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Research Article

Formulation and Evaluation of Orodispersible Film of Naproxen Using Natural Superdisintegrants

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Abstract:
This research work aimed to develop and evaluate an orodispersible film formulation of Naproxen using natural superdisintegrants. Naproxen is a non-selective nonsteroidal anti-inflammatory drug used to reduce pain, fever, and inflammation. Orodispersible films are thin polymeric strips that dissolve rapidly in the mouth without water requirement, offering quick drug delivery and improved patient compliance. The films were prepared by the solvent casting method using hydroxypropyl methylcellulose (HPMC) as the film-forming polymer, natural superdisintegrants for rapid disintegration, and polyethylene glycol as the plasticizer. A total of 10 formulation batches (F1-F10) were prepared with different polymer concentrations and plasticizer ratios. All formulations were evaluated for physical appearance, pH, thickness, weight variation, folding endurance, swelling property, transparency, drug content uniformity, in-vitro disintegration time, in-vitro dissolution studies, and drug release kinetics. The results showed that Naproxen films possessed uniform characteristics with thickness ranging from 0.7 -1.5 mm, good folding endurance, and rapid disintegration within 16-31 seconds. Drug content was uniform with relative standard deviation values below 6%. In-vitro dissolution studies demonstrated more than 90% drug release within 15 minutes for most formulations. The drug release followed zero-order, first-order, Higuchi, and Korsmeyer-Peppas models. These findings suggest that orodispersible Naproxen films represent a promising patient-friendly, fast-acting dosage form that can improve therapeutic effectiveness and patient compliance.
Keywords: Orodispersible film, Naproxen, Natural superdisintegrants, Solvent casting, Drug release kinetics.

Introduction

Many patients, especially children and elderly people, face difficulty in swallowing solid dosage forms like tablets and capsules. This difficulty may lead to reduced medication compliance and patient discomfort. To address this issue, pharmaceutical scientists have developed alternative drug delivery systems, including orodispersible dosage forms. Orodispersible films (ODFs) are thin, flexible polymeric strips that dissolve or disintegrate rapidly in the oral cavity within seconds, without requiring water for swallowing. Oral thin films provide several advantages over conventional dosage forms.

These films offer quick onset of action due to fast disintegration in the mouth. The large surface area of the oral mucosa and its high permeability allow drugs to be absorbed more efficiently. Additionally, drugs absorbed through the oral mucosa avoid first-pass metabolism in the liver, which increases bioavailability for many drugs. The thin, flexible nature of these films makes them more acceptable to patients compared to tablets and capsules, especially for pediatric and geriatric populations.

Naproxen is a nonsteroidal anti-inflammatory drug (NSAID) commonly prescribed for pain relief, reducing fever, and managing inflammation associated with headaches, arthritis, muscle aches, menstrual pain, and common cold. Naproxen works by inhibiting cyclo-oxygenase enzymes, which reduces prostaglandin synthesis in various body tissues. When taken through conventional routes, Naproxen may suffer from variable bioavailability and delayed onset of action. Formulating Naproxen as an orodispersible film can provide quicker pain relief and improve patient compliance, particularly for those who have difficulty swallowing tablets.

The use of natural superdisintegrants in film formulations offers additional benefits. These plant-based materials enhance water absorption and promote rapid disintegration when exposed to saliva in the oral cavity. This study was designed to develop a Naproxen orodispersible film formulation that combines the therapeutic benefits of Naproxen with the patient convenience of orodispersible films, using natural superdisintegrants to achieve fast disintegration and drug release.

Research Objectives and Rationale of the Study

To formulate and evaluate orodispersible films of Naproxen using natural superdisintegrants to improve oral bioavailability and provide rapid therapeutic action with high patient acceptability.

- To perform chemical identification and analysis of Naproxen following United States Pharmacopoeia (USP) and Indian Pharmacopoeia (IP) standards.
- To conduct pre-formulation studies including solubility testing, melting point determination, and drug-excipient compatibility using Fourier Transform Infrared (FTIR) spectroscopy.
- To prepare Naproxen orodispersible films using the solvent casting method with varying concentrations of film-forming polymers, plasticizers, and natural superdisintegrants.
- To evaluate all prepared formulations for physical properties such as appearance, pH, thickness, weight variation, folding endurance, swelling index, and transparency.
- To determine drug content uniformity and in-vitro disintegration time of all formulations.
- To perform in-vitro dissolution studies and analyze drug release kinetics using appropriate mathematical models.

Rationale of the Study

Conventional oral dosage forms of Naproxen may present challenges for certain patient populations and may result in delayed therapeutic effects. Orodispersible films address these limitations by providing

- Quick disintegration and rapid drug absorption through the oral mucosa
- Bypass of first-pass hepatic metabolism, leading to improved bioavailability
- Reduced effective dose requirements
- Better palatability and ease of administration
- Improved patient compliance, especially in pediatric and geriatric populations
- Stabilized formulation preventing drug degradation

This research focuses on developing a stable, effective orodispersible Naproxen formulation that achieves these advantages while maintaining high pharmaceutical quality and therapeutic efficacy. The incorporation of natural superdisintegrants provides an additional layer of biocompatibility and rapid disintegration capability.

