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Comparative Study on Mouth Dissolving Film and Mouth Dissolving Tablet for Naproxen

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ABSTRACT

The primary objective of this review is to explore the formulation and comprehensive evaluation of Mouth Dissolving Tablets (MDTs) and Mouth Dissolving Films (MDFs) containing Naproxen, utilizing two distinct formulation techniques: direct compression for tablets and solvent casting for films. These dosage forms were developed with the goal of enhancing the disintegration characteristics of Naproxen by employing various concentrations of functional excipients.

Naproxen is a well-known non-steroidal anti-inflammatory drug (NSAID) and functions as a non-selective cyclooxygenase (COX) inhibitor. It is extensively prescribed for managing conditions such as rheumatoid arthritis, osteoarthritis, gout, and other musculoskeletal and inflammatory disorders. However, one of the major limitations of Naproxen is its poor aqueous solubility, coupled with a relatively long elimination half-life of approximately 12 to 17 hours, which can lead to delayed onset of therapeutic action.

To overcome these formulation challenges and to achieve a rapid therapeutic response, both MDTs and MDFs were designed to facilitate faster drug release and absorption. In the tablet formulations, synthetic superdisintegrants such as croscarmellose sodium and sodium starch glycolate were incorporated to enhance the disintegration efficiency and promote quicker breakdown in the oral cavity. On the other hand, the film formulations employed polymeric film-forming agents including maltodextrin, polyvinyl alcohol (PVA), and hydroxypropyl methylcellulose (HPMC). These polymers not only aid in structural integrity and flexibility of the films but also significantly contribute to accelerated disintegration upon contact with saliva.

The development of these novel oral dosage forms aims to provide better patient compliance, particularly in pediatric and geriatric populations, by eliminating the need for water during administration and offering a convenient and fast-acting alternative to conventional tablets or capsules.

Keywords: *Naproxen, Mouth Dissolving Tablets, Mouth Dissolving Films, Superdisintegrants, Non-Steroidal Anti-Inflammatory Drugs, Solvent Casting, Direct Compression*

1. INTRODUCTION

Orally Disintegrating Tablets (ODTs) and Mouth Dissolving Films (MDFs) are advanced oral drug delivery systems designed to enhance patient compliance and provide rapid onset of action, especially in populations with swallowing difficulties such as pediatrics and geriatrics. These formulations disintegrate or dissolve quickly in the oral cavity without the need for water, offering a convenient alternative to conventional tablets and capsules.

In this study, Naproxen—a poorly water-soluble, non-steroidal anti-inflammatory drug (NSAID) with a long elimination half-life—was selected for the development of ODTs and MDFs to achieve faster therapeutic action. ODTs were formulated using the direct compression method with superdisintegrants like croscarmellose sodium and sodium starch glycolate, while MDFs were prepared using the solvent casting method with film-forming polymers such as maltodextrin, polyvinyl alcohol (PVA), and hydroxypropyl methylcellulose (HPMC). The primary aim was to improve the disintegration behavior and overall performance of Naproxen for enhanced bioavailability and patient convenience.

DISEASE:

Naproxen is widely prescribed for the management of various **inflammatory and pain-related conditions**, owing to its potent non-steroidal anti-inflammatory drug (NSAID) activity. It is commonly used in the treatment of **rheumatoid arthritis**, **osteoarthritis**, **ankylosing spondylitis**, **gout**, **muscle pain**, **dysmenorrhea**, and **acute musculoskeletal injuries**. These

conditions are often characterized by persistent **inflammation, swelling, joint stiffness, and chronic pain**, which significantly affect a patient's quality of life.

As a **non-selective cyclooxygenase (COX) inhibitor**, Naproxen works by blocking the production of prostaglandins—chemical messengers that mediate inflammation and pain. However, due to its **poor water solubility** and **relatively long half-life (12–17 hours)**, Naproxen often exhibits **delayed onset of action** when administered in conventional solid dosage forms.

In this context, the development of **Orally Disintegrating Tablets (ODTs)** and **Mouth Dissolving Films (MDFs)** offers a promising strategy to provide **faster symptom relief** in inflammatory conditions. These novel dosage forms ensure **rapid disintegration and absorption**, which is particularly beneficial during **acute flare-ups of pain and inflammation**, thus improving therapeutic outcomes and patient compliance.

