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"DEVELOPMENT AND ASSESSMENT OF NAPROXEN FAST DISSOLVING TABLETS: FORMULATION AND EVALUATION"

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Abstract:

The primary objective of this study is to develop and evaluate fast-dissolving naproxen tablets, aimed at improving patient compliance, especially for individuals with difficulty swallowing conventional tablets. Naproxen, a widely used pain reliever, benefits from this formulation by ensuring rapid dissolution in the mouth while maintaining sufficient strength for packaging and transport. The study focuses on optimizing the tablet's dissolution rate, stability, and absorption.

Physical evaluation confirmed naproxen's quality and purity with a consistent melting point of 153°C. Solubility studies in various solvents demonstrated the drug's compatibility with different formulation vehicles. Compatibility studies under various environmental conditions identified formulation F8 as the most favorable for fast-dissolving tablets. This formulation maintained stable concentrations across different temperatures and humidity levels, indicating robustness for long-term storage.

Characterization using UV-spectrophotometry and Differential Scanning Calorimetry (DSC) confirmed the presence of both free and entrapped naproxen, and provided insights into the thermal behavior of excipients like Mannitol and Aspartame. In vitro drug release kinetics of formulation F8 showed efficient drug delivery and therapeutic efficacy.

Stability studies over one month highlighted formulation F8's superior stability compared to other formulations (F7 and F9). The results suggest that formulation F8 holds significant potential for commercial production and distribution, ensuring an effective and user-friendly way for patients to manage pain and inflammation.

Keywords: Naproxen, fast-dissolving tablet, DSC, FT-IR etc.

Introduction:

Naproxen is a non-steroidal anti-inflammatory drug (NSAID) commonly used to alleviate pain, inflammation, and stiffness caused by conditions such as arthritis, menstrual cramps, and various musculoskeletal disorders. It belongs to the class of medications known as propionic acid derivatives. Naproxen works by inhibiting the production of prostaglandins, which are substances in the body that contribute to inflammation and pain. 1

It is available in various forms, including tablets, capsules, and oral suspension, and is often prescribed at doses ranging from 250 mg to 500 mg, depending on the severity of the condition being treated. Naproxen is typically taken orally with food or milk to reduce the risk of stomach upset. Like other NSAIDs, Naproxen may cause side effects such as gastrointestinal irritation, ulcers, and bleeding, particularly in high doses or with long-term use. It may also increase the risk of cardiovascular events, such as heart attack or stroke, especially in individuals with pre-existing cardiovascular conditions.

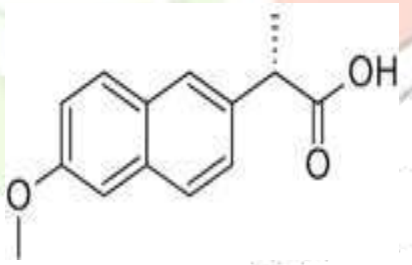


Figure no. 01: Structure and IUPAC name: Naproxen [2-(6-methoxynaphthalen-2-yl) propanoic acid]

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 that disintegrate or dissolve rapidly in the mouth without the need for water or chewing. They offer several advantages over conventional tablets, especially in scenarios where swallowing a pill may be difficult, such as for pediatric, geriatric or dysphagic patients. Here's some information about fast dissolving tablets:

Composition: Fast dissolving tablets are typically composed of active pharmaceutical ingredients (APIs), along with excipients such as superdisintegrants, fillers, sweeteners, and flavoring agents.

Superdisintegrants like Crospovidone, Croscarmellose sodium, and sodium starch glycolate play a crucial role in rapid disintegration.

Manufacturing Techniques: Various manufacturing techniques are employed to produce fast dissolving tablets. Some common methods include direct compression, freeze-drying, sublimation, and spray-drying. Each method has its advantages and challenges in terms of product stability, manufacturing efficiency, and cost.

Advantage:

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

Disintegration Mechanism:

1. Fast dissolving tablets disintegrate rapidly upon contact with saliva.
2. The mechanism of disintegration involves the swelling of superdisintegrants, which creates pressure within the tablet matrix, leading to its fragmentation into smaller particles.
3. These particles dissolve or disperse in the saliva, facilitating easy swallowing or absorption through the oral mucosa.

Applications:

1. Fast dissolving tablets find applications across various therapeutic areas, including pediatrics, geriatrics, psychiatry, and pain management, allergy, and travel medicine.
2. They are particularly useful for on-the-go medication administration, emergency situations, and for patients with swallowing difficulties.

Formulation Considerations: Formulation development of fast dissolving tablets requires careful consideration of factors such as the choice of: 2

1. Superdisintegrants,
2. Excipients Compatibility,
3. Taste-Masking Strategies,
4. Stability of the Formulation, And,
5. Manufacturing Feasibility.

Packaging:

1. Packaging of fast dissolving tablets is critical to maintaining their stability and integrity.
2. Typically, these tablets are packaged in blister packs or unit-dose pouches to protect them from moisture and environmental factors.

