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RESEARCH ARTICLE

Expansion and Valuation of Naproxen Sodium Fast Dissolving Tablet

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ABSTRACT

The evaluation of Naproxen Sodium Fast Dissolving Tablets emphasizes the critical role of careful formulation design and thorough testing in pharmaceutical development. Among the formulations, F7 demonstrated outstanding properties, including excellent flow characteristics and optimal tablet hardness. Stability testing over a four-week period showed consistent performance, though minor variations in tablet attributes were observed. Continuous monitoring is advised to ensure sustained efficacy. The in-vitro release profile revealed rapid disintegration and dissolution, crucial for prompt drug release. These results highlight the necessity of stringent quality control measures and ongoing optimization to enhance patient outcomes and ensure the reliability of Naproxen Sodium Fast Dissolving Tablets. In a parallel evaluation, the stability and performance of Naproxen Sodium Fast Dissolving Tablets were assessed under various environmental conditions, showing that temperature and humidity significantly impacted Naproxen Sodium concentration and dissolution rates. Formulation F7 emerged as the most promising, offering superior flow properties, compressibility, and dosage consistency. In-vitro tests confirmed rapid disintegration and dissolution, aligning with Pharmacopoeial standards. Four-week stability studies indicated consistent tablet characteristics, with only slight changes in hardness, friability, and drug content. Continued monitoring is recommended to ensure long-term stability and product quality. These findings underscore the importance of rigorous formulation optimization and stability testing to ensure reliable drug release and sustained efficacy.

Keywords: Naproxen Sodium Fast Dissolving Tablets; UV; HPLC; DSC; FTIR

INTRODUCTION

Naproxen Sodium fast-dissolving tablets are a formulation of the nonsteroidal anti-inflammatory drug (NSAID) designed for rapid dissolution in the mouth, eliminating the need for water and enabling quick absorption into the bloodstream. This fast-acting form of Naproxen Sodium is commonly used to alleviate pain, inflammation, and swelling associated with conditions such as arthritis, menstrual cramps, tendonitis, and gout. Its quick-dissolving feature provides convenience, particularly for individuals who have difficulty swallowing conventional tablets or require rapid relief from pain or inflammation.

As with any medication, it's essential to adhere to the dosage and usage guidelines provided by your healthcare provider or pharmacist. Be mindful of potential side effects and drug interactions and consult a healthcare professional if you have any questions or concerns about using Naproxen Sodium. [1]

Information of fast dissolving tablets (FDTs)

Fast dissolving tablets (FDTs), also known as orally disintegrating tablets (ODTs) or mouth-dissolving tablets (MDTs), are solid dosage forms designed to disintegrate or dissolve quickly in the mouth without the need for water or chewing. These tablets offer several advantages over conventional forms, particularly for individuals who may have difficulty swallowing, such as paediatric, geriatric, or dysphagic patients. Below is an overview of fast dissolving tablets:

Composition

Fast dissolving tablets typically consist of active pharmaceutical ingredients (APIs) along with excipients such as superdisintegrants, fillers, sweeteners, and flavouring agents. Superdisintegrants like Crospovidone, Croscarmellose sodium, and sodium starch glycolate are essential for ensuring rapid disintegration.

MANUFACTURING TECHNIQUES

Various methods are employed to produce fast dissolving tablets, including direct compression, freeze-drying, sublimation, and spray-drying. Each technique offers different benefits and challenges concerning product stability, manufacturing efficiency, and cost.[2]

Advantages

1. Improved patient compliance: particularly for those who have difficulty swallowing conventional tablets or capsules.
2. Rapid onset of action: due to the tablet's quick disintegration and absorption in the oral cavity.
3. Convenient administration: especially in situations where water is not readily available.
4. Enhanced bioavailability: for certain drugs through absorption via the oral mucosa.

Disintegration Mechanism

1. Fast dissolving tablets disintegrate quickly upon contact with saliva.
2. The disintegration process is driven by the swelling of superdisintegrants, creating pressure within the tablet that causes it to fragment into smaller particles.
3. These particles either dissolve or disperse in the saliva, making them easy to swallow or absorb through the oral mucosa.

Applications

1. Fast dissolving tablets are used in various therapeutic areas, including pediatrics, geriatrics, psychiatry, pain management, allergy treatment, and travel medicine.
2. They are particularly valuable for on-the-go medication administration, emergency situations, and patients with swallowing difficulties.[3–5]

EXPERIMENT

Chemicals and Reagents

A gift sample of Naproxen Sodium was provided by Aarti Drugs Pvt. Ltd., Tarapur (Boisar), Maharashtra, India. Croscarmellose and Aspartame were obtained as gift samples from Stallion Lab Pvt. Ltd., Bawla, Gujarat. Additional excipients, including Sodium Starch Glycolate, Crospovidone, Mannitol, Sodium Lauryl Sulfate, and Microcrystalline Cellulose, were gifted by Aura Nutraceuticals Ltd., Budasan, and Gujarat.