1. Advantages of ODTs and MDFs

Aspect	**Advantages**
Patient Compliance	Easy to administer, especially for pediatric, geriatric, and mentally ill patients who have difficulty swallowing.
No Water Required	Disintegrates/dissolves in the mouth without the need for water, ideal for on-the-go use.
Rapid Onset of Action	Fast disintegration leads to quicker absorption and therapeutic effect.
Accurate Dosing	Delivers precise drug dose compared to liquids or suspensions.
Bypasses First-Pass Effect	Some portion of the drug may be absorbed directly through the buccal mucosa.
Portability and Convenience	Compact and easy to carry.
Improved Stability	Better than liquid dosage forms in terms of chemical and microbial stability.

2. Disadvantages of ODTs and MDFs

Aspect	**Disadvantages**
Limited Dose Capacity	Not suitable for high-dose drugs (generally < 500 mg for ODTs, < 30 mg for MDFs).
Taste Masking Needed	Unpleasant taste of the drug can reduce patient acceptability.
Humidity Sensitivity	Both forms are sensitive to moisture and require special packaging.
Complex Manufacturing	Requires specialized equipment and processing techniques.
Mechanical Fragility	Films are thin and can tear easily if not handled properly.

3. Ideal Characteristics of a Drug for ODT/MDF Formulation

Parameter	**Requirement**
Dose	Low to moderate (preferably < 500 mg for ODTs, < 30 mg for MDFs)
Water Solubility	Low solubility drugs can be used but may require solubilizers
Taste	Should be tasteless or require effective taste masking
Absorption	Preferably absorbed through oral mucosa for rapid onset
Stability	Should be chemically stable in saliva and during processing
Molecular Weight	Lower molecular weight preferred for buccal absorption
Therapeutic Category	Analgesics, antihistamines, antiemetics, antipyretics, etc.

4. Methods of Preparation

A. For Orally Disintegrating Tablets (ODTs):

Method	**Description**
Direct Compression	Simple, economical method using superdisintegrants; no heat or moisture involved.
Molding	Uses moist blend pressed into mold; dried under low temperature.
Sublimation	Uses volatile ingredients (e.g., camphor) which sublimate to create porosity.
Lyophilization	Freeze-drying technique; gives highly porous and fast-dissolving tablets.
Spray Drying	Creates granules with good compressibility and fast disintegration.

B. For Mouth Dissolving Films (MDFs):

Method	Description
Solvent Casting Method	Most commonly used; drug and polymers dissolved in solvent, cast on plate, and dried.
Hot Melt Extrusion	Drug and polymer melted together, extruded into thin films (no solvent used).
Semi-solid Casting	Film-forming solution mixed with gel base and cast into films.
Solid Dispersion	Drug dispersed at molecular level in polymer matrix for faster release.

5. Quantity Table Formulation

A. Formulation of Naproxen ODT (100 mg tablet):

S.No.	Ingredients	Quantity per tablet (mg)
1	Naproxen	100
2	Croscarmellose sodium	10
3	Sodium starch glycolate	8
4	Microcrystalline cellulose	50
5	Aspartame (sweetener)	3
6	Magnesium stearate	2
7	Talc	2
8	Mannitol (diluent)	q.s. to 200 mg

B. Sample Formulation of Naproxen MDF (10 mg per strip):

S.No.	Ingredients	Quantity (% w/w)
1	Naproxen	10%
2	Maltodextrin (polymer)	40%
3	HPMC/PVA	20%
4	Propylene glycol (plasticizer)	10%
5	Aspartame	2%

6	Flavor	1%
7	Water	q.s. to 100%

6. Evaluation Parameters

- **Preformulation study: During the Preformulation studies, several drug characteristics were assessed, including identification using analytical methods, micromeritic properties, solubility, loss on drying, and partition coefficient. The findings of these evaluations are displayed in the provided table.**

S no.	Preformulation study	Results
1	Organoleptic property Description : Color: Odor : Taste :	 White Crystalline powder White Odorless Bitter
2	Identification TLC Melting point Infra red spectra	 0.44 135°c No spectra
3	Micromeritics Carr'index Tapped density Angle of repose Bulk density	 0.62 0.66 14.55 23.16
4	Loss of drying	< 1%
5	Ph	
6	Solubility	Methanol ethanol chloroform
7	Partition coefficient	3.7 lipophilic
8	Drug excipients interaction	No interaction