Regulatory Considerations:

1. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) provide guidelines for the development, evaluation, and approval of fast dissolving tablets.
2. These guidelines address aspects such as quality, safety, efficacy, and labeling requirements.

Fast dissolving tablets offer a patient-friendly dosage form with rapid disintegration and absorption characteristics. Their development involves careful formulation and manufacturing considerations to ensure product stability, efficacy, and patient compliance.

Experimental:

Chemical and reagent: Gift Sample of Naproxen was obtained from Dr. Reddy's Laboratories at Headquartered in Hyderabad, India Croscarmellose were received as a gift sample from Stallion Lab. Pvt. Ltd., Bawla, Gujarat. Sodium Starch Glycolate, Crospovidone, mannitol, sodium Lauryl sulfate and microcrystalline cellulose were gifted from Aura Nutraceuticals Ltd., Budasan, and Gujarat. The procured samples were tested to confirm their identity and this included UV-visible wavelength scan, and recording of FT-IR spectra. FT-IR spectra were recorded. The sample was prepared as KBr pallet for recording the spectra.[11-15]

Preparation and Optimization of Naproxen Fast Dissolving Tablets:

Pre-compression Parameters:: Bulk density, tap density, Carr's index, Hausner ratio, and angle of repose were measured to ensure powder flow properties and compressibility.

Tablet Formulation: Materials were sieved, mixed, and compressed using a direct compression technique with a Cadmach compression machine. Various formulations (F1-F9, S1) were prepared with different proportions of excipients to optimize the fast-dissolving properties.

Compatibility Study: Drug-excipients mixtures were stored under different conditions (25°C/RH 60% and 40°C/RH 75%) and analyzed weekly for physical changes and content via UV-visible spectrophotometer.

Characterization: Tablets were analyzed for free and entrapped Naproxen using UV-Spectrophotometric method at 331 nm. FT-IR spectra were recorded to confirm formulation stability.

Evaluation: Tablets were evaluated for weight variation, thickness, hardness, friability, drug content, and wetting time using standard methods to ensure quality and performance.

In-Vitro Release Profile: Disintegration time was measured, and in-vitro dissolution studies were conducted using the USP paddle method. Drug release kinetics were analyzed using various mathematical models to ensure efficient drug delivery.

Stability Studies Stability studies were conducted over three months at different temperatures and humidity levels. Naproxen content was determined weekly using UV-Visible spectrophotometer to ensure long-term stability.

Results and discussion:

Procurement and Confirmation of Identity of Naproxen: Gift samples of Naproxen were obtained from Dr. Reddy's Laboratories, Hyderabad. Croscarmellose and Aspartame were sourced from Stallion Lab. Pvt. Ltd., and other excipients from Aura Nutraceuticals Ltd., Gujarat. The identity of samples was confirmed via UV-visible wavelength scan and FT-IR spectra using methanol as the solvent.

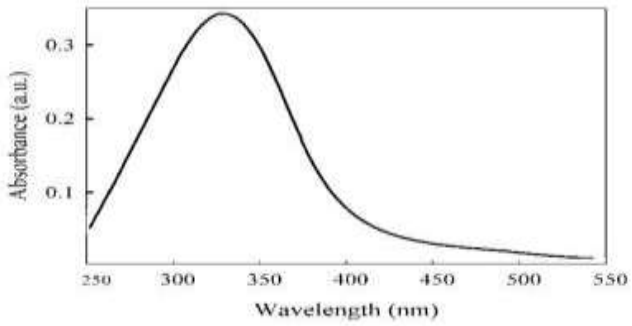


Figure no. 02: Naproxen λ-max maximum absorbance at 331 nm.

Table no.01: Std. calibration curve for Naproxen:

Concentration µg/ml	Absorbance
00	0.00
10	0.123
20	0.224
30	0.482
40	0.641
50	0.869
60	1.222

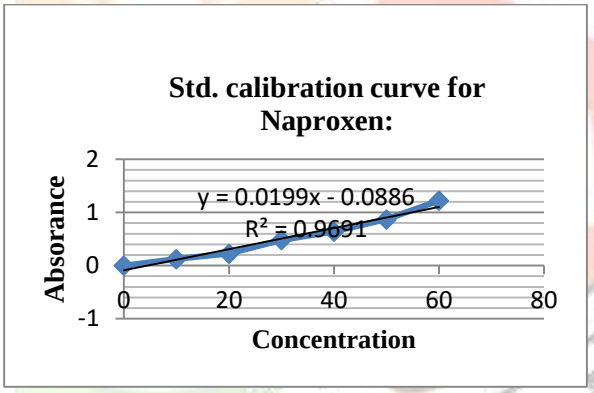


Figure no. 03: Std. calibration curve for Naproxen.

The UV-Visible spectra of Naproxen were recorded using methanol and water as solvents on a Shimadzu instrument. Naproxen typically exhibits its maximum absorbance at around 331 nanometers (nm), indicating its strongest light absorption at this wavelength. This absorption peak is crucial for the quantitative analysis of Naproxen in pharmaceutical formulations and research studies.

