

A Research of Formulation of Fast Dissolving Tablets Using Isabgol Mucilage and Crospovidone as Binary Superdisintegrants

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Abstract

Objective: To investigate the effects of a supplied co-processed Plantago ovata (Isabgol) excipient and crospovidone on the quality and early dissolution of directly compressed ondansetron orally disintegrating tablets.

Methods: A 3² full factorial design comprised nine 200 mg formulations containing 5 mg ondansetron hydrochloride dihydrate, approximately equivalent to 4 mg ondansetron. The supplied excipient and crospovidone were varied at 10–30 mg and 4–12 mg per tablet, respectively. Tablet properties, disintegration, wetting and dissolution in pH 6.8 phosphate buffer were evaluated. Quadratic models were refitted to the nine reported batch means. A selected composition was evaluated as F-OPT and stored at 40 ± 2 °C/75 ± 5% relative humidity for three months.

Results: Across design batches, disintegration ranged from 12 to 44 s, friability from 0.32 to 0.61%, and drug release at 10 min from 67.2 to 93.1%. Crospovidone had the larger standardized-range main effect on disintegration. The disintegration model had an R² of 0.9990, although only three residual degrees of freedom were available. F-OPT contained 20 mg supplied excipient and 12 mg crospovidone, disintegrated in 13 ± 1.0 s, and showed 0.54% friability and approximately 92.0% release at 10 min. At three months, disintegration was 16 s and 10 min release was 89.4%.

Conclusion: The selected combination supported rapid in vitro disintegration with low friability. Undefined co-processing composition, limited independent batch replication and analytical-range uncertainties restrict reproducibility and interpretation. Additional material qualification, analytical validation and stability studies are needed.

Keywords: Ondansetron; orally disintegrating tablet; Plantago ovata; co-processed excipient; crospovidone; full factorial design; direct compression.

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Introduction

Orally disintegrating tablets (ODTs) aim to reduce the practical difficulty of swallowing an intact tablet with water. Their development requires simultaneous control of tablet strength, liquid uptake and rapid breakup, rather than optimization of disintegration time alone. The United States Food and Drug Administration recommends an in vitro disintegration time of approximately 30 s or less as a characteristic of this dosage form [1].

Ondansetron is available in conventional and orally disintegrating oral dosage forms. An ODT formulation may offer administration convenience, but faster laboratory disintegration does not establish improved systemic exposure or earlier antiemetic action. Approved labeling describes

corresponding strengths of ondansetron ODTs and conventional tablets as bioequivalent; such equivalence cannot be assumed for a newly developed formulation [2]. Plantago ovata mucilage is a candidate hydrophilic disintegrant, and its use alongside crospovidone in directly compressed fast-disintegrating tablets has previously been investigated. This precedent supports formulation exploration but does not establish equivalence between plain mucilage and a supplied co-processed material whose composition is undisclosed [3].

The present study examined nine combinations of a supplied co-processed Isabgol material and crospovidone in a fixed-weight ondansetron tablet.

The objectives were to characterize the material, estimate formulation-response relationships, select a practical composition balancing rapid disintegration and friability, and describe its short-term storage performance.

The experimental scope was evaluation of a supplied excipient, not development or validation of a co-processing method.

Materials and Methods

Materials and Experimental Design:

Ondansetron hydrochloride dihydrate and the supplied pharmaceutical-grade co-processed Isabgol excipient were reported as gift samples from Cipla Ltd., Mumbai. Crospovidone (Kollidon CL-M), directly compressible mannitol (Pearlitol SD 200), microcrystalline cellulose (Avicel PH-

102), aspartame, menthol, magnesium stearate and talc were used as listed in the thesis. The supplied material was used as received; its component proportions and co-processing conditions were unavailable. Consequently, "Isabgol amount" throughout this article refers to the mass of supplied material, not a verified mass of pure mucilage. The two factors were supplied excipient at 10, 20 and 30 mg/tablet and crospovidone at 4, 8 and 12 mg/tablet, corresponding to coded levels -1, 0 and +1. All tablets had a nominal mass of 200 mg. Mannitol was adjusted to compensate for changes in factor levels. Table 1 presents the experimental matrix and the selected F-OPT composition; the design therefore estimates effects of replacing mannitol with the tested factors rather than isolated factor additions at fixed diluent content.