Procurement and Identity Confirmation of Naproxen Sodium

Naproxen Sodium samples were procured from Aarti Drugs Pvt. Ltd. and their identity was confirmed through UV-visible wavelength scanning, High-Performance Liquid Chromatography (HPLC), and Fourier Transform Infrared (FT-IR) spectroscopy.

Preparation and Optimization of Naproxen Sodium Fast Dissolving Tablets

Pre-compression parameters, including bulk density, tap density, Carr's index, Hausner ratio, and angle of repose, were evaluated for the drug. The tablets were formulated using the direct compression technique.

Compatibility Study of Drug and Excipients

The compatibility between Naproxen Sodium and excipients was assessed by storing the mixture under different environmental conditions for one month.

Characterization of Naproxen Sodium Fast Dissolving Tablets

The tablets were characterized for free and entrapped Naproxen Sodium content using a UV-spectrophotometric method.

Evaluation of Naproxen Sodium Fast Dissolving Tablets

The tablets were evaluated for several parameters, including weight variation, thickness, hardness, friability, drug content, and wetting time.

In-vitro Release Profile of Naproxen Sodium Fast Dissolving Tablets

Disintegration time and dissolution studies were carried out to assess the release profile of Naproxen Sodium from the tablets.

Stability Studies of Naproxen Sodium Fast Dissolving Tablets

The stability of the tablets was examined over one month at different temperatures and humidity levels.[6–10]

RESULTS AND DISCUSSION

Confirmation of Identity of Naproxen Sodium other excipients

Gift Sample of Naproxen Sodium was obtained from Aarti Drug Pvt. Ltd. Tarapur (Bhoisar), Maharashtra, India. The samples' identities were confirmed via UV-visible wavelength scan and FT-IR spectra. FT-IR spectra were recorded, and the UV-visible spectra of Naproxen Sodium were recorded using methanol and water as solvents on a Shimadzu 1900 instrument.

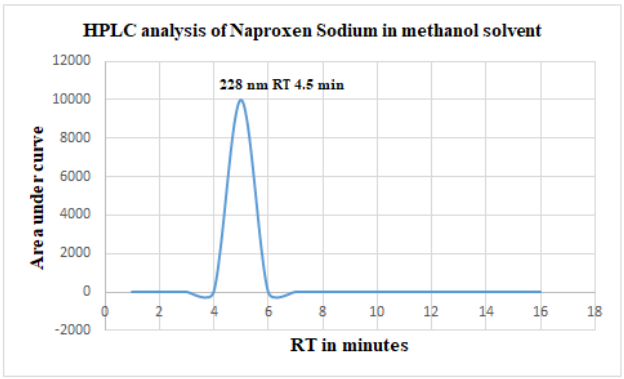

Fig. 1: HPLC analysis of pure Naproxen Sodium at 228 nm

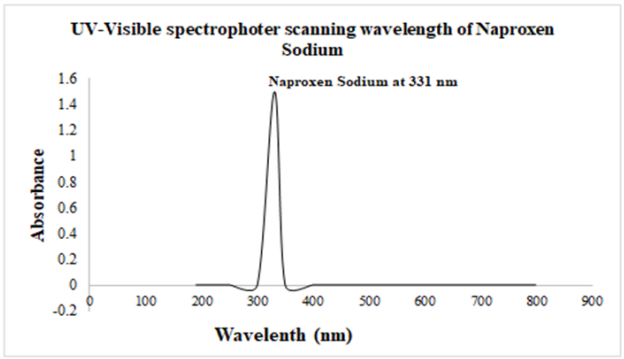

Fig. 2: Naproxen Sodium λ-max maximum absorbance at 331 nm

The UV-Visible spectra of were recorded using methanol as solvent were recorded using water as solvent on Shimadzu Instrument. Naproxen Sodium typically exhibits its maximum absorbance at around 331 nanometers (nm), indicating that it absorbs light most strongly at this wavelength. This characteristic absorption peak is often used for the quantitative analysis of Naproxen Sodium in pharmaceutical formulations and research studies.

The HPLC analysis were recorded using methanol as solvent were recorded using methanol as solvent on Agilent 1100 series Instrument. Naproxen Sodium typically exhibits its maximum absorbance at around 228 nanometers (nm),

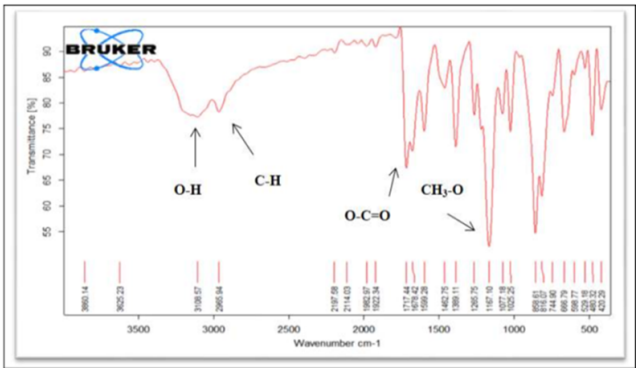

Fig. 3: FT-IR Interpretation of pure Naproxen Sodium

The Fourier-transform infrared (FT-IR) spectrum of Naproxen Sodium typically shows characteristic peaks corresponding to functional groups present in the molecule. Some prominent peaks in the FT-IR spectrum of Naproxen Sodium. Interpreting the FT-IR spectrum involves matching peaks with known vibrational frequencies to identify specific functional groups in the molecule shown in Figures 1, 2 and 3.