The Fourier-transform infrared (FT-IR) spectrum of Naproxen typically shows characteristic peaks corresponding to the functional groups present in the molecule. Some prominent peaks in the FT-IR spectrum of Naproxen include:

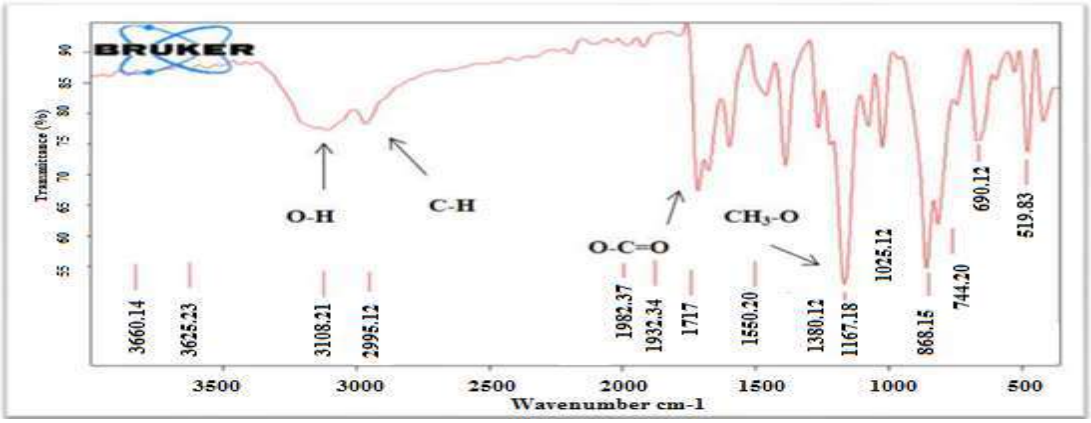


Figure no. 04: FT-IR spectra of pure Naproxen.

Organoleptic Properties: Naproxen appears white to light yellow, with a characteristic odor and bitter taste.

Melting Point: The melting point, determined using the capillary tube method, is 153°C, within the standard range of 153-154°C.

Solubility: Naproxen solubility varies with different solvents: Sparingly soluble in water, chloroform, and dichloromethane. Moderately soluble in ethanol, methanol, acetone, and Acetonitrile Highly soluble in Dimethyl sulfoxide. Practically insoluble in oil. Solubility in buffered solutions depends on pH and ionic strength. Solubility can be enhanced with specific formulations of surfactants or co-solvents.

Result of Preparation and Optimization of Naproxen Fast Dissolving Tablets: Throughout the process, it's essential to monitor and optimize parameters such as particle size distribution, blend uniformity, granule flow properties, and compression settings to ensure the production of high-quality fast-dissolving tablets containing naproxen.

Table no. 02: Result of Angle of Repose (θ), Loose Bulk Density (gm/cm3), and Tapped Bulk Density (gm/cm3), % Compressibility, Carr's index, Hausner's ration of FAST DISSOLUTION TABLET for Naproxen tablets:

Formulation Code	Angle of Repose (θ)	Loose Bulk Density (gm/cm3)	Tapped Bulk Density (gm/cm3)	% Compressibility	Carr's index (%)	Hausner's ratio
F1	26.44±0.02	0.37±0.01	0.49±0.01	34.28±0.04	12.65±0.03	1.23±0.02
F2	26.36±0.02	0.37±0.02	0.48±0.02	35.42±0.03	12.34±0.04	1.23±0.03
F3	27.77±0.01	0.38±0.01	0.49±0.01	31.38±0.05	13.89±0.02	1.12±0.03
F4	26.99±0.01	0.38±0.01	0.47±0.01	32.21±0.02	14.56±0.01	1.25±0.01
F5	26.13±0.03	0.37±0.03	0.48±0.02	31.42±0.03	15.67±0.03	1.18±0.01
F6	25.55±0.04	0.38±0.03	0.54±0.02	32.93±0.02	14.58±0.01	1.25±0.01
F7	26.65±0.02	0.37±0.02	0.49±0.03	32.83±0.01	12.44±0.02	1.27±0.03
F8	**23.24±0.04**	**0.37±0.01**	**0.48±0.03**	**24.27±0.04**	**12.44±0.02**	**1.26±0.03**
F9	29.62±0.03	0.38±0.02	0.47±0.01	31.78±0.03	12.34±0.02	1.14±0.01

Each data represents Mean ±SD (n=3)

Result of Compatibility study of Drug and Excipients:

Compatibility Study of Drug and Excipients which used Naproxen Fast Dissolving Tablets formulation were mixed in equal proportions and stored at Storage different environmental conditions of, 40,250 C /RH 60%, and 400C /RH 75% for one month. The samples were analyzed for the content of curcumin at weekly intervals by UV visible spectrophotometer. The samples were also observed for any change in the physical appearance at weekly intervals. FT-IR spectrum for Naproxen Fast Dissolving Tablets formulation F9 was recorded. (Ni = No Interaction, I= Interaction)