Table 1: Factorial design and variable ingredient quantities per 200 mg tablet.

Batch	Coded X1	Coded X2	Supplied excipient (mg)	Crospovidone (mg)	Mannitol (mg)
F1	-1	-1	10	4	125
F2	-1	0	10	8	121
F3	-1	1	10	12	117
F4	0	-1	20	4	115
F5	0	0	20	8	111
F6	0	1	20	12	107
F7	1	-1	30	4	105
F8	1	0	30	8	101
F9	1	1	30	12	97
F-OPT	0	+1	20	12	107

Fixed ingredients (mg/tablet): ondansetron HCl dihydrate, 5; MCC, 40; aspartame, 6; menthol, 2; magnesium stearate, 4; talc, 4. All compositions total 200 mg. F-OPT has the same nominal composition as F6. X1 = (supplied excipient – 20)/10; X2 = (crospovidone – 8)/4. Source: thesis formulation table

Material characterization and compatibility:

Swelling index was determined after dispersing 1 g material in water to 100 mL and allowing 24 h hydration, with intermittent shaking. Loss on drying was measured at 105 °C to constant mass, and pH was measured in a 1% w/v dispersion. Bulk and tapped densities, Carr's index, Hausner ratio and fixed-funnel angle of repose were used to compare the supplied material with plain mucilage [4]. The number of independent material lots was not documented.

Fourier-transform infrared (FTIR) spectra were recorded using potassium bromide discs over 4000–400 cm⁻¹ at 4 cm⁻¹ resolution.

Differential scanning calorimetry used approximately 5 mg sample, heating from 40 to 300 °C at 10 °C/min under nitrogen at 50 mL/min. Drug–excipient mixtures were also examined visually after four weeks at 40 °C/75% relative humidity. These tests were treated as compatibility screens rather than definitive evidence excluding chemical degradation.

Direct-compression manufacture: Each design batch comprised 200 tablets. Processing was

conducted below 25 °C and below 40% relative humidity. Drug, supplied excipient and crospovidone were passed through a No. 40 sieve and geometrically blended for 10 min. Sieved mannitol and MCC were added and mixed for 10 min, followed by aspartame and menthol for 5 min. Talc was mixed for 2 min, and magnesium stearate was blended for no more than 3 min. Tablets were compressed on a rotary press using 8 mm flat-faced round punches, targeting 200 mg and the thesis-reported hardness range of approximately 2.5–3.0 kg/cm². Tablets were stored airtight with desiccant. Compression force and press speed were not reported.

Tablet testing and drug determination: Tablet mass was measured individually for 20 tablets; thickness and diameter were measured for 10 tablets using a digital caliper. Hardness was measured on 10 tablets using a Monsanto-type tester. The source reports hardness in kg/cm²; these values are retained without conversion because force calibration and test geometry were unavailable. Friability was tested using approximately 6.5 g tablets at 25 rpm for 100 revolutions, with a study criterion below 1.0% [6].

Drug content was determined from 10 individually crushed tablets using 0.1 N hydrochloric acid and UV measurement at 310 nm. Full individual assay data were unavailable.

Disintegration was measured using six tablets in purified water at 37 ± 0.5 °C. Wetting time was measured on folded tissue paper in a 6.5 cm Petri dish containing 6 mL dyed water. Water absorption ratio was calculated as $100 \times (\text{wet mass} - \text{dry mass})/\text{dry mass}$. Dispersion time was measured in 10 mL pH 6.8 phosphate buffer at 37 ± 0.5 °C. Replicate counts for wetting, absorption and dispersion were not explicitly recoverable from the source methods; their reported SDs are reproduced without assigning an assumed sample size.

The source UV calibration covered 2–20 µg/mL in 0.1 N hydrochloric acid and pH 6.8 buffer at 310 nm. Recovery was assessed at 80%, 100% and 120% nominal concentration, with intra-day and inter-day precision also reported. No new validation experiments were performed in this manuscript preparation. Specificity against excipient and degradation-product interference, the drug-base versus salt calculation basis and coverage of low-concentration dissolution samples require verification [6].