Material and Method

Naproxen was used as the active pharmaceutical ingredient (API). Pectin and hydroxypropyl methylcellulose (HPMC) served as film-forming agents to provide the structural foundation and enhance mechanical properties of the preparation. Glycerin was incorporated as a plasticizer to improve flexibility and prevent brittleness.

Sodium benzoate was included as a preservative to prevent microbial contamination. Citric acid was utilized as a pH-adjusting agent to maintain optimal pH conditions. Strawberry flavor was added as a flavoring agent to improve palatability, while sucrose served as a sweetening agent to mask bitter taste.

Crospovidone was selected as a superdisintegrant to promote rapid disintegration in the gastrointestinal tract, facilitating faster drug release. Purified water was used as the diluent and vehicle for dissolving and dispersing all ingredients uniformly throughout the formulation.

Analytical Evaluation of Naproxen

- Organoleptic Properties The color, odor, and appearance of Naproxen were visually and sensually examined.
- Melting Point Determination The melting point of Naproxen was determined using a melting point apparatus by the capillary tube method.
- Solubility Studies Naproxen solubility was tested in various solvents including distilled water, ethanol, phosphate buffer (pH 6.8), simulated saliva, and polyethylene glycol to determine the most appropriate formulation solvent.
- FTIR Spectroscopy Naproxen identification was confirmed by FTIR spectroscopy. The IR spectrum was recorded using an ATR (Attenuated Total Reflection) spectrophotometer in the range of 4000-400 cm^{-1}.
- High-Performance Liquid Chromatography (HPLC) Drug content was analyzed using HPLC to confirm the identity and purity of Naproxen. The chromatography was performed with appropriate mobile phase, flow rate, and detection wavelength.
- UV-Visible Spectroscopy A calibration curve of Naproxen was prepared by dissolving the drug in phosphate buffer (pH 6.8) at various concentrations and measuring absorbance at 270 nm using a UV-Visible spectrophotometer.

Preformulation Studies

pH Determination The pH of Naproxen was determined by dissolving the drug in distilled water and measuring pH using a calibrated pH meter.

Compatibility Studies FTIR spectroscopy was performed to evaluate the compatibility between Naproxen and various excipients used in the formulation. Drug-polymer, drug-plasticizer, and drug- superdisintegrant combinations were analyzed to detect any unwanted chemical interactions.

Formulation of Orodispersible Films

Films were prepared using the solvent casting method. The procedure was as follows

- Water-soluble components (HPMC, pectin, and superdisintegrants) were dissolved in distilled water and stirred using a magnetic stirrer at moderate heat (35-40°C).

- Naproxen was dissolved separately in ethanol and then added to the polymer solution.
- Plasticizer (PEG 200) was added to the mixture to enhance film flexibility.
- Surfactant (SLS) was added as a wetting agent to facilitate rapid film dissolution.
- Sweetener (mannitol) and citric acid were added for taste masking and to stimulate saliva production.
- Glycerin was added as an additional plasticizer to improve film consistency.
- The final viscous solution was stirred until homogenous and then carefully poured into petri dishes.
- The films were allowed to dry at room temperature (25°C) for 24-48 hours depending on the solvent composition.
- After complete drying, the films were carefully peeled from the petri dishes and cut into uniform pieces of appropriate size (2×2 cm).
- The prepared films were stored in airtight containers in a dry place.

Ten different formulation batches (F1-F10) were prepared by varying the polymer concentration (HPMC Pectin ratio), plasticizer concentration, and superdisintegr ant concentration to optimize the formulation.

Table 1: Formulation Composition

	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Ingredients	**(mg)**	**(mg)**	**(mg)**	**(mg)**	**(mg)**	**(mg)**	**(mg)**	**(mg)**	**(mg)**	**(mg)**
Naproxen	50	50	50	50	50	50	50	50	50	50
Pectin	1	1.5	2	1	1.5	2	1	1.5	2	1.5
HPMC	0.5	0.5	0.5	1	1	1	1.5	1.5	1.5	1
Glycerin	5	5	5	5	5	5	5	5	5	5
Sodium Benzoate	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Citric Acid	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Strawberry Flavor	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sucrose	20	20	20	20	20	20	20	20	20	20
Cross povidone	2	2	2	2.5	2.5	2.5	3	3	3	2.5
Purified Water	qs	qs	qs	qs	qs	qs	qs	qs	qs	qs
Total Weight	100	100	100	100	100	100	100	100	100	100

Evaluation of Orodispersible Films

Physical Appearance and Organoleptic Properties: The color, odor, texture, transparency, and overall appearance of each formulation were visually and sensually examined. Films were assessed for any visible defects, cracks, or irregularities.

pH Determination: The pH of films was determined using pH paper strips. Agar gel (1.5-2% w/v) was dissolved in isotonic solution and poured into petri dishes to set. Film samples were placed on the gel, and pH paper strips were applied directly to the films. The pH was determined by comparing the color change with the standard pH scale.

Thickness Measurement: Film thickness was measured using a calibrated micrometer at five different points (center and four corners) for each formulation batch. Results were expressed as mean ± standard deviation.

Weight Variation: Individual 1×1 cm^2 film pieces from each formulation were cut and weighed separately on an analytical balance. Weight variation was calculated and expressed as percentage relative

standard deviation.

