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Development and Evaluation of Fast Dissolving Tablets of Ondansetron

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Abstract: *The present study aimed to formulate and evaluate Fast Dissolving Tablets (FDTs) of Ondansetron to enhance patient compliance and achieve rapid onset of action. Ondansetron, a selective 5-HT3 receptor antagonist, is widely used as an antiemetic. Using the direct compression technique, six formulations (F1–F6) were developed with varying concentrations of superdisintegrants—Crospovidone and Sodium Starch Glycolate (SSG). Preformulation studies confirmed drug purity and compatibility with excipients through FTIR analysis. Evaluation of powder blends indicated excellent flow properties. The compressed tablets were assessed for hardness, friability, weight variation, drug content, disintegration time, and in vitro drug release.*

Among all, F3 and F6 demonstrated optimal results, showing disintegration within 20–25 seconds and >90% drug release in 10 minutes. Taste evaluation revealed acceptable palatability. Stability studies (under ICH guidelines) over three months confirmed formulation integrity. The study concluded that fast dissolving tablets of Ondansetron can be successfully formulated using superdisintegrants via direct compression, offering a promising solution for rapid therapeutic action and improved patient adherence.

Keywords: Fast Dissolving Tablet, Ondansetron, Crospovidone, Sodium Starch Glycolate, Direct Compression, Superdisintegrants, Taste Masking, Patient Compliance.

I. INTRODUCTION

1.1 Oral Drug Delivery System

The oral route is the most preferred and commonly used method for drug administration, primarily because of its simplicity, convenience, cost-effectiveness, and high patient compliance. Oral dosage forms include tablets, capsules, powders, and liquids, among which tablets are the most widely accepted due to their accuracy of dosage, portability, stability, and ease of production.

Oral drug delivery systems are designed to deliver drugs through the mouth into the gastrointestinal tract, where the drug is then absorbed into the systemic circulation.

Advantages of Oral Drug Delivery

- Non-invasive and safe compared to parenteral routes.
- Easy to administer, especially for chronic therapy.
- Flexible dosage forms (e.g., tablets, capsules, suspensions).
- Cost-effective manufacturing.
- Improved compliance, especially in outpatient settings.

Challenges Associated with Oral Drug Delivery

- Poor bioavailability of some drugs due to enzymatic degradation or first-pass metabolism.
- Delayed onset of action compared to other routes like intravenous or sublingual.

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- Variability in absorption due to food effects or gastrointestinal pH.
- Not suitable for unconscious, vomiting, or dysphagic patients.

1.2 Fast Dissolving Tablets (FDTs)

Fast Dissolving Tablets (FDTs)—also known as orodispersible tablets (ODTs), mouth-dissolving tablets, or rapidly disintegrating tablets—are a novel class of solid oral dosage forms designed to disintegrate and dissolve rapidly in the saliva (typically within 30–60 seconds) without the need for water or chewing.

According to the European Pharmacopoeia, an orodispersible tablet is a tablet that disintegrates in less than three minutes in the oral cavity before swallowing. However, most FDTs are formulated to disintegrate within 30 seconds to 1 minute.

Key Features of FDTs

- Disintegrate or dissolve quickly in saliva
- Do not require water for administration
- Can be taken anywhere, anytime
- Masking of unpleasant taste is often necessary
- May provide faster onset of action due to pre-gastric absorption

1.3 Need for Fast Dissolving Tablets

The development of Fast Dissolving Tablets (FDTs) addresses several clinical and practical limitations associated with conventional oral dosage forms. The need for FDTs arises primarily from the demand for improved patient compliance, faster onset of action, and greater convenience in drug administration.

1.4 Advantages of Fast Dissolving Tablets

- Improved Patient Compliance
- No Need for Water
- Rapid Onset of Action
- Convenient Administration
- Enhanced Bioavailability
- Better Taste and Mouthfeel
- Reduced Risk of Choking
- Customizable for Different Drug Classes

1.5 Challenges in FDT Formulation

- Mechanical Strength vs. Disintegration Time
- Taste Masking
- Moisture Sensitivity
- Limited Drug Loading
- Uniformity and Content Consistency
- Compatibility with Superdisintegrants
- Cost and Technology Constraints

1.6 Technologies Used in Formulation of FDTs

- Direct Compression
- Lyophilization (Freeze Drying)
- Sublimation
- Spray Drying

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- Molding
- Mass Extrusion
- Cotton Candy Process
- Nanotechnology-based FDTs

1.7 Selection Criteria for Drugs Suitable for FDT Formulation

Not all drugs are ideal candidates for Fast Dissolving Tablet (FDT) formulation. Selection depends on several factors related to dose, solubility, stability, therapeutic need, and pharmacokinetics.

1.7.1 Dose of the Drug

Ideal for drugs with a low to moderate dose (typically ≤500 mg). High-dose drugs may compromise tablet size, mechanical strength, and disintegration time. Examples: Cetirizine (10 mg), Rizatriptan (5–10 mg), Loratadine (10 mg).
Examples of Suitable Drugs for FDTs

Drug	Category	Dose (mg)	Suitability for FDT
Cetirizine	Antihistamine	10	Yes (low dose, rapid onset)
Ondansetron	Antiemetic	4–8	Yes (nausea/vomiting)
Rizatriptan	Antimigraine	5–10	Yes (acute migraine)
Paracetamol	Analgesic/antipyretic	250–500	Yes (with taste masking)
Loratadine	Antiallergic	10	Yes

II. DRUG PROFILE

2.1 Drug Name

Ondansetron

2.2 Classification

- Therapeutic Class: Antiemetic
- Pharmacological Class: 5-HT3 receptor antagonist

2.4 Molecular Formula and Molecular Weight

- Molecular Formula: C18H19N3O
- Molecular Weight: 293.37 g/mol

2.5 IUPAC Name

9-methyl-3-[(2-methyl-1H-imidazol-1-yl) methyl]-1,2,3,9-tetrahydro-4H-carbazol-4-one

2.6 Description

Ondansetron is a selective serotonin 5-HT3 receptor antagonist used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy, or surgery. It acts both centrally and peripherally, making it highly effective for chemotherapy-induced nausea and vomiting (CINV).

2.7 Mechanism of Action

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Ondansetron blocks the action of serotonin at 5-HT3 receptors, which are found on vagal nerve terminals in the peripheral nervous system and centrally in the chemoreceptor trigger zone (CTZ) of the area postrema. This inhibition helps suppress the nausea reflex triggered by various stimuli, including cytotoxic agents.

2.8 Pharmacokinetics

Parameter	Description
Absorption	Rapidly absorbed after oral administration
Bioavailability	~60% due to first-pass metabolism
Tmax	1.5 to 2 hours
Protein Binding	~70%
Half-life	3 to 6 hours
Metabolism	Hepatic via CYP3A4, CYP1A2, CYP2D6
Excretion	Urine (renal), feces (biliary)

2.9 Therapeutic Uses

- Chemotherapy-induced nausea and vomiting (CINV)
- Post-operative nausea and vomiting (PONV)
- Radiation-induced nausea and vomiting
- Off-label: Gastroenteritis, hyperemesis gravidarum

2.10 Dosage

Population	Typical Oral Dose
Adults (CINV)	8 mg 1-2 hours before chemotherapy
Post-operative	4-8 mg single dose
Pediatrics	0.15 mg/kg (max 16 mg/day)

2.11 Side Effects

- Headache
- Dizziness
- Constipation
- Fatigue
- QT interval prolongation (rare but serious)

2.12 Marketed Formulations

Brand Name	Strength	Form
Ondem MD	4 mg, 8 mg	Mouth dissolving tablet

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Brand Name	Strength	Form
Emeset MD	4 mg, 8 mg	Orodispersible tablet
Zofer MD	4 mg, 8 mg	Fast dissolving tablet

III. LITERATURE REVIEW

3.1 Introduction

A comprehensive literature review provides the necessary scientific background for any pharmaceutical formulation project. For Fast Dissolving Tablets (FDTs), literature review is crucial to understand previous research outcomes, analyze technological developments, assess the effectiveness of excipients, identify research gaps, and refine formulation strategies.

3.2 Review on Fast Dissolving Tablets

Since their introduction in the 1990s, FDTs have drawn considerable attention due to their ease of administration, rapid onset of action, and improved patient compliance. Studies emphasize the critical role of disintegration time and tablet porosity, importance of excipient compatibility, and formulation approaches to improve bioavailability and organoleptic properties.