Dissolution and storage evaluation: Dissolution was performed in triplicate using USP apparatus II at 50 rpm with 900 mL pH 6.8 phosphate buffer at 37 ± 0.5 °C. Samples of 5 mL were withdrawn at 2, 4, 6, 8, 10, 15, 20 and 30 min and replaced with fresh medium. Samples were analyzed at 310 nm. Published thesis values were transcribed without reconstructing unavailable vessel-level measurements or applying an undocumented sampling correction. Release at 10 min is denoted Q10.

F-OPT tablets in aluminium blisters were stored at 40 ± 2 °C/ $75 \pm 5\%$ relative humidity, with evaluation at baseline and one, two and three months. Appearance, hardness, friability, disintegration, wetting, drug content and release were monitored. This was a three-month

accelerated-condition screening study, not a complete shelf-life assessment [7].

Statistical reanalysis and selection: Ordinary least-squares quadratic models were refitted to the nine published batch means for disintegration time, wetting time and Q10.

Each model contained an intercept, two main effects, their interaction and two squared terms. R^2 , adjusted R^2 , the overall model F-test and leave-one-out prediction R^2 were calculated from those means. Each model had five regression and three residual degrees of freedom. No independent pure-error estimate was available for a lack-of-fit test; tablet or vessel replicates were not treated as independently manufactured formulation batches.

$$Y = b_0 + b_1 X_1 + b_2 X_2 + b_{12} X_1 X_2 + b_{11} X_1^2 + b_{22} X_2^2$$

For comparison of tested formulations, equally weighted linear desirabilities were recalculated using the thesis-stated limits: disintegration, 8–45 s; wetting, 10–60 s; Q10, 60–100%; and friability, 0.2–1.0%. The first, second and fourth responses were minimized, and Q10 was maximized. Individual desirabilities were clipped to 0–1 and combined as their geometric mean [9].

The selected composition was evaluated as F-OPT. Checkpoint predictions were recalculated using the refitted models, with percentage error defined as $100 \times (\text{observed} - \text{predicted})/\text{predicted}$.

Results

Supplied material and compatibility screens:

Compared with plain mucilage, the supplied co-processed material had a lower angle of repose and lower compressibility index, with a higher bulk density. Its swelling index was lower but remained substantial at 33.8 ± 0.9 mL/g. These results support the handling characteristics of the particular material evaluated, without identifying which component or processing step produced the differences. Selected characterization data are shown in Table 2.

Table 2: Characterization of plain mucilage and supplied co-processed material.

Property	Plain mucilage	Supplied material
Swelling index (mL/g, 24 h)	41.6 ± 1.2	33.8 ± 0.9
Loss on drying (% w/w)	9.4 ± 0.3	6.8 ± 0.2
pH (1% w/v dispersion)	6.7 ± 0.1	6.9 ± 0.1
Bulk density (g/mL)	0.312 ± 0.006	0.468 ± 0.005
Tapped density (g/mL)	0.428 ± 0.007	0.541 ± 0.006
Carr's index (%)	27.10	13.49
Hausner ratio	1.37	1.16
Angle of repose (°)	41.8 ± 1.1	27.4 ± 0.8

Values are reproduced as reported in the thesis; mean $\pm$ SD where provided. Replicate counts and independent lot numbers were not specified. Source: thesis material-characterization table.

The drug carbonyl FTIR band was reported at 1640 cm^{-1} and retained at 1638 cm^{-1} in the physical mixture. The drug thermal event was retained near 178.2 °C in the mixture compared with 179.0 °C for the drug alone. No marked visual changes were reported after four weeks, apart from slight reversible caking in one mixture.

A thermal event near 166 °C was attributed in the thesis to mannitol in the supplied material; the proprietary composition was not independently confirmed.