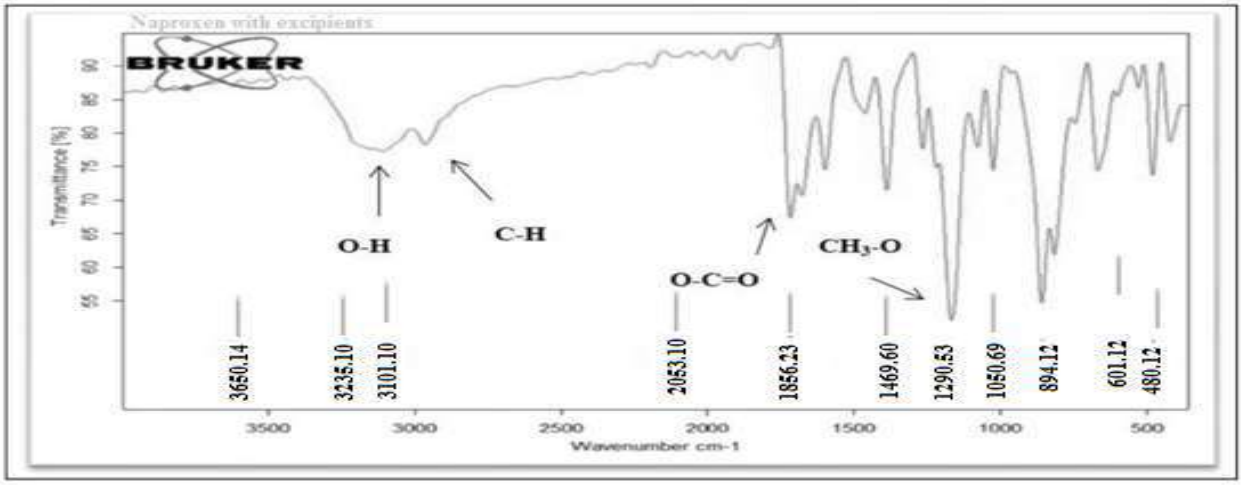


Figure no. 05: FT-IR spectra of Naproxen and excipients for Compatibility study.

Interpretation:

In drug-excipients compatibility studies, analyzing FT-IR spectra helps detect interactions. If the mixture's spectra show no significant shifts, disappearances, or new peaks compared to individual components, it suggests good compatibility. Conversely, noticeable changes indicate potential interactions, requiring further investigation.

Result of Characterization of the FAST DISSOLUTION TABLET for Naproxen tablets:

The Naproxen Fast Dissolving Tablets were analyzed for free and entrapped naproxen using UV-Spectrophotometry at 331 nm. To measure entrapped naproxen, 250 mg of dried tablets were dissolved in distilled water and appropriately diluted. Free naproxen was also diluted with distilled water and measured at 331 nm. This characterization provided data on both free and entrapped naproxen in the formulations.

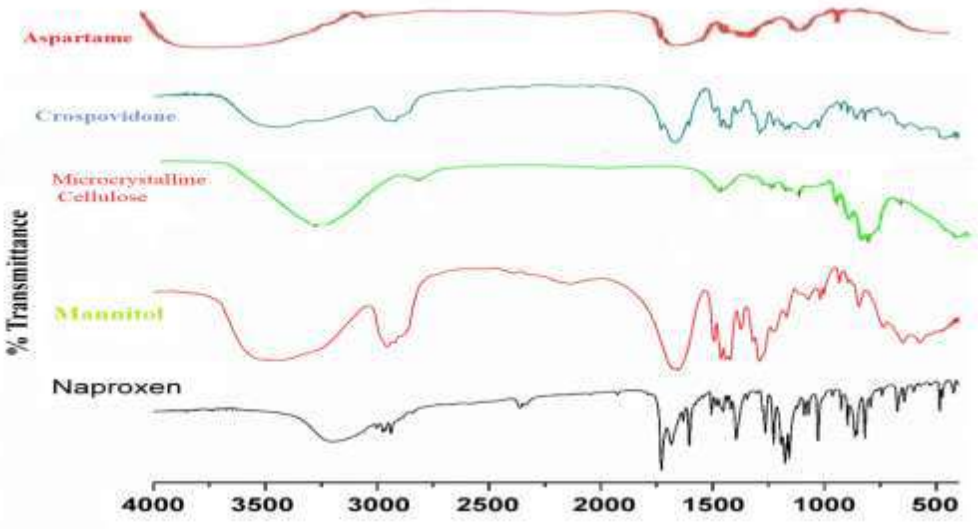


Figure no. 06: FTIR-Spectra for Naproxen physical mixture.

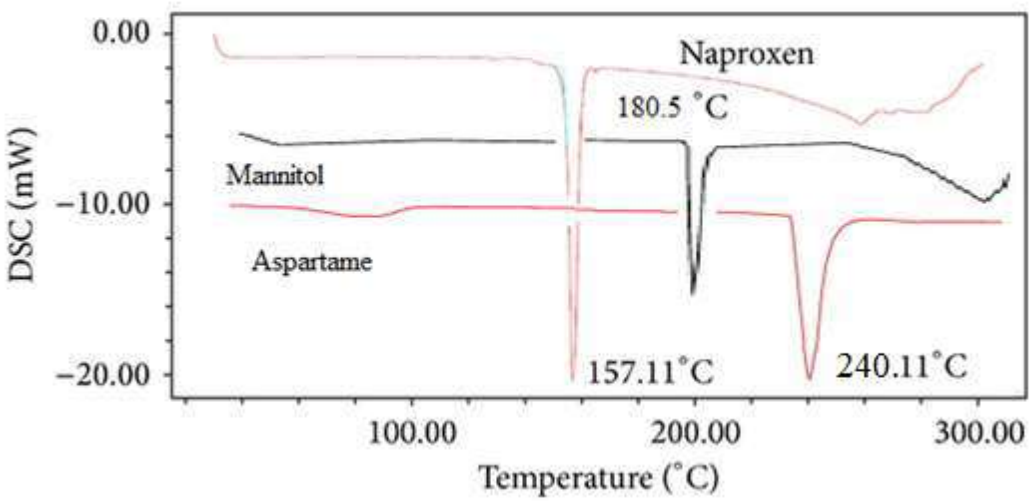


Figure no.07: DSC for physical mixture of for Naproxen tablets formulation.

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, Mannitol, and Aspartame: Naproxen: Melting Point: Naproxen typically exhibits a sharp endothermic peak corresponding to its melting point, which is around 157.11°C. Mannitol: Melting Point: Mannitol typically shows a well-defined endothermic peak around 180.5 °C, corresponding to its melting point. Aspartame: Melting Point: Aspartame generally exhibits a broad endothermic peak around 240°C, corresponding to its melting point.

Result of Evaluation of the FAST DISSOLUTION TABLET for Naproxen tablets: [20-35]

a) Weight Variation Test: Twenty tablets were individually weighed using a Sartorius balance (Model CP-224 S). The average weight was calculated, and each tablet's weight was compared to the average weight.

b) Tablet Thickness: The thickness of five tablets was measured using Vernier calipers.

c) Tablet Hardness: Tablet hardness, measured as the force required breaking a tablet in diametric compression, was determined using a Monsanto hardness tester.

d) Tablet Friability: Friability was assessed using a Roche friabilator. Twenty tablets were dedusted and subjected to 100 revolutions in the drum. Percentage friability was calculated, with a maximum allowable loss of 1%.

e) Drug Content: Twenty tablets were crushed, and the equivalent of 100 mg of drug was dissolved in methanol and phosphate buffer pH 6.8. The solution was filtered and analyzed for drug content by UV spectrophotometer at 363 nm.

Table no. 04: Evaluation parameters and results of FAST DISSOLUTION TABLET for Naproxen tablets:

Formulation Code	Angle of Repose (θ)	Loose Bulk Density (gm/cm3)	Tapped Bulk Density (gm/cm3)	% Compressibility
S1	25.69±0.02	0.37±0.04	0.58±0.03	23.53±0.02
F1	26.44±0.02	0.38±0.01	0.48±0.01	21.28±0.04
F2	27.36±0.02	0.38±0.02	0.48±0.02	20.42±0.03
F3	28.77±0.01	0.39±0.01	0.47±0.01	17.38±0.05
F4	27.99±0.01	0.39±0.01	0.48±0.01	21.21±0.02
F5	25.13±0.03	0.38±0.03	0.48±0.02	20.42±0.03
F6	24.55±0.04	0.38±0.03	0.53±0.02	22.93±0.02
F7	25.65±0.02	0.38±0.02	0.48±0.03	20.83±0.01
F8	**24.22±0.04**	**0.38±0.01**	**0.47±0.03**	**15.23±0.04**
F9	24.62±0.03	0.38±0.02	0.49±0.01	18.78±0.03

Each data represents Mean ±SD (n=3)

F8 is the optimal choice among Fast Dissolution Tablet for Naproxen tablets due to several key factors:

1. Weight: It averages 299.6 mg, aligning with the desired dosage.
2. Thickness: Tablets measure 3.85 mm, facilitating easy handling and swallowing.
3. Hardness: With a rating of 3.5, they exhibit adequate mechanical strength.
4. Friability: F8 shows minimal loss at 0.61%, indicating robustness.
5. Drug Content: Achieving 99.57%, it ensures consistent dosage.
6. Wetting Time: Dispersing in 34 seconds, it offers rapid dissolution.

Overall, F8 excels in drug content, disintegration time, and mechanical strength, making it the preferred Fast Dissolution Tablet formulation.

