

Formulation and Evaluation of Xanthan Gum-Based Naproxen Matrix Tablets for Controlled Drug Release

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ABSTRACT

Current research focuses on the formulation and assessment of the skillful announcement medium tablet of Naproxen by means of Xanthan secretion as a natural hydrophilic polymer. Matrix pills were formulated using the direct compression technique with separate concentrations of xanthan gum (100–300 mg), and was evaluated for physical chemical parameters including rigidity, magnitude, weight variation, thickness and pharmaceutical materials, including all Indian pharmacopial borders. The FTIR and DSC confirmed pharmaceutical compatibility-polymer without any significant talks. The drug material uniformity ranged from 93.2% to 101.23%, ensuring homogeneous drug delivery. In vitro pharmacological announcement educations remained conducted in 0.1 Normal HCL (Ph1 1.2) for 2 times, succeeded through Phosphate bumper (pH 6.8) for 10H. Formulation F -3 performed 71% cumulative release in 12 hours, equivalent to marketing formulation (73%). Kinetic Modeling Reveled That The medication announcement adhered to a nothing-instruction kinetics model Kinetics ($R^2 = 0.9587$ for sgf, 0.9691 for mf) with strong linearity, Whilee Korsmeyer-Peppas Analysis ($n = 0.7321-0.8431$) indicated a non-budgetian (anomalous) transport mechanism, governed by both polymer Relaxation/Erosion and DIFFUSION. Quick constancy educations ($40 \pm 2^\circ \text{C}$, 75, 5% Rh, 60 days) did not make slightly important changes to hardness, horrific, pharmaceutical material or release profiles, ensuring good stability. Finally, Xanthan gum proved to be an effective, safe and affordable polymer to develop controlled-controlled-naproxen pills, achieve prolonged pharmaceutical release, enhanced bioavailability, and improved patient adherence.

Keywords: *Naproxen, Xanthan gum, Skillful announcement, Medium drugs, In-vitro drug announcement, Stability education, Release kinetics, Direct Compression.*

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INTRODUCTION

There are several routes of drug administration to achieve a systemic pharmacological effect. Among them, the oral route is the most widely used, accounting for nearly 90% of drug delivery¹. Oral dosage forms remain the most popular, with tablets being the preferred formulation due to their low production, packaging, and transportation costs, along with enhanced stability and resistance to tampering². More than 80% of therapeutic agents intended for sustained systemic activity are developed as oral formulations, with tablets representing the most frequently prescribed dosage form.

Their popularity is attributed to ease of administration, dose uniformity, stability under varying storage conditions, and suitability for large-scale production via high-speed compression³.

Controlled release systems (CRS) have been extensively studied because they provide multiple therapeutic advantages over conventional dosage forms. Natural hydrophilic polymers are particularly attractive in CRS development due to their cost-effectiveness, safety, biocompatibility, and biodegradability⁴. These polysaccharides can be chemically or biologically modified

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to achieve specific drug delivery characteristics, making them an active area of research in pharmaceutical sciences⁵. CRS are particularly beneficial as they improve patient compliance by reducing dosing frequency, minimize adverse effects by controlling drug release, and maintain relatively constant plasma drug concentrations for uniform pharmacological action⁶. The design of CRS is influenced by various physicochemical and biological parameters, which must be carefully optimized⁷.

Research continues to emphasize the potential of usual polymers in controlled medication distribution. Compared to synthetic or semi-synthetic polymers, natural polymers are more economical, biodegradable, non-toxic, and readily available, making them highly suitable for controlled release (CR) formulations⁸. Among them, xanthan gum, guar gum, and gum karaya have been widely used in the development of CR matrix tablets⁹. In recent studies, Xanthan Gum has been implemented in the construction of NeProxon Matrix Tablet to maintain drug release and check its ability to increase medical efficacy. Xanthan gum, a high molecular load secreted by ex -seraselular polysaccharide xanthomonas campestris, possesses favorable swelling, gel-forming, and release-modulating properties that make it a valuable excipient in CRS. Beyond its pharmaceutical applications, xanthan gum is also recognized for its biodegradability, biocompatibility, and safety in oral formulations¹⁰.

MATERIALS AND METHODS

MATERIALS:

The supplier of Naproxen was Granules India Limited, Hyderabad, India. Labh Additives - Xanthan Gum, in Mumbai, M.S. India, while Talc and magnesium stearate were provided by local market medical store, shirpur, M.S. India. Analytical-grade substances were employed in addition.

METHODS

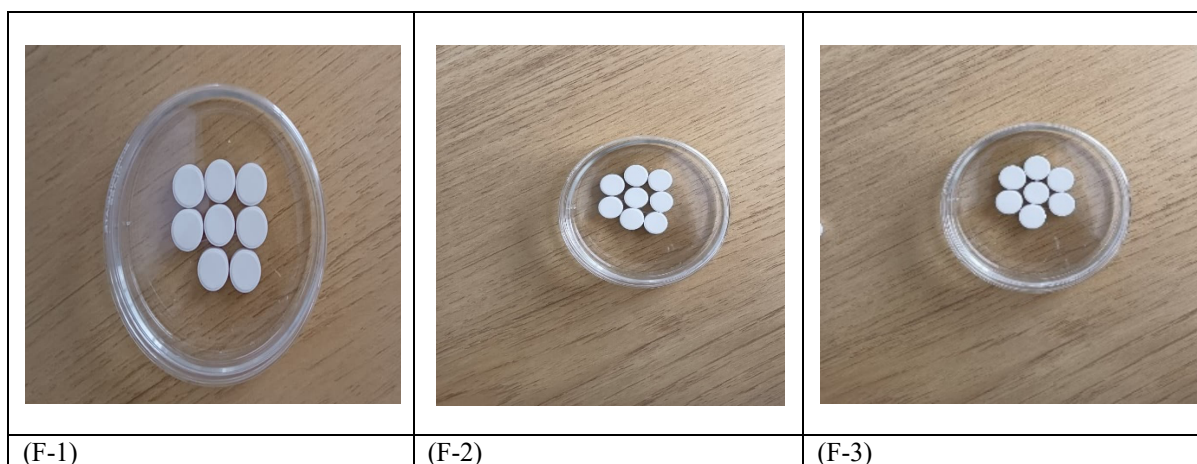
Preparation of Matrix Tablets:

Neproxon's matrix tablet was designed using a direct compression method with Xanthan secretion (XG) as a medium-forming polymer. Microcystline cellulose was included as a retarder, while the talaq and magnesium stearate were employed as lubricants. All materials were sieved through a #100 net to obtain a unchanging atom size. The accurately worn component, as specified in Table 1, was well varied to achieve a same combination. The combination was then lubricated with talc and magnesium (Mg) steiratory.

The final powder mixture was compressed into tablets of 600 mg average weight using an eight-station rotary tablet press. Different formulations were developed by varying the concentration of xanthan gum to study its effect on drug release characteristics. A total of five yogas were prepared after the same process. The formulation composition is provided cutting-edge Table 1 and is exemplified in Figure 1.

Table 1. Composition of Naproxen Matrix Tablet Formulations Prepared by Direct Compression

No.	Composition (% w/w)	Quantity (milligram) per Tablet	(F-1)	(F-2)	(F-3)	(F-4)	(F-5)
1	Naproxen	100	100	100	100	100	100
2	Xanthan gum	100	150	200	250	300	300
3	Microcrystalline cellulose (MCC)	375	325	275	225	175	175
4	Mg. stearate	010	010	010	010	010	010
5	Talc	15	15	15	15	15	15
Total weight	—	600	600	600	600	600	600



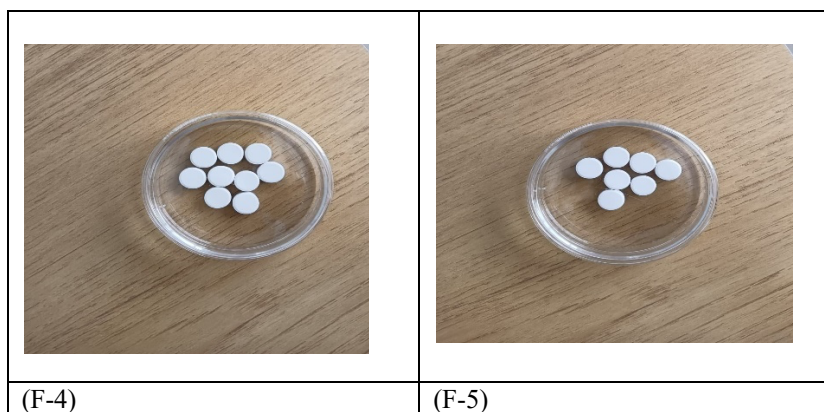


Fig. No.1: Matrix Tablets Prepared

Evaluation of Matrix Tablets Prepared

Tablet Hardness:

The tablet's mechanical strength was determined in the context of tensile strength (kilo/cm of). The stiffness of the tablet refers to the force necessary to fracture a tablet, and it directly affects important factors such as bioavailability, dissolution time and dissolution behavior. The stiffness of the prepared Naproxen -Xanthan Gum Matrix Tablet was measured using the Physics Rigidity Examiner, and the crushing load was recorded for each formulation.

Weight Fluctuation:

The examination was conducted in compliance with the standards of the Indian Pharmacopoeia. Ten drugs after respectively formulation lot remained arbitrarily chosen, then their individual weights were recorded. The average tablet weight and percentage weight deviations were calculated to ensure compliance with pharmacopoeial boundaries and to confirm the uniformity of the finished tablet.

Table 2. Tablet Specifications per Indian Pharmacopoeia

Sr. No.	Mean Tablet Weight	Permissible Deviation	%
1.	080 mg or less	±010%	
2.	More than 080 mg but less than 0250 mg	±07.5%	
3.	0250 mg or more	±05%	

Fragility:

The Fragility of formulated drugs remained evaluated utilizing a Roche Fragilitor. Twenty pre-considered drugs from each formulation were located in the fragilitor drum and exposed to rolling and impact shocks for 100 rotations. Subsequent to the test cycle, the drugs were dedusted, reweighed, and the fraction heaviness damage was intended, indicating the friability of the tablets. Weight loss below 1% is typically deemed acceptable, signifying sufficient mechanical integrity of the pills.

$$\% \text{Friability} = \frac{\text{Weight before test} - \text{Weight after test}}{\text{Weight before test}} \times 100$$

Width:

The thickness of each pill was assessed utilizing a micrometer screw gauge to assess variation within the batch. "Controlling tablet thickness is important for uniform packaging, handling, and patient compliance. According to standard guidelines, the thickness should not deviate more than ±5% from the average value to ensure consistency across the batch¹¹.

$$\% \text{Thickness Variation} = \times 100 \frac{\text{Average Thickness} - \text{Tablet Thickness}}{\text{Average Thickness}}$$

Drug Content Uniformity

"Drug content homogeneity was evaluated using twenty finely powdered naproxen-xanthan gum matrix tablets. A precisely measured amount of dust, corresponding to 100 mg of naproxen, was placed into a 100 mL volumetric flask. To achieve total dissolve, 50 mL of 0.1 N NaOH was introduced, and the combination remained sustained for 6 hours with periodic sonication. The resulting volume was calibrated to 100 mL using 0.1 N NaOH, subsequently undergoing filtration. From the filtrate, 1 mL was appropriately weak and analyzed. The drug content was determined using a double-beam UV spectrophotometer at 276 nm¹², and the results are presented in Table 6."

