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Research Article

Design and Characterization of Naproxen Fast Dissolving Tablets Employing *Coccinia grandis* Leaf Mucilage as a Natural Binder and Disintegrant

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ABSTRACT

The present study aimed to develop and evaluate fast disintegrating tablets (FDTs) of Naproxen using *Coccinia grandis* leaf mucilage as a natural superdisintegrant, alone and in combination with synthetic superdisintegrants. Naproxen, a poorly water-soluble non-steroidal anti-inflammatory drug, was selected to enhance dissolution rate and improve onset of action. A total of twelve formulations (F1–F12) were prepared by the direct compression method. Formulations F1–F4 contained natural mucilage alone, F5–F8 combined mucilage with croscarmellose sodium (CCS), F9–F10 with sodium starch glycolate (SSG), and F11–F12 with crospovidone (CP). Precompression studies indicated acceptable flow properties, with improved flow observed in combination batches. Post compression evaluation confirmed compliance with pharmacopeial limits for hardness, friability, weight variation, and drug content. Wetting time and disintegration time decreased significantly in formulations containing synthetic superdisintegrants, particularly crospovidone. In-vitro dissolution studies demonstrated that drug release improved in the order: natural polymer < SSG < CCS < crospovidone. The optimized formulation F12 exhibited rapid disintegration (38 sec) and achieved 100% drug release within 15 minutes. Drug release kinetics followed the Korsmeyer Peppas model, indicating a non-fickian diffusion mechanism. Stability studies conducted under accelerated conditions ($40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \text{ RH} \pm 5\%$) for 30 one months showed no significant changes in physical parameters or drug release profile, confirming stability. The study concludes that the combination of natural mucilage with crospovidone is an effective strategy for developing stable and efficient FDTs of Naproxen.

INTRODUCTION

The oral route is considered the most traditional and widely used method for administering

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medications. Tablets are among the most commonly prescribed dosage forms because they are easy to self-administer, stable, and simple to manufacture. However, many patients especially children and the elderly face difficulty swallowing standard tablets, a challenge that becomes more pronounced during travel when access to water may be limited. These limitations of conventional tablets can be overcome by formulating mouth-dissolving tablets. Such tablets rapidly disintegrate in the mouth, typically within 20–30 seconds, allowing the active ingredient to interact with saliva and exert its therapeutic effect. Compared with conventional tablets, mouth-dissolving tablets offer improved patient compliance and acceptance, along with enhanced bioavailability, efficacy, and overall biopharmaceutical performance¹

The mouth-dissolving drug delivery approach is especially beneficial for patients suffering from life-threatening conditions such as neurological disorders, radiation therapy-related complications, Parkinson's disease, and AIDS who commonly experience dysphagia. Alternative dosage forms like effervescent tablets or dry syrups often cause discomfort in such patients because they must be taken with water. In contrast, mouth-dissolving tablets eliminate the need for water, thereby significantly improving patient convenience and adherence. These tablets are also known by several other terms, including orally disintegrating tablets, fast-dissolving tablets, and fast-melting tablets. According to the European Pharmacopoeia, an "orodispersible" tablet is one that rapidly disintegrates in the mouth without requiring water. Mouth-dissolving tablets (MDTs) have therefore become increasingly popular in pharmaceutical development due to these distinct advantages.

Advantages of Mouth Dissolving Tablets (MDTs)²⁻⁴

Mouth-dissolving tablets (MDTs) are convenient oral dosage forms that quickly disperse in the mouth without the need for water, making them ideal for children, elderly individuals, and patients with swallowing difficulties. They provide a faster therapeutic effect because the drug can be absorbed through the buccal mucosa, bypassing the gastrointestinal tract. This also enhances bioavailability by reducing first-pass metabolism, allowing more of the drug to reach systemic circulation compared to conventional tablets.

Mouth-dissolving tablets (MDTs) offer improved taste and acceptability through the use of flavors and sweeteners, making them especially suitable for pediatric patients. Their high portability allows easy administration without water, making them convenient for travel or outdoor use. MDTs also support adaptable dosing, which is useful for drugs requiring precise dose adjustments. These features, along with their ease of use, enhance patient compliance. Additionally, MDTs provide formulation flexibility, enabling the incorporation of a wide range of active pharmaceutical ingredients, including those with poor solubility or stability in conventional forms. Advanced formulation technologies have significantly improved the performance of mouth-dissolving tablets (MDTs). Methods like lyophilization create highly porous structures for rapid dissolution, while direct compression uses specialized excipients to ensure quick disintegration without losing strength. The addition of superdisintegrants such as croscarmellose sodium, crospovidone, and sodium starch glycolate further enhances their breakdown in the mouth. These innovations allow MDTs to be tailored for optimal disintegration, taste masking, and stability. Overall, MDTs represent a major advancement in oral drug



delivery, offering fast action, improved bioavailability, and better patient compliance, especially for pediatric, geriatric, and dysphagic patients.⁵⁻⁷