***In-vitro* release profile Fast Dissolution Tablet for Naproxen tablets:**

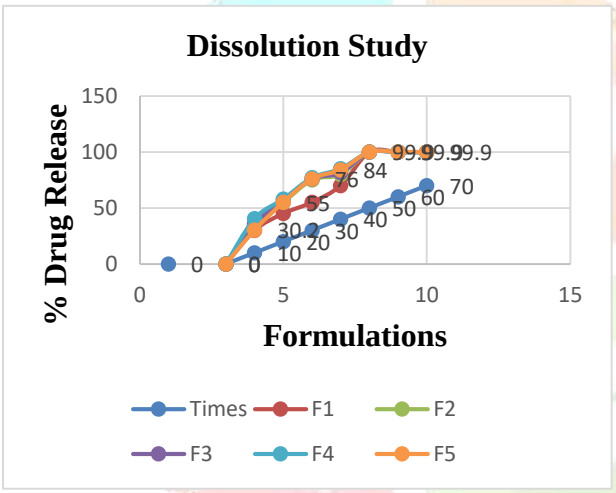
A. In the in-vitro disintegration test, tablets were individually placed in tubes of a disintegration test apparatus with a stainless-steel screen bottom, submerged in a 37 ± 2°C water bath. The time for complete disintegration was recorded. Compliance with Pharmacopoeial standards requires dispersible tablets to disintegrate within 3 minutes.

B. In-vitro dissolution studies for Fast Dissolution Tablet for Naproxen tablets utilized the USP paddle method at 50 rpm in 900 ml of phosphate buffer pH 6.8 at 37 ± 0.5°C. Samples were withdrawn at intervals, replaced with fresh dissolution medium, and their absorbance measured at 363 nm using a Shimadzu 1900 Spectrophotometer.

Table no. 05: In- Vitro dissolution studies and results of Fast Dissolution Tablet for Naproxen tablets:

Times Sec.	F1	F2	F3	F4	F5	F6	F7	F8	F9	S1
0	0	0	0	0	0	0	0	**0**	0	0
10	30	35	35.5	40.5	30.2	30.2	45	**60.0**	40.2	20.5
20	45	55	57	58	55	52	65	**80.0**	68.3	35.5
30	55	75	76	77	76	70.5	70	**99.0**	80.5	65.5
40	70	80	81.5	85	84	86	82	**99.90**	90.5	70.5
50	99.90	99.90	99.90	99.90	99.90	99.90	99.90	**99.90**	99.90	99.90
60	99.90	99.90	99.90	99.90	99.90	99.90	99.90	**99.90**	99.90	99.90
70	99.90	99.90	99.90	99.90	99.90	99.90	99.90	**99.90**	99.90	99.90

Each data represents Mean ±SD (n=3).



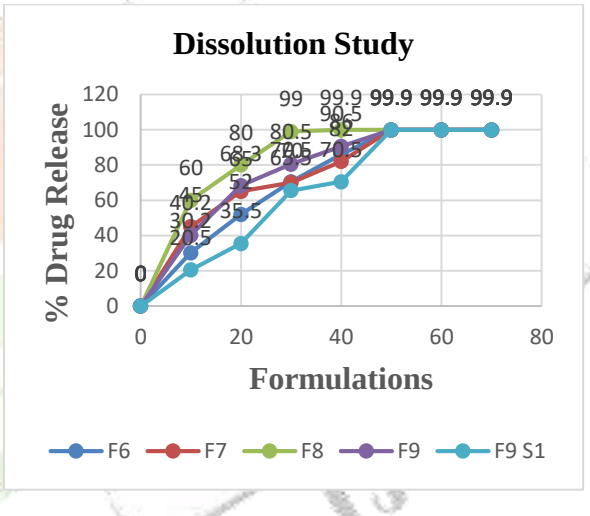


Figure no. 09: In-Vitro release Dissolution study of Fast Dissolution Tablet for Naproxen tablet.

F8 demonstrates remarkable stability and reliability throughout the dissolution study, showcasing consistent drug release percentages over time. This underscores F8's reliability and robustness as a formulation choice. When compared to other formulations, although some may show similar drug release percentages at specific time points, none consistently outperform F8 across all intervals. F8 emerges as the superior option, ensuring rapid and complete drug release within the designated timeframe.

Release kinetics of *In-vitro* Drug release: [23-48]

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 Hixon Crowell. The result obtained were represented in table 06, and shown in figure no. 10.

Table no. 06: Different Release kinetics of In-vitro Drug release:

Kinetics Models					
Sr. no	**Zero order**	**First order**	**Higuchi model**	**Korsmeyer Peppas**	**Hixon Crowell**
	R^2	**R^2**	**R^2**	**R^2**	**R^2**
F1	0.9716	0.9716	0.9716	0.9486	0.9819
F2	0.9662	0.9878	0.9864	0.9861	0.9243
F3	0.9534	0.9534	0.9534	0.9946	0.9292
F4	0.9726	0.9449	0.9534	0.9929	0.9373
F5	0.9762	0.9178	0.9844	0.9477	0.9942
F6	0.9818	0.8992	0.9917	0.9892	0.9383
F7	0.9721	0.9778	0.9791	0.9971	0.9701
F8	**0.9991**	**0.9231**	**0.9941**	**0.9998**	**0.9987**
F9	0.9844	0.9762	0.9942	0.9878	0.9878

