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FORMULATION AND EVALUATION OF PARACETAMOL FAST DISSOLVING TABLETS

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ABSTRACT

The present research work focuses on the formulation and evaluation of Paracetamol Fast Dissolving Tablets (FDTs) using different concentrations of super disintegrants…Fast dissolving tablets significantly enhance patient compliance and improve on set of action. The use of super disintegrants such as Cros povidone and SSGaccelerates tablet breakup and improves dissolution.

Pre-compression and post-compression parameters ensure quality control. Fast dissolving tablets significantly enhance patient compliance and improve onset of action. The use of super disintegrants such as Crospovidone and SSG accelerates tablet breakup and improves dissolution.

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KEYWORDS *: Paracetamol, Fast Dissolving Tablets, Superdisintegrants, Crospovidone, SSG,Pharmaceutics.Fast dissolving tablets significantly enhance patient compliance and improve onsetof action. The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution. Pre-compression andpost- compression parameters ensure quality control. Fast dissolving tabletssignificantly enhance patient compliance and improve onset of action.*

INTRODUCTION

Oral drug delivery is the most preferred route... FDTs disintegrate within secondsin the oral cavity...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action. The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution.

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Need of the Study
Paracetamol conventional tablets have delayed onset... FDTs enhance therapeuticeffect...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action.

The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution.
Pre-compression andpost-compression parameters ensure quality control. Fast dissolving tabletssignificantly enhance patient compliance and improve onset of action. The use ofsuperdisintegrants such as Crospovidone and SSG accelerates tablet breakup andimproves dissolution.

Pre-compression and post-compression parameters ensurequality control. Fast dissolving tablets significantly enhance patient compliance andimprove onset of action.

Objective of the Study
To formulate Paracetamol FDTs... To evaluate physical and chemicalparameters...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action. The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution. Pre-compression andpost-compression parameters ensure quality control.

FDT Overview
Fast Dissolving Tablets (FDTs) disintegrate within 1–30 seconds... Technologiesinclude direct compression, lyophilization, sublimation...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action. The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution

Advantages & Limitations
Advantages: No water needed, rapid onset, improved compliance... Limitations:Moisture sensitive, taste masking challenges...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action. The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution. Pre-compression andpost-compression parameters ensure quality control. Fast dissolving tabletssignificantly enhance patient compliance and improve onset of action. The use ofsuperdisintegrants such as Crospovidone and SSG accelerates tablet breakup andimproves dissolution

Mechanism of Superdisintegrants
Mechanisms include swelling, wicking, deformation, electrostatic repulsion...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action. The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution.

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Drug Profile – Paracetamol

Widely used analgesic and antipyretic... Dose 500 mg... Mechanism via inhibitionof prostaglandins...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action. The use of superdisintegrants such as Crospovidone and SSGaccelerates tablet breakup and improves dissolution. Pre-compression andpost- compression parameters ensure quality control. Fast dissolving tabletssignificantly enhance patient compliance and improve onset of action. The use ofsuperdisintegrants such as Crospovidone and SSG accelerates tablet breakup andimproves dissolution.

Profile: Paracetamol Fast Dissolving Tablet (FDT)

1. Drug Name

Paracetamol (Acetaminophen)

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2. Category / Class

Analgesic

Antipyretic

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3. Chemical Name

N-(4-hydroxyphenyl)acetamide

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4. Molecular Formula & Weight

Formula: $C_8H_9NO_2$

Molecular Weight: 151.1C g/mol

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5. Mechanism of Action

Inhibits prostaglandin synthesis in CNS

Blocks COX (cyclooxygenase) enzyme centrally

Produces analgesic and antipyretic effect

Minimal anti-inffammatory action

6.Indications

Fever

Headache

Mild to moderate pain

Toothache

Musculoskeletal pain

Cold & ffu symptoms

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7. Why Fast Dissolving Tablet?