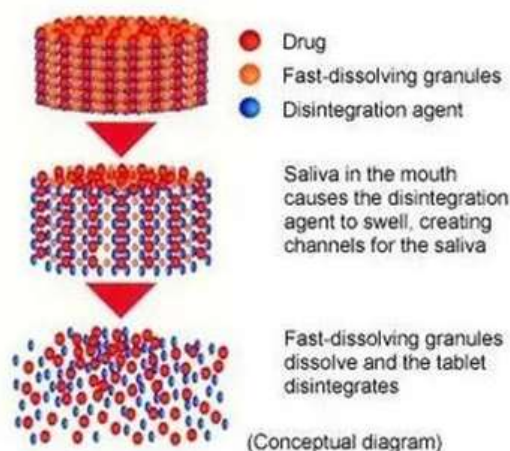


Figure 1: Disintegration of Fast Dissolving Tablet⁸

Ideal Properties of Drugs for Formulating Mouth-Dissolving Tablets⁹⁻¹¹

Selecting an appropriate drug candidate is crucial for the effective development of mouth-dissolving tablets (MDTs). Ideal drugs should dissolve quickly in the oral cavity for rapid action, have acceptable taste or be easily taste-masked, and require low doses to maintain small tablet size. They must also remain stable in saliva, exhibit good bioavailability, and preferably avoid extensive first-pass metabolism. Additionally, compatibility with excipients like superdisintegrants is important to ensure proper tablet strength and fast disintegration. Drugs that allow flexible formulation approaches are most suitable, as they enhance overall performance, patient acceptability, and therapeutic effectiveness.

Manufacturing of Mouth Dissolving Tablets¹²⁻¹³

The production of mouth-dissolving tablets (MDTs) involves several carefully controlled steps

to ensure rapid disintegration and effective drug release. It begins with formulation development, where a suitable drug and excipients such as superdisintegrants, diluents, binders, and flavoring agents are selected. The ingredients are then uniformly blended, followed by granulation (wet or dry) if needed to improve flow and compressibility. The prepared blend or granules are compressed into tablets using appropriate tooling and optimized pressure to balance strength and fast dissolution. In some cases, taste-masking coatings are applied to enhance palatability. The final tablets undergo quality control tests, including disintegration, dissolution, hardness, and friability, before being packaged in moisture-resistant materials to ensure stability and maintain product quality.

Evaluation of Fast Dissolving Tablets (FDTs)¹⁴

Fast dissolving tablets (FDTs) undergo various evaluation tests to ensure their quality, safety, and effectiveness. Key parameters include disintegration time (ideally under 30 seconds) to confirm rapid breakdown in saliva-like conditions, and dissolution testing to measure drug release using techniques like UV-Visible spectrophotometry or HPLC. Mechanical properties such as hardness and friability are assessed to ensure tablets are strong yet resistant to damage, with friability typically below 1%. Additional tests include weight variation and content uniformity to ensure consistent dosage, taste-masking evaluation for patient acceptability, and moisture content analysis for stability. In some cases, in-vivo studies are conducted to evaluate pharmacokinetics, bioavailability, and overall therapeutic performance.

Recent Developments in Fast Dissolving Tablets (FDTs)¹⁵⁻¹⁶

Recent advancements in fast dissolving tablet (FDT) technology have significantly improved patient convenience, bioavailability, and manufacturing efficiency. Innovations such as advanced superdisintegrants and co-processed excipients enhance tablet strength, flow properties, and rapid disintegration. Modern techniques like 3D printing, freeze-drying, spray drying, and improved direct compression enable the production of highly porous and fast-acting

tablets. The integration of nanotechnology improves solubility and drug release, while advanced taste-masking methods increase patient acceptability. Additionally, developments in orally disintegrating films (ODFs), moisture stability, and higher drug-loading capacity further expand the applicability of FDTs, making them a highly effective and patient-friendly drug delivery system.

Table 1: Marketed fast-dissolving/oro-dispersible tablet (FDT/ODT) product¹⁷⁻¹⁸

Brand Name	Active Drug (API)	Manufacturer / Company
Feldene Melt	Piroxicam	Pfizer Inc. (Pharmacy Journal)
Claritin RediTabs	Loratadine	Schering-Plough Corp. (WJPR)
Maxalt MLT	Rizatriptan	Merck & Co. (Pharmacy Journal)
Zyprexa Zydis	Olanzapine	Eli Lilly / Catalent (Zydis platform) (Catalent)
Pepcid RPD	Famotidine	Merck & Co. (WJPR)
Zofran ODT	Ondansetron	GlaxoSmithKline (GSK) (Pharmacy Journal)
Zomig ZMT	Zolmitriptan	AstraZeneca / CIMA Labs
Benadryl FastMelt	Diphenhydramine	Pfizer / Warner Lambert
Tempra Quicklets	Acetaminophen (Paracetamol)	Bristol-Myers Squibb / CIMA Labs (WJPR)
Nimulid MDT	Nimesulide	Panacea Biotech (India)

OBJECTIVES OF STUDY

1. To extract and purify mucilage from *Coccinia grandis* leaves using a standardized extraction procedure.
2. To characterize the extracted mucilage for its physicochemical properties such as solubility, swelling index, viscosity, pH, moisture content, and micromeritic characteristics.
3. To formulate Naproxen fast dissolving tablets using *Coccinia grandis* mucilage in varying concentrations as a natural binder and disintegrant.
4. To evaluate the prepared FDTs for parameters like: Disintegration time, Wetting time, Hardness, Friability, Weight variation, Drug content uniformity, In-vitro dissolution studies

5. To compare the performance of mucilage-based tablets with tablets formulated using synthetic excipients (e.g., croscarmellose sodium or PVP).
6. To analyze drug excipient compatibility using FTIR or DSC studies.
7. To select the optimized formulation based on disintegration time, dissolution profile, and mechanical strength.
8. To establish the suitability of *Coccinia grandis* mucilage as a natural, safe, cost-effective, and efficient binder/disintegrant in FDT formulations.

