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FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF NAPROXEN SODIUM

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ABSTRACT

The current study aims to formulate and evaluate mouth dissolving tablets (MDTs) of Naproxen Sodium to enhance patient compliance and provide rapid onset of action. The MDTs were prepared using direct compression and sublimation methods employing various superdisintegrants including Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium, with urea as the sublimating agent. Preformulation studies confirmed the identity and purity of Naproxen Sodium. Nine different formulations (F1–F9) were developed and evaluated for micromeritic properties, drug content, disintegration time, wetting time, water absorption ratio, friability, and in vitro drug release. Among the formulations, F9 containing 4% Crospovidone showed the best performance with disintegration time of 16 seconds and 97.34% drug release within 60 minutes. Stability studies confirmed the formulation's stability under accelerated conditions. The results demonstrated that the formulated MDTs of Naproxen Sodium could be a promising alternative to conventional tablets for immediate pain relief.

KEYWORDS: Naproxen Sodium, Mouth Dissolving Tablets, Superdisintegrants, Crospovidone, Sublimation, In-vitro Drug Release.

INTRODUCTION

Naproxen Sodium, a non-steroidal anti-inflammatory drug (NSAID), is widely used for managing pain, inflammation, and fever associated with conditions such as arthritis, migraine, dysmenorrhea, and gout. Despite its therapeutic effectiveness, the conventional tablet formulation of Naproxen Sodium is often associated with delayed onset of action and

gastrointestinal irritation, leading to poor patient compliance, particularly in pediatric, geriatric, and dysphagic populations.

Mouth dissolving tablets (MDTs) offer a patient-friendly alternative to conventional oral dosage forms. They disintegrate rapidly in the oral cavity without the need for water, enabling faster drug onset and improved compliance. However, formulating an MDT that provides rapid disintegration without compromising mechanical strength and content uniformity remains a technical challenge. Several studies have explored MDTs of various drugs using superdisintegrants or lyophilization techniques, but limited work has focused on optimizing Naproxen Sodium MDTs using a combination of **sublimation** and **direct compression** for enhanced porosity and disintegration speed.

The novelty of this study lies in the integration of a sublimating agent (urea) with commonly used superdisintegrants Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodiumat varied concentrations to formulate MDTs of Naproxen Sodium. While prior studies have examined either superdisintegrants or sublimation techniques in isolation, their combined effect on disintegration time, wetting efficiency, and drug release has not been fully optimized for Naproxen Sodium.

This study addresses this gap by formulating and evaluating nine distinct MDT batches using a direct compression method. The significance lies in developing a robust, scalable formulation with rapid onset, improved bioavailability, and enhanced patient compliance. The findings could contribute substantially to the field of fast-dissolving drug delivery systems and pave the way for future commercial development of improved Naproxen Sodium formulations.

MATERIALS AND METHODS

Materials

Naproxen Sodium was obtained as a gift sample from a reputed pharmaceutical industry. Superdisintegrants such as Crospovidone, Croscarmellose Sodium, and Sodium Starch Glycolate were procured from LobaChemiePvt. Ltd., Mumbai. Urea was used as a sublimating agent. Other excipients including Microcrystalline Cellulose (MCC), Mannitol, Aspartame, Talc, and Magnesium Stearate were of analytical grade and used as received. All chemicals and reagents used were of analytical or pharmaceutical grade.

Methods

Identification of Drug

UV-Spectrophotometric Analysis

The absorption maxima (λmax) of Naproxen Sodium were determined using UV-visible spectrophotometer in methanol. The absorbance was recorded in the range of 230–240 nm, and λmax was found to be 230 nm, in accordance with reported literature values.

Melting Point Determination

The melting point was determined using the open capillary method. The apparatus was calibrated using standard substances such as L-ascorbic acid and Sodium bicarbonate. The melting point of the drug was recorded as the average of three readings.

FTIR Study

Fourier-transform infrared (FTIR) spectroscopy was used to confirm the identity of Naproxen Sodium and assess potential drug-excipient interactions. The sample was mixed with potassium bromide (KBr), compressed into a pellet, and analyzed in the range of 4000–400 cm^{-1} using a Shimadzu FTIR spectrometer.

Solubility Study

The solubility of Naproxen Sodium was tested in various solvents including ethanol and water. The drug was found to be freely soluble in ethanol and poorly soluble in water (15.9 mg/L).

Drug-Excipient Compatibility Study

Differential scanning calorimetry (DSC) analysis was performed using DSC-60 (Shimadzu) to evaluate the thermal behavior and compatibility between Naproxen Sodium and selected excipients. Approximately 3 mg of each sample was placed in a sealed aluminum pan and scanned from 50°C to 300°C at a heating rate of 20°C/min under nitrogen atmosphere.

Preparation of Calibration Curve

A stock solution of Naproxen Sodium was prepared by dissolving 100 mg of drug in pH 6.8 phosphate buffer and diluting it to 100 mL. From this, a 100 µg/mL working solution was prepared. Aliquots of 0.5 to 5 mL were diluted to 10 mL to obtain concentrations of 5–50 µg/mL. Absorbance of each solution was recorded at 230 nm to generate a calibration curve.

Formulation of Mouth Dissolving Tablets (MDTs)

Mouth dissolving tablets were prepared using the direct compression method. Nine formulations (F1 to F9) were developed using three different superdisintegrants (Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium) at concentrations of 2%, 3%, and 4%, respectively. Urea was used as a sublimating agent to enhance porosity and promote rapid disintegration. All ingredients were weighed, sieved through mesh #40, blended thoroughly, and compressed into tablets (average weight: 220 mg) using a rotary tablet press.

Evaluation of Powder Blend

The flow properties of the prepared powder blends intended for compression into mouth dissolving tablets were evaluated using standard pharmacopeial procedures. The angle of repose was determined by the fixed funnel method, which provides insight into the powder's flowability by measuring the angle formed between the horizontal surface and the slope of the powder pile. Bulk density and tapped density were measured by transferring an accurately weighed quantity of powder into a 100 ml graduated measuring cylinder. The bulk volume was recorded before tapping, and the tapped volume was noted after subjecting the cylinder to mechanical tapping until no further volume change occurred. Using these values, Carr's Index and Hausner Ratio were calculated. Carr's Index, which indicates the compressibility of the powder, was computed as the percentage difference between the tapped and bulk densities. Hausner Ratio, which reflects the ease of flow, was calculated as the ratio of tapped density to bulk density. These micromeritic properties collectively provide essential information regarding the suitability of the powder blend for direct compression and ensure uniform die filling during tablet manufacturing.

Evaluation of Mouth Dissolving Tablets

The formulated mouth dissolving tablets were subjected to a series of evaluation parameters to assess their physical, mechanical, and functional properties. The general appearance of the tablets was examined visually for attributes such as color, shape, surface texture, and uniformity among batches. Tablet thickness was measured using a Vernier caliper to ensure consistency, as variations can influence packaging and dissolution behavior. Hardness testing was performed using a Monsanto hardness tester to assess the mechanical strength of the tablets, which is crucial for handling and transportation. Weight variation was evaluated by individually weighing twenty tablets from each formulation and comparing the individual

weights to the average tablet weight, as per Indian Pharmacopoeia standards, to ensure uniformity in dosage.

Friability was determined using a Roche friabilator operated at 25 revolutions per minute for a total of 4 minutes. The tablets were weighed before and after the test, and the percentage weight loss was calculated to ensure that the tablets could withstand mechanical stresses. Wetting time and water absorption ratio were assessed using a petri dish lined with filter paper saturated with eosin dye. A tablet was placed on the paper, and the time taken for the dye solution to reach the upper surface of the tablet was recorded as the wetting time, while the change in tablet weight before and after wetting was used to calculate the water absorption ratio.

Content uniformity was determined by powdering five tablets and dissolving an amount equivalent to 100 mg of drug in phosphate buffer pH 6.8. The solution was filtered and analyzed spectrophotometrically at 230 nm to estimate the drug content. The in-vitro dispersion time was measured by placing a tablet in 6 mL of demineralized water in a measuring cylinder and recording the time required for complete dispersion. Disintegration time was evaluated using the USP disintegration apparatus in 1 liter of distilled water maintained at 37±2°C, and the time taken for the complete breakdown of tablets was noted. The in-vitro drug release profile was studied using the USP type II paddle dissolution apparatus containing 900 mL of phosphate buffer pH 6.8 maintained at 37±0.5°C. The paddles were rotated at 50 rpm, and samples were withdrawn at predetermined time intervals, filtered, and analyzed at 230 nm using a UV-visible spectrophotometer. Sink conditions were maintained by replacing the withdrawn volume with fresh medium after each sampling. This comprehensive evaluation helped determine the most effective formulation in terms of disintegration efficiency, mechanical integrity, and drug release performance.

Stability Studies

Stability testing was conducted as per ICH guidelines. Optimized batches were stored at 37±1°C/75%±5% RH, 40±1°C, and 50±1°C for three months. Tablets were analyzed at monthly intervals for drug content, disintegration time, and dissolution characteristics to determine their stability profile.

RESULTS AND DISCUSSION

The development of mouth dissolving tablets (MDTs) of Naproxen Sodium was undertaken to overcome the limitations of conventional oral dosage forms, especially the delayed onset of action and poor patient compliance due to swallowing difficulties and gastric irritation. A total of nine formulations (F1 to F9) were prepared using varying concentrations (2%, 3%, and 4%) of three different superdisintegrants—Croscarmellose Sodium, Sodium Starch Glycolate, and Crospovidone—via direct compression and sublimation method, using urea as the sublimating agent.

Preformulation studies confirmed the identity and purity of Naproxen Sodium. The UV-spectrophotometric analysis showed an absorption maximum at 230 nm, consistent with the literature. The melting point was found to be 156°C, aligning well with the reported range of 155–159°C. FTIR spectral analysis displayed characteristic peaks corresponding to functional groups in Naproxen Sodium, including aromatic C–H stretching at 3078 cm^{-1}, C=O stretching at 1683 cm^{-1}, and C–O bending at 1182 cm^{-1}, confirming the chemical integrity of the drug. Drug-excipient compatibility studies conducted via DSC indicated no significant interaction between Naproxen Sodium and the selected superdisintegrants, as no major shifts in endothermic peaks were observed.

Micromeritic properties of the powder blends were evaluated prior to compression. The angle of repose for all formulations was found to be within the range of 25° to 30°, indicating good flow properties. Carr's Index and Hausner Ratio values were within acceptable limits (<15% and <1.25 respectively), confirming that the blends possessed good compressibility and were suitable for direct compression.

Evaluation of physical parameters revealed that all formulated tablets exhibited uniform appearance, acceptable weight variation, and adequate mechanical strength. The thickness ranged between 4.0 to 4.3 mm, and hardness was found to be in the range of 2.5 to 3.2 kg/cm^2. Friability values were below 1%, indicating the tablets had sufficient resistance to abrasion and mechanical stress. All formulations passed the content uniformity test, with drug content ranging between 96.70% and 98.75%, which complies with pharmacopoeial specifications.

The disintegration and dispersion performance of the tablets was significantly influenced by the type and concentration of the superdisintegrants used. Among all formulations, F9, which

contained 4% Crospovidone, demonstrated the fastest disintegration time of 16 seconds, shortest wetting time of 45 seconds, and highest water absorption ratio of 85%. In contrast, formulations containing Croscarmellose Sodium and Sodium Starch Glycolate showed longer disintegration times and lower water absorption capacity. The enhanced performance of Crospovidone can be attributed to its high capillary activity and excellent swelling properties, which facilitate rapid uptake of saliva and promote tablet disintegration in the oral cavity.

In-vitro drug release studies further validated the performance of the formulations. The dissolution profile showed that the cumulative percentage of drug released from F9 was 97.34% within 60 minutes, which was significantly higher compared to other formulations. Formulations F1 to F6, which included Croscarmellose Sodium and Sodium Starch Glycolate, exhibited slower drug release rates, particularly at lower concentrations. The improved drug release from F9 may be attributed to the combined effect of enhanced porosity due to sublimation of urea and the superior disintegration efficiency of Crospovidone.

The calibration curve for Naproxen Sodium in phosphate buffer pH 6.8 was linear in the concentration range of 5–50 µg/ml with a correlation coefficient (R^2) of 0.998, confirming the reliability of the UV spectrophotometric method used for drug estimation. Stability studies conducted for three months under accelerated conditions at 37°C/75% RH, 40°C, and 50°C showed no significant changes in drug content, disintegration time, or drug release profiles for formulation F9, indicating good physical and chemical stability.

Overall, the results clearly demonstrate that Crospovidone at 4% concentration is the most effective superdisintegrant for developing fast-disintegrating Naproxen Sodium tablets. The direct compression method combined with sublimation technique using urea successfully produced porous, robust, and highly efficient MDTs. This formulation approach offers a promising alternative for enhancing the bioavailability, patient compliance, and therapeutic performance of Naproxen Sodium.

Table 1: Calibration Curve Data: **Includes absorbance values corresponding to 5–50 µg/mL concentrations.**

Concentration (Âµg/mL)	Absorbance at 230 nm
5	0.098
10	0.189
15	0.287
20	0.373

25	0.468
30	0.552
35	0.648
40	0.732
45	0.812
50	0.894

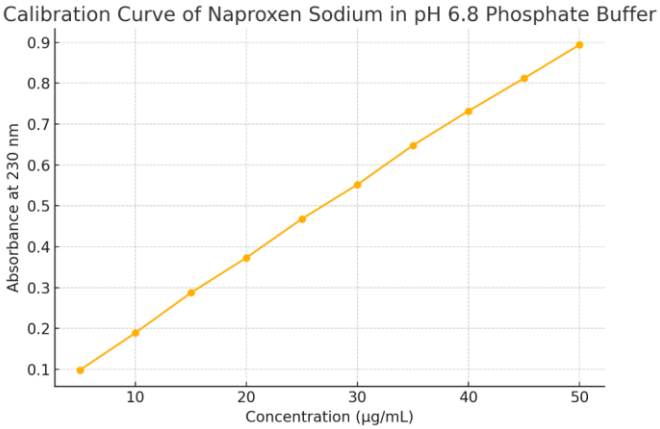

Figure 1: Calibration Curve of Naproxen Sodium in pH 6.8 Phosphate Buffer.

Table 2: Evaluation of Powder Blend for Mouth Dissolving Tablets of Naproxen Sodium.

Formulation Blend	Angle of Repose (°)	Bulk Density (g/cm³)	Tapped Density (g/cm³)	% Compressibility	Hausner Ratio
F1	28.00 ± 0.623	0.540 ± 0.004	0.822 ± 0.002	30.30%	1.53
F2	30.03 ± 0.765	0.535 ± 0.007	0.852 ± 0.004	31.20%	1.40
F3	27.05 ± 0.543	0.561 ± 0.002	0.857 ± 0.003	34.53%	1.52
F4	26.07 ± 0.645	0.583 ± 0.006	0.845 ± 0.008	31.00%	1.44
F5	25.02 ± 0.456	0.545 ± 0.007	0.801 ± 0.012	31.96%	1.46
F6	24.17 ± 0.234	0.567 ± 0.002	0.834 ± 0.004	32.01%	1.47
F7	27.45 ± 0.342	0.540 ± 0.015	0.869 ± 0.008	29.85%	1.60
F8	26.74 ± 0.368	0.535 ± 0.005	0.823 ± 0.003	34.99%	1.53
F9	28.65 ± 0.356	0.540 ± 0.014	0.846 ± 0.007	29.17%	1.56

Table 3: Evaluation Parameters of Mouth Dissolving Tablets of Naproxen Sodium.

Formulation Code	Thickness (mm)	Weight Variation	Hardness (kg/cm²)	Friability (%)	Content Uniformity (%)
F1	4.1 ± 0.004	PASS	3.0 ± 0.267	0.679 ± 0.135	96.27 ± 0.654
F2	4.1 ± 0.003	PASS	2.7 ± 0.345	0.826 ± 0.245	97.65 ± 0.576
F3	4.0 ± 0.008	PASS	2.8 ± 0.567	0.606 ± 0.541	99.01 ± 0.634
F4	4.2 ± 0.007	PASS	3.0 ± 0.654	0.755 ± 0.326	95.67 ± 0.234
F5	4.1 ± 0.003	PASS	2.8 ± 0.734	0.687 ± 0.256	97.45 ± 0.276
F6	4.1 ± 0.001	PASS	3.0 ± 0.392	0.823 ± 0.412	98.45 ± 0.134
F7	4.0 ± 0.005	PASS	2.5 ± 0.437	0.954 ± 0.264	97.60 ± 0.463
F8	4.1 ± 0.002	PASS	2.6 ± 0.649	0.755 ± 0.321	96.00 ± 0.865
F9	4.2 ± 0.004	PASS	2.7 ± 0.412	0.603 ± 0.348	97.34 ± 0.768

Table 4: Disintegration and Wetting Properties of Mouth Dissolving Tablets of Naproxen Sodium.

Formulation Code	Wetting Time (sec)	Water Absorption Ratio (%)	Disintegration Time (sec)	In-vitro Dispersion Time (sec)
F1	85	69	28	75
F2	79	71	26	70
F3	75	81	25	68
F4	65	73	23	48
F5	60	75	22	46
F6	60	73	22	40
F7	52	80	19	30
F8	48	92	17	25
F9	45	85	16	23

Table 5: In-vitro Drug Release Data: Includes cumulative % drug release for formulations F1 to F9 at multiple time points (0–60 min).

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	22.5	25	26.1	20.2	23.5	25.8	30	32.2	35.1
10	38.9	41.2	44	35.7	39.8	42.5	49.5	52.4	55.7
20	57.4	61.5	63.8	53.3	58.6	60.1	68.4	70.3	74.9
30	68.2	72.3	74.1	65	69.7	71.4	79.1	82.5	86.2
40	74	77.5	80.3	70.8	74.9	76	85.3	88.2	91.8
50	80.5	82	85.4	76.2	80.1	81.7	90.5	93.1	95.6
60	84.9	86.7	89.6	80	84.3	86.2	94	96.4	97.3

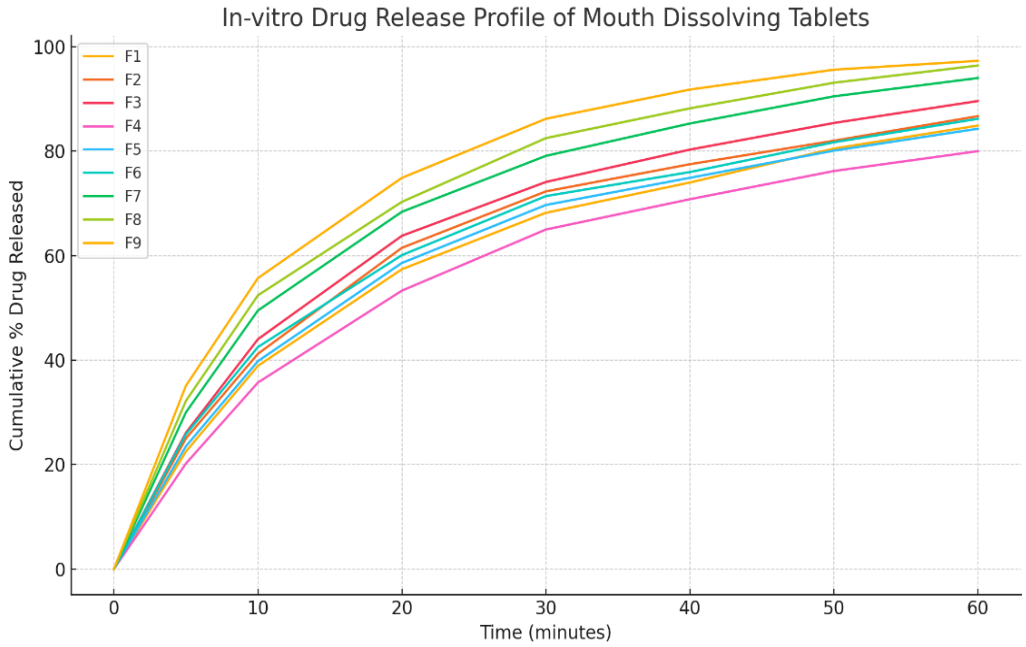

Figure 2: In-vitro Drug Release Profile of Mouth Dissolving Tablets (F1–F9).

CONCLUSION

The present study was undertaken with the aim of formulating and evaluating mouth dissolving tablets (MDTs) of Naproxen Sodium, a widely used NSAID known for its efficacy in treating pain and inflammation, but often associated with gastrointestinal side effects and delayed onset when administered through conventional tablets. In light of the need for a more patient-friendly dosage form, especially for pediatric, geriatric, and dysphagic patients, the development of MDTs provides an effective solution by ensuring rapid disintegration in the oral cavity without the need for water.

Nine formulations (F1–F9) were prepared using a direct compression technique, incorporating three different superdisintegrants—Croscarmellose Sodium, Sodium Starch Glycolate, and Crospovidone—in varying concentrations (2%, 3%, and 4%). Additionally, the sublimating agent urea was utilized to enhance tablet porosity, thereby promoting faster disintegration. All formulations underwent thorough pre-compression and post-compression evaluations including micromeritic properties, physical characterization, disintegration behavior, drug content uniformity, and in-vitro drug release studies.

Among the formulations, F9, which contained 4% Crospovidone, emerged as the most promising. This batch demonstrated the shortest wetting time (45 seconds), highest water absorption ratio (85%), minimum disintegration time (16 seconds), and fastest in-vitro dispersion (23 seconds). The mechanical strength and friability of F9 were within acceptable limits, confirming its robustness. Furthermore, F9 achieved a cumulative drug release of 97.34% within 60 minutes, which was significantly higher than the other formulations, indicating an improved dissolution profile. The enhanced performance of Crospovidone can be attributed to its excellent swelling, wicking, and rapid water uptake properties, which facilitate quick disintegration and drug release.

Drug-excipient compatibility was confirmed through FTIR and DSC studies, ensuring chemical stability and absence of interactions. Stability testing under accelerated conditions (as per ICH guidelines) further affirmed that the optimized formulation retained its critical quality attributes over a period of three months without any significant degradation or performance loss.

In conclusion, this research successfully demonstrated that mouth dissolving tablets of Naproxen Sodium can be effectively formulated using Crospovidone as a superdisintegrant

and urea as a sublimating agent via direct compression. The optimized formulation (F9) not only addresses the limitations of conventional oral tablets but also enhances patient compliance through its rapid onset of action, improved dissolution, and ease of administration. This formulation strategy holds potential for industrial scalability and can be extended to other poorly soluble or gastric-irritant drugs, thereby broadening its applicability in pharmaceutical development.

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