In Vitro Medication Announcement Study

"In vitro drug release of naproxen from the matrix tablets was studied using a USP Type I (basket) dissolution apparatus. The test was performed in 900 mL of dissolution medium maintained at 37 ± 0.5 °C with a basket rotation speed of 50 rpm for 12 hours. To simulate physiological conditions, 0.1 N HCl (pH 1.2) was used as the medium for the first 2 hours, followed by pH 6.8 phosphate buffer for the remaining 10 hours. At predetermined hourly intervals, 10 mL of the medium was withdrawn, filtered, and immediately replaced with an equal volume of fresh medium of the same pH. The drug concentration in the samples was measured using a UV spectrophotometer, and

the cumulative percentage release of naproxen was calculated." ¹³.

"Release Kinetics: The medication The announcement information were examined utilizing many moving replicas."

Zero-order model: $Q = K_0 t$ $Q = K_0 t$

Higuchi model: $Q = K_H t^{1/2}$ $Q = K_H t^{1/2}$

where Q represents the amount of drug released at time t, K_0 is the zero-order release constant, and K_H is the Higuchi dissolution rate constant ¹⁴

Korsmeyer-Peppas Model

"The Korsmeyer–Peppas model is frequently applied to evaluate drug release from polymeric dosage forms, particularly when the release mechanism is uncertain or involves a combination of processes. This model is based on the linear segment of the plot of log cumulative percentage drug release versus log time ¹⁵. The reckoning is expressed as:"

$M_t/M_\infty = K. t^n$

"The value of n in the Korsmeyer–Peppas model depends on both the release mechanism and the geometry of the dosage form. For a slab matrix, n = 0.5 corresponds to Fickian diffusion, whereas values of 0.5 < n < 1.0 indicate non-Fickian (anomalous) transport, which involves a combination of polymer chain relaxation or erosion and diffusion through the hydrated outer layers of the matrix." ¹⁵.

Stability Study

"The purpose of stability studies is to establish the shelf life and suitable storage conditions of a drug product by evaluating changes in its quality, safety, and efficacy over time when exposed to environmental factors such as temperature, humidity, and light. Both active pharmaceutical ingredients and finished formulations are tested to assess thermal stability and, when relevant, sensitivity to moisture. These studies are carried out under long-term, intermediate, and accelerated conditions, as per regulatory requirements." ¹⁶.

Accelerated Stability Testing:

Accelerated testing is performed under stress conditions to hasten chemical degradation or physical changes in the drug product. For the optimized naproxen–xanthan gum matrix tablets, "An accelerated stability study was performed by storing the tablets in airtight glass containers at 40 ± 2 °C and 75 ± 5% relative humidity (RH). Samples were collected at predetermined time intervals and analyzed for parameters such as hardness, friability, drug content, and in vitro release, in order to predict the formulation’s stability under normal storage conditions." ¹⁶.

RESULTS & DISCUSSION

UV Spectroscopy: Determination of Wavelength (λ_{max})

"The maximum absorbance wavelength (λ_{max}) of naproxen was determined using a UV–visible spectrophotometer, as this parameter is essential for accurate quantitative analysis of the drug in different formulations. A standard solution of naproxen was prepared in 0.1 N NaOH and scanned across the wavelength range of 200–400 nm. The λ_{max} was identified as the point of maximum absorbance, and this value was subsequently

employed for drug content estimation and in vitro release studies." ⁹.

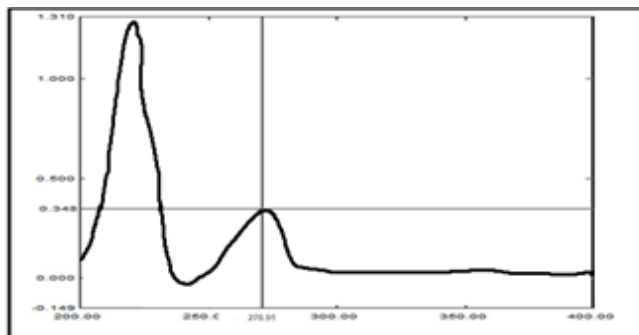


Figure No.2: UV scan of Naproxen in pH 6.8 buffer at 276 nm

"A stock solution of naproxen (100 µg/mL) was prepared in phosphate buffer (pH 6.8). The UV spectrum of the solution was recorded using a Shimadzu UV-1800 spectrophotometer within the 200–400 nm range. The maximum absorbance wavelength (λ_{max}) was found to be 276 nm, which was subsequently employed for quantitative evaluation in drug content determination and in vitro release studies." ⁹.

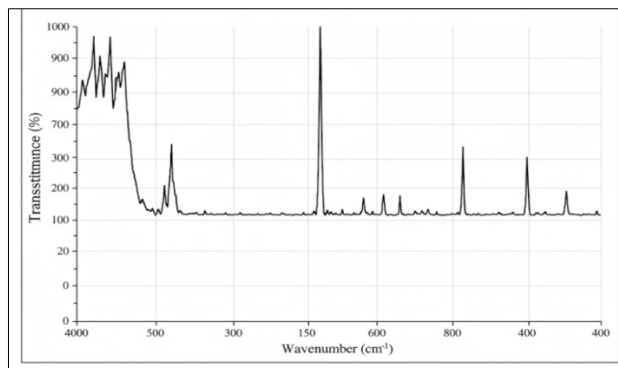


Figure No 3: Naproxen IR spectrum

Figure displays the IR spectra of Naproxen obtained in a KBr. Below Table No.3 is a list of some of the typical bands' assignments.

Table No.3: IR Spectra of Naproxen

Peak Observed (cm ⁻¹)	Reference Range (cm ⁻¹)	Functional Group (as per spectrum)
3257	3500–3100	(carboxylic acid) C-O stretching
1716	1758–1700	(carboxylic acid) C=O stretching
1558	1600–1500	(aromatic) C=C stretching
1282	1320–1210	(carboxylic acid) C-O stretching
1166	1300–1000	(ether) C-O stretching
746	785–540	(aromatic) C-H out-of-plane bending

Polymer identification: F-T-I-R spectroscopy was conducted employed to classify the polymers used in the study. xanthan gum was seen as distinct peaks in IR spectra.

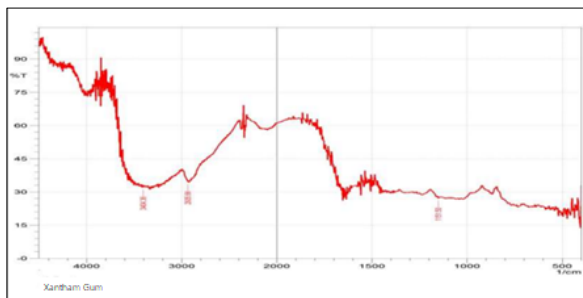


Figure No 4: Xanthan gum IR spectrum

The IR range of Xanthan gum occupied in a KBr is shown in figure. Assignments for some of the characteristic bands are listed below table No.4.

Table No. 4: IR Spectra of Xanthan gum

Peak Observed (cm ⁻¹)	Reference Range (cm ⁻¹)	Functional Group
3404	3400	-OH stretch
2935	3000-2850	-C-H stretch
1151	1300-1000	-C-O stretch

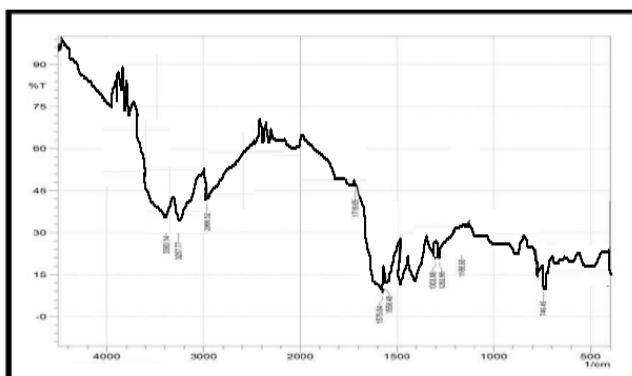


Figure No.5: Xanthan gum + IR spectrum of Naproxen FT-IR of Naproxen + Xanthan gum: IR spectra shown prominent peaks of Naproxen + Xanthan gum

Table No. 5: Naproxen IR Spectrum

Peak Observed (cm ⁻¹)	Functional Group
1716	(Carboxylic acid) C=O stretch
1600-1450	(Aromatic ring)C=C stretch
1200-1100	C-O stretch

Table No. 5: Xanthan Gum IR Spectrum

Peak Observed (cm ⁻¹)	Functional Group
~3400	(Hydroxyl group) O-H stretch
1624	Carboxylate stretch
1412	Carboxylate stretch

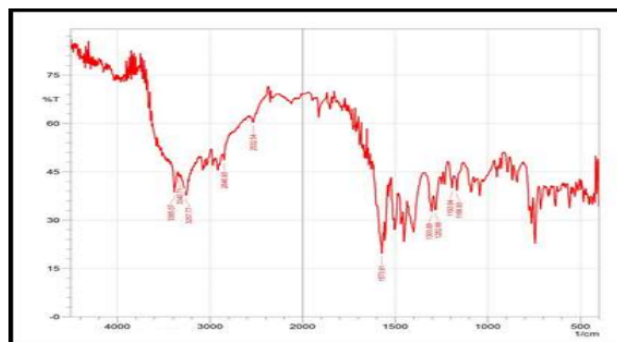


Figure No.6: IR spectrum of Drug + Polymer + all Excipients

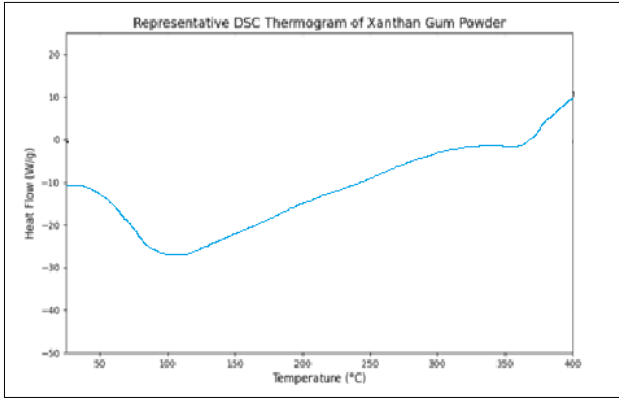
“The IR spectrum of SGF recorded using the KBr pellet method is presented in Figure X, and the characteristic absorption bands along with their respective assignments are summarized in Table No. 6.”