RATIONALE OF THE STUDY

Fast dissolving tablets have emerged as a patient-friendly dosage form, offering advantages for pediatric, geriatric, bedridden, and dysphagic patients who experience difficulty swallowing conventional tablets. Naproxen, a widely used



NSAID, suffers from delayed onset of action due to its poor aqueous solubility and slow dissolution rate. Formulating it into fast dissolving tablets can significantly enhance its onset of analgesic and anti-inflammatory effects. *Coccinia grandis* (ivy gourd) is a commonly available plant containing natural mucilage known for its swelling, binding, and disintegrating properties. Natural mucilages offer several advantages over synthetic excipients biodegradability, non-toxicity, low cost, biocompatibility, and environmental friendliness. However, its application as a binder and disintegrant in Naproxen fast dissolving tablets has not been extensively investigated. This study aims

to explore the potential of *Coccinia grandis* leaf mucilage as a multifunctional excipient that can provide both rapid disintegration and sufficient mechanical strength to FDTs. The successful utilization of this natural mucilage may lead to the development of safer, more economical, and sustainable pharmaceutical formulation

EXPERIMENTAL WORK

MATERIALS:

The following materials collected for the experimental work done.

Table 2 : List of materials

Sr. No.	DRUG/ EXCIPIENTS	GRADE	GIFTED/MFG.BY
1	Naproxen	AR	Elikem Pharmaceuticals Pvt Ltd
2	Croscarmellose Sodium	AR	Merck, India
3	Sodium Lauryl Sulfate	AR	S.D. Fine Chemicals Ltd
4	HPMC	AR	Merck, India
5	Magnesium stearate	AR	S.D. Fine Chemicals Ltd
6	Microcrystalline cellulose	AR	S.D. Fine Chemicals Ltd
7	Lactose	AR	S.D. Fine Chemicals Ltd
8	Aspartame	AR	S.D. Fine Chemicals Ltd

Table 3: Natural Polymer List

Sr. No.	POLYMER / Mucilage Source	ISOLATED FROM (Plant & Part)	Family
1	<i>Coccinia grandis</i> leaf mucilage	Leaves of <i>Coccinia grandis</i> (ivy gourd / “kova / tindora / kundru”)	Cucurbitaceae

Table 4: List of Equipments

Sr. No.	INSTRUMENTS	SUPPLIER/ MANUFACTURER
1	Digital weighing balance	Sartorius balance– BT124S
2	UV Spectrophotometer	UV–1800,M/s Shimadzu
3	Infrared spectro photometer	FTIR–8700,M/s Shimadzu
4	Dissolution test apparatus	Dissolution test apparatus Lab India Ltd.
5	pH meter	Lab India, pH meter
6	Hardness Tester	Monsanto Hardness Tester
7	Friability test apparatus	Roche Friability test apparatus
8	Tablet Compression Machine	Cadmach, Ahmedabad.

EXTRACTION OF MUCILAGES¹⁹⁻²¹

The mucilage can be extracted through the following steps:

1. **Collection:** Collect ~500 g fresh leaves of *Coccinia grandis*.



2. **Preparation:** Wash thoroughly → (optional) blanch briefly → chop into small pieces. Λ max Determination: Scan in UV range (200–400 nm), λ_{max} ≈ 231 nm
3. **Extraction (Maceration):** Soak leaves in distilled water (1:10 ratio) for 24 hrs with occasional stirring. Absorbance Measurement: Set instrument at 231 nm , Measure absorbance of all solutions
4. **Filtration:** Filter using muslin cloth/filter paper to obtain aqueous extract. Calibration Curve: Plot Absorbance vs Concentration , Get equation (e.g., $Y = 0.045X + 0.002$) and Check linearity ($r^2 \approx 0.999$)
5. **Concentration:** Evaporate at ≤50 °C to reduce volume to ~100–150 mL. 4. **Sample Analysis :** Powder tablets and take amount = 10 mg drug ,Dissolve, filter, dilute and Measure absorbance at λ_{max} , Compare with standard to confirm identity & content
6. **Precipitation:** Add 2–3 volumes of chilled ethanol → keep at 4 °C for 24 hrs.
7. **Separation:** Centrifuge (5000 rpm, 15–20 min) → collect precipitate → wash with cold ethanol.
8. **Drying:** Dry at ≤40 °C (or freeze dry) until constant weight.
9. **Yield:** From 500 g leaves → ~48 g dried mucilage.

RESULTS & DISCUSSIONS

Physicochemical Characterization of *Coccinia grandis* Mucilage

The isolated mucilage of *Coccinia grandis* was evaluated for its physicochemical properties to determine its suitability as a natural superdisintegrant.

The mucilage appeared as a white, amorphous, tasteless powder with a characteristic odor, making it acceptable for oral dosage forms. It exhibited slight solubility in hot water and formed a viscous colloidal solution in cold water, indicating strong hydration and swelling ability key requirements for a superdisintegrant.

A swelling index of 46.3% confirms excellent swelling capacity, which promotes rapid tablet disintegration. The pH of 6.7 indicates near neutrality, ensuring compatibility with most drugs and minimizing irritation.²⁵⁻²⁸

However, micromeritic properties revealed poor flow characteristics, as indicated by:

- Low bulk density (0.083 g/cm³)
- High Carr's index (33.6%)

IDENTIFICATION OF DRUG²²⁻²⁴

1. Organoleptic Properties : Observe and record color, odor and taste of the drug.

2. Melting Point : Take a small amount of powder in a fusion tube. Place in melting point apparatus (with castor oil). Heat gradually and Note the Temperature when melting starts Temperature when completely melted

3. Solubility Study (UV Method using Naproxen)

Stock Solution: Weigh 10 mg drug and Dissolve in 10 mL methanol → 1 mg/mL solution

Working Solutions: Dilute stock to get 2–10 µg/mL concentrations



- Hausner's ratio (1.50)
- Angle of repose (39.5°)

These findings suggest the need for flow enhancers during formulation.

Thermal analysis showed stability up to ~200°C, indicating suitability for pharmaceutical

processing. Overall, the mucilage demonstrates good swelling ability but poor flow, making it effective when combined with other excipients.⁷

Calibration Curve of Naproxen

The UV spectrophotometric analysis of Naproxen was carried out at $\lambda_{\text{max}} = 231 \text{ nm}$, and a calibration curve was prepared.

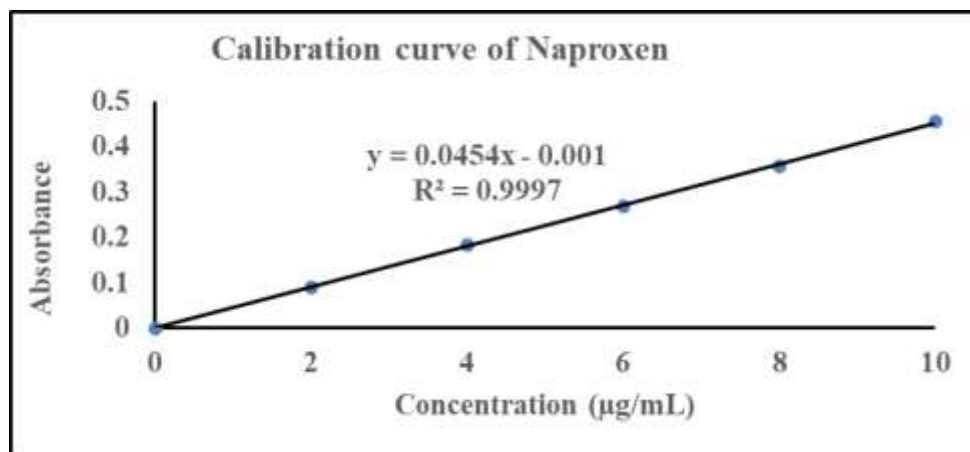


Figure 2: Calibration curve of Naproxen in pH 6.8 phosphate buffer

The calibration curve showed a linear relationship between concentration and absorbance with equation:

$$y = 0.0454x - 0.001$$

and $R^2 = 0.9997$, indicating excellent linearity.

This confirms that the method is reliable for quantitative estimation of Naproxen in formulations.²⁹

Drug-Excipient Compatibility (FTIR Study)

FTIR analysis was performed to evaluate possible interactions between Naproxen and mucilage.³⁰