Tablet quality and hydration responses: Design batches showed mean tablet masses of 199.2–200.0 mg, thicknesses of 3.17–3.25 mm and reported drug content of 99.11–100.57%. Hardness

decreased overall from 3.03 kg/cm^2 in F1 to 2.48 kg/cm^2 in F9, while friability increased from 0.32 to 0.61%. All reported friability values remained below the study criterion of 1.0%. Individual assay acceptance values were not available to establish formal content-uniformity compliance. Disintegration and wetting times decreased as crospovidone increased, with diminishing additional benefit from higher supplied-exipient levels (Table 3 and Figure 1).

At 4 mg crospovidone, increasing supplied material from 10 to 20 to 30 mg reduced disintegration from 44 to 31 to 27 s. At 12 mg crospovidone, the corresponding values were 22, 13 and 12 s. Six of nine design-batch mean disintegration times were below 30 s.

Table 3: Mechanical properties and key performance responses.

Batch	Hardness†	Friability (%)	DT (s)	WT (s)	Q10 (%)
F1	3.03 ± 0.13	0.32	44 ± 2.3	58 ± 3.3	67.2 ± 0.5
F2	2.92 ± 0.08	0.37	31 ± 1.7	40 ± 2.4	76.1 ± 1.2
F3	2.76 ± 0.12	0.42	22 ± 1.4	30 ± 1.9	83.2 ± 1.2
F4	2.87 ± 0.13	0.42	31 ± 1.7	42 ± 2.5	76.6 ± 1.3
F5	2.86 ± 0.11	0.46	21 ± 1.3	28 ± 1.8	84.9 ± 1.7
F6	2.67 ± 0.13	0.51	13 ± 1.0	18 ± 1.3	93.1 ± 1.3
F7	2.73 ± 0.11	0.48	27 ± 1.6	37 ± 2.2	80.4 ± 1.1
F8	2.64 ± 0.15	0.56	17 ± 1.2	22 ± 1.5	88.8 ± 1.2
F9	2.48 ± 0.09	0.61	12 ± 1.0	18 ± 1.3	92.7 ± 1.6

DT: disintegration time; WT: wetting time; Q10: cumulative release at 10 min. Values are means ± reported SD where available; DT n = 6, hardness n = 10, dissolution n = 3. WT replicate count and friability replicate number were not documented. †Hardness unit retained as kg/cm^2 from the source; calibration requires verification. Source: thesis tablet evaluation and dissolution tables.

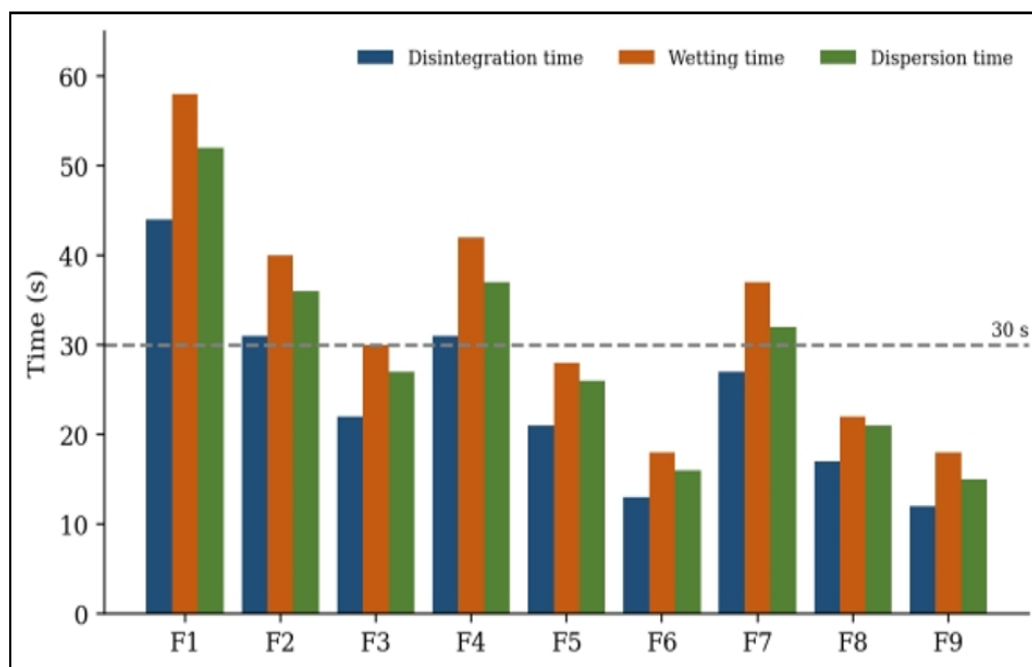


Figure 1: Disintegration and wetting times for design formulations F1–F9. Bars show reported means and SDs; disintegration n = 6, wetting replicate count unspecified.

The dashed line marks the approximately 30 s FDA ODT benchmark, not a wetting-time acceptance limit [1]. Data reconstructed from the thesis.

Water absorption increased from $51.9 \pm 1.5\%$ in F1 to $95.8 \pm 1.8\%$ in F9. Nevertheless, the greater uptake in F9 did not translate into a proportionate reduction in disintegration relative to F6 ($83.5 \pm 1.4\%$ uptake; 13 ± 1.0 s disintegration). This divergence indicates that bulk liquid uptake alone was insufficient to describe the formulation response.

Dissolution and factorial models: At 10 min, release ranged from $67.2 \pm 0.5\%$ for F1 to $93.1 \pm 1.3\%$ for F6, while F9 released $92.7 \pm 1.6\%$. All nine reported mean profiles reached at least 94.1% by 30 min. The most pronounced separation occurred in the earlier samples, although the earliest low-concentration measurements require analytical-range verification. Figure 2 reproduces all measured design-batch profiles without inventing an F-OPT profile from its endpoint summaries.

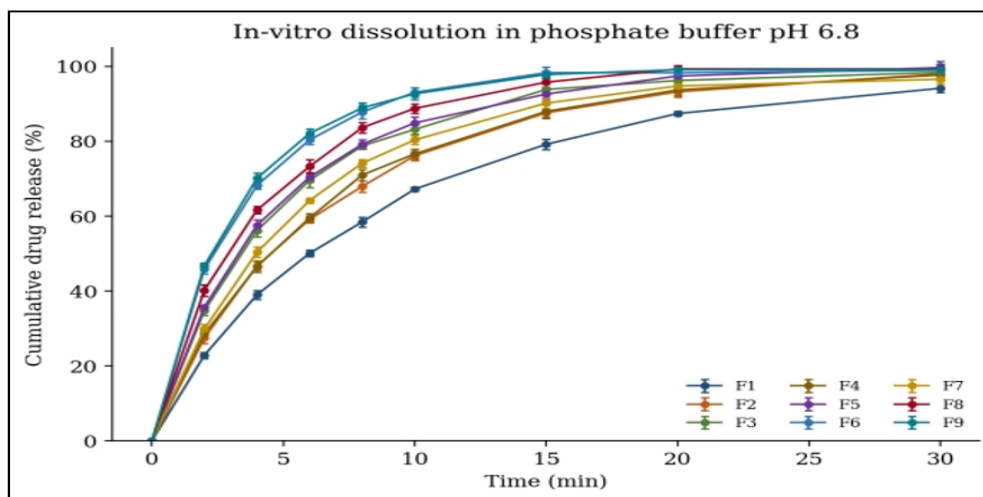


Figure 2: Reported dissolution profiles of F1–F9 in 900 mL phosphate buffer pH 6.8 at 37 ± 0.5 °C, USP apparatus II, 50 rpm. Points and error bars represent reported mean $\pm$ SD ($n = 3$). Only measured sampling times are plotted; no zero-time observation is assumed. Source: thesis dissolution table.

The refitted disintegration, wetting and Q10 models yielded R^2 values of 0.9990, 0.9969 and 0.9940, respectively (Table 4). Crospovidone had the larger absolute main-effect coefficient over the studied factor ranges. Positive interaction coefficients for

disintegration and wetting indicate attenuation of the combined time-reduction benefit relative to a purely additive response; they do not establish mechanistic synergy. The model contour in Figure 3 illustrates this response within the tested domain.

Table 4: Quadratic coefficients and fit statistics recalculated from reported means.