The UV-Visible spectra of Naproxen Sodium were recorded using methanol and water as solvents on a Shimadzu instrument. Naproxen Sodium typically exhibits its maximum absorbance around 331 nanometers (nm), which is used for the quantitative analysis of the drug in pharmaceutical formulations and research studies.

The HPLC analysis was conducted using methanol as the solvent on an Agilent 1100 series instrument, where Naproxen Sodium shows maximum absorbance at approximately 228 nanometers (nm).

The Fourier-transform infrared (FT-IR) spectrum of Naproxen Sodium displays characteristic peaks that correspond to the functional groups in the molecule. Interpreting the FT-IR spectrum involves identifying specific functional groups by matching the peaks with known vibrational frequencies, as shown in Figures 1, 2 and 3.[11–15]

Preformulation Studies Naproxen Sodium Fast Dissolving Tablets[16–25]

Evaluation of tablet: Evaluation parameter:

Appearance of Tablet: Color: Uniform white. Odor: No unusual odors. Surface Texture: Smooth, free from cracks or roughness.

Particles: No visible particles or foreign matter.

Size and Shape of Tablet: Size: Uniform within specified range. Shape: Consistent, as per design (round or oval).

Uniformity of Weight: Uniformity: Consistent appearance with no significant deviations in color, shape, texture, or size.

Thickness and Diameter: Ensures consistent dosing, handling, packaging, and administration.

Hardness (Crushing Strength): Measured in kilograms or Newton's. Ensures tablets withstand mechanical stress and remain intact until use.

Friability Test: Low friability ensures tablets remain intact during handling and transportation, minimizing dose variability.

Wetting Time: Indicates how quickly the tablet absorbs saliva and starts to disintegrate, ensuring fast onset of action and better patient compliance.

Disintegration Time: Measures how quickly the tablet breaks down in the mouth, ideally within a few seconds for rapid drug release and absorption.

Fig. 4: Wetting time of Naproxen Sodium fast dissolving tablet formulation F7

Dissolution test

In-Vitro dissolution studies: In vitro dissolution studies for Naproxen Sodium Fast Dissolving Tablets was carried out using USP paddle method at 50 rpm in 900 ml of phosphate buffer pH 6.8 as dissolution media, maintained at 37±0.5°C. 5 ml aliquot of the solution was withdrawn from the dissolution apparatus after suitable time intervals, and the samples were replaced with fresh dissolution medium. Absorbance of these solutions was measured at 331 nm using a Shimadzu UV- Shimadzu 1900 UV/VIS spectrophotometer.