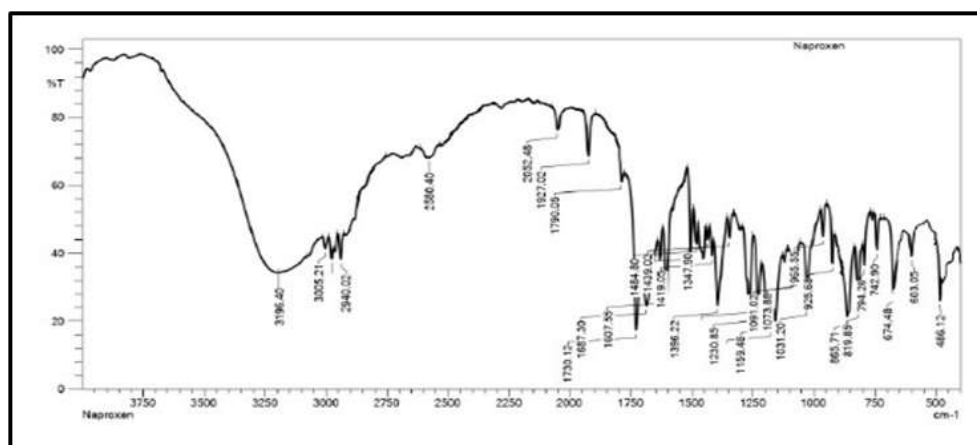


Figure 3: FTIR study of Naproxen

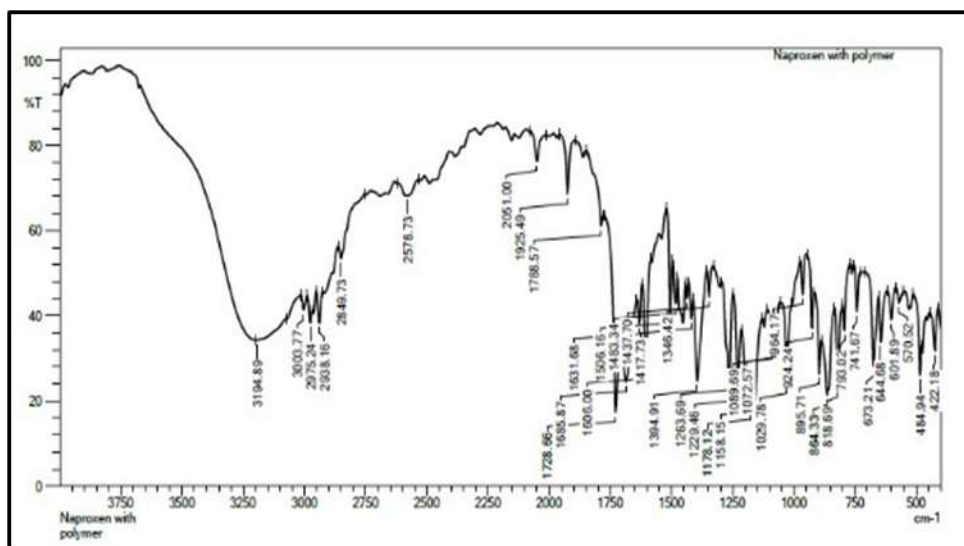


Figure 4: FTIR study of of Naproxen + polymer mixture

The FTIR spectrum of pure Naproxen showed characteristic peaks: $\sim 3196\text{ cm}^{-1}$ (O–H stretching), $\sim 1730\text{ cm}^{-1}$ (C=O group), $1600\text{--}1500\text{ cm}^{-1}$ (aromatic C=C)

In the drug–polymer mixture, all peaks were retained with only minor shifts, indicating: No chemical interaction, Good compatibility between drug and mucilage

Thus, the mucilage is suitable for formulation.

Precompression Parameters³¹⁻³³

The powder blends (F1–F12) were evaluated for flow properties :

Angle of repose range to 33.8° to 27.8° , indicating improved flow , Bulk density range from 0.44 to 0.52 g/cm^3 and Carr's index shows 18.5% to 13%

This improvement is due to the addition of synthetic superdisintegrants such as: Croscarmellose sodium (CCS), Sodium starch glycolate (SSG), Crospovidone. Formulations F11–F12 showed the best flow properties, making them ideal for compression.

Post-Compression Evaluation³¹⁻³⁴

All formulations met pharmacopeial limits for: Weight variation, Hardness ($3.2\text{--}3.7\text{ kg/cm}^2$) and Friability and disintegration test

- F1–F4 (Natural mucilage only): Slow disintegration due to gel formation
- F5–F8 (with CCS): Faster disintegration due to swelling + wicking
- F9–F10 (with SSG): Moderate improvement
- F11–F12 (with Crospovidone): Fastest disintegration

F12 showed:

- Wetting time: 34 sec
- Disintegration time: 38 sec

Thus, Crospovidone-based formulations performed best.

In-Vitro Dissolution Studies³¹⁻³⁴

Dissolution studies showed significant variation in drug release.

(a) Natural Polymer (F1–F4)

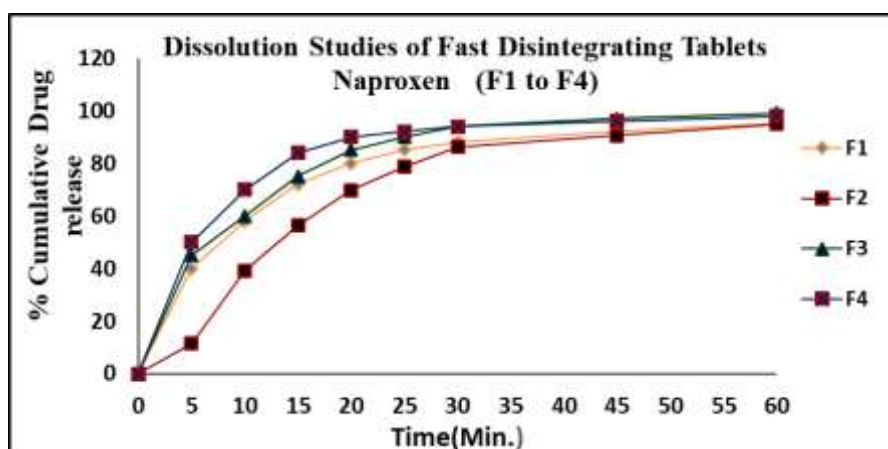


Figure 5: *In-Vitro* Dissolution Studies of FDT of Naproxen using Coccinia grandis mucilage (F1 to F4)