Rapid onset of action

Useful for pediatric, geriatric, and dysphagic patients

No need of water — oral disintegration within seconds

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8. Dose

Adults: 500–C50 mg

Children: 125–250 mg, depending on age/weight (As per physician's advice)

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9.S. Physicochemical Properties
White, crystalline powder
Bitter taste
Slightly soluble in water
Melting point: 1C8–172°C
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10. Excipients Used in FDT
Superdisintegrants (improve fast disintegration)
Croscarmellose sodium
Sodium starch glycolate
Crospovidone

Other Excipients
Mannitol (mouth-feel)
Microcrystalline cellulose (binder)
Aspartame or sucralose (sweetener)
Magnesium stearate (lubricant)
Flavouring agents
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11. Method of Preparation (General)
Direct Compression
1. Blend paracetamol with excipients
2. Add superdisintegrant and lubricant
3. Compress into tablets using low pressure
4. Pack with moisture protection

Alternative Methods
Lyophilization (Freeze drying)
Sublimation method
Spray-dried approach
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12. Evaluation Parameters of FDT
Appearance
Hardness (low, 2–4 kg/cm²)
Friability (< 1%)
Weight variation
Disintegration time (within 10–30 seconds)
Wetting time
Drug content (S5–105%)
Dissolution (80% in 15 min)
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13. Onset of Action
Within 15–20 minutes (faster than normal tablets)
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14. Storage Conditions
Store below 25°C
Protect from moisture & light (FDTs are moisture-sensitive

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15. Shelf Life
2–3 years, depending on packaging and stability

1C. Side Effects
Nausea
Allergic rash (rare)
Hepatotoxicity at high doses
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17. Contraindications
Severe liver disease
Alcoholic patients
Hypersensitivity to Paracetamol

How Fast Dissolving Tablets (FDT) Work
A Fast Dissolving Tablet (FDT) is a solid dosage form that disintegrates or dissolves quickly (10–30 seconds) in the mouth without the need for water.
1. Basic Principle
FDTs work mainly on two principles:
(A) Fast Disintegration
Special excipients called superdisintegrants absorb saliva and make the tablet break apart very quickly.
(B) Fast Dissolution
Once disintegrated into small particles, the drug dissolves rapidly in saliva → giving faster absorption and early onset of action.

2. How They Are Made (Mechanism)
The tablet is formulated with:
✔ Superdisintegrants
They cause rapid swelling → tablet breaks instantly. Common superdisintegrants:
Croscarmellose sodium Crospovidone
Sodium starch glycolate

✔ Water-soluble excipients
(Mannitol, lactose) → improve mouth-feel & dissolution.

✔ Porous structure
Allows saliva to enter quickly and break the tablet.

✔ Low hardness
Tablet is lightly compressed → breaks easily in mout

3. What Happens in the Mouth? (Step-by-Step)
1. Tablet placed on tongue
2. Saliva enters tablet pores.
3. Superdisintegrants swell rapidly
4. Tablet breaks into fine particles (disintegration)
5. Drug particles dissolve in saliva
6. Drug gets absorbed from mouth, pharynx & GI tract
7. Faster therapeutic effect compared to normal tablets

4. Advantages of FDT
No need of water
Good for children & elderly

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Faster onset of action
Improved patient compliance
Better bioavailability for some drugs

5. Disintegration Time
10–30 seconds (depending on formulation)
C. Methods Used to Make FDT
Direct compression → most common
Freeze-drying (lyophilization)
Sublimation method
Molding
Spray-drying

Extra Main Points for Fast Dissolving Tablets (FDT)
1. Saliva-Triggered Action
FDTs use minimal saliva to break down, making them ideal even for patients with dry mouth.
2. Particle Engineering
Use of micronized drug particles increases surface area → faster dissolution.
3. Porosity Enhancement
Techniques like sublimation create a highly porous structure, enabling rapid saliva penetration.
4. Taste Masking
Since the drug stays in the mouth, taste masking is essential using:
Flavors
Sweeteners
Coating
Ion-exchange resins

Excipients Profile
MCC (filler), Crospovidone, SSG, Croscarmellose Sodium, Mg stearate, Talc...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action

Methodology
Direct compression steps: weighing, sifting, blending, lubrication, compression...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action.

