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FORMULATION, OPTIMIