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Research Article

FORMULATION AND EVALUATION OF TENOXICAM GASTRORETENTIVE TABLET

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ABSTRACT:
The present study successfully developed and evaluated Tenoxicam gastroretentive floating tablets aimed at providing sustained drug release and prolonged gastric retention. The preformulation and post-compression parameters confirmed the suitability of the excipients and ensured consistent tablet quality with acceptable flow properties, mechanical strength, and uniform drug content. FTIR studies indicated no significant drug-excipient interactions, affirming chemical compatibility. The in-vitro buoyancy studies demonstrated efficient floating behavior with prolonged retention over 10 hours, essential for effective gastroretentive delivery. Among all batches, formulations such as F5 and F6 exhibited optimal physicochemical and performance characteristics, making them promising candidates for further in-vivo studies and potential commercial formulation development.

Keywords: Tenoxicam, Gastroretentive Tablet, FTIR.

INTRODUCTION

The majority of oral dosage forms have a number of physiological constraints, including GI transit time, poor drug absorption from partial drug release from the dosage forms, and an inadequate amount of time for the dosage forms to remain in the GI tract's absorption zone. Drugs' gastric residence period can be further extended by gastro-retentive mechanisms, which can stay in the stomach area for several hours. Long-term gastro retention of the therapeutic component may have several benefits, including increased solubility of medications that are less soluble in the high pH environment of the small intestine, less drug waste, and higher bioavailability.[1] Additionally, it can be utilized to deliver drugs locally to the proximal small intestine and stomach.[2]

Drugs can be continuously and continuously injected into the upper portion of the gastrointestinal tract thanks to gastroretentive drug delivery systems (GRDDS), which are made to stay in the stomach for a long time and release their active components.[3,4] For medications that act locally in the stomach, have an absorption window in the stomach or upper part of the small intestine, are unstable in the colonic or intestinal environments, or have low solubility at high pH values, GRDDS's prolonged stomach residence time is of particular interest.[5] One of the best GRDDS strategies for extending stomach residence duration and achieving adequate drug bioavailability is floating drug delivery systems (FDDS). [6,7] One of the best GRDDS strategies for extending stomach residence duration and achieving adequate drug bioavailability is floating drug delivery systems (FDDS). [8] Long-term adequate local therapeutic levels are provided by the gradual, regulated administration of the medication in the stomach, which also reduces systemic exposure to the medication. [9]

Tenoxicam is a non-stereospecific cox-2 inhibitor (NSAID) that has been demonstrated to have strong anti-inflammatory, analgesic, and antipyretic properties. NSAIDs are typically used to address disorders including pain and inflammation, whether they are acute or chronic. It is used to treat pain related to headaches, post-operative pain, dental discomfort, menstrual cramps, muscular pains, tendinitis, and metastatic bone pain.[10] It is also used to lessen joint stiffness, edema, and discomfort brought on by gout and arthritic flare-ups. When used orally, NSAIDS are known to produce renal side effects and gastrointestinal problems. Nevertheless, these side effects are dose-dependent and frequently severe enough to increase the risk of ulcer development, bleeding in the upper gastrointestinal tract, and even death.[11] It has a 99% binding strength to plasma protein. Food and alkali like magnesium oxide and aluminum hydroxide interfere with its absorption from the upper gastrointestinal tract. Tenoxicam has a half-life of ten to thirteen hours. Tenoxicam is eliminated in the urine as

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either the conjugated product or as the drug itself in around 95% of cases. Because of their limited bioavailability as a result of first-pass metabolism and enzymatic breakdown in the gut wall, as well as the fact that they might cause gastrointestinal issues and renal consequences, NSAIDs were mostly administered orally. In elderly and comatose patients, intravenous administration is extremely unpleasant and challenging. [12,13]

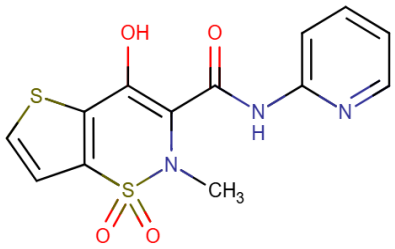

Figure.1 Structure of Tenoxicam[14]

METHODOLOGY

Description and Solubility

Tenoxicam is a white crystalline powder. It was found to be highly soluble in water.