Term/statistic	DT model	WT model	Q10 model
Intercept	20.444	26.778	85.578
X1	-6.833	-8.500	5.900
X2	-9.167	-11.833	7.467
X1 $\times$ X2	1.750	2.250	-0.925
X1 ²	3.833	4.833	-3.467
X2 ²	1.833	3.833	-1.067
R ²	0.9990	0.9969	0.9940
Adjusted R ²	0.9972	0.9919	0.9839
Leave-one-out R ²	0.9914	0.9744	0.9349
Overall F	580.200	195.977	98.755
Overall p	0.000113	0.000571	0.001585

Responses: DT and WT in seconds; Q10 in percent. Each model uses nine batch means, five regression degrees of freedom and three residual degrees of freedom. Leave-one-out R^2 is an internal prediction diagnostic, not external validation. Minor Q10 differences from the thesis coefficient/ANOVA tables arise from refitting the displayed dissolution values; raw unrounded data were unavailable. Source: reanalysis of thesis numerical tables.

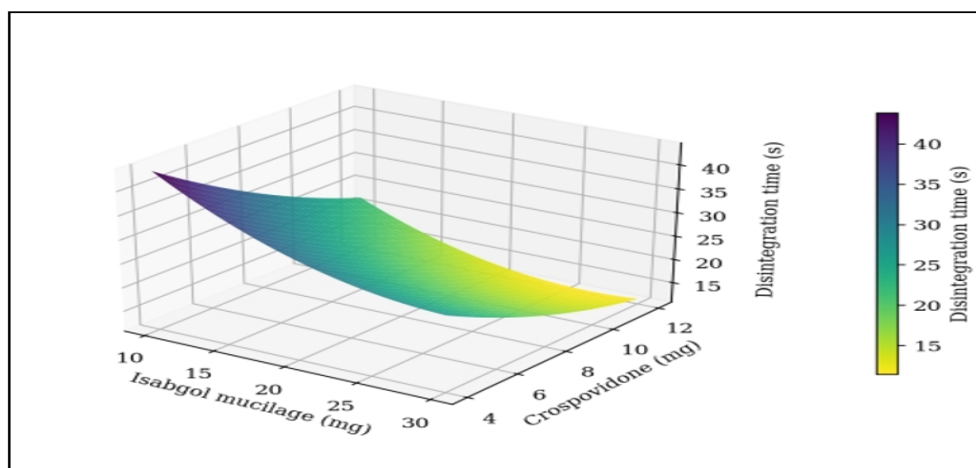


Figure 3. Quadratic model prediction for disintegration time across the tested supplied-excipient and crospovidone ranges. Open circles denote the nine design compositions and the star denotes the selected F-OPT composition (20/12 mg). Contours show model estimates, not additional experiments or a validated regulatory design space. The mass on the horizontal axis is supplied material.

Selected composition and storage performance:

Recalculated desirability was highest among tested batches for F6 (0.779), followed by F9 (0.739) and F8 (0.691). F6 therefore provided a practical compromise between rapid breakup, early release and friability.

The same nominal composition was evaluated as F-OPT; it is described as the selected formulation, not a proven global optimum. The refitted model predicted 13.11 s disintegration, 18.78 s wetting and 91.98% Q10, compared with observed values

of 13 s, 20 s and 92.01%, respectively. Absolute checkpoint errors for CP-1 and CP-2 were at most 8.55% across these three responses. F-OPT had reported hardness of 2.64 ± 0.11 kg/cm², friability of 0.54%, drug content of $99.7 \pm 0.6\%$, disintegration of 13 ± 1.0 s, wetting of 20 ± 1.3 s and dispersion of 15 ± 1.1 s. Its mass data gave a recalculated mean of 200.11 mg and SD of 0.85 mg for 20 tablets, with a maximum absolute deviation of approximately 1.05% from the mean. The storage results in Table 5 show gradual changes rather than absence of change.

Table 5: F-OPT during three-month accelerated-condition storage.