Table No 6: IR Spectra of Drug + Polymer + all Excipients

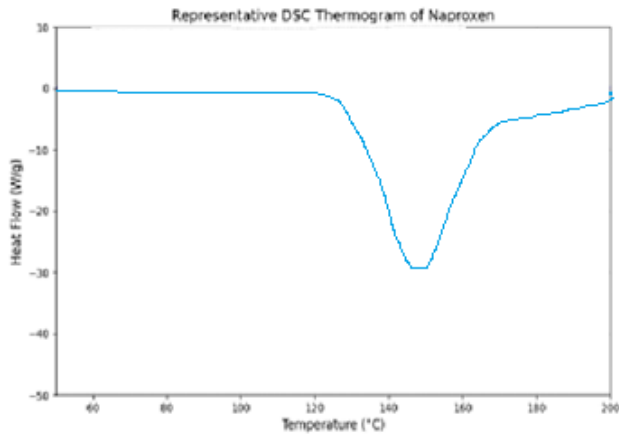
Peak Observed (cm ⁻¹)	Reference Range (cm ⁻¹)	Functional Group
1153	1300-1000	-O- stretch
1168	1300-1000	-C-CO-C stretch
1295	1320-1210	-C-O stretch
1580	1600-1475	-C=C stretch
3258	3500-3100	N-H stretch
3495	3400	-OH stretch

DSC Study:

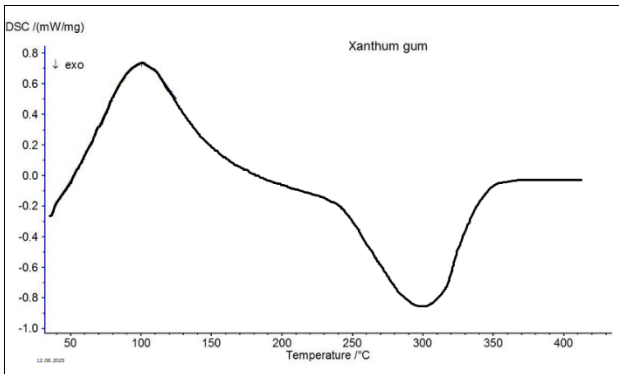
Naproxen, Xanthan gum powder, tablet powder, and a physical mixture of the drug with Xanthan gum were subjected to DSC. The DSC thermograms of these samples were compared with that of pure Naproxen. Except for a few minor variations that are commonly observed, all the analyzed samples exhibited similar thermal behavior as shown in Figure No. 12. From the peak position and peak shape, it is evident that there is little to no difference between pure Naproxen, Xanthan gum powder, and the physical mixture of the drug with excipients. The comparative DSC curves are illustrated in Figure No. 7.



A) DSC of Xanthan gum



B) DSC Thermograms of Naproxen: exhibiting a sharp endothermic top at 152-153°C



C) DSC of drug + Xanthanum at 150°C.

Figure No. 7: DSC thermogram of A) DSC of Xanthan gum powder, B) DSC of Drug (Naproxen), C) DSC of drug + Xanthan gum

Standardization Arc of Naproxen In 0.1 N NaOH
 In the attentiveness variety of 4–40 g/ml, the standardization arcs for Naproxen in 0.1 N NaOH demonstrated linearity. Therefore, it adhered to the Beer-Lambert law. (Figure No. 8)

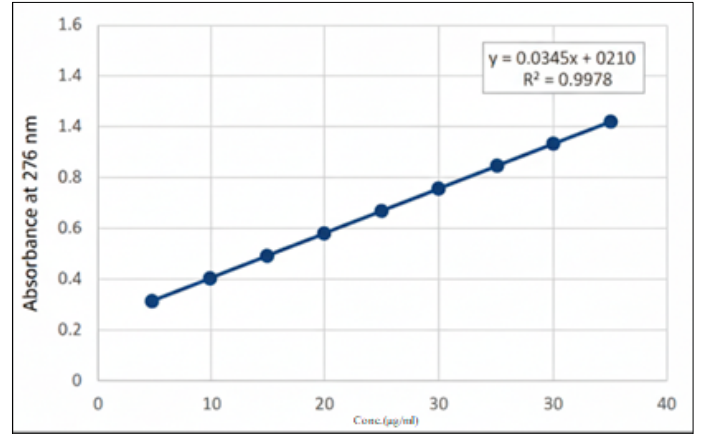


Figure No. 8: Calibration Curve of Naproxen in 0.1 N NaOH

Naproxen in PH 6.8 Phosphate Bumper of Standardization Arc

The standardization curves for Naproxen in 6.8 Phosphate Bumper showed linearity in attentiveness variety of 4-40µg/ml. thus it followed the Beer-Lambert law. (Figure No. 9)

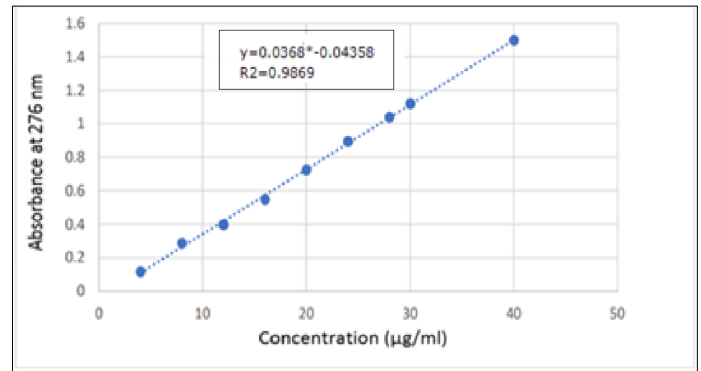


Figure No. 9: Calibration Curve of Naproxen in pH 6.8 Phosphate Buffer

In Vitro Medication Announcement Study of Ready Formulation

"Owing to naproxen's poor solubility in acidic environments, all formulations exhibited restricted medication announcement in 0.1 N HCl during the first two hours." thereby minimizing release under gastric conditions. After 12 hours, formulation F-1 released 86% of the drug, formulation F-2 released 79%, while formulations F-3 and F-4 released 71% and 62%, respectively. These findings indicate that the pH-dependent solubility of naproxen played a key role in modulating medication announcement across different media. A significant improvement in solubility was observed once the pH exceeded the drug's pKa, confirming the impact of medium pH on dissolution behavior. The attendance of xanthan secretion in the formulations likely contributed to their sustained-release characteristics."

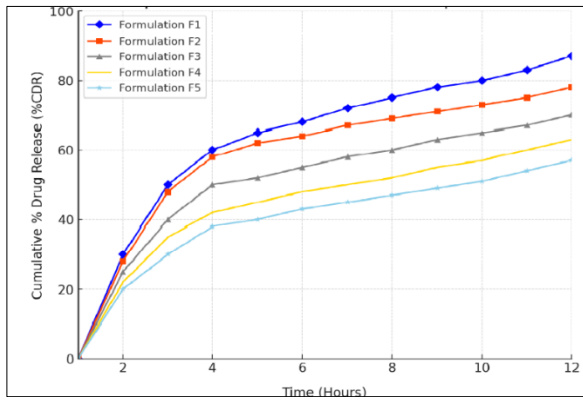


Figure No. 10: In Vitro Comparative Dissolution Profiles of Naproxen Matrix Tablet Formulations

Table No. 7: Tablets evaluation (Comparative Study of SGF & MF)

Sr. No.	Test parameters	Formulation code	
		SGF MF	SGF MF
	Hardness (kg/cm ²)	7.95	8.82
	% Friability	0.08	0.02
	% Drug content	97.85	99.12
	Weight Variation(mg)	610.5mg	602.3mg

In-Vitro Dissolution Profiles of Prepared SGF and MF Containing Naproxen

Due to the poor solubility of Naproxen in acid pH, the formulations released only a small amount of drug in 0.1N HCl during the initial two hours, thereby minimizing release in gastric conditions. At the end of 12 hrs, formulation F-3 exhibited 71% drug release, while the marketed formulation (MF) showed 73% release within the same period. These findings confirm the pH-dependent solubility of Naproxen and the ability of Xanthan gum-based formulations to sustain medication announcement over an lengthy period.

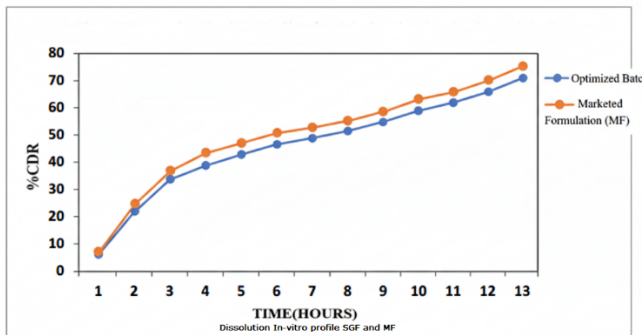


Figure No. 11: - The in vitro dissolution profiles of different formulations from the optimized batch were

evaluated and compared with the marketed formulation (MF) in simulated gastric fluid (SGF) Release Kinetic Studies

The in vitro medication announcement data remained evaluated employing many moving replicas. Zero-order plots produced constant of resolve (R^2) standards of 0.9587 for the simulated gastric fluid (SGF) and 0.9691 for the marketed formulation (MF), demonstrating strong linearity. The Higuchi model yielded R^2 standards of 0.8956 and 0.9083 for SGF and MF, correspondingly, indicating that dispersal frolicked a part in the announcement process. The Korsmeyer–Peppas perfect analysis yielded release exponent (n) values of 0.8431 for SGF and 0.7289 for MF, revealing of non-Fickian (anomalous) transport, wherein medication announcement is governed by a mixture of Fickian dispersal finished the hydrated xanthan gum medium and polymer reduction or corrosion. Literature reports also confirm that such anomalous release behaviour is typical for naproxen formulations employing matrix systems."

Table no. 8: Release Kinetic Studies for SGF and MF

Sr.No.	Equation	SGF	MF
1	Zero-order (R^2)	0.9587	0.9691
2	Higuchi (R^2)	0.8956	0.9083
3	Korsmeyer–Peppas (R^2)	0.8431	0.7289

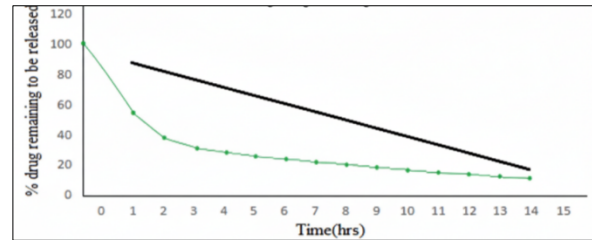


Figure no.12:- Zero-Order Plot Depicting the Percentage of Drug Remaining for Release over Time in SGF"

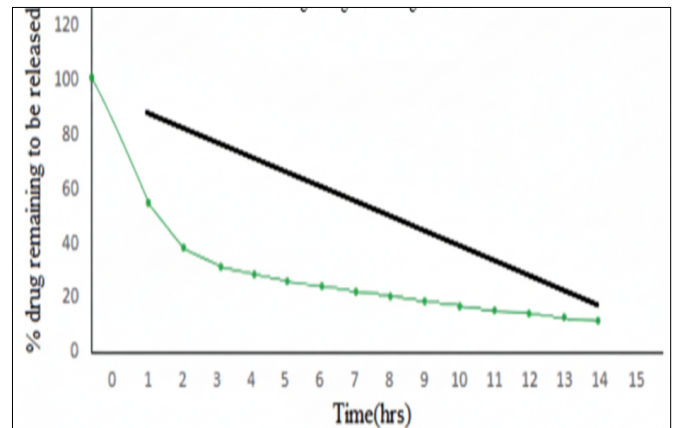


Figure No. 13: Zero-Order Plot of Depicting the Percentage Drug Remaining to be Released versus Time in MF's