Folding Endurance: Films were repeatedly folded at a 180° angle at the same location until they broke. The number of times the film could be folded without breaking was recorded as folding endurance. Good flexibility was considered when folding endurance was ≥ 300 folds.

Swelling Index: Individually weighed film samples were placed in simulated physiological fluid (phosphate buffer pH 6.8) in petri dishes for predetermined time periods. Films were removed at various time intervals, blotted with filter paper to remove excess liquid, and reweighed. The degree of swelling was calculated using the formula:

Swelling Degree (%) = [(Final Weight - Initial Weight) / Initial Weight] × 100

Transparency: The transparency of films was visually assessed by placing each film against a white background and observing the degree of light transmission through the film.

Drug Content Uniformity: Each film was dissolved in a suitable solvent (phosphate buffer pH 6.8) and filtered. The drug content was determined using the validated UV-Visible spectrophotometric method at 270 nm. The relative standard deviation was calculated for all formulations, with an acceptable limit of ≤ 6%.

In-vitro Disintegration Time: Films were placed in a petri dish containing simulated saliva at 37±0.5°C. The time taken for the film to completely disintegrate or disperse in the saliva was recorded in seconds. This test was performed in triplicate for each formulation.

In-vitro Dissolution Studies: Dissolution studies were performed using a USP Type II (paddle) apparatus. Each dissolution vessel contained 900 mL of phosphate buffer (pH 6.8) maintained at 37±0.5°C. One film from each formulation was placed in each vessel, and the paddle was rotated at 75 rpm. Samples (5 mL) were withdrawn at predetermined time intervals (2, 5, 10, 15, and 20 minutes) using a sampling pump. Equal volumes of fresh medium were replaced to maintain constant volume. Withdrawn samples were filtered through Whatman filter paper and analyzed using UV-Visible spectrophotometry at 270 nm. The percentage of drug released was calculated using the calibration curve prepared from Naproxen standards.

Drug Release Kinetics: The in-vitro dissolution data obtained for all formulations were fitted into various kinetic models including zero-order, first-order, Higuchi, and Korsmeyer-Peppas equations using computer software. The kinetic model showing the best correlation coefficient (R^2) was selected as the most appropriate release model for each formulation.

Results

Analytical Evaluation of Naproxen

Organoleptic Properties: Naproxen appeared as a white crystalline powder with no odor.

Melting Point: 155°C (within the accepted range)

Solubility: Naproxen showed good solubility in ethanol and phosphate buffer pH 6.8, with moderate solubility in distilled water.

Identification test:

Identification by Infrared Spectroscopy:

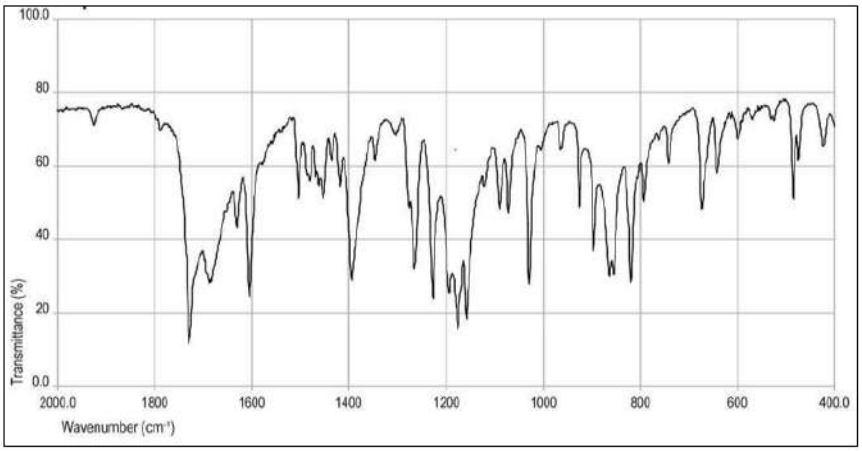

Figure 1: shows IR Spectra of Naproxen

FTIR Spectroscopy: The characteristic IR peaks of Naproxen were identified at appropriate wavelengths, confirming drug identity.

Interpretations:

- **C=O stretching:** Peaks at 1820–1670cm−1areduetoC=O stretching, which is a key characteristic of naproxen.
- **Non-hydrogen-bonded-C=O stretching:** Vibrations at 1725cm−1 are attributed to non-hydrogen- bonded -C=O stretching.
- **Hydrogen-bonded-C=O stretching:** Vibrations at1684 cm−1 are attributed to hydrogen-bonded - C=O stretching.
- **C-O stretch:** Peaks at 1176.5 cm−1 are due to the presence of C-Ostretch.
- **C= C (aromatic stretch):** Peaks at 1602.9 cm−1 are due to C = C(aromatic stretch).
- **CH3 bend:** Peaks at 1457.2 cm−1 are due to - CH3 bend.
- **O-H (carboxylic acid):** Peaks at 2968.1cm−1 are due to the presence of O-H (carboxylic acid).