Preparation of Standard Calibration Curve of Tenoxicam

A standard calibration curve of Tenoxicam was constructed to determine the linear relationship between its concentration and the corresponding absorbance (peak area), which was used for subsequent quantification in formulation studies.

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Drug-Excipients Compatiblity study:

Tenoxicam was mixed with all excipients, used in the formulation in different ratios and subjected to Physical observation/FTIR.

Drug-Excipient Compatiblity study (FTIR):

FT-IR spectroscopy was performed to evaluate any potential chemical interactions between Tenoxicam and the excipients used in the formulation, particularly the polymer. The spectra of the pure drug, polymer, and the final drug-polymer formulation were recorded using the potassium bromide (KBr) pellet method. Samples were finely ground, mixed with dry KBr, and compressed into translucent pellets, then scanned over a wavelength range of 4000–400 cm^{-1} using an FT-IR spectrophotometer. The characteristic peaks of Tenoxicam remained unaltered in the spectra of the physical mixture and final formulation, indicating the absence of any significant chemical interaction between the drug and the polymer. These results confirm the compatibility of Tenoxicam with the selected excipients used in the formulation.

EXPERMENTAL METHODS

FORMULATION AND PREPARATION OF TENOXICAM FLOATING TABLETS:

All the formulations were prepared by direct compression method using different Polymers.

PROCEDURE:

- Tenoxicam and all other ingredients were individually passed through sieve 60.
- All the ingredients were mixed thoroughly by triturating up to 15 min.
- The powder mixture was lubricated with Magnesium stearate the tablets were prepared by using direct compression method according to the formulation table.

Table.1: Composition of different formulations

Ingredient (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Tenoxicam	15	15	75	75	75	15	75	75	75
HPMC	105	122.5	140	-	-	-	-	-	105
Xanthan gum	-	-	105	-	-	-	105	-	-
Guar gum	-	-	-	105	-	-	-	-	-
Ethylcellulose	-	-	-	-	105	-	-	-	-
PVP	175	115	115	115	75	175	115	115	115
Sodium bicarbonate	52.5	52.5	52.5	52.5	92.5	52.5	52.5	52.5	52.5
MCC	96.5	9	61.5	96.5	96.5	96.5	61.5	61.5	61.5
Magnesium stearate	35	35	35	35	35	35	35	35	35
Total weight	350mg	350mg	350mg	350mg	350mg	350mg	350mg	350mg	350mg

EVALUATION OF PRE COMPRESSION PARAMETERS

Bulk density

Bulk density of a compound varies substantially with the method of crystallization, milling or formulation. Bulk density is determined by pouring pre sieved granules into a graduated cylinder via a large funnel and measure the volume and weight.

Tapped density:

Tapped density is determined by placing a graduated cylinder containing a known mass of granules and mechanical tapper apparatus, which is operated for a fixed number of taps until the powder bed volume has reached a minimum volume. Using the weight of the drug in the cylinder and this minimum volume, the taped density may be computed.

Carr's Index (CI)

Carr's index is measured using the values of bulk density and tapped density. The following equation is used to find the Carr's index.

Hausner's Ratio:

It indicates the flow properties of the powder and ratio of Tapped density to the Bulk density of the powder or granules.

Hausner's Ratio = Tapped density / Bulk density

Angle of repose:

The manner in which stresses are transmitted through a bead and the beads response to applied stress are reflected in the various angles of friction and response. The method used to find the angle of repose is to pour the powder ion a conical heat on a level, flat surface and measure the included angle with the horizontal.

EVALUATION OF TABLETS:

The formulated tablets were evaluated for the following physicochemical characteristics:

General appearance:

The formulated tablets were assessed for its general appearance and observations were made for shape, color, texture and odor.

Hardness:

Hardness of the tablet was determined by using the Monsanto hardness tester. The lower plunger was placed in contact with the tablet and a zero reading was taken. The plunger was then forced against a spring by turning a threaded bolt until the tablet fractured. As the spring was compressed a pointer rides along a gauge in the barrel to indicate the force

Weight Variation

20 tablets were selected and weighed collectively and individually. From the collective weight, average weight was calculated. Each tablet weight was then compared with average weight to ascertain whether it was within the permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage.