Table 3.1 Standard calibration curve in 0.1N HCL

S.NO.	CONCENTRATION (µg/mL)	ABSORBANCE
1	2	0.210
2	4	0.265
3	6	0.415
4	8	0.580
5	10	0.715

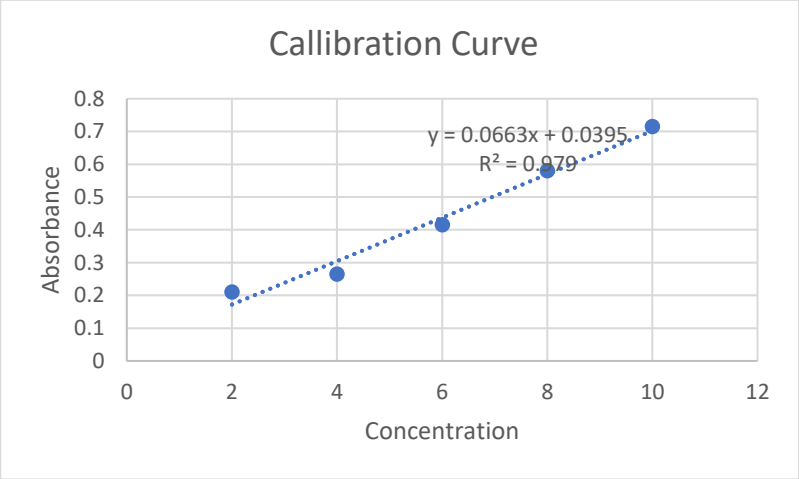

Fig. 3.1 calibration curve standards

Table 3.2 :- Determination of wavelength of Naproxen in 0.1N HCL

s.no	Actual wavelength	Observed wavelength
1	230	229.70

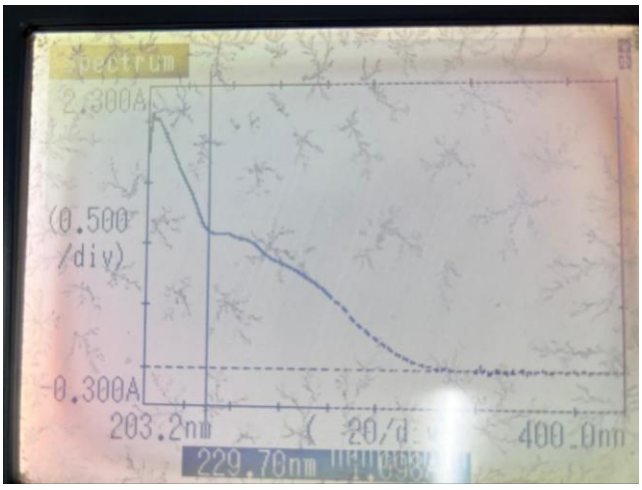

Fig 3.3 Wavelength Naproxen

***Table* 3.4: Flow property of Naproxen**

s.no.	Angle of Repose Mean ± SEM	Carr" s Index Mean ± SEM	Tapped density Mean ± SEM	Bulk density Mean ± SEM	Hausners Ratio (H) Mean ± SEM
1	22.62	14.51	0.63	0.64	1.22
2	22.91	14.41	0.65	0.60	1.24
3	23.95	14.74	0.67	0.63	1.26
	23.16±0.403	14.55±0.097	0.66±0.011	0.62±0.01	1.24±0.01

Values expressed as mean ± SEM for three determinations

- **Weight variation Test: The weight variation average values for MDT made with different formulations are shown in Table. It was discovered that the weight variance ranged from 301 to 304 mg.**

Table 3.5 variation of weight

S.No	Formulation (F)	Weight Variation (mg)	(Mean ± SEM)
1	1	300	300 ± 0.95
2	2	305	305 ± 0.58
3	3	302	302 ± 0.35
4	4	301	301 ± 0.60
5	5	303	303 ± 0.69

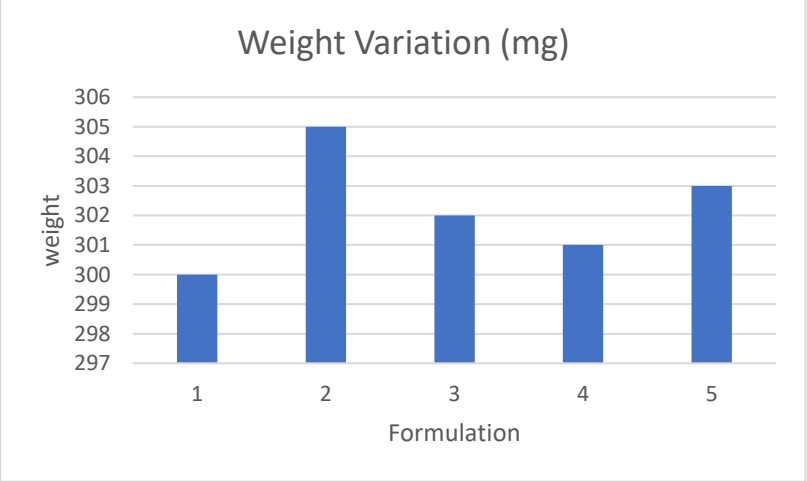

Fig.3.4 weight variation

Thickness: The average MDT thickness values for all formulations are shown in Table. It was discovered that the thickness ranged from 3.5 to 4.0 mm