3.3 Superdisintegrants Used in FDTs

- Crospovidone (Polyplasdone XL): Swells without forming a gel; facilitates wicking.
- Croscarmellose Sodium: Absorbs water and swells instantly.
- Sodium Starch Glycolate (SSG): Exhibits rapid swelling through capillary action.
- Low-Substituted Hydroxypropyl Cellulose (L-HPC): Useful in direct compression with minimal gelling.
- Pregelatinized Starch: Dual function as binder and disintegrant.

3.4 Technologies Used for FDT Formulation

Direct Compression: The most practical method for industrial scale-up, especially for moisture- and heat-sensitive drugs (Kalyan and Bansal, 2009).

Freeze Drying (Lyophilization): Produces highly porous, fragile tablets with fast disintegration; costly and time-consuming (Reddy et al., 2002).

Sublimation Technique: Uses volatile substances like camphor or menthol that are sublimated post-tablet formation, leaving a porous matrix (Patel et al., 2007).

3.8 Gaps Identified in Literature

- Simultaneous Taste Masking and Fast Disintegration: Limited studies combining both effectively.
- Scalable Production Techniques: Freeze-drying and molding methods have poor industrial scalability.
- Long-Term Stability Data: Many studies do not evaluate tablet stability under ICH conditions.
- Use of Natural Superdisintegrants and Bioenhancers: Scope for exploring natural, biodegradable excipients.

IV. AIM AND OBJECTIVES

4.1 Aim of the Study

The primary aim of this project is to formulate and evaluate Fast Dissolving Tablets (FDTs) of a selected drug using various superdisintegrants and formulation techniques, with the goal of enhancing patient compliance, onset of action, and therapeutic efficacy.

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4.2 Objectives of the Study

1. Preformulation Studies
   - To perform drug identification and characterization.
   - To evaluate solubility, melting point, compatibility with excipients (FTIR).
   - To study flow properties of the drug and excipient blends.

2. Selection of Excipients
   - To choose suitable superdisintegrants (e.g., Crospovidone, SSG, CCS).
   - To select appropriate binders, diluents, lubricants, and flavoring agents.

3. Formulation Development
   - To formulate a series of FDTs using direct compression.
   - To prepare trial batches (F1 to F9) using varying concentrations of superdisintegrants.

4. Evaluation of FDTs
   - To evaluate pre-compression parameters: bulk density, tapped density, Carr's index, Hausner's ratio, angle of repose.
   - To evaluate post-compression parameters: weight variation, hardness, thickness, friability, drug content.
   - To assess FDT-specific tests: disintegration time, wetting time, water absorption ratio, in vitro dispersion.

4.3 Significance of the Study

- Enhancing the therapeutic utility of drugs needing rapid onset.
- Developing a patient-friendly dosage form for those with swallowing difficulties.
- Improving formulation design and manufacturing feasibility for industrial application.

V. MATERIALS AND METHODS

5.1 Materials

Sr. No.	Name of Material	Purpose
1	Ondansetron	Active pharmaceutical ingredient
2	Crospovidone	Superdisintegrant
3	Sodium Starch Glycolate	Superdisintegrant
4	Croscarmellose Sodium	Superdisintegrant
5	Mannitol	Diluent
6	Aspartame	Sweetener
7	Talc	Glidant
8	Magnesium Stearate	Lubricant
9	Vanilla flavor	Flavoring agent
10	Distilled Water	Used wherever required

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5.2 Instruments Used

Sr. No.	Instrument/Equipment	Purpose
1	Digital balance	Weighing ingredients
2	Tablet punching machine	Tablet compression
3	Vernier caliper	Tablet diameter/thickness
4	Disintegration test apparatus	Disintegration time measurement
5	Friabilator	Friability testing
6	Hardness tester	Tablet hardness
7	UV-Visible spectrophotometer	Drug content / dissolution studies
8	pH meter	pH measurement
9	Hot air oven	Drying / stability study
10	Sieves	Powder uniformity

5.3 Method of Preparation: Direct Compression Method

Step 1: Sifting
All ingredients (except magnesium stearate and talc) were passed through sieve #60 to ensure uniform particle size.

Step 2: Dry Mixing
The sifted materials were mixed thoroughly in a mortar for 10–15 minutes to achieve uniform blending.

Step 3: Addition of Lubricants
Talc and magnesium stearate were added and blended gently for 2–3 minutes.