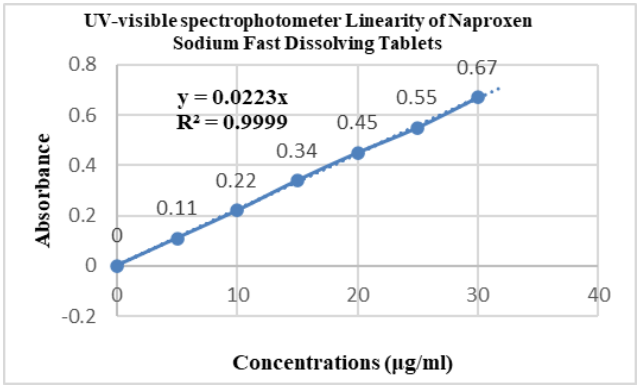

Fig. 5: Calibration curve of Naproxen Sodium Fast Dissolving Tablets

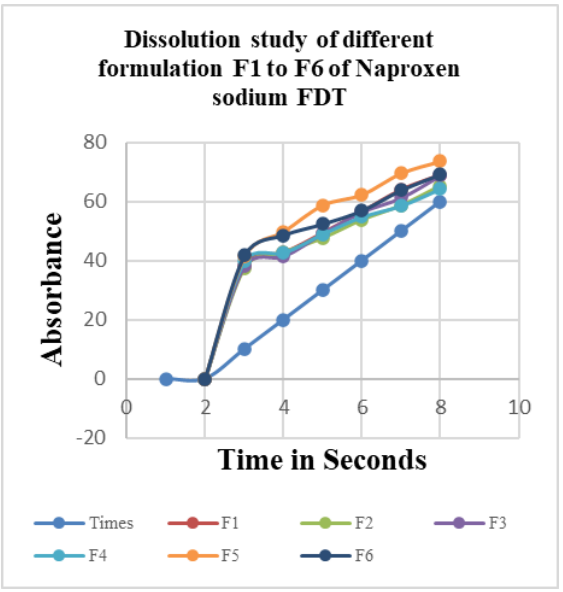

Fig. 6: Dissolution study of Naproxen Sodium Fast Dissolving Tablets formulation

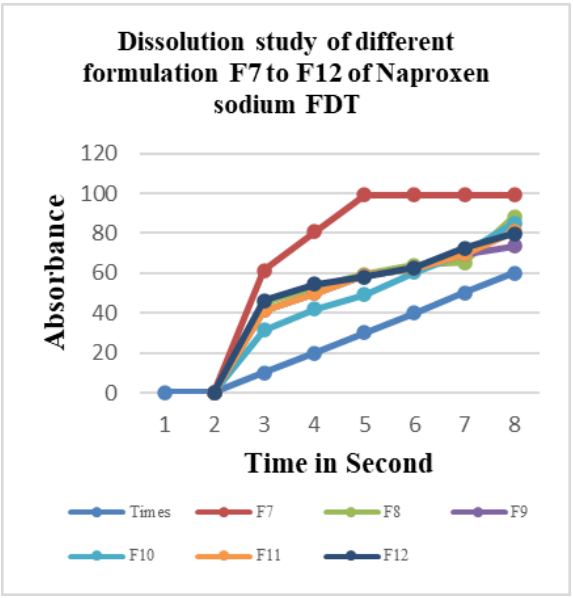

Fig. 7: Dissolution study of Naproxen Sodium Fast Dissolving Tablets formulation

Formulation Development of Naproxen Sodium Fast Dissolving Tablets[16–18]

Formulation F6 stands out as the most suitable option for the development of Naproxen Sodium Fast Dissolving Tablets due to its optimized superdisintegrants concentration, proper diluents content, consistent drug dosage, uniform tablet weight, effective lubrication, and proper manufacturing techniques.

Table 1: Evaluation and results of Naproxen Sodium Fast Dissolving Tablets (F1 to F12) formulations

Formulation of tablet dosage form	Hardness of tablet (Kg/cm)	Friability of tablet (%)	Thickness of tablet (mm)	Disintegration time (sec) of tablet	Weight Variation (average weight) (mg)	Wetting time (sec)
F1	3.2	0.38	2.8	49	204 ± 1.52	165
F2	3.8	0.4	2.8	49	203 ± 1.42	161
F3	4	0.41	2.8	45	204 ± 1.23	160
F4	3.5	0.42	2.8	44	201 ± 1.29	153
F5	3.4	0.41	2.6	40	202 ± 1.22	138
F6	3.4	0.37	2.7	32	198 ± 1.28	134
F7	**3.5**	**0.36**	**2.6**	**21**	**201 ± 1.21**	**45**
F8	4.1	0.38	2.6	28	204 ± 1.29	85
F9	3.8	0.32	2.5	31	199 ± 1.22	55
F10	4	0.48	3	48	197 ± 1.26	160
F11	3.6	0.45	3	49	195 ± 1.16	150
F12	3.9	0.44	3.1	47	198 ± 1.21	155

Each data represents Mean ± SD (n=3)

Table 2: Calibration curve of Naproxen Sodium Fast Dissolving Tablets

Sr. no.	Concentration (μg/ml)	Absorbance (331 nm)
1.	0	0
2.	5	0.11
3.	10	0.22
4.	15	0.34
5.	20	0.45
6.	25	0.55
7.	30	0.67

Each data represents Mean ± SD (n=3)

Table 3: Dissolution study of Naproxen Sodium Fast Dissolving Tablets formulation

Times Sec.	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0	0	0	0	0	0	0
10	38.32	37.45	38.02	39.65	41.32	41.66	61.2	45.33	41.32	31.3	41.32	46.33
20	42.69	42.78	41.36	42.58	49.77	48.54	80.8	52.88	49.77	42	49.77	54.58
30	49.36	47.65	49.21	48.98	58.77	52.33	99.2	59.28	58.77	49.2	58.77	57.99
40	56.58	53.82	56.44	54.78	62.33	56.88	99.2	63.99	62.33	60.2	62.33	62.77
50	63.98	58.69	61.25	58.57	69.56	63.77	99.2	65.35	69.56	70	69.56	72.58
60	68.99	65.32	68.77	64.28	73.65	69.11	99.2	88.37	73.65	85	80.65	79.74

Each data represents Mean ± SD (n=3)

Table 4: Procedure for selecting super disintegrants

Sr. no.	Batch No	Naproxen Sodium (mg)	Ac-Di-Sol (mg)	Mannitol (mg)	Mg. Stearate (mg)	Total weight (mg)
1.	F1	20	10	166	4	200
2.	F2	20	14	162	4	200
3.	F3	20	18	158	4	200
4.	F4	20	22	154	4	200
5.	F5	20	26	150	4	200
6.	F6	20	30	146	4	200

Each data represents Mean ± SD (n=3)

Optimization Naproxen Sodium Fast Dissolving Tablets

To plan experiments efficiently, statistical techniques such as factorial design, response surface methodology, or Taguchi methods are utilized. Factors are systematically varied within predetermined ranges, and experiments are conducted at selected combinations of factor levels.