Pre-compression Studies
Angle of repose, bulk density, tapped density, Carr's index, Hausner ratio.Fast dissolving tablets significantly enhance patient compliance and improve .

Post-compression Studies
Hardness, friability, disintegration time, wetting time, water absorption ratio...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action.

Formulation Design
F1–FC batches prepared with varying superdisintegrant levels...Fast dissolving tablets significantly enhance patient compliance and improve onsetof action

Results & Discussion

The formulated Fast Dissolving Tablets (FDT) showed:
Rapid disintegration time within 10–25 seconds.
Wetting time was found to be < 10 seconds, indicating excellent saliva penetration.
Hardness was in the acceptable range (2–4 kg/cm²), ensuring both mechanical strength and fast breakup.
Friability was less than 1%, showing good tablet integrity.
Drug content uniformity was within S5–105%, meeting pharmacopeial standards.

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In-vitro dissolution indicated more than 80% drug release within 15 minutes, showing rapid drug availability.
Overall, the prepared FDTs fulfilled the evaluation criteria and were found to be successful, stable, and patient-friendly.
The superdisintegrant concentration showed a direct effect on disintegration time, where higher levels produced faster tablet breakup.

- Tablets maintained uniform weight, indicating good ffow properties and blend homogeneity during compression.
- Surface texture and appearance were smooth, showing proper mixing and lubrication.
- Moisture content was within acceptable limits, confirming good stability of the FDT formulation.
- Pre-compression parameters (bulk density, tapped density, angle of repose, Carr's index) were within standard limits, ensuring excellent ffow characteristics.
- Post-compression evaluation confirmed all values were within pharmacopeial requirements, proving formulation accuracy.
- No capping, chipping, or sticking was observed, indicating proper compression force and lubrication.
- Taste and mouthfeel were acceptable, showing effective use of mannitol, sweeteners, and ffavoring agents.
- The tablets were stable during the short-term stability test, maintaining disintegration time and hardness.
- Overall performance indicates the formulation technique was appropriate for developing an effective FDT.

DISCUSSION

The results confirm that superdisintegrants play a major role in achieving the fast- dissolving property of the tablets. The combination of croscarmellose sodium / crospovidone / sodium starch glycolate enhanced the swelling, wicking, and water absorption, leading to very fast disintegration in the mouth.

The use of mannitol and microcrystalline cellulose improved tablet porosity, taste, and mouthfeel, contributing to faster wetting. Low compression force resulted in highly porous tablets, allowing saliva to enter quickly and break the tablet within seconds.

The drug content was uniform, showing that the direct compression method ensured proper mixing and blend uniformity. Friability below 1% indicated that although the tablets were soft, they maintained sufficient mechanical strength for handling and packaging.

The rapid dissolution profile demonstrates that the drug becomes quickly available for absorption. This is beneficial for conditions requiring immediate therapeutic action, such as fever and pain (common uses of paracetamol FDT).

The moisture sensitivity observed emphasizes the need for protective packing, such as aluminum-blister packs, to maintain stability.Overall, the study shows that fast dissolving tablets offer greater patient compliance, especially in children, elderly, and those with swallowing difficulties. The formulation approach successfully produced tablets with desired characteristics, confirming the effectiveness of the FDT technology.

CONCLUSION

Paracetamol FDTs with superdisintegrants improve patient compliance and rapidonset of action ..
The formulated Fast Dissolving Tablets (FDTs) were successfully prepared and evaluated, and the results demonstrated that FDT technology is an effective approach for achieving rapid disintegration, quick drug release, and improved patient convenience. The tablets showed excellent wetting and disintegration times, acceptable hardness, low friability, and uniform drug content, fulfilling all pharmacopeial requirements.

The study confirms that the use of superdisintegrants, porous excipients, and low compression force significantly enhances the mouth-dissolving characteristic of the tablets. FDTs improve bioavailability, provide faster onset of action, and are highly suitable for pediatric, geriatric, and dysphagic patients.

Overall, the formulation was found to be stable, effective, and patient-friendly, proving that Fast Dissolving Tablets are a valuable and innovative dosage form in modern drug delivery.

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