Step 4: Compression
The final blend was compressed into tablets using a single-punch tablet machine using 6 mm flat-faced punches.

5.4 Formulation Design

Ingredients (mg/tab)	F1	F2	F3	F4	F5	F6
Ondansetron	4	4	4	4	4	4
Crospovidone	4	6	8	—	—	—
SSG	—	—	—	4	6	8
Mannitol	70	68	66	70	68	66
Aspartame	2	2	2	2	2	2
Vanilla flavor	1	1	1	1	1	1
Magnesium Stearate	1.5	1.5	1.5	1.5	1.5	1.5

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Ingredients (mg/tab)	F1	F2	F3	F4	F5	F6
Talc	1.5	1.5	1.5	1.5	1.5	1.5
Total	84	84	84	84	84	84

VI. PREFORMULATION STUDIES

6.1 Introduction

Preformulation studies are the preliminary investigations that provide critical information about the physicochemical properties of the drug and its compatibility with excipients.

6.2 Preformulation Parameters Studied

6.2.1 Organoleptic Properties

Parameter	Observation
Appearance	White, crystalline powder
Taste	Bitter
Odor	Odorless
Solubility	Soluble in water and methanol, slightly soluble in ethanol

6.2.2 Melting Point Determination

- Method Used: Capillary method
- Observed Melting Point: 180–182°C
- Reported MP: 181°C
- Inference: Confirms purity of drug.

6.2.4 Drug-Excipient Compatibility Study (FTIR Analysis)

Purpose: To detect any possible physical or chemical interactions between Ondansetron and excipients. FTIR spectra of pure drug and mixtures were recorded using KBr pellet technique.

Key Functional Groups Identified: C=O (carbonyl group) stretching around 1700 cm-1, N-H bending, Aromatic C-H stretching.

Inference: No major shifting or disappearance of characteristic peaks in the drug-excipient mixtures — indicates no interaction.

6.2.5 Flow Properties of Powder Blend

Parameter	Formula / Method	Result (Avg.)	Inference
Angle of Repose (°)	Fixed funnel method	26.8 ± 1.5	Good flow
Bulk Density (g/cm³)	Mass / Bulk volume	0.48 ± 0.03	—
Tapped Density (g/cm³)	Mass / Tapped volume	0.56 ± 0.02	—
Carr's Index (%)	(TD − BD) / TD × 100	14.3 ± 1.2	Good flow

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Parameter	Formula / Method	Result (Avg.)	Inference
Hausner's Ratio	Tapped Density / Bulk Density	1.17 ± 0.03	Acceptable flow

6.2.6 Calibration Curve of Ondansetron

- Solvent Used: Phosphate buffer pH 6.8
- λmax: 248 nm
- Concentration Range: 2–10 µg/mL
- Linearity Equation: y = 0.087x + 0.003
- Correlation Coefficient (R^2): 0.999
- Inference: The method is linear in the tested range.

VII. FORMULATION OF FAST DISSOLVING TABLETS

7.1 Introduction

The development of fast dissolving tablets (FDTs) involves careful selection of excipients, formulation technique, and optimization of superdisintegrants to achieve quick disintegration and acceptable mechanical strength. In this study, direct compression was chosen due to its simplicity, cost-effectiveness, and feasibility for scale-up.

7.2 Method of Preparation

Technique Used: Direct Compression

1. **Weighing:** All ingredients were accurately weighed.
2. **Sifting:** Drug and excipients (except talc and magnesium stearate) were passed through sieve #60.
3. **Mixing:** Ingredients were mixed homogeneously using geometric dilution method for 15 minutes.
4. **Lubrication:** Magnesium stearate and talc were added and mixed for 2–3 minutes.
5. **Compression:** Tablets were compressed using a single-punch tablet machine using 6 mm flat-faced punches.

VIII. EVALUATION OF FAST DISSOLVING TABLETS

8.2 Pre-Compression Parameters

Parameter	Method	Result Range	Inference
Angle of Repose (°)	Funnel method	26.3 – 29.7	Good flow
Bulk Density (g/cm³)	Bulk volume method	0.48 – 0.52	Acceptable
Tapped Density (g/cm³)	Tapped volume method	0.55 – 0.59	Acceptable
Carr's Index (%)	CI = [(TD − BD)/TD] × 100	12 – 15%	Good compressibility
Hausner's Ratio	HR = TD / BD	1.13 – 1.18	Acceptable flow

8.3 Post-Compression Parameters

8.3.3 Hardness

- Method: Monsanto hardness tester
- Range: 3.2 – 3.8 kg/cm²
- Inference: Sufficient to withstand handling and transportation.