Based on the Design of Experiments (DOE), formulation F9 appears to be the most promising among the provided formulations for several reasons:

1. **Optimal Superdisintegrants (Ac-Di-Sol) Concentration:** F7 contains 20 mg of Ac-Di-Sol, which is consistent with the amounts used in other formulations. This ensures adequate disintegration properties without compromising tablet integrity.
2. **Adjusted Mannitol Content:** F7 contains 124 mg of Mannitol, which is lower than formulations F1 to F7 but higher than F8 and F12. This balance likely provides sufficient bulk and ensures proper tablet formation while facilitating rapid disintegration.
3. **Absence of Additional Flavoring Agents:** F7 does not contain additional flavoring agents like Camphor, Menthol, or Thymol. While these agents may enhance palatability, their absence in F7 simplifies the formulation and may reduce potential side effects or interactions.
4. **Uniform Total Tablet Weight:** All formulations, including F7, maintain a total tablet weight of 200 mg, ensuring consistency in dosage delivery and manufacturing processes.
5. **Proper Lubrication:** Magnesium stearate (4 mg) is included in F7, ensuring proper lubrication during tablet compression, and preventing sticking, which is crucial for maintaining tablet integrity.
6. **Optimization:** The methodology likely considered various factors such as disintegration time, dissolution profile, and tablet hardness to determine the best formulation, and F7 emerged as the optimal choice based on these criteria.

Overall, formulation F7 stands out as the most suitable option for the intended purpose based on the analysis, balancing disintegration properties, tablet composition, and simplicity of formulation.[18–20]

Based on the provided table, formulation F9 appears to be the most suitable formulation for several reasons:

1. **Hardness of Tablets:** F7 has a hardness of 3.7 Kg/cm, which falls within the acceptable range for tablet hardness, indicating sufficient mechanical strength.
2. **Friability:** F7 has the lowest friability of 0.35%, indicating minimal tablet breakage or crumbling during handling or transportation.
3. **Thickness of Tablet:** The thickness of F7 tablets is 2.8 mm, which is within the desired range for ease of swallowing and packaging.
4. **Disintegration Time:** F7 exhibits the shortest disintegration time of 27 seconds, indicating rapid breakdown of the tablet into smaller particles when exposed to saliva, facilitating quick dissolution and absorption.
5. **Weight Variation:** F7 has a weight variation of 199 ±1.22 mg, demonstrating consistency in tablet weight, which is crucial for accurate dosing and uniformity of drug delivery.
6. **Wetting Time:** F7 shows a wetting time of 65 seconds, indicating rapid dispersion and absorption of saliva by the tablet, which is essential for Fast Dissolving Tablets to dissolve quickly in the mouth without the need for water.

Release kinetics of In-vitro Drug release

The kinetics of In-vitro drug release was determined by applying the drug release data to various kinetic models such as zero order, first order, Higuchi, Peppas-Korsmeyer and Hixson Crowell. The result obtained were represented in Table 7 and shown in Figure 8.[20,21,23]

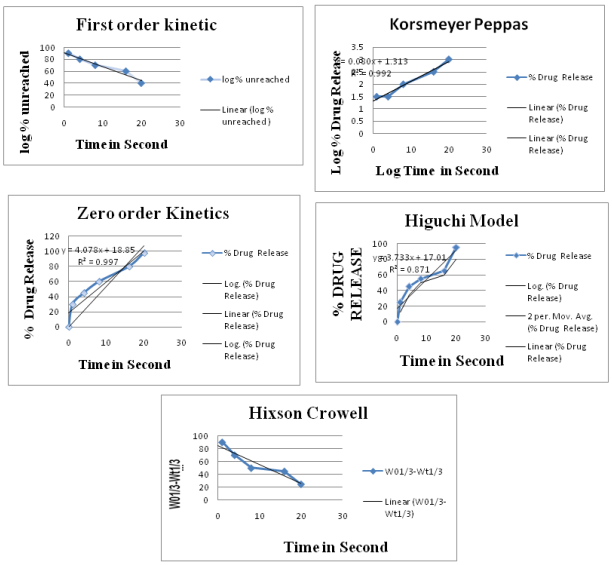

Fig. 8: Graph of different Release kinetics of In-vitro Drug release

Physical Characterization Naproxen Sodium Fast Dissolving Tablets

The Naproxen Sodium Fast Dissolving Tablets formulations were analyzed using UV-spectrophotometric methods to quantify both free and entrapped Naproxen Sodium.