Friability test:

20 previously weighed tablets were placed in the friability apparatus, which was given 100 revolutions and the tablets were reweighed. The percentage friability was calculated by using the following formula,

Percentage friability = initial weight-final weight /initial weight × 100.

Drug content:

20 tablets of each formulation were weighed and powdered. The quantity of powder equivalent to 100 mg of Tenoxicam was transferred in to a 100 ml volumetric flask and the volume adjusted to 100ml with 0.1N HCl. Further 1ml of the above solution was diluted to 100 ml with 0.1N HCl and check the absorbance of the resulting solution was observed at 216nm.

In-vitro Buoyancy studies:

The in-vitro buoyancy was determined by floating lag time, and total floating time. The tablets were placed in a 100ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and the duration of the time the tablet constantly floats on the dissolution medium was noted as the Total Floating Time respectively (TFT).

Swelling Index Studies:

The swelling behaviour of a dosage unit was measured by studying its weight gain. The swelling index of tablets was determined by placing the tablets in the basket of dissolution apparatus using dissolution medium as 0.1N HCl at 37±0.5°C. After 1, 4 and 6h each dissolution basket containing tablet was withdrawn, blotted with tissue paper to remove the excess water and weighed on the analytical balance (Schimdzu, AX 120). The experiment was performed in triplicate for each time point. Swelling index was calculated by using the following formula.

In-Vitro Dissolution Studies of Tablets:

Dissolution parameters:

Apparatus -- USP-II Paddle Method
Dissolution Medium -- 0.1 N HCl
RPM -- 50
Sampling intervals (hrs) -- 0.5,1,2,3,4,5,6,8 and 10
Temperature -- 37 + 0.5°C

Dissolution Study:

900ml 0f 0.1 HCl was placed in the vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37 + 0.5°C. Tablet was placed in the vessel and the vessel was covered, the apparatus was operated for 10 hours at 50 rpm. At definite time intervals, 5 ml of the fluid was withdrawn; filtered and again 5ml of the fresh buffer was replaced. Suitable dilutions were done with the dissolution fluid and the samples were analyzed spectrophotometrically at 216 nm.

Stability studies

Stability studies were carried out according to ICH guidelines by exposing the. Formulations f5 in their final packing mode to the temperature 40±2°C and relative humidity 75±5 % in programmable environmental test chamber (CHM-10S, Remi Instruments Ltd., Mumbai, India). Aliquot were withdrawn at 30 and 60 days and analyzed for change in drug content and invitro dissolution profile

Selected Formulation was subjected to stability studies as per ICH guidelines. Following conditions were used for

Stability Testing:

- 21˚C/45% RH analyzed every month for period of three months.
- 25˚C/60% RH analyzed every month for period of three months.
- 30˚C/70% RH analyzed every month for period of three months.

RESULTS AND DISCUSSION

STANDARD GRAPH OF TENOXICAM:

A standard calibration curve of Tenoxicam was constructed to establish a correlation between the concentration of Tenoxicam and its corresponding absorbance. The table presents the data points used to generate the calibration curve.