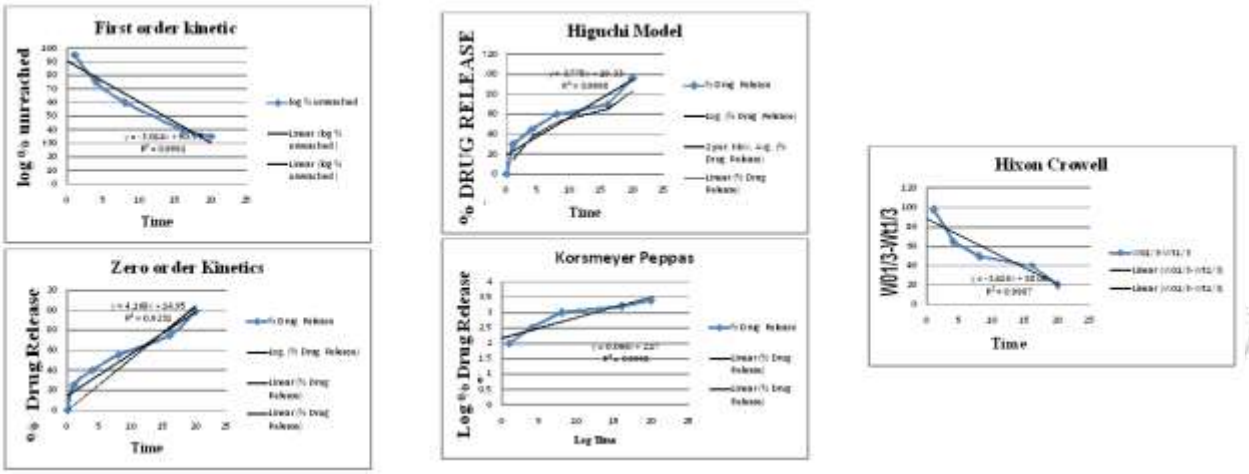


Figure no. 10: Graph of different Release kinetics of *In-vitro* Drug release

Stability studies of Fast Dissolution Tablet for Naproxen tablets: [61-74]

The product was evaluated for following parameters: Weight variation, Hardness, Friability, Drug content, Dissolution analysis. **Storage condition at 40°C ± 2°C/75 %RH ± 5%:**

Table no. 07: Stability Study of Optimized Batch of F8 Fast Dissolution Tablet for Naproxen tablets:

Time in Days	**Parameters**				
	Hardness (Kg/cm2)	**Uniformity of weight**	**Friability (%)**	**Disintegration time(sec)**	**Drug content (%)**
0 Days	3.6±0.57	200.2±0.32	0.64±0.02	18±1.02	99.57±0.09
30 Days	3.4±0.15	200.3±0.28	0.68±0.01	17±1.59	98.83±0.11
60 Days	3.3±0.10	200.6±0.34	0.69±0.01	17±0.83	97.49±0.12
90 Days	3.1±0.15	200.8±0.33	0.71±0.01	16±0.93	96.71±0.15

Each data represents Mean ±SD (n=3).

Table no. 08: % drug release during Stability Study of Optimized Batch of F8 Fast Dissolution Tablet for Naproxen 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

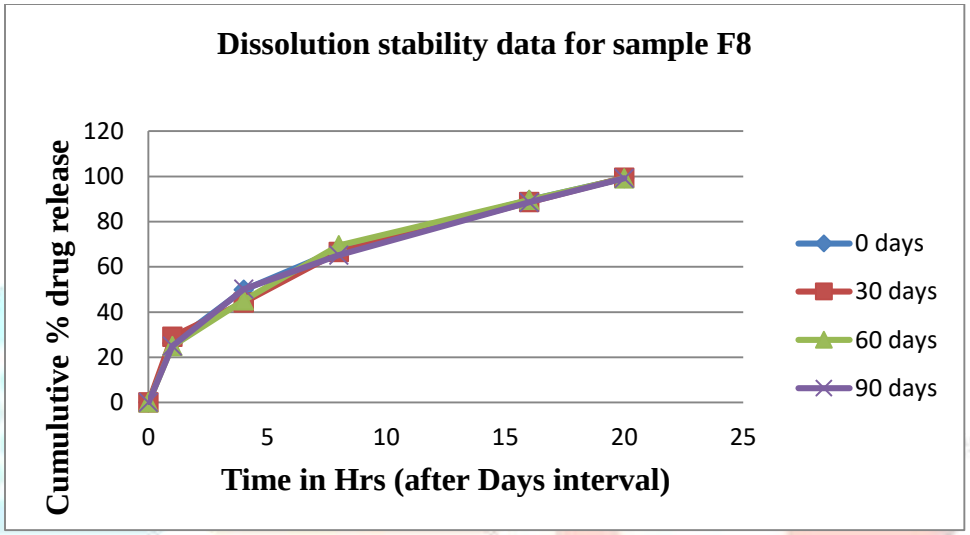


Figure no. 11: % drug release during Stability Study of Optimized Batch of F8 Fast Dissolution Tablet for Naproxen tablets by dissolution testing.

Based on the mean concentrations of each formulation across different temperature and humidity conditions, it is observed that formulation F8 remains relatively stable over the one-month stability study period compared to F7 and

F9. This conclusion is drawn from the fact that the concentration variation in F8 is relatively lower compared to F7 and F9, indicating better stability.[20-22]

Discussion:

The main goal of this study is to create and test a new form of naproxen tablets that dissolve quickly in the mouth.