In their 80–90% release at 20 min and show slower (b) With CCS (F5–F8)
due to viscous gel barrier

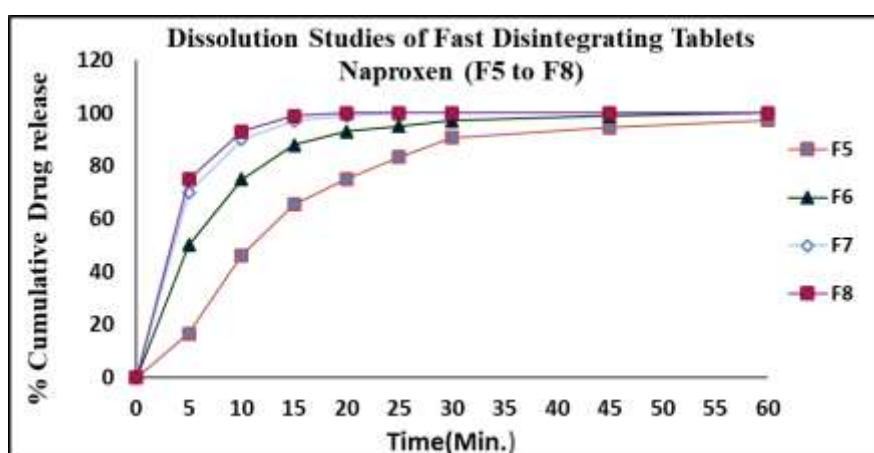


Figure 6: *In-Vitro* Dissolution Studies of FDT of Naproxen using Coccinia grandis mucilage with Croscarmellose sodium (F5 to F8)

Shows Nearly 100% release within 20 min due to (c) With SSG (F9–F10)
it Mechanism swelling + wicking .F8 showed
optimal performance.

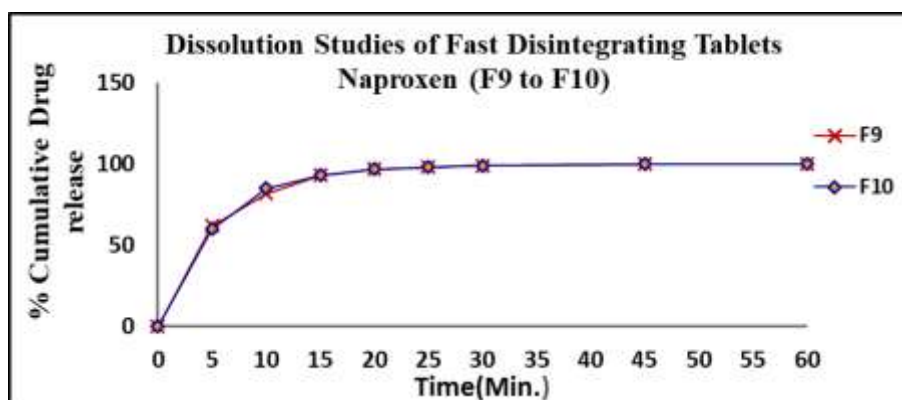


Figure 7: *In-Vitro* Dissolution Studies of FDT of Naproxen using Coccinia grandis mucilage with Sodium Starch Glycolate, SSG (F9 to F10)

In their 97-98% release within 20 min, slightly promotes fast disintegration and drug release (d) With Crospovidone (F11–F12)³⁵⁻³⁹

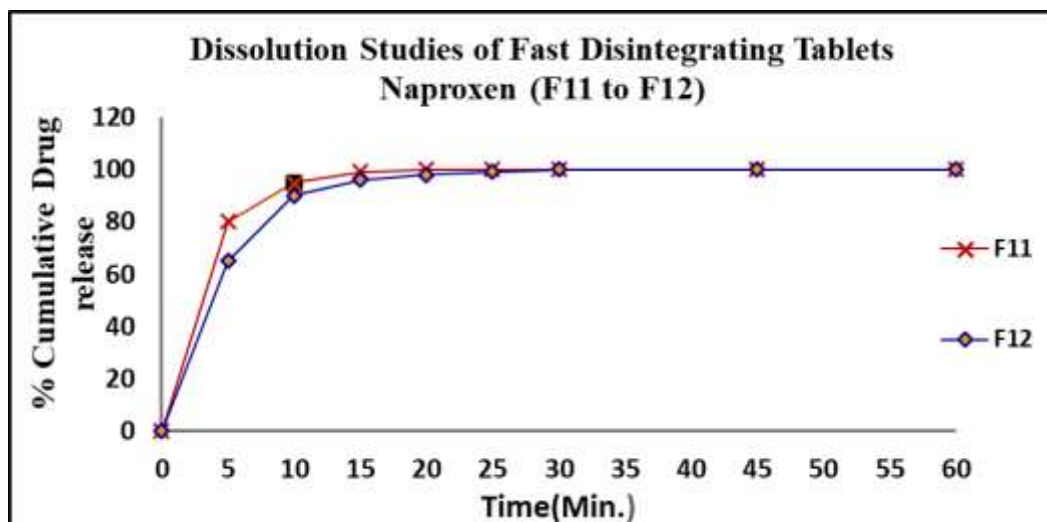


Figure 8: *In-Vitro* Dissolution Studies of FDT of Naproxen using *Coccinia grandis* mucilage with Crospovidone (F11 to F12)

complete release within 15 minutes due to Mechanism: wicking without gel formation ,F12 was identified as the optimized formulation.