Table 5: Naproxen Sodium Fast Dissolving Tablets (F1 to F12) formulations

Ingredients (mgs)	Formulation Code (in mg)											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F10
Naproxen Sodium	20	20	20	20	20	20	20	20	20	20	20	20
Mannitol	144	134	124	144	134	124	124	134	144	144	144	176
Ac-Di-Sol	20	20	20	20	20	20	20	20	20	20	20	0
Xylitol	2	2	2	2	2	2	2	2	2	2	2	0
Camphor	10	20	30	0	0	0	0	0	0	0	0	0
Menthol	0	0	0	10	20	30	0	0	0	0	0	0
Thymol	0	0	0	0	0	0	30	20	10	10	10	0
Magnesium stearate	4	4	4	4	4	4	4	4	4	4	4	4
Total	200	200	200	200	200	200	200	200	200	200	200	200

Each data represents Mean ± SD (n=3)

Table 6: Optimization of Naproxen Sodium Fast Dissolving Tablets (F1 to F12) formulations results

Formulation of tablet dosage form	Hardness of tablet (Kg/cm)	Friability of tablet (%)	Thickness of tablet (mm)	Disintegration time (sec) of tablet	Weight variation (average weight) (mg)	Wetting time (sec)
F1	3.5	0.4	2.9	59	204 ± 1.52	180
F2	4	0.45	3	56	203 ± 1.42	165
F3	4.1	0.43	2.8	49	204 ± 1.23	160
F4	3.9	0.46	2.7	42	201 ± 1.29	153
F5	3.8	0.48	2.8	38	202 ± 1.22	146
F6	3.9	0.4	2.9	36	198 ± 1.28	135
F7	3.7	0.35	2.8	27	199 ± 1.22	65
F8	4.2	0.38	2.5	30	204 ± 1.29	95
F9	4.6	0.52	3.3	58	197 ± 1.26	191
F10	4.5	0.51	3.1	58	197 ± 1.26	190
F11	4.2	0.38	2.8	33	201 ± 1.21	110
F12	4	0.39	2.6	35	201 ± 1.21	110

Each data represents Mean ± SD (n=3)

Table 7: Different Release kinetics of In-vitro Drug release

Sr. no	Kinetics Models				
	Zero order	First order	Higuchi model	Korsmeyer Peppas	Hixson Crowell
	R2	R2	R2	R2	R2
F1	0.9729	0.8176	0.9504	0.9486	0.9819
F2	0.9662	0.9878	0.9864	0.9861	0.9243
F3	0.9977	0.8906	0.9921	0.9946	0.9746
F4	0.9726	0.9449	0.9534	0.9929	0.9716
F5	0.9292	0.9178	0.9844	0.9762	0.9942
F6	0.9373	0.8992	0.9917	0.9818	0.9383
F7	**0.9991**	**0.9231**	**0.9941**	**0.9998**	**0.9987**
F8	0.9979	0.9331	0.9741	0.9998	0.9789
F9	0.9721	0.9778	0.9791	0.9971	0.9701
F10	0.9722	0.9778	0.9798	0.9970	0.9705
F11	0.9721	0.9778	0.9791	0.9971	0.9704
F12	0.9722	0.9779	0.9790	0.9979	0.9708

Each data represents Mean ± SD (n=3)

Result of determination of Free Naproxen Sodium: Tablets were analyzed for free Naproxen Sodium using a UV-spectrophotometric method at a wavelength of 354 nm against an appropriate blank. Tablets were dissolved in distilled water, and the solution was appropriately diluted to ensure the absorbance fell within the range of the standard curve. The absorbance of the diluted solution was measured at 354 nm using a UV-visible spectrophotometer.

Result of determination of Entrapped Naproxen Sodium: Approximately 200 mg of dried Naproxen Sodium Fast Dissolving Tablets were accurately weighed and dissolved in distilled water. The resulting solution was then appropriately diluted with distilled water to obtain absorbance readings within the range of the standard curve. The absorbance of the diluted solution was measured at 331 nm using a UV-visible spectrophotometer. By employing these methods, both free and entrapped Naproxen Sodium in the Fast-Dissolving Tablets were quantified, providing valuable insights into the formulation's efficacy and ensuring the desired drug release profile is achieved.

Look for characteristic peaks associated with the functional groups present in Naproxen Sodium For:O-H Stretch: Broad peak around 3200-3500 cm^{-1} due to the stretching vibration of the O-H bond in the carboxylic acid group. C=O Stretch: Strong, sharp peak around 1700-1720 cm^{-1} due to the stretching vibration of the carbonyl group (C=O) in the carboxylic acid. C-H Stretch: Typically observed in the range of 2900-3000 cm^{-1}, representing the stretching vibration of C-H bonds, mainly from the aromatic rings and methyl groups. These peaks provide diagnostic information about the functional groups present in Naproxen Sodium, aiding in its identification and characterization using FT-IR spectroscopy.

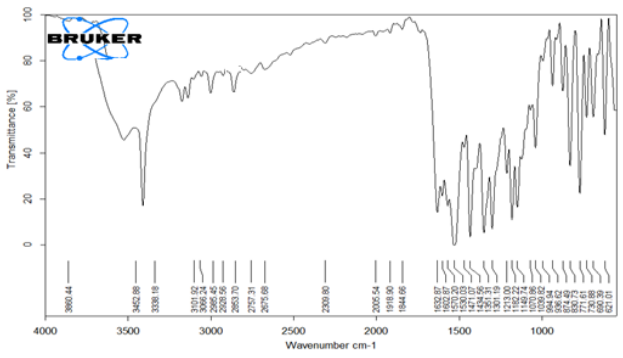

Fig. 9: FT-IR-Spectra of Naproxen Sodium from Fast Dissolving Tablets

Characteristic Peaks in FTIR Spectrum

Naproxen Sodium

- Aromatic C-H stretching: 3100-3000 cm^{-1}
- Carboxylic acid C=O stretching: 1700-1750 cm^{-1}
- Carboxylic acid C-O stretching: 1200-1300 cm^{-1}