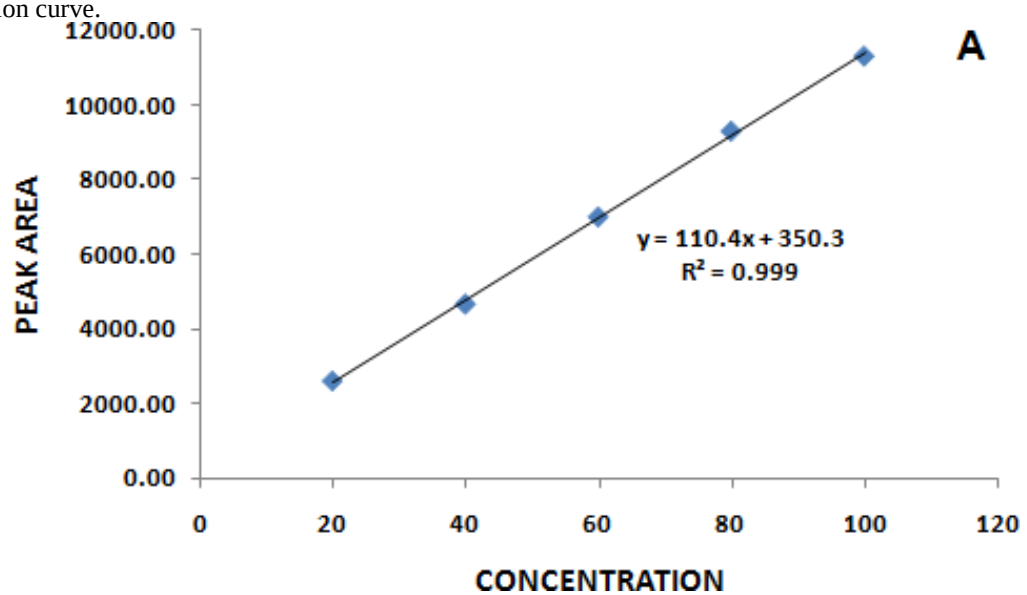

Figure.2 Standard calibration curve of Tenoxicam

Discussion:

The linearity was found to be in the range of 20-100µg/ml in0.1N HCl. The regression value was closer to 1 indicating the method obeyed Beer-lambert's law.

FT-IR STUDIES:

The FTIR spectra of the drug (alone), polymer (alone) and the drug-polymer (mixture) were recorded by the potassium bromide pellet method. From the infrared spectra it is clearly evident that there were no drug-polymer interactions of the drug.

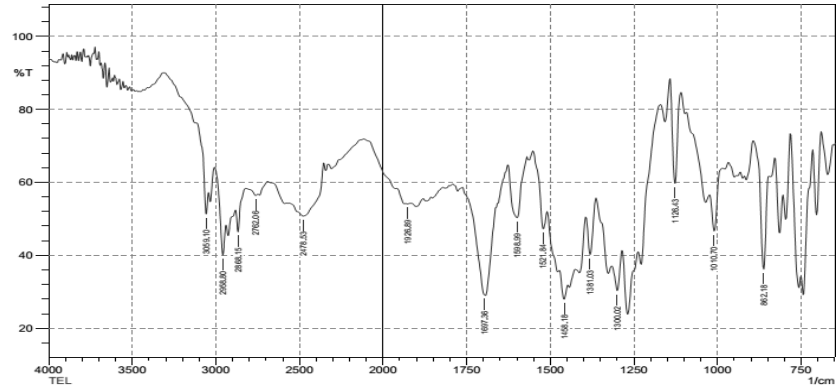

Figure.3 FTIR Spectra of Tenoxicam

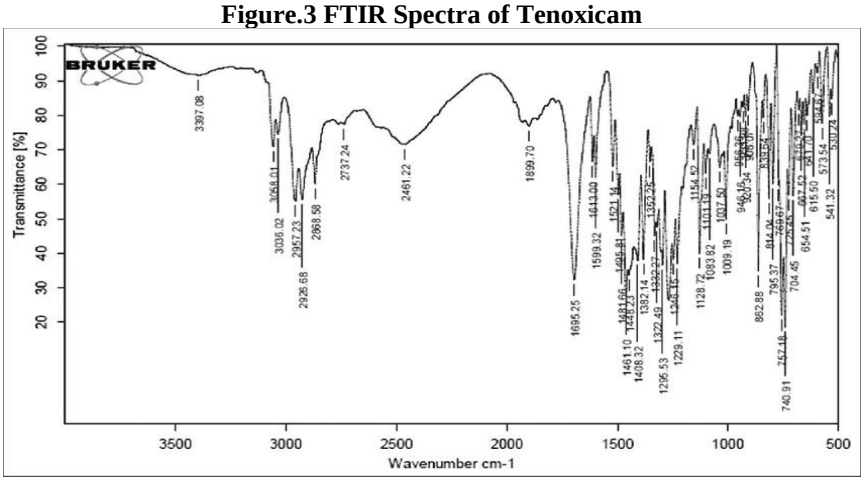

Figure.4 FTIR Spectra of Tenoxicam final formulation

Discussions:

The FTIR spectra of the drug (alone), polymer (alone) and the drug-polymer (mixture) were recorded by the potassium bromide pellet method. From the infrared spectra it is clearly evident that there were no drug-polymer interactions of the drug.