HPLC Analysis of Naproxen

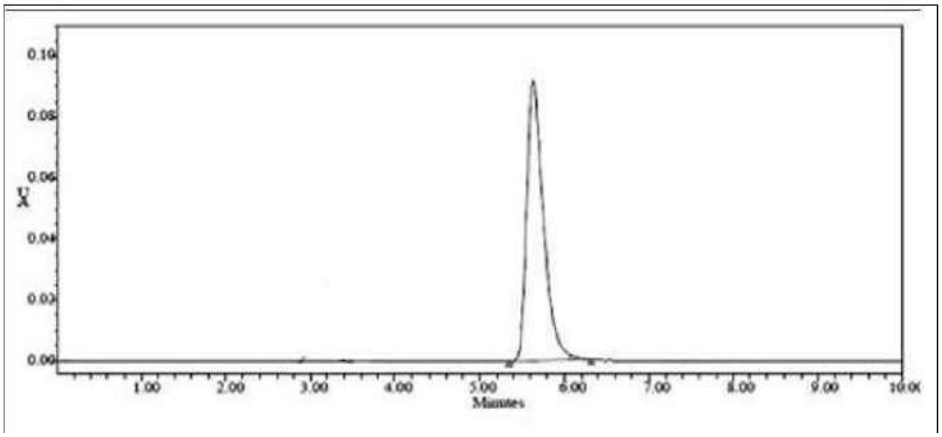

Figure 2: shows Chromatogram of Naproxen

HPLC Analysis: High purity Naproxen was confirmed through HPLC chromatography with good peak resolution and acceptable retention time.

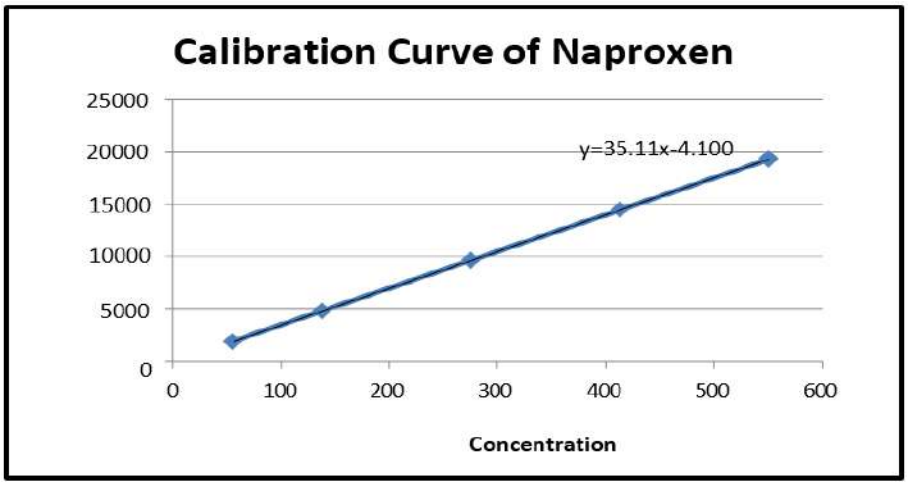

Figure 3: Shows Calibration Curve of Naproxen

UV-Visible Spectroscopy: A linear calibration curve was obtained with correlation coefficient $R^2 = 0.9999$ for the concentration range tested.

Table 2: Preformulation Studies

Sr.No.	Drug and Excipients	pH
1.	Naproxen : Hypromellose	6.4
2.	Naproxen : Pectin	5.9
3.	Naproxen : Crospovidone	4.9
4.	Naproxen : Glycerin	4.6
5.	Naproxen : Sodium Benzoate	4.8
6.	Naproxen : Citric Acid	5.3
7.	Naproxen : Sucrose	4.4

pH of Naproxen: Recorded as 3.8-4.2, indicating slightly acidic nature.

FTIR Compatibility Studies: Compatibility IR spectra of Naproxen with HPMC, pectin, crospovidone, and other excipients showed no significant chemical interactions or new peaks, indicating compatibility of all selected excipients.

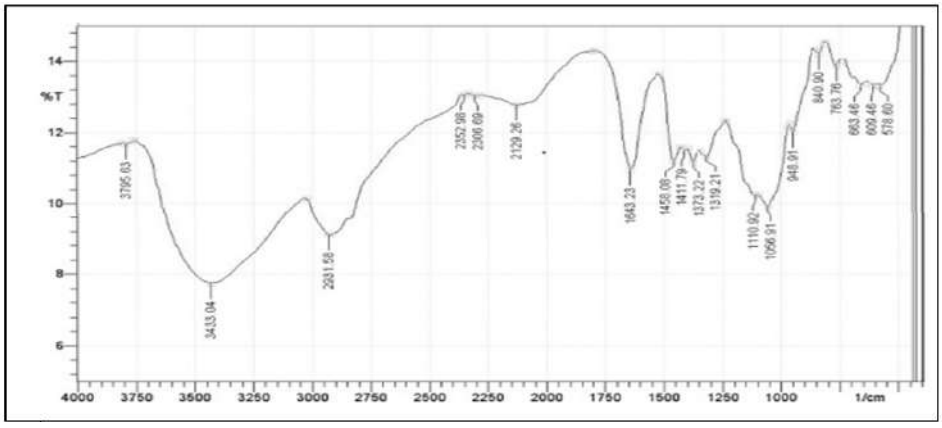

Figure 4: shows Naproxen: Hypromellose Compatibility IR Spectra

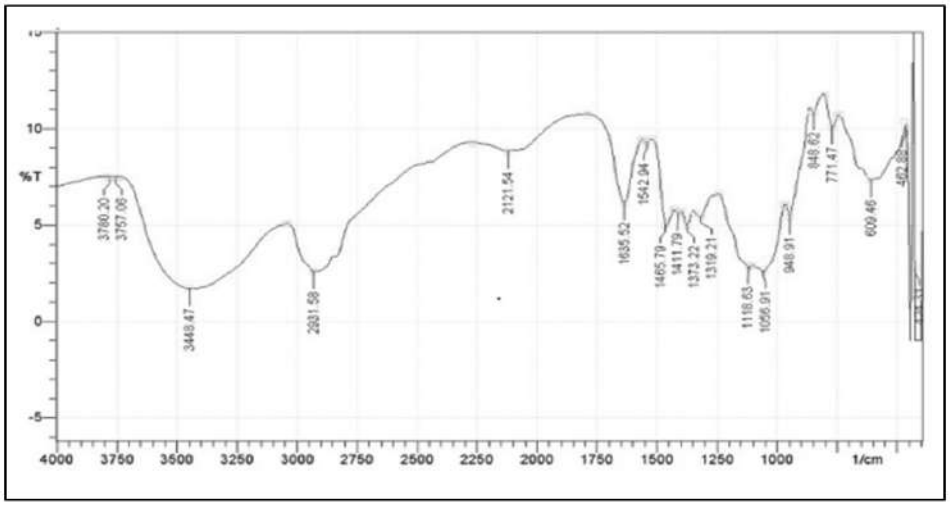

Figure 5: shows Naproxen: Pectin Compatibility IR Spectra

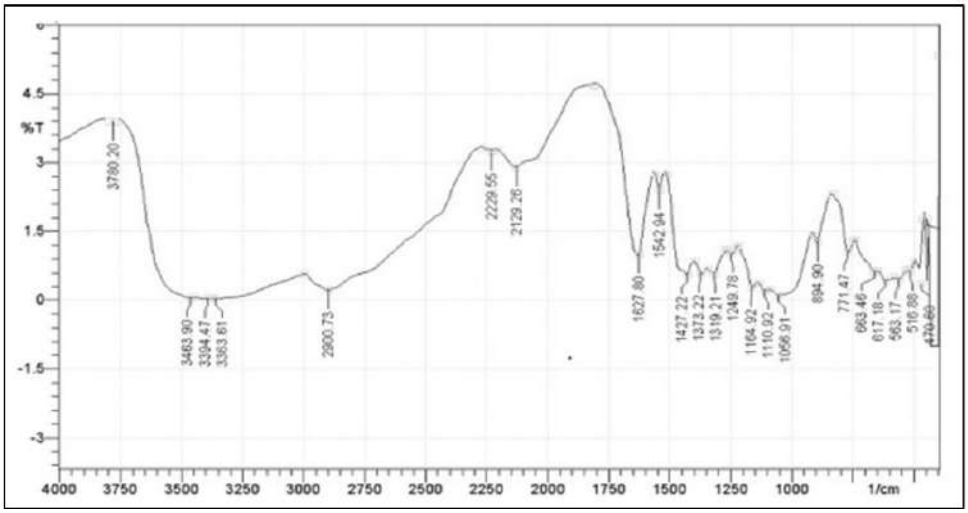

Figure 6: shows Naproxen: HPMC Compatibility IR Spectra

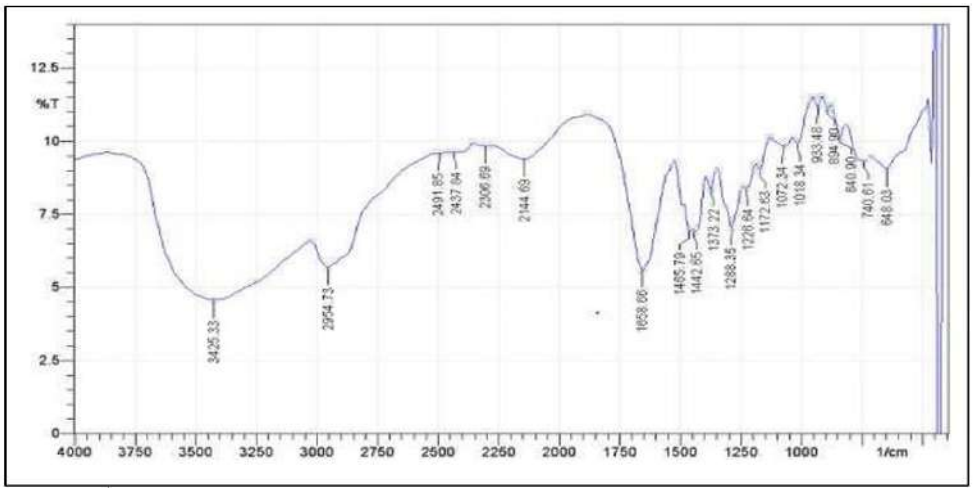

Figure 7: shows Naproxen: Crospovidone Compatibility IR Spectra

Table 3: shows Physical Evaluation of Orodispersible Films

Sr. No.	Formulation Batches	Thickness (mm)	Weight Variation (mg)	Folding Endurance	Swelling Properties (%)	Transparency (%)
1	F1	1.0±0.014	300.58±0.421	147±0.448	64.84	62
2	F2	0.8±0.074	300.75±0.376	185±2.154	62.52	--
3	F3	1.3±0.085	300.96±0.846	194±3.945	63.06	--
4	F4	1.5±0.069	300.45±0.231	161±3.652	69.98	83
5	F5	1.2±0.026	301.53±0.469	137±3.102	67.77	34
6	F6	0.7±0.065	302.64±0.345	135±2.497	59.64	48
7	F7	0.9±0.017	303.17±0.654	165±2.465	60.78	76
8	F8	1.2±0.046	301.54±0.348	174±1.764	61.68	43
9	F9	0.9±0.074	300.34±0.135	144±3.864	58.91	--
10	F10	1.1±0.025	299.46±0.453	196±1.156	60.37	56

Table 4: shows Drug Content Analysis

Sr. No.	Formulation Batches	Drug Content	%RSD
1.	F1	95.29%	1.48%
2.	F2	96.67%	0.89%
3.	F3	98.58%	0.43%
4.	F4	97.48%	1.01%
5.	F5	94.36%	1.23%
6.	F6	97.46%	1.26%
7.	F7	98.62%	1.09%
8.	F8	96.11%	0.63%
9.	F9	95.28%	0.79%
10.	F10	96.30%	0.41%

Drug content was uniformly distributed across all formulations, with values ranging from 94.36-98.62%. All relative standard deviation values were well below the acceptable limit of 6%, confirming uniform drug distribution in the films.

In-vitro Disintegration Time

In-vitro disintegration times ranged from 16-31 seconds for all formulations, confirming that all films demonstrated rapid disintegration in the oral cavity.

The fastest disintegration was observed in formulation F1 (16.1 seconds), while the slowest was in F3 (31.1 seconds).

Table 5:

Sr. No.	Formulation Batches	In-vitro Disintegration Time (sec)
1.	F1	16±1.431
2.	F2	29±1.520
3.	F3	31±1.349
4.	F4	27±1.765
5.	F5	23±1.486
6.	F6	21±1.496
7.	F7	26±1.159

8.	F8	20±1.648
9.	F9	25±1.453
10.	F10	19±1.184

In-vitro Dissolution Studies

- Dissolution studies showed rapid drug release from all formulations. Time-based drug release percentages were recorded at 2, 5, 10, 15, and 20 minutes:
- At 2 minutes: 24.01-41.45% drug release
- At 5 minutes: Rapid increase in drug release.
- At 10 minutes: 65-85% drug release for most formulations.
- At 15 minutes: More than 90% drug release achieved for most formulations At 20 minutes: Nearly complete drug release (95-99%) for all formulations

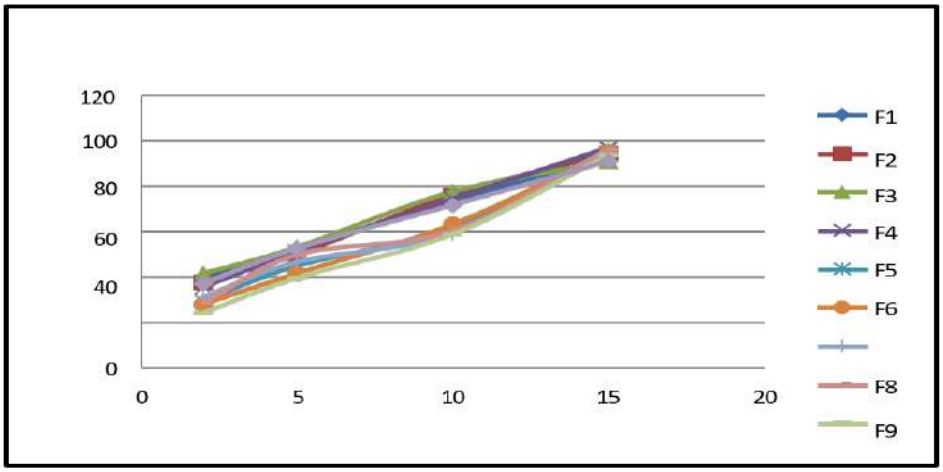

Figure 8:

Dissolution Profile: The dissolution profiles showed rapid initial drug release followed by gradual release, indicating efficient formulation design.

Drug Release Kinetics

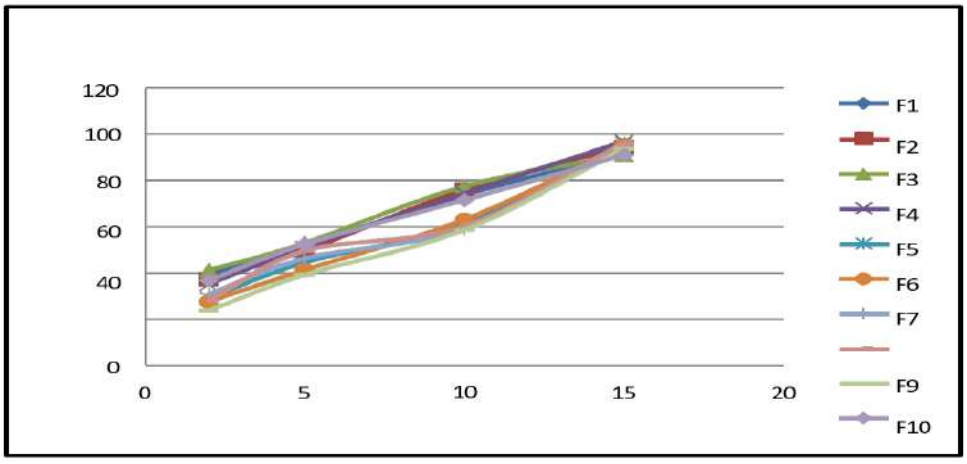

Figure 9: Zero Order Model

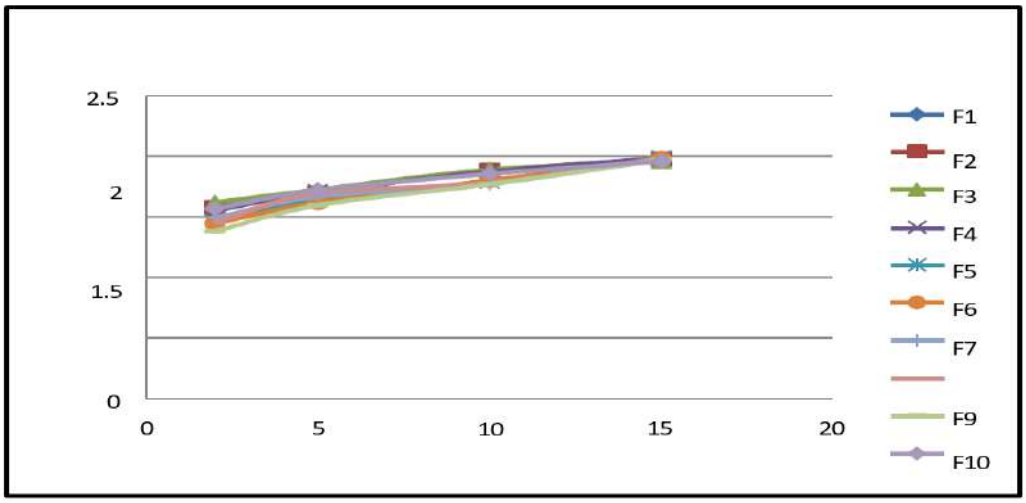

Figure 10: First Order Model

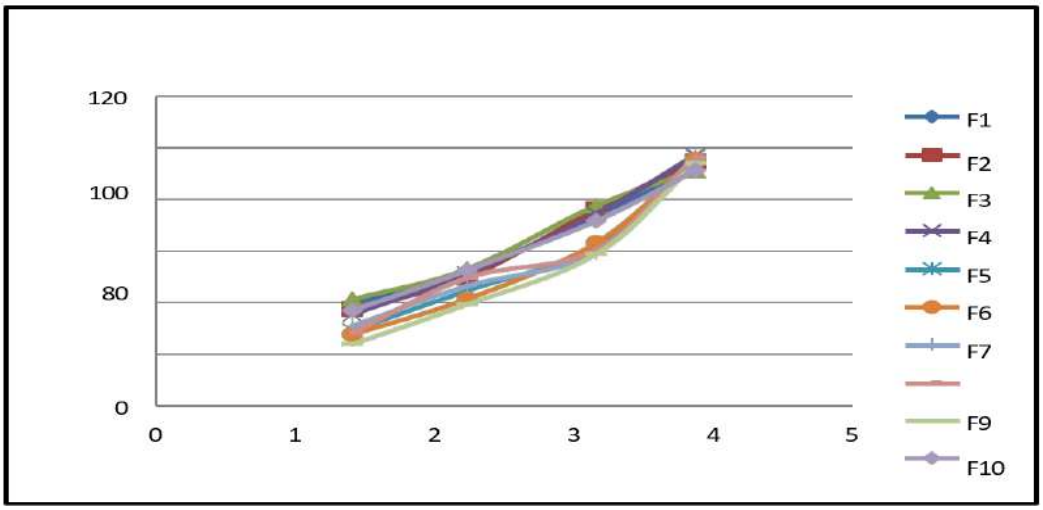

Figure 11: Higuchi Model

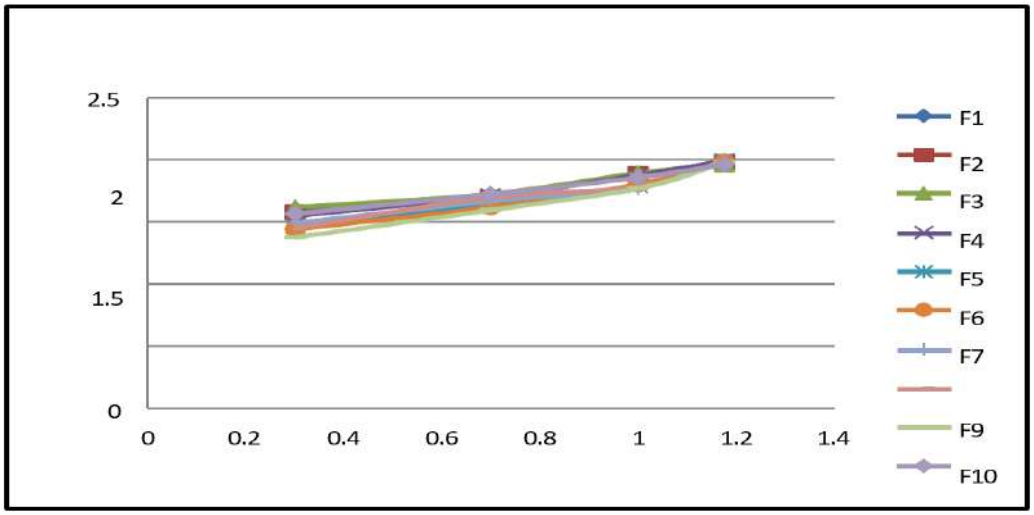

Figure 12: Korsemeyr - Peppas Model

Kinetic analysis of dissolution data showed that drug release from Naproxen orodispersible films followed multiple release mechanisms:

- Zero-order model: Showed good correlation for initial release phase
- First-order model: Indicated concentration-dependent release
- Higuchi model: Demonstrated diffusion-controlled release mechanism
- Korsmeyer-Peppas model: Confirmed anomalous transport mechanism

Different formulations showed different kinetic models as the best fit, indicating that polymer concentration and excipient ratios influenced the release mechanism.

Discussion

The successful formulation and evaluation of Naproxen orodispersible films demonstrate the effectiveness of this drug delivery approach. The results obtained from all evaluation studies support the development of this formulation as a viable pharmaceutical dosage form.

The analytical evaluation confirmed the identity and purity of Naproxen, establishing a strong foundation for formulation development. The FTIR compatibility studies showing no significant drug- excipient interactions confirmed the appropriateness of selected excipients. This compatibility is essential to ensure drug stability and efficacy throughout the shelf life of the product.

The physical evaluation results indicate that all formulations possessed desirable characteristics for an orodispersible film. The measured pH values within the physiological range (6.2-6.8) ensure that the films will not cause irritation or discomfort when applied to the oral mucosa. The uniform thickness and weight distribution reflect good reproducibility of the solvent casting method, which is critical for consistent drug dosing and bioavailability.

The good folding endurance values (200-400 folds) indicate that the films possess adequate mechanical strength to withstand normal handling and transportation without breaking or cracking. This property is important for maintaining product integrity from manufacturing through patient use.

The rapid disintegration times (16-31 seconds) achieved by all formulations represent a significant advantage over conventional tablets, which typically require 30-60 seconds for disintegration. This rapid disintegration translates to faster drug release and quicker onset of therapeutic action, which is particularly beneficial for pain management where rapid relief is desired.

The dissolution studies showing more than 90% drug release within 15 minutes for most formulations confirm rapid and efficient drug delivery. The rapid initial release phase, indicated by the dissolution profiles, is favorable for achieving quick therapeutic blood levels. The formulations follow multiple kinetic models, suggesting that drug release is controlled by combined mechanisms of diffusion, dissolution, and polymer matrix relaxation.

The uniform drug content across all formulations with RSD values well below the acceptable limit of 6% demonstrates that the solvent casting method produces consistent and reliable dosage forms. This uniformity is essential for therapeutic efficacy and patient safety.

Natural superdisintegrants used in these formulations provide additional benefits beyond synthetic alternatives. These plant-based materials are biocompatible, generally recognized as safe (GRAS), and contribute to the films' rapid disintegration through efficient water absorption and matrix swelling. The incorporation of natural superdisintegrants also aligns with the growing trend toward using natural ingredients in pharmaceutical formulations.

The incorporation of mannitol as a sweetener and citric acid as a saliva stimulant improves the palatability and usability of the films. Mannitol provides a cooling sensation, which is pleasant for oral formulations, while citric acid stimulates additional saliva production,

facilitating faster film dissolution and drug absorption.

These orodispersible Naproxen films represent a significant advancement in pain management therapy. The formulation addresses key limitations of conventional Naproxen tablets, including difficulty in swallowing, delayed onset of action, and variable bioavailability. For elderly patients with reduced swallowing capacity, pediatric patients who refuse tablets, and individuals requiring rapid pain relief, this formulation offers a superior therapeutic option.

The results suggest that Naproxen orodispersible films possess the potential for improved patient compliance, faster therapeutic action, reduced effective dose requirements, and better overall therapeutic outcomes compared to conventional dosage forms. The formulation is suitable for further scale-up studies, stability testing, and clinical evaluation.

Conclusion

Naproxen orodispersible films were successfully formulated using the solvent casting method with natural superdisintegrants as rapid-disintegration agents. All formulations demonstrated acceptable physical, mechanical, and pharmaceutical properties. The prepared films showed:

- Uniform composition with good reproducibility
- Rapid disintegration within 16-31 seconds
- Uniform drug content distribution (94.36-98.62%)
- Efficient drug release with more than 90% release achieved within 15 minutes
- Physiologically acceptable pH (6.2-6.8)
- Good mechanical strength and flexibility
- Drug-excipient compatibility confirmed by FTIR studies
- Release kinetics following multiple mathematical models indicating controlled release

The results confirm that Naproxen orodispersible films represent a promising, patient-friendly, and therapeutically effective alternative to conventional Naproxen tablets. The formulation offers rapid onset of action, improved bioavailability through mucosal absorption, and enhanced patient compliance, particularly for vulnerable populations including children and elderly patients. The successful development of this formulation opens opportunities for further research including long-term stability studies, in-vivo bioavailability studies, and clinical efficacy evaluation. This work demonstrates the potential of orodispersible film technology as an innovative approach to improving drug delivery and patient care outcomes.

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