Naproxen is a commonly used pain reliever, and the idea behind fast-dissolving tablets is to make it easier for patients to take their medication. This could be especially beneficial for individuals who have difficulty swallowing regular tablets.

The study is focused on developing the best possible formula for these fast-dissolving tablets. Researchers are looking at various factors to ensure the tablets dissolve quickly once in the mouth, but also remain strong enough to handle packaging and transportation without breaking apart. Another important aspect is making sure the tablets have a pleasant taste, as this can significantly impact patient compliance.

In addition to these factors, the study examines several key properties of the tablets:

1. Dissolution rate: How quickly the tablets dissolve in the mouth.
2. Stability: How well the tablets maintain their effectiveness and structural integrity over time.
3. Absorption: How the body absorbs the medication once it is taken.

The ultimate aim of this research is to create a more effective and user-friendly way for patients to take naproxen. By improving the ease of administration and potentially speeding up the onset of relief, these fast-dissolving tablets could enhance the management of pain and inflammation.

The UV-Visible spectra of Naproxen were measured using methanol as the solvent and recorded on a Shimadzu instrument. Naproxen typically displays its peak absorbance around 331 nanometers (nm), indicating its strongest light absorption at this wavelength. This peak serves as a crucial marker for the quantitative analysis of naproxen in pharmaceutical formulations and research investigations. Regarding the Fourier-transform infrared (FT-IR) spectrum of Naproxen, it exhibits distinctive peaks corresponding to its functional groups. Notable peaks in the FT-IR spectrum of naproxen.

Physical Evaluation and Solubility Studies:

The study commenced with a comprehensive physical evaluation of Naproxen, utilizing sensory perception (sight, taste, smell) as per Indian Pharmacopeia standards.

Additionally, the melting point determination revealed a consistent range of 153°C, ensuring the quality and purity of the drug.

Solubility studies were conducted using different commonly used solvents, indicating the drug's compatibility with various vehicles, which is crucial for formulation development.

Compatibility Study of Drug and Excipients:

A compatibility study between Naproxen and excipients was conducted under different environmental conditions, simulating storage scenarios.

Observations indicated that formulation F8 exhibited the most favorable characteristics, suggesting its suitability for Naproxen Fast Dissolving Tablets.

Concentration Analysis under Different Temperature and Humidity Conditions:

The concentration of Naproxen in fast-dissolving tablets was assessed under varying temperature and humidity conditions.

Notably, formulation F8 maintained relatively stable concentrations across different environmental conditions compared to other formulations (F7 and F9), indicating its robustness and suitability for long-term storage.

Characterization Using UV-Spectrophotometric and DSC Methods:

Characterization of Naproxen Fast Dissolving Tablets was conducted using UV-spectrophotometric methods to determine both free and entrapped Naproxen.

Differential Scanning Calorimetry (DSC) analysis provided insights into the thermal behavior of Naproxen, Mannitol, and Aspartame, further validating formulation F8's suitability.

In-Vitro Drug Release Kinetics:

The kinetics of in-vitro drug release was evaluated using various mathematical models.

The results indicated that formulation F8 exhibited desirable drug release kinetics, ensuring efficient drug delivery and therapeutic efficacy.

Stability Study:

Stability studies over one month at different temperatures and humidity conditions revealed formulation F8's superior stability compared to other formulations (F7 and F9).

This stability profile underscores its potential for commercial production and distribution.3.85 mm, Hardness: 3.5 Kg/cm², Friability: 0.61%, Drug content: 99.57%, floating time: 18 seconds.

Conclusion:

In conclusion, the objective of this study was to develop and evaluate fast-dissolving tablets of naproxen, aiming to improve patient convenience and compliance, particularly for those with difficulty swallowing conventional tablets. The investigation focused on formulating tablets with rapid dissolution, adequate stability, and enhanced absorption properties.

The UV-Visible spectra of naproxen, conducted in methanol solvent, showcased a characteristic absorbance peak at 331 nm, facilitating its quantitative analysis in pharmaceutical formulations.

Furthermore, compatibility studies with excipients and environmental conditions highlighted formulation F8 as the most promising candidate for Naproxen Fast Dissolving Tablets. This formulation demonstrated favorable characteristics in terms of dissolution rate, stability under varying temperature and humidity conditions, and concentration maintenance over time.

Characterization studies using UV-Spectrophotometric and DSC methods validated the suitability of formulation F8, confirming its optimal drug content and thermal behavior.

Moreover, in-vitro drug release kinetics revealed that formulation F8 exhibited desirable drug release profiles, ensuring efficient drug delivery and therapeutic efficacy.

Stability studies conducted over one month further emphasized formulation F8's superior stability compared to other formulations (F7 and F9), indicating its potential for commercial production and distribution seconds, making it the optimal formulation for effective and reliable drug delivery.

Conflict of interest:

Authors do not have any conflict of interest

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