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8.3.4 Friability

- Apparatus: Roche friabilator
- Limit: Should be <1%
- Result: 0.42 – 0.58%
- Inference: Passed friability test.

8.3.6 Disintegration Time (DT)

- Apparatus: USP disintegration test apparatus (in 900 mL water at 37 ± 2°C)
- Limit: Should disintegrate within 1 minute
- Result: 18 to 36 seconds
- Inference: All formulations met FDT criteria.

8.3.9 Drug Content Uniformity

- Method: UV Spectrophotometry at 248 nm
- Limit: 90–110% (as per IP)
- Result: 98.6 – 101.2%
- Inference: Within acceptable range.

8.3.10 In Vitro Dissolution Studies

- Apparatus: USP Type II (Paddle)
- Medium: 900 mL phosphate buffer pH 6.8
- Speed: 50 rpm
- Temperature: 37 ± 0.5°C
- Result: F3 (8% Crospovidone) and F6 (8% SSG) showed >90% drug release within 10 minutes

8.4 Conclusion

All six formulations met the essential criteria for FDTs. Among them, F3 (Crospovidone 8%) and F6 (SSG 8%) demonstrated the most desirable characteristics with fastest disintegration time, excellent drug release profile, and acceptable taste and mouthfeel.

IX. STABILITY STUDIES

9.1 Introduction

Stability studies are essential to determine the effect of environmental factors such as temperature, humidity, and light on the quality of the formulated tablets.

9.3 Methodology

- Storage Conditions: 40°C ± 2°C and 75% ± 5% RH (Relative Humidity)
- Duration: 3 months
- Packaging: Tablets were stored in amber glass vials with desiccants.
- Sampling Intervals: 0, 30, 60, and 90 days

9.5 Results

Parameter	Initial	1 Month	2 Months	3 Months	Inference
Physical	White, no	No change	No change	No change	Stable physical form

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Parameter	Initial	1 Month	2 Months	3 Months	Inference
Appearance	change				
Hardness (kg/cm²)	3.5	3.4	3.3	3.3	Slight decrease but acceptable
Friability (%)	0.45	0.48	0.51	0.53	<1% - Stable
Disintegration Time (sec)	20	21	22	23	Slight increase but within limit
Drug Content (%)	99.8	99.2	98.7	98.3	Within acceptable limits (90-110%)
Drug Release (%) at 10 min	92	90	89	88	Slight decrease but acceptable

9.6 Discussion

The optimized formulations (F3 and F6) showed minimal changes under accelerated stability conditions. The tablets maintained their physical integrity, mechanical strength, and drug release profiles indicating good formulation stability. The fast dissolving tablets of Ondansetron formulated by direct compression with crospovidone and sodium starch glycolate as superdisintegrants are stable for at least 3 months under accelerated conditions, suggesting a promising shelf life.

X. SUMMARY AND CONCLUSION

10.1 Summary

This study focused on the formulation and evaluation of fast dissolving tablets of Ondansetron by the direct compression method, aiming to enhance patient compliance and ensure rapid onset of action.

- Preformulation studies confirmed drug purity, compatibility with excipients, and suitable flow properties for compression.
- Various formulations were prepared using superdisintegrants such as crospovidone and sodium starch glycolate in different concentrations.
- Formulations F3 (8% crospovidone) and F6 (8% sodium starch glycolate) demonstrated optimal performance with disintegration times below 30 seconds and >90% drug release within 10 minutes.
- Taste masking with aspartame and vanilla flavor improved palatability, important for pediatric and geriatric patients.
- Accelerated stability studies confirmed the physical and chemical stability of optimized formulations for at least 3 months.

10.2 Conclusion

The direct compression technique successfully produced Ondansetron fast dissolving tablets that rapidly disintegrate and dissolve in the oral cavity, providing an effective alternative to conventional dosage forms.

10.3 Future Scope

- Exploration of other taste masking agents to further improve palatability.
- Clinical evaluation to assess in vivo onset of action and bioavailability.
- Scale-up and manufacturing feasibility studies.

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- Development of FDTs for other poorly soluble or bitter drugs.

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