PREFORMULATION STUDIES OF POWDERED BLEND

Flow Properties:

Table.2: Flow Properties of all formulations

Formulation code	Bulk density (gm/mL)	Tapped density (gm / mL)	Compressibility index (%)	Hausner's ratio	Angle of repose (θ)
F1	0.821 ± 0.045	0.770± 0.02	16.126 ± 0.6	1.306 ± 0.06	16.62 ± 0.21
F2	0.810 ± 0.043	0.773 ± 0.01	18.714 ± 0.7	1.151 ± 0.04	25.46 ± 0.11
F3	0.51 ± 0.045	0.583 ± 0.4	14.113 ± 0.8	1.128 ± 0.08	27.32 ± 0.31
F4	0.55 ± 0.045	0.522 ± 0.02	16.60 ± 0.2	1.14 ± 0.02	22.06 ± 0.31
F5	0.55 ± 0.045	0.512 ±0.04	13.3 ± 0.6	1.17 ± 0.04	27.58 ± 0.15
F6	0.64 ± 0.044	0.530 ±0.07	13.27± 04	1.17 ± 0.08	25.44 ± 0.11
F7	0.55 ± 0.035	0.563 ± 0.2	12.1 ± 0.4	1.13 ± 0.02	27.58 ± 0.18
F8	0.75 ± 0.043	0.673 ± 0.4	17.2 ± 0.1	1.12 ± 0.08	29.58 ± 0.17
F9	0.58 ± 0.044	0.543 ± 0.1	15.1 ± 0.6	1.11 ± 0.03	24.58 ± 0.25

POST COMPRESSION PARAMETERS

The results of the weight variation, hardness, friability, drug content, Buoyancy lag time and Total floating time of the Tablets are given in table

In-vitro Buoyancy studies:

In-vitro buoyancy of the tablets from each formulation (F1 to F9) was evaluated and the results are mentioned in Table 14. Where, the highest and lowest floating lag time (FLT) was observed with the formulation F1 and F6 respectively. The concentration of the natural polymers increases the floating lag time also increases and total floating time observed for all the formulations was >10 hours.

Figure.5 At initial time

Figure.6 After 20 Sec

Figure.7 After 10 hrs

Evaluation parameters

Table.3: Evaluation parameters

Formulation No.	Avg Weight (Mean ± S.D.)	Hardness (kg/cm^2) (n = 3)	Friability (Mean ±S.D) (n = 6)	% Drug content (mg)	Buoyancy Lag time (min)	Total floating Time (hrs)
F1	355.5 ± 0.8	9.7 ± 0.6	0.446	99± 0.7	27	6
F2	352.5 ± 1.1	10.0 ± 0.6	0.512	98± 0.5	19	7
F3	349.5 ± 0.5	9.9 ± 0.8	0.727	99 ± 0.6	21	10
F4	353.5 ± 0.6	10.1 ± 0.3	0.511	98 ± 0.6	32	7
F5	348.5 ± 1.0	10.1 ± 0.8	0.425	98 ± 0.6	63	9
F6	356.5 ± 1.0	9.8 ± 0.6	0.755	98 ± 0.5	37	11
F7	348.3 ± 1.2	9.7 ± 0.8	0.680	99 ± 0.7	32	8
F8	350.4 ± 0.8	9.5 ± 0.8	0.710	99 ± 0.3	43	9
F9	352.3 ± 0.7	9.6 ± 0.8	0.536	98 ± 0.8	29	10

Swelling index ratio (%)

The swelling index ratio (%) for formulations F1 to F9 at different time points is as follows:

Table.4: Swelling index studies of Tenoxicam floating Tablets

Time (hr)	Swelling index ratio (%)								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	0	0	0	0	0	0	0	0	0
2	31	33	41	45	51	54	40	32	33
4	47	49	53	55	57	64	52	48	50
6	55	55	58	65	67	72	57	56	63
8	49	50	52	54	59	64	51	51	50