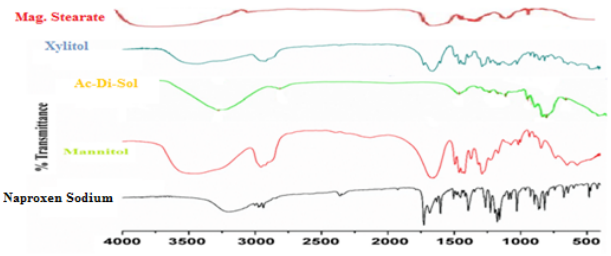

Fig. 10: FT-IR-Spectra for Naproxen Sodium physical mixture

Mannitol

- O-H stretching: 3600-3100 cm^{-1} (broad)
- Intermolecular hydrogen bonding: ~3500 cm^{-1}
- Alcohol C-H stretching: 2900-2800 cm^{-1}
- C-O stretching: 1200-1000 cm^{-1}
- C-O stretching: 1100-1050 cm^{-1} and 1060-1030 cm^{-1}

Xylitol

- O-H stretching: 3200-3600 cm^{-1} (broad)
- C-H stretching: 2800-3000 cm^{-1}
- Primary alcohol C-O stretching: 1050-1150 cm^{-1}
- Secondary alcohol C-O stretching: 1000-1050 cm^{-1}

Ac-Di-Sol

O-H stretching: 3200-3600 cm^{-1} (broad)
Carboxylate C=O stretching: 1600-1650 cm^{-1}
C-O stretching: 1100-1300 cm^{-1}
Na-O stretching: 600-700 cm^{-1}

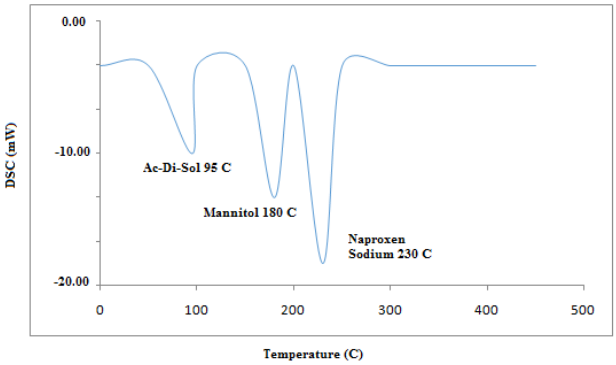

Fig. 11: DSC for physical mixture of Naproxen Sodium Fast Dissolving Tablets

Differential Scanning Calorimetry (DSC) is a thermal analysis technique used to study the thermal behavior of materials, including their melting points, glass transition temperatures, crystallization, and thermal stability. Here's

a general overview of what you might observe in a DSC analysis of Naproxen Sodium, Mannitol, and Ac-Di-Sol:

Naproxen Sodium: Melting Point: Naproxen Sodium typically exhibits a sharp endothermic peak corresponding to its melting point, which is around 230°C.

Mannitol: Melting Point: Mannitol typically shows a well-defined endothermic peak around 180 °C, corresponding to its melting point.

Ac-Di-Sol: Melting Point: Ac-Di-Sol generally exhibits a broad endothermic peak around 90 °C, corresponding to its melting point.

Compatibility Study Naproxen Sodium Fast Dissolving Tablets

The compatibility study of Naproxen Sodium Fast Dissolving Tablets formulation, where the drug and excipients were mixed in equal proportions and stored under different environmental conditions (40°C/RH 60% and 40°C/RH 75%) for 3month, revealed no interaction between the drug and excipients.

Weekly analysis of the samples for curcumin content using UV-visible spectrophotometer showed consistent levels, indicating stability of the formulation under the tested conditions. Additionally, no significant changes in the physical appearance of the samples were observed throughout the study period.

Furthermore, the FT-IR spectrum recorded for Naproxen Sodium Fast Dissolving Tablets formulation F7 confirmed the absence of any notable interactions between the drug and excipients, supporting the overall compatibility of the formulation.[22–25]

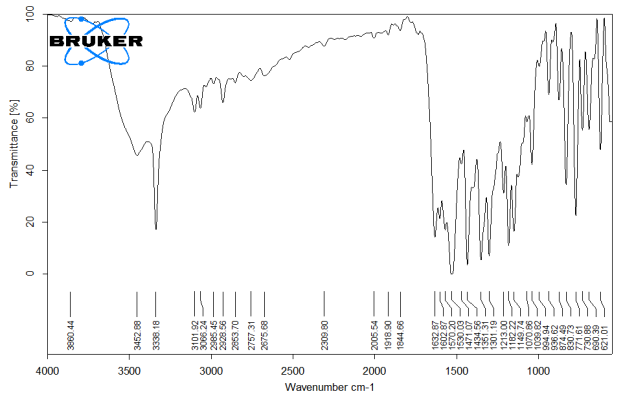

Fig. 12: FT-IR spectra of drug with excipients in Naproxen Sodium Fast Dissolving Tablets formulation