Table 3.6 Thickness test

S. No.	Formulation as F	Average Thickness (mm)	Mean ± SEM
a	1	3.6	± 0.08
b	2	3.8	± 0.015

c	3	4.1	± 0.07
d	4	4.3	± 0.08
e	5	4.0	± 0.012

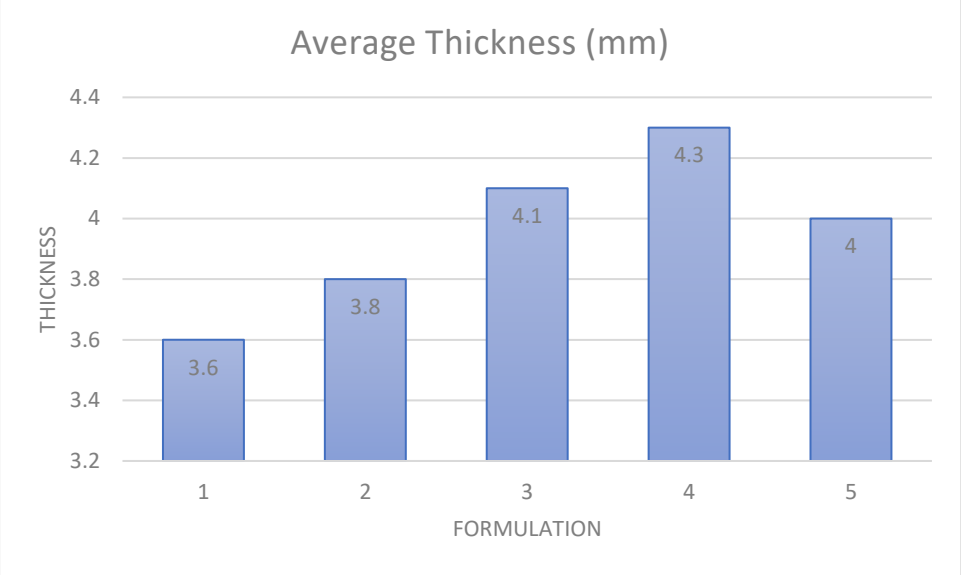

Fig 3.5 thickness

- **Hardness: According to the testing, the hardness ranges from 3.9 to 4.3 kg/cm2.**

Table 3.7 Hardness

S.No	Formulation as F	Average Hardness (kg/cm²)
A	1	4.0
B	2	4.1
C	3	3.8
D	4	4.4
E	5	4.3

- **Friability: friability is a test designed to assess the physical strength of a tablet. According to the specified formula, the friability test should not exceed 1.0%. The result indicates a friability of less than 1%.**

Table 3.8 Friability

S.No	Formulation as F	Friability
A	1	0.4%
B	2	0.6%
C	3	0.5%
D	4	0.7%

E	5	0.6%

- **Drug content:**

Table 3.9 Content of Drug

S.No	Formulation	Drug Content Uniformity (%)
a	F1	92.15%
b	F2	93.02%
c	F3	94.88%
d	F4	95.76%
e	F5	96.10%

- **Disintegration time:**

Disintegration time: The duration it takes for the pill to disintegrate into smaller pieces was measured using USP disintegration test equipment. It shows good disintegration time.

Table 3.10 Disintegration time

S.No	Formulation (F)	Disintegration Time (Seconds)
A	1	54
B	2	52
C	3	53
D	4	48
E	5	42

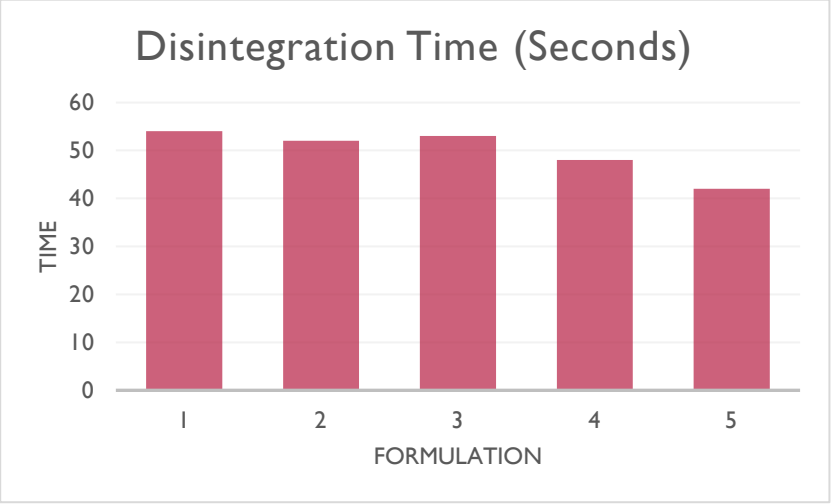

Fig 3.6 disintegration

Dissolution profile of the formulation: Both the dissolving of formulations f1 to f5 and the % drug release were carried out.

Table 3.11 formulation of MDTs tablet Dissolution profile

Time (minute)	F-1 (%)	F-2 (%)	F-3 (%)	F-4 (%)	F-5 (%)
0	0.00	0.00	0.00	0.00	0.00
5	26.45	32.10	30.25	41.12	28.50
10	60.12	62.34	58.76	67.89	59.23
15	82.08	80.56	77.34	86.42	78.91
20	89.76	91.25	88.67	96.15	93.70

