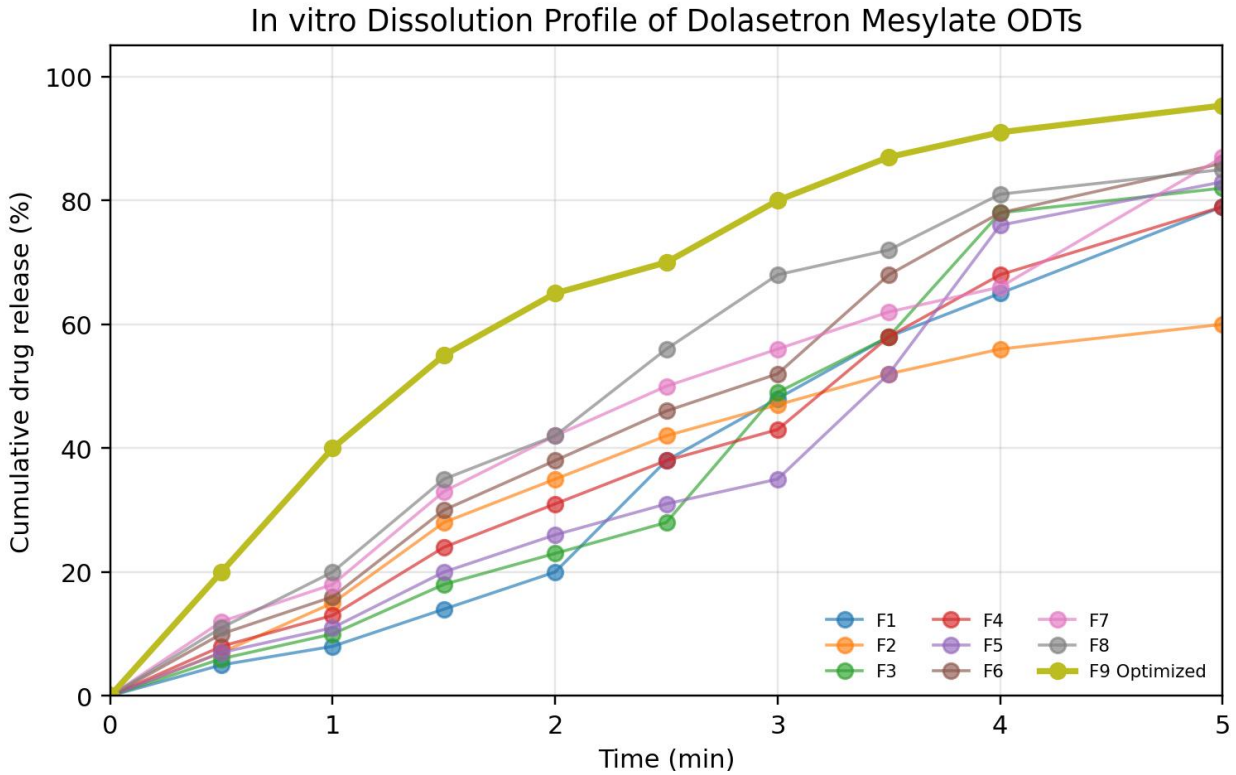

Figure 3.7: In vitro cumulative drug release profile of ODT formulations.

3.6 Stability Study

The optimized formulation remained stable for three months under the selected storage conditions. Drug content decreased only slightly from 98% initially to 97% at three months. Disintegration time increased marginally from 30 sec to 32 sec, while dissolution remained practically unchanged at approximately 95%. Hardness increased slightly from 2.4 to 2.5 kg/cm² and friability increased from 0.60% to 0.62%, remaining within acceptable limits. These results suggest that the optimized ODT retained its physical integrity and release performance during the stability study period.

Table 3.6: Stability study of optimized dolasetron mesylate ODT.