Stability Studies Naproxen Sodium Fast Dissolving Tablets

Stability study of Naproxen Sodium Fast Dissolving Tablets formulations for 3 months at different temperatures 4^0, 25^0C /RH 60%, and 40^0C /RH 75% Samples of the formulations stored at various conditions of temperature and humidity were taken out at weekly intervals and the concentration of Naproxen Sodium in these were determined using UV-Visible spectrophotometer. The samples were dissolved in water and suitably diluted to read absorbance against water blank at 331 nm. Formulation was subjected to stability studies at 40 ^{0}C ± 2 ^{0}C / 75% RH ± 5% for 3 months.

The product was evaluated for following parameters:

1. Weight variation
2. Hardness
3. Friability
4. Drug content
5. Dissolution analysis

Storage condition at 40°C ± 2°C/75 %RH ± 5%.

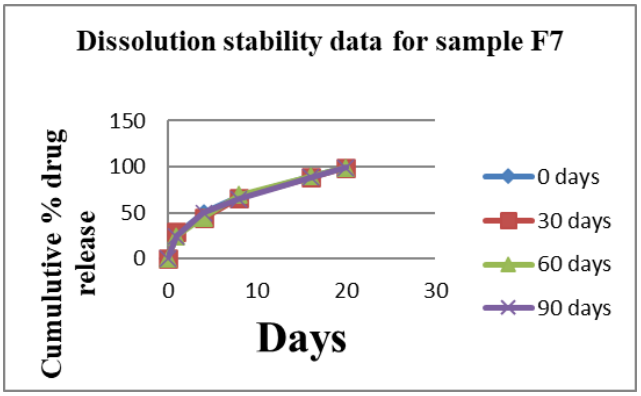

Fig. 13: % drug release during Stability Study of Optimized Batch of F7 Naproxen Sodium Fast Dissolving Tablets by dissolution testing

The stability studies for optimized formulation F7 were carried out based accelerated stability conditions and study of various parameters carried out at 0, 30, 60, 90 days of intervals and the results found satisfactorily and that reveals that the optimized formulation was stable under accelerated condition.

DISCUSSION

The study on Naproxen Sodium Fast Dissolving Tablets (ODTs) aims to enhance patient compliance, particularly for individuals with swallowing difficulties. Key points of the research include:

- **Objective:** To develop ODTs of Naproxen Sodium to assist patients with swallowing challenges, especially the elderly and those with mental health conditions.
- **Material Procurement and Confirmation:** Naproxen Sodium and excipients were procured and their identities confirmed through UV-visible spectroscopy and FT-IR analysis.

Table 8: Stability Study of Optimized Batch of F7 Naproxen Sodium Fast Dissolving Tablets

Time	Parameters				
	Hardness (Kg/cm^2)	Uniformity of weight	Friability (%)	Disintegration time (sec)	Drug content (%)
0 Days	3.5±0.56	200.2±0.31	0.64±0.01	20±1.01	99.57±0.04
30 Days	3.4±0.12	200.3±0.28	0.68±0.03	22±1.52	98.83±0.15
60 Days	3.3±0.12	200.6±0.35	0.69±0.02	21±0.83	97.49±0.12
90 Days	3.3±0.14	200.8±0.33	0.71±0.01	25±0.91	98.71±0.11

Each data represents Mean ± SD (n=3)

Table 9: % drug release during Stability Study of Optimized Batch of F7 Naproxen Sodium Fast Dissolving Tablets by dissolution testing

Time (Sec)	0 days	30 days	60 days	90 days
0	0	0	0	0
1	26.20	29.10	24.90	24.91
4	49.80	44.20	45.10	50.10
8	67.56	66.56	69.46	65.16
16	89.50	88.56	89.59	88.50
20	99.20	99.40	99.10	99.10

- **Formulation Development:** Multiple formulations were created and optimized for rapid disintegration and dissolution, with Formulation F6 initially identified as optimal.
- **Optimization:** Further experimental designs revealed Formulation F9 as the best option, due to its superior disintegration properties and ideal composition.
- **Preformulation Studies:** Various parameters were evaluated, including tablet appearance, melting point, taste, size, weight uniformity, hardness, friability, wetting time, and disintegration time.
- **Dissolution Test:** The dissolution profile of the ODTs was determined using the USP paddle method.
- **Compatibility Study:** The stability of Naproxen Sodium and excipients was confirmed under different environmental conditions.
- **Physical Characterization:** UV-spectrophotometric methods and FT-IR spectroscopy were used for the physical analysis of the tablets.
- **Stability Studies:** The stability of the ODTs was monitored over three months under varying temperature and humidity conditions to determine shelf life.

CONCLUSION

The study provides a comprehensive overview of the formulation, characterization, and stability of Naproxen Sodium ODTs, demonstrating their potential to improve patient adherence and medication efficacy.

Conflict of interest

Authors don't have any conflict of interest.

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