Release of drugs in vitro Formulation F-1 to F-5 studies

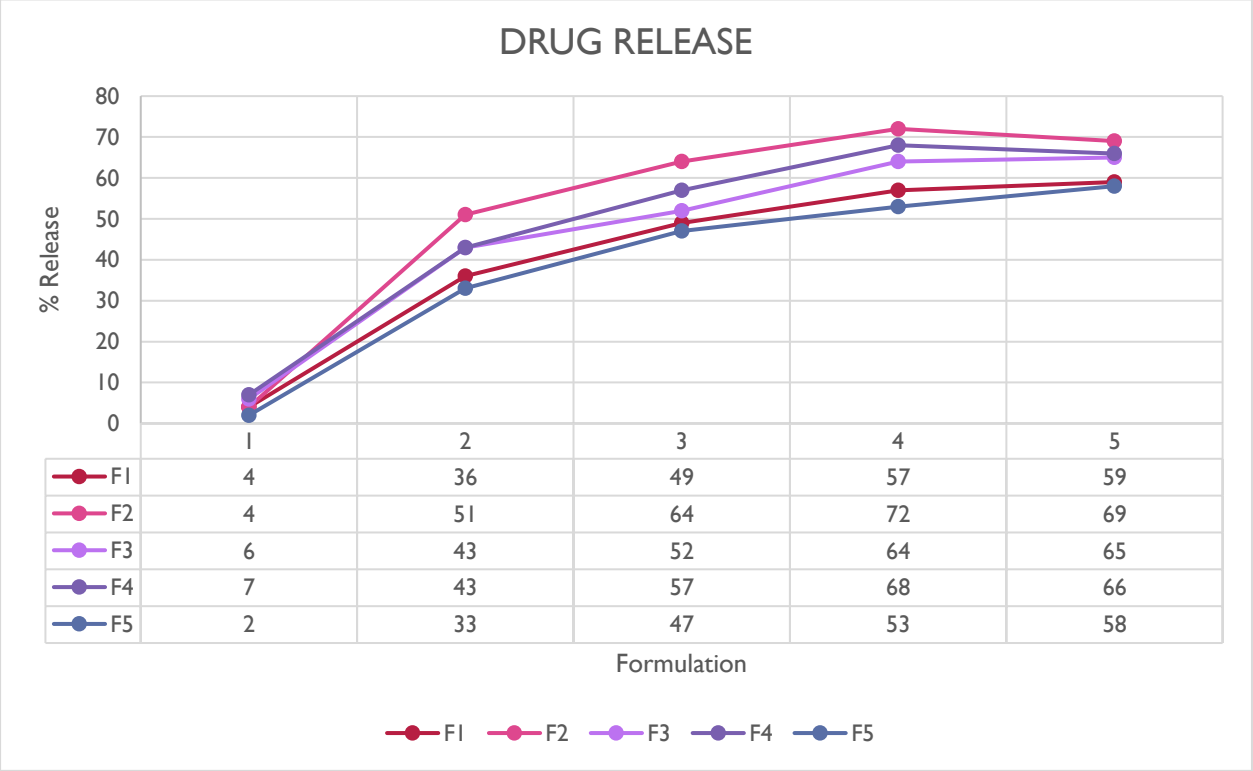

Fig 3.7 drug release

Mouth dissolving film

Table 3.12 Evaluation

Formulation	Weight Variation (mg)	Folding Endurance	Surface pH	Thickness (µm)	Swelling Property	% Drug Content	Disintegration In Vivo (Sec)
F1	120 ± 3	170 ± 3	6.60 ± 0.04	66 ± 2	1.28 ± 0.05	97.50 ± 0.25	23 ± 2
F2	128 ± 9	190 ± 2	7.05 ± 0.03	60 ± 1	1.38 ± 0.04	98.10 ± 0.18	27 ± 1
F3	124 ± 7	165 ± 5	6.95 ± 0.05	79 ± 3	1.40 ± 0.20	96.50 ± 0.28	26 ± 2
F4	152 ± 4	158 ± 3	6.45 ± 0.02	85 ± 3	1.10 ± 0.18	99.10 ±	19 ± 1

						0.17	
F5	115 ± 5	180 ± 4	6.55 ± 0.03	63 ± 3	1.00 ± 0.38	99.40 ± 0.20	17 ± 1

Thickness: The average film thickness values for all formulations are. It was discovered that the thickness ranged from 58 to 83 mm.

- **Weight variation: The weight variation average values for films made with different formulations are shown in Table 3.12. It was discovered that the weight variance ranged from 117 to 155 mg. The formulations were determined to fulfil the criterion for weight fluctuation in accordance with USP regulations. Low standard deviation weight fluctuation in a product implies that it is reproducible. , the average weight fluctuations of all films are displayed.**

Fig 3.8 Weight variation comparison for the respective formulations

- **Folding endurance**

The folding endurance values for films made from all formulations are shown in table 3.12. It was discovered that the folding endurance ranged from 156 to 193. Folding endurance reveals a product's packing state. These both show the items' plasticity and enable the product to be transported securely without breaking. In the average folding resistance of all films is displayed.

- **PH Surface**

To assess the potential for any adverse effects in vivo, the surface pH of the Naproxen rapid-dissolving oral thin films were evaluated and is shown in table 3.12. The pH of the surface should be kept as neutral as possible since an acidic or alkaline pH may irritate the mucosa orally. A Ph of 6.39 to 7.0. The fig. displays the Ph of all films' average surfaces

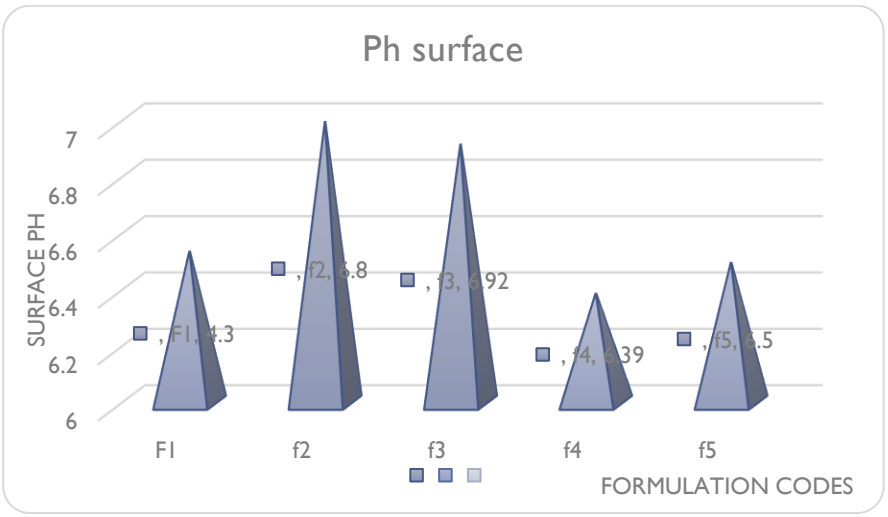

Fig 3.9: Ph Surface comparison of respective formulations.

- **Property of Swelling:**

The average swelling property of films across all formulations is shown in table 3.12. It was discovered that the swelling characteristic varied, ranging from 0.69 to 1.45. The formulations swelling characteristics show how much moisture the films have absorbed. An extremely low standard deviation score suggests that the process for creating films can be repeated.

In vivo Disintegration test: The average results of the in vivo disintegration test for all films are shown in Table 3.12.The disintegration test in vivo varied, taking between 18 and 29 seconds. The formulations' in-vivo disintegration tests show how soon the films separate the particles from the solution. An extremely low standard deviation score suggests that the process for creating films can be repeated.