Parameter	Baseline	1 month	2 months	3 months
Hardness (kg/cm ²)	2.64	2.62	2.57	2.53
Friability (%)	0.54	0.56	0.59	0.61
Disintegration time (s)	13	14	15	16
Wetting time (s)	20	21	22	23
Drug content (%)	99.7	99.3	98.9	98.5
Drug release at 10 min (%)	92.0	92.0	91.1	89.4
Drug release at 30 min (%)	99.3	99.5	98.9	99.1

Aluminium-blister storage at 40 ± 2 °C/ $75 \pm 5\%$ RH. Appearance remained unchanged. Numbers are reproduced from the thesis; storage-table SDs, replicate counts and independent stability-batch counts were unavailable. Hardness unit is kg/cm² as reported. These data do not establish shelf life or formal ICH compliance. From baseline to three months, disintegration increased from 13 to 16 s, friability from 0.54 to 0.61%, and wetting from 20 to 23 s. Drug content decreased from 99.7 to 98.5%, and Q10 from 92.0 to 89.4%; release at 30 min remained 99.1%. Without replicate-level storage data, statistical equivalence or a claim of “no significant change” was not assessed.

Discussion

The tested combination achieved the intended in vitro balance: rapid breakup without friability exceeding the study criterion. The smaller improvement between 20 and 30 mg supplied material, particularly at 12 mg crospovidone, supports selecting the intermediate material level rather than maximizing total Disintegrant. Because mannitol decreased as factor amounts increased and tablet hardness changed concurrently, the response cannot be attributed exclusively to either polymer.

Hydration-induced swelling of mucilage and recovery of compressed crospovidone particles offer plausible explanations, but these mechanisms were not measured directly. Imaging research has

identified strain recovery as important for crospovidone; describing its action only as wicking would therefore be incomplete [9]. Formulation dependence also limits transfer of an optimum between products. Prior experimental work on disintegrant mixtures demonstrates that their effects depend on drug and compaction conditions, including possible slowing at higher concentrations [10]. In this study, positive time-response interaction terms and curvature are consistent with diminishing benefit, but do not independently prove gel formation or a particular microscopic mechanism. The high model R^2 values summarize the nine reported means well, but six fitted coefficients leave only three residual degrees of freedom. The checkpoint batches provide limited support for local prediction; they do not replace independent multi-batch confirmation, process robustness testing or material-lot assessment. Furthermore, characterization of a co-processed material cannot establish a co-processing advantage at tablet level without matched formulations containing plain mucilage or appropriate single-disintegrant controls. Analytical range is a material qualification. A nominal 4 mg dose distributed in 900 mL corresponds to approximately 4.44 $\mu\text{g/mL}$ at complete release on an ondansetron-base basis. Consequently, release below approximately 45% would produce concentrations below the stated 2 $\mu\text{g/mL}$ calibration minimum before any further dilution. This affects several early observations, although Q10 values are above that threshold on the same basis. Verification is needed for sample preparation, the salt/base basis, lower-range accuracy and specificity; current validation guidance links reportable range to demonstrated response, accuracy and precision [7].

The three-month study supports preliminary resistance to accelerated-condition exposure, with measurable trends in early release and disintegration. General-case ICH Q1A(R2) accelerated stability packages describe six months of data and stability-indicating procedures; the present shorter study cannot establish a commercial shelf life. A UV content assay without demonstrated discrimination of degradation products is not sufficient evidence of chemical stability [6, 7]. This in vitro report does not establish palatability, improved adherence, increased bioavailability or earlier clinical antiemetic action. Taste observations described in the thesis were not used to support these conclusions because approval identifiers and the full assessment protocol were not available in the supplied document. A target-journal submission should be supported by source records, independently verified material identity and appropriately documented confirmatory studies.

Conclusion

Within the tested formulation ranges, a 200 mg tablet containing 20 mg supplied co-processed Plantago ovata material and 12 mg crospovidone achieved 13 ± 1.0 s in vitro disintegration, 0.54% friability and approximately 92.0% release at 10 min. The selected composition showed promising short-term performance but remains an exploratory formulation. Reproducible material specifications, confirmation of analytical suitability, independent batch validation and longer stability assessment are necessary before stronger product-development claims are justified.

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