Conclusion

Drug release increased in the order: *Coccinia grandis* mucilage < SSG < CCS < crospovidone, reflecting differences in disintegration efficiency. Combining natural and synthetic polymers

improved dissolution through synergistic effects. Formulation F12 showed the best performance, achieving complete drug release within 15 minutes. Overall, both the type and concentration of disintegrants significantly influence Naproxen release from FDTs.

Drug Release Kinetics analysis⁴⁰⁻⁴³

Different kinetic models were applied to F12

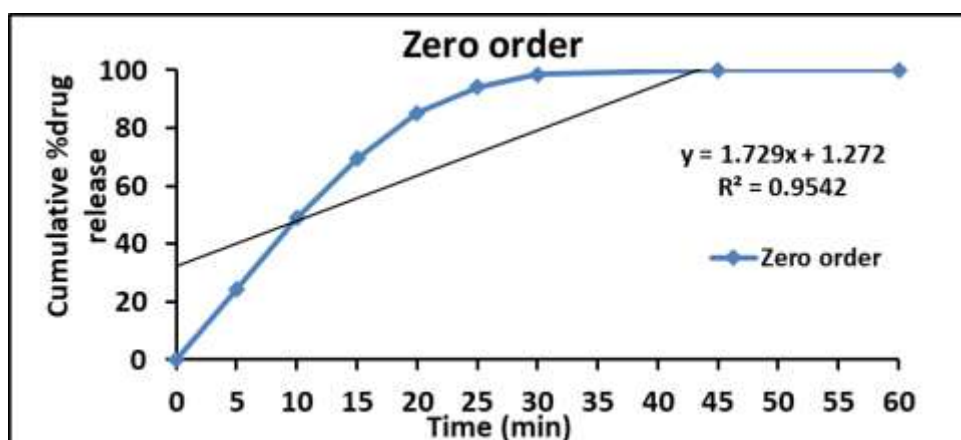


Figure 9: Zero order plot for the Optimized formulation FDT of Naproxen (F12)

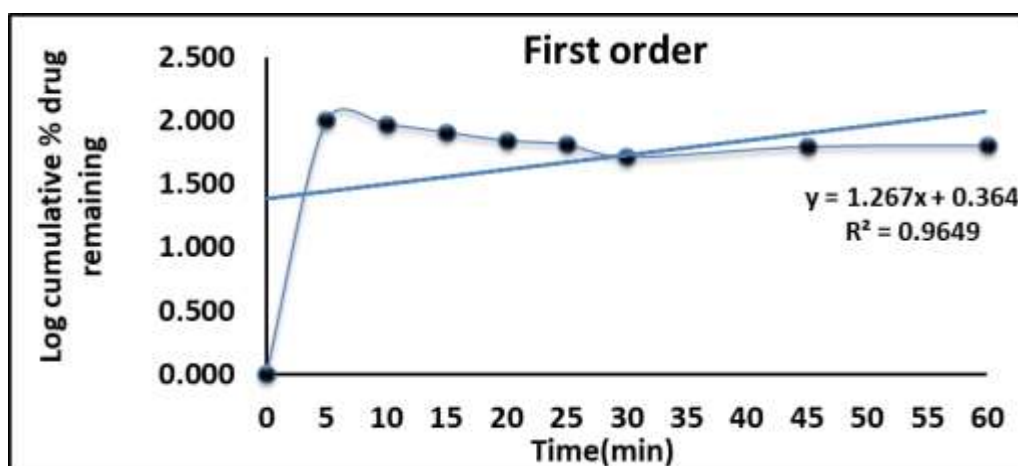


Figure 10: First order plot for the Optimized formulation FDT of Naproxen (F12)