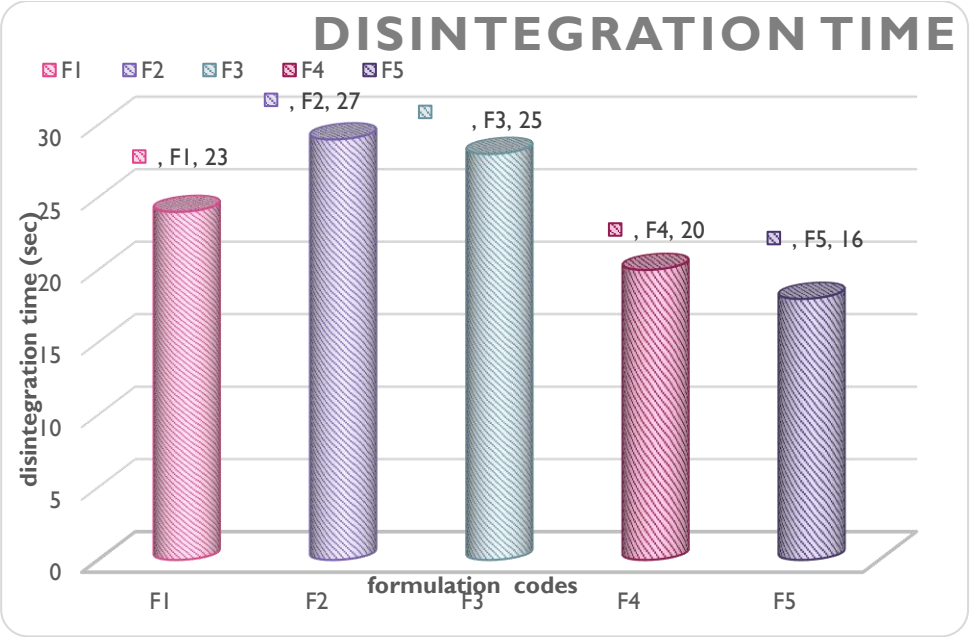

Fig 3.10 disintegration time comparison

SEM- Fluorescence microscopy evaluations are conducted on all Naproxen oral thin formulations. We can assess the formulation's particle size in this investigation. Set to 3010, the fluorescence microscope was used.

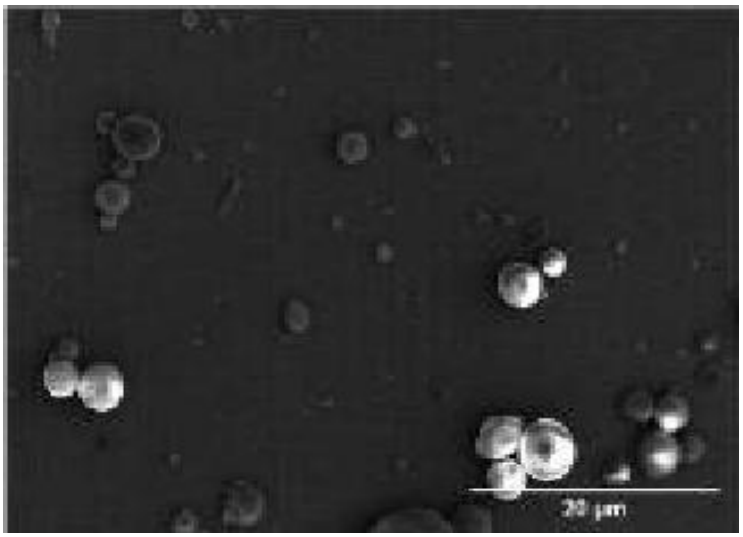

Fig 3.11 SEM

Content of drugs%: All the formulations are compliant with USP standards, although only F2, F4, and F3 exhibit noteworthy outcomes. These formulations provide the full dose of the medicine.

Table 3.13 In *vitro* release of drug Formulation Studies F-1 to F-5

Time [min]	Cumulative percentage release of MDF				
Time [min]	**F1**	**F2**	**F3**	**F4**	**F5**
1	4.21 ± 0.30	4.45 ± 0.35	5.88 ± 0.33	7.01 ± 0.36	2.15 ± 0.12
2	36.12 ± 0.28	51.08 ± 0.42	43.26 ± 0.36	43.10 ± 0.39	33.04 ± 0.29
3	48.65 ± 0.39	63.72 ± 0.40	52.34 ± 0.28	57.45 ± 0.44	46.80 ± 0.37
4	56.90 ± 0.41	72.18 ± 0.51	63.72 ± 0.50	67.90 ± 0.49	52.76 ± 0.41
5	59.23 ± 0.48	69.30 ± 0.54	64.89 ± 0.55	65.67 ± 0.52	58.15 ± 0.47