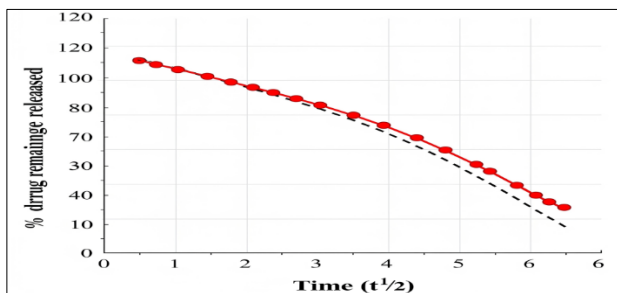


Figure No. 14: "Higuchi Plot Showing the Percentage of Drug Remaining for Release as a Function of the Square Root of Time (t^{1/2}) in SGF"

Stability Study

The primary aim of constancy challenging is to control the ledge lifetime of a pharmaceutical creation or the proper length for studying a pharmacological material, while also advising on optimal storage settings. "This is accomplished by observing variations in the constancy of the medication material or formulation ended period is influenced by environmental conditions, including temperature, humidity, and light. In alignment with best standards, the temperature stability of the active ingredient must be evaluated, and, when applicable, its vulnerability to moisture under storage circumstances should also be studied.

The current investigation involved the stability assessment of Naproxen–Xanthan gum formulations under three distinct storage conditions: long-term, intermediate, and expedited, as necessary. These conditions facilitate the prediction of real-time deterioration behavior and the establishment of valid shelf-life data. Tables 9 and 10.

Table No. 9: General case of Stability

Sr. No.	Study Type	Storage Conditions	Minimum Duration Covered by Data at Submission
1	Long-term	25 ± 2 °C / 60 ± 5 % RH or 30 ± 2 °C / 65 ± 5 % RH	12 months
2	Intermediate	30 ± 2 °C / 65 ± 5 % RH	6 months
3	Accelerated	40 ± 2 °C / 75 ± 5 % RH	6 months

Table No.10: General case sample Storage

Sr. No.	Storage Condition	Sampling Intervals (Months)
1	Real-time storage 30 °C / 75 % RH	0, 3, 6, 9, 12, 18, 24, 36, 48, 60
2	Accelerated 40 °C / 75 % RH	0, 1, 3, 6

"Any product developed in the formulation stage must exhibit consistent stability. "The selected formulation underwent accelerated stability testing for two months,

during which Pole-density characteristics, Limits such as rigidity, friability, drug content, and percentage medication release were evaluated at 40–50 °C and 75 ± 5 % comparative moisture."

The results (Table No. 11) indicate that no significant changes occurred in any of the measured characteristics over the 60-day period, demonstrating that the manufactured tablets are stable and do not require special storage conditions.

Table No. 11: Accelerated Stability study results

Sr. No.	Test Parameters	Sample testing time		
		0 Day	30 Days	60 Days
	Hardness Kg/cm2	8.06	7.98	8.25
	Thickness mm	4.03	3.76	3.86
	% Friability	0.0826	0.0820	0.0986
	Weight variation(mg)	625.24	625.24	625.24
	% Drug content	99.20	98.20	98.25
	Cumulative %drug release after 12hrs	73	69.20	71.02

Evaluation of Tablet Parameters

The following parameters were assessed for each formulated matrix tablet:

"Tablet Hardness: Tablet hardness refers to The force necessary to fracture or compress a tablet. This is a crucial quality criterion, since it affects disintegration, dissolving rate, and the overall bioavailability of the medicine. This study assessed tablet hardness with a Pfizer Hardness Tester, with data compiled in Table 12."

Table No.12: - Hardness of the prepared tablets formulation

Hardness(kg /cm2)	Formulation code				
	(F-1)	(F-2)	(F-3)	(F-4)	(F-5)
	6.4± 0.3	7.6± 0.2	8.03± 0.1	7.2± 0.2	7.8± 0.3

Test of Weight Variation

The weight variation test is a reliable method to assess the uniformity of drug distribution in the granules or powder used for tablet formulation, as well as the consistency of the active ingredient in the final tablets. Typically, 90–95% of the tablets are expected to contain the labeled amount of drug." 17

In this study, Twenty pills were weighed individually to ascertain the regular heaviness of a pill. The heaviness of each pill was thereafter likened to the regular to determine the percentage weight variance. The consequences are abridged in Table

Table No. 13: Weight and Weight Variation of Different Tablet Formulations

Weight Variation (milligram)	Formulation code				
	(F-1)	(F-2)	(F-3)	(F-4)	(F-5)
	516.03	514.5	516.2	515.2	514.3

Fragility Test

" The fragility of the medications was evaluated utilizing a Roche Friabilator. Twenty pre-considered tablets were positioned in the friabilator and exposed to rolling and repeated drops to replicate mechanical stress. Upon completion of 100 revolutions, the tablets were reweighed, and any fractured or pulverized material was gathered. The fraction of heaviness damage was computed to assess the friability of the tablets. The findings are displayed in Table 14."

TABLE No.14: - Friability of different prepared formulations

Friability %	Formulation code				
	F1	F2	F3	F4	F5
	0.468	0.376	0.0739	0.419	0.272

Tablet Thickness

"Tablet Thickness: The thickness of each tablet was measured using a micrometer to assess uniformity (17). Consistent tablet thickness is important for ease of packaging and handling. To ensure uniformity, the tablet thickness was maintained within ±5% of the normal value. The corresponding consequences are shown in Table 15

Table No. 15: - Thickness of different prepared formulation

Thickness(mm)	Formulation code				
	(F-1)	(F-2)	(F-3)	(F-4)	(F-5)
	3.78	3.96	3.86	3.89	3.99

Drug Content Uniformity

" Twenty tablets of the naproxen-xanthan gum mixture were meticulously pulverized, and a precisely measured quantity A quantity of the dust was deposited into a 100 mL volumetric bottle. To achieve full dissolution of the medication, 50 mL of 0.1 N NaOH was introduced, and the combination was permitted to attitude for 6 hours with periodic sonication. The final volume was subsequently modified to 100 mL utilizing 0.1 N NaOH."