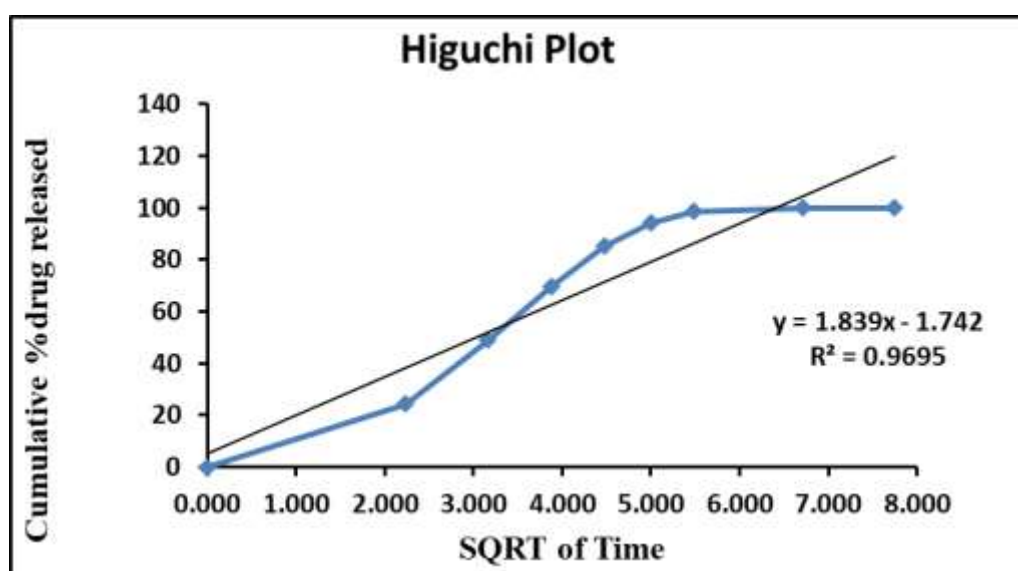


Figure 11: Higuchi plot for the Optimized formulation FDT of Naproxen(F12)

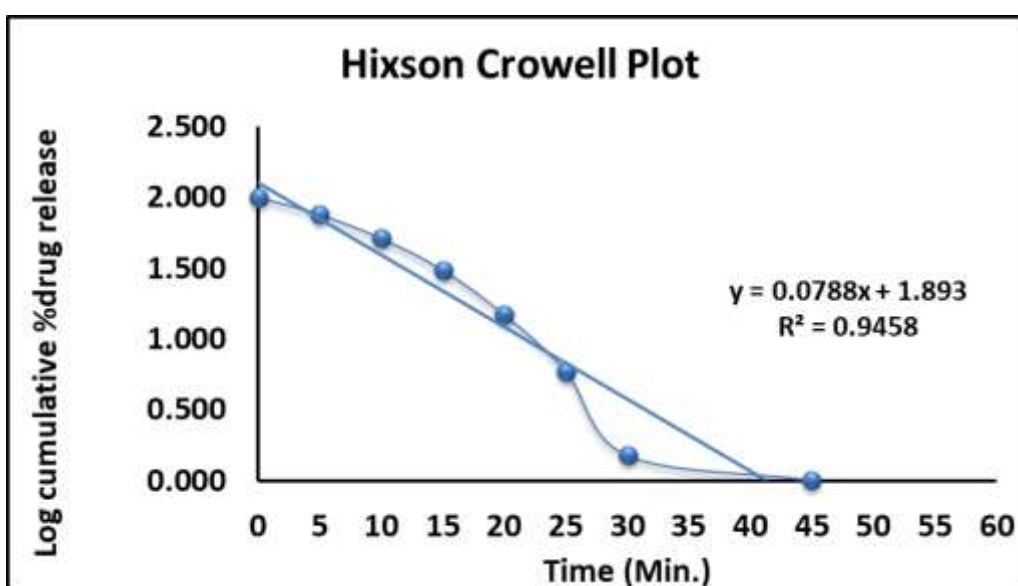


Figure 12: Hixson Crowell plot for Optimized formulation FDT of Naproxenn (F12)

RESULTS

- Higuchi model: $R^2 = 0.9695$ (best fit)
- First order: good correlation
- Zero order: poor fit

This indicates: Diffusion-controlled release and Non-Fickian (anomalous) mechanism where drug release occurs via wicking (crospovidone), swelling (mucilage) and diffusion.

Stability Studies⁴⁰⁻⁴³

Accelerated stability studies (40°C, 75% RH) showed: No significant change in hardness, friability, or drug content, drug release remained consistent and disintegration time unchanged

Thus, F12 is stable and suitable for further development.

Final Conclusion

Natural mucilage alone shows moderate performance due to gel formation and combination with synthetic disintegrants significantly improves performance where drug release order is Mucilage < SSG < CCS < Crospovidone

F12 (Crospovidone + mucilage) is the optimized formulation for fastest disintegration, highest drug release and excellent stability

SUMMARY AND CONCLUSION

Naproxen was selected as a model drug due to its poor solubility, delayed onset, and gastrointestinal side effects, making it suitable for formulation as a fast disintegrating tablet (FDT) to enhance dissolution, improve onset, and increase patient compliance. The study utilized *Coccinia grandis* mucilage as a natural superdisintegrant, supplemented with synthetic agents—

croscarmellose sodium, sodium starch glycolate, and crospovidone—to overcome limitations like poor flow and gel formation. Twelve formulations prepared via direct compression showed that combinations improved flow, disintegration, and drug release compared to natural mucilage alone, with crospovidone batches performing best. All tablets met pharmacopeial standards, and formulation F12 (mucilage + crospovidone) exhibited the fastest disintegration and complete drug release within 15 minutes. Drug release followed the Higuchi model with a non-Fickian mechanism. Stability studies confirmed no significant changes under accelerated conditions, establishing F12 as the optimized, stable formulation with excellent performance and potential for further development.

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