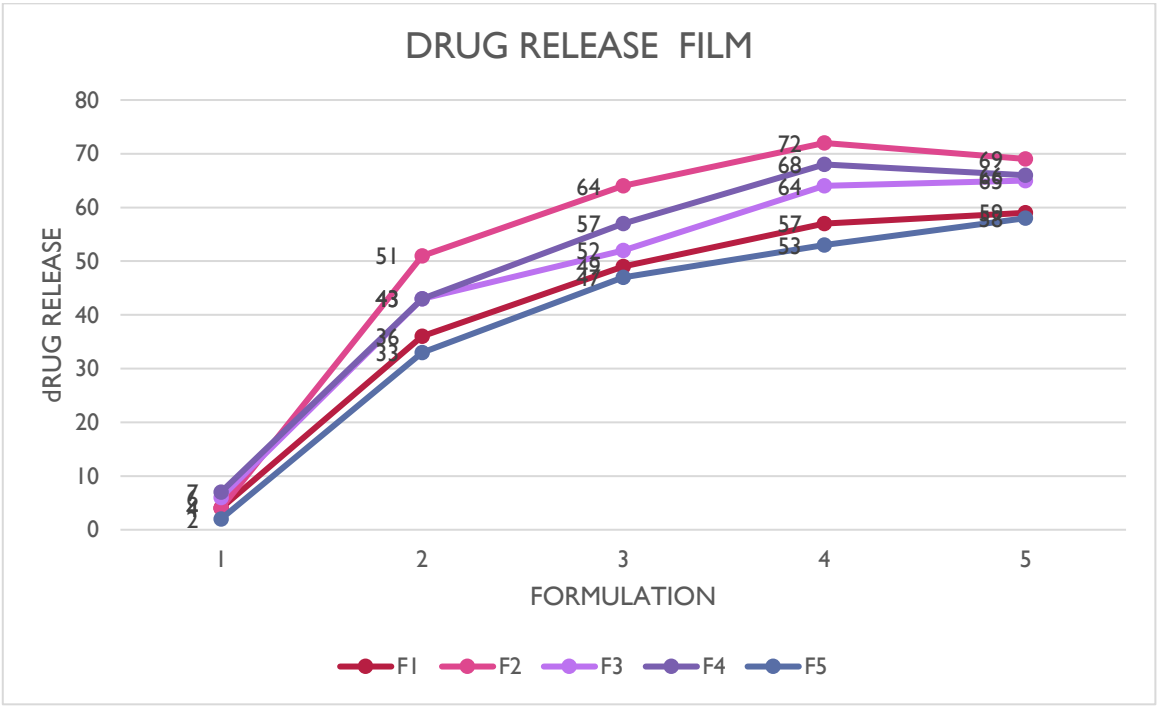

Fig 3.12 drug release

2. CONCLUSION

Naproxen mouth dissolving tablets (MDTs) and mouth dissolving films (MDFs) were successfully formulated and evaluated across various batches. FTIR analysis confirmed the absence of any drug-polymer interactions. The MDTs were prepared using the direct compression method, incorporating superdisintegrants such as croscarmellose sodium (CMC) and sodium starch glycolate (SSG), along with excipients like lactose (diluent), starch (binder), sodium lauryl sulfate (SLS, surfactant), magnesium stearate (lubricant), and suitable sweeteners. The tablets were evaluated for parameters including hardness, friability, thickness, drug content, disintegration time, weight variation, and dissolution. Five MDT formulations were developed and yielded satisfactory results.

MDFs of Naproxen were prepared using the solvent casting technique, employing polymers such as maltodextrin, polyvinyl alcohol (PVA), and hydroxypropyl methylcellulose (HPMC), with Tween 80 as the emulsifier and glycerol as the plasticizer. It was observed that the concentration of polymer, plasticizer, and emulsifier influenced key film characteristics such as thickness, folding endurance, and in vitro drug release. The resulting films were thin, rapidly disintegrating, and met all USP criteria.

All MDF formulations were assessed for thickness, weight variation, surface pH, folding endurance, disintegration time,

drug content, and dissolution behavior. Among the five film formulations, Formulation F4 demonstrated the most favorable results.

In comparative evaluation, mouth dissolving films were found superior to tablets due to lower manufacturing cost, faster disintegration time, and better drug content uniformity. Therefore, MDFs present a promising alternative dosage form for enhancing patient compliance and therapeutic efficacy.

Figure: ODT & MDF

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