Dissolution studies

Table.5: % Drug release of F1-F9

TIME	% of Drug Release								
(hr)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
1	18.8	14.3	11.3	16.5	12.4	9.2	13.3	19.8	18.8
2	39.9	22.2	21.4	29.8	30.8	19.3	21.2	38.9	39.9
3	52.3	37.6	32.8	41.9	42.3	26.9	38.6	51.3	52.3
4	76.9	46.8	46.1	50.2	49.4	38.2	46.8	72.9	76.9
5	92.8	76.8	58.4	61.1	60.3	46.8	74.8	90.8	93.2
6	92.8	96.3	69.5	72.7	76.4	58.3	93.3	91.8	93.6
8	92.8	96.3	79.9	96.3	90.2	71.4	95.3	93.8	92.8
10	92.8	96.3	90.4	96.3	97.4	84.9	96.2	92.8	93.8

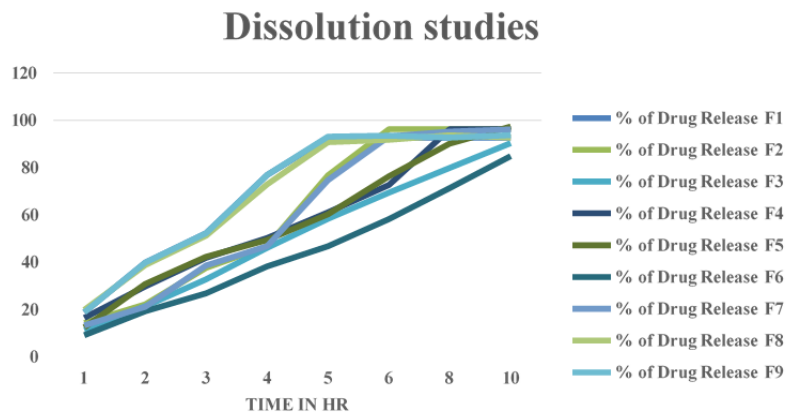

Figure.8 Dissolution studies

Discussion: These data represent the percentage of drug release from the tablets at each specified time point. The dissolution profile provides insights into the release kinetics and the performance of the tablets in delivering the drug over time.

STABILITY OF TENOXICAM FLOATING TABLETS

Table.6: Stability data of optimised formulation F5

S.No	Time points	Initial	Cumulative %Drug Release			
			25 ° C / 60% RH		40 ° C / 75% RH	
	(hr)		1st Month	3rd Month	1st Month	3rdMonth
1	1	12.4	12.2	11.7	11.2	10.7
2	2	30.8	30.4	30.1	29.4	29.1
3	3	42.3	42.1	41.8	39.6	39.2
4	4	49.4	49.0	48.6	47.8	47.4
5	5	60.3	58.3	59.4	59.1	58.6
6	6	76.4	76.1	75.5	75.1	74.9
7	8	90.2	89.8	89.2	88.7	88.1
8	10	97.4	97.1	96.5	96.1	95.8
9	**Assay**	99.5	99.2	99.1	98.7	98.5

Discussion:

The optimized formula was kept for stability studies. The cumulative % Drug release kinetics was used to predict the stability of the preparation. The mean values of these parameters were compared with that obtained on 1st month as described in table. There was less significant change in % entrapment efficiency at storage temperatures after 3 month of production which indicates the stability of preparation.

SUMMARY AND CONCLUSION

The study involved the formulation and evaluation of gastroretentive floating tablets of Tenoxicam aimed at prolonging gastric residence time and enhancing drug bioavailability. A standard calibration curve for Tenoxicam exhibited strong linearity, validating the analytical method. FTIR analysis confirmed the absence of interactions between Tenoxicam and excipients, indicating good compatibility. Pre-compression evaluations (e.g., bulk density, tapped density, compressibility index, Hausner's ratio, and angle of repose) for formulations F1 to F9 showed satisfactory flow and compressibility. Post-compression assessments, including tablet hardness, weight variation, friability (<1%), and drug content (98–99%), confirmed the physical integrity and uniformity of the tablets. In-vitro buoyancy studies demonstrated floating lag times within acceptable limits and total floating durations exceeding 10 hours, affirming the gastroretentive nature of the tablets. Overall, the formulations exhibited ideal characteristics for sustained drug release. Among them, F5 or F6 emerged as promising formulations for further in-vivo evaluation and possible commercial development.

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