Time Point	Drug Content (%)	Disintegration Time (sec)	Dissolution (%)	Hardness (kg/cm²)	Wetting Time (sec)	Friability (%)
Initial (0 month)	98	30	95.33	2.4	10	0.60
1 Month	98	30	95.00	2.4	11	0.60
2 Months	97	31	95.00	2.5	11	0.61
3 Months	97	32	95.00	2.5	12	0.62

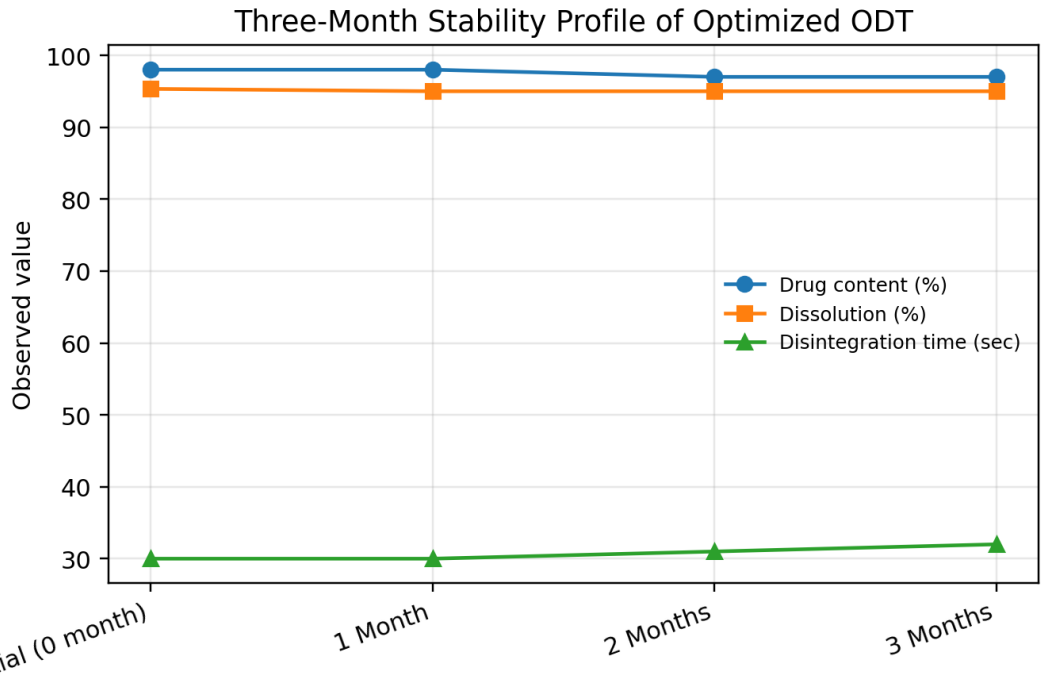

Figure 3.8: Three-month stability profile of the optimized ODT.

4. CONCLUSION

Dolasetron mesylate orally disintegrating tablets were successfully formulated by direct compression using superdisintegrants. Preformulation studies confirmed suitable physicochemical and analytical properties of the drug. FTIR and DSC studies indicated compatibility between dolasetron mesylate and the selected excipients. Factorial design established that crospovidone and croscarmellose sodium were important formulation variables affecting disintegration time, hardness, drug release and wetting time. The optimized formulation achieved rapid disintegration within 30 sec, acceptable hardness, friability below 1%, drug content of 98% and 95.33% drug release within 5 min.

Stability data showed no major change in key quality attributes during three months. The study confirms that ODT technology is a suitable patient-centric strategy for dolasetron mesylate and may improve convenience and compliance in patients experiencing nausea, vomiting or swallowing difficulty.

5. Future Perspective

Further work may include taste-masking optimization, in vivo disintegration assessment, pharmacokinetic comparison with conventional tablets, patient acceptability studies and scale-up validation. Additional accelerated and long-term stability studies should be performed according to regulatory guidelines. The use of co-processed superdisintegrants, orally disintegrating films and advanced manufacturing methods such as 3D printing may also be explored for personalized antiemetic therapy.

Declarations

Funding: No external funding information was provided in the source thesis.

Conflict of interest: The authors declare no conflict of interest.

Ethical approval: Not applicable; the study was a formulation and in vitro evaluation study.

Data availability: Data used in this manuscript were obtained from the thesis document supplied for manuscript preparation.

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