"An aliquot of 1 mL of the answer was appropriately diluted and filtered, and the attentiveness of the drug was quantified using a dual-ray UV spectrophotometer at a wavelength of 276 nm." The assay results, presented in Table 16, indicate uniform drug content across the batch¹⁸."

"Table 16. Assay results showing the drug content of different naproxen tablet formulations."

% Drug content	Formulation code				
	F1	F2	F3	F4	F5
	94.03	93.2	97.86	101.23	96.99

In Prepared Formulation In-Vitro Medication Announcement Education

" The in vitro drug announcement of the prepared formulations was assessed by means of USP Type I (basket) device. The dissolution research was conducted in 900 mL of closure medium at a temperature of 37 ± 0.5 °C, with stirring at 50 rpm for 12 hours. Initially, 0.1 N HCl (pH 1.2) was utilized for 2 hours to simulate gastric conditions, followed by a transfer to a pH 6.8 phosphate buffer for the subsequent 10 hours to duplicate intestinal conditions. At hourly intervals, 10 mL samples were extracted and directly substituted with an equivalent capacity of new average of the similar pH. The examples were subsequently analyzed to control the percentage of medication announcement. "The consequences of the education are summarized in Table 14, illustrating the medication release profile from the formulated tablets."

Table No. 17: - "In Vitro Dissolution Profile of the Prepared Tablets"

Hours	"Cumulative In Vitro Drug Release Profile of SG Tablets"				
	Formulations code				
	(F-1)	(F-2)	(F-3)	(F-4)	(F-5)
0	0	0	0	0	0
1	31	28	33	27	23
2	54	49	45	37	32
3	62	60	49	39	35
4	66	62	51	42	38
5	69	64	54	45	40
6	73	67	57	48	43
7	77	69	59	50	46
8	80	72	61	52	48
9	83	74	64	55	51
10	87	77	66	58	55
11	88	79	69	61	57
12	90	80	72	63	59

Comparative Evaluation of prepared tablets and marketed formulation

*SGF- Sesbania gum formulation and MF- marketed formulation

Tablets hardness: Table No 18: - Hardness of the prepared tablets

Sr. No.	Hardness (kg/cm ²)	
	SGF	MF
1.	8.03±0.1	8.89

Friability: Table No. 19: - Friability of different prepared formulations

% Friability	Formulation code	
	SGF	MF
	0.0729	0.00

Drug Content Uniformity: Table no. 20: - Drug content of different formulation of tablets

% Drug content	Formulation code	
	SGF	MF
	97.30	93.60

Weight Variation: Table No. 21: - weight variation of different formulation of tablets

Tablet No.	Hardness (kg/cm ²)	
	SGF	MF
	1.	8.03±0.1

"Table 22. "Comparative In Vitro Drug Release of Prepared Formulations in SGF and Marketed Formulation (MF)"

In-vitro cumulative % drug release ±SEM(n=3)		
Time (hrs)	Formulation code	
	SGF	MF
0	0	0
1	31	33
2	43	45
3	46	47
4	49	51
5	52	53
6	56	57
7	58	59
8	62	63
9	62	65
10	64	65
11	68	69
12	72	74

RELEASE KINETICS:

Table No. 23: - Release Kinetic studies for SGF and MF

Sr. No.	Equation		SGF	MF
1.	Zero-order equation	r ²	0.8622	0.8629
2.	Higuchi equation	r ²	0.7232	0.7236
3.	Korsmeyer equation	r ²	0.6911	0.6916
		N	0.7321	0.7326

Conclusion

This study successfully produced controlled-release matrix tablets of naproxen via direct compression, employing xanthan gum as a natural hydrophilic polymer. Both pre- and post-compression evaluations—comprising hardness, friability, thickness, weight fluctuation, and drug content—conformed to the standards set by the Indian Pharmacopeia, thus confirming the formulations' mechanical integrity, homogeneity, and reproducibility.

In vitro release experiments revealed the pH-dependent solubility of naproxen, exhibiting minimal release in acidic

medium (0.1 N HCl, pH 1.2) and sustained release in phosphate buffer (pH 6.8). Increasing xanthan gum concentration significantly hindered drug release, demonstrating its effectiveness as a release-modifying agent. Of the assessed formulations, F-3 delivered 72% of the medicine over 12 hours, closely mirroring the marketed formulation (74%), indicating that xanthan gum can effectively replicate traditional release profiles. The kinetic research exposed that the enhanced preparation shadowed nil-directive kinetics ($R^2 = 0.8622$ for SGF; 0.8629 for MF), exhibiting a controlled release profile with notable linearity. The Higuchi model posited a diffusion-controlled process; however, the Korsmeyer–Peppas announcement advocate ($n = 0.73$) indicated non-Fickian (anomalous) transport, implying that medication announcement is governed by both dispersal and the erosion or relaxation of the polymer medium.

Faster constancy challenging conducted at 40 ± 2 °C and $75 \pm 5\%$ RH for 60 days revealed not at all important changes in rigidity, friability, medication gratified, or closure outline, thereby confirming the tablets' stability below standard storage circumstances.

Overall, the findings demonstrate that xanthan gum is a safe, cost-effective, biodegradable, and efficient excipient for developing controlled-release naproxen tablets. The optimized formulation (F-3) exhibited a release profile comparable to the marketed product, validating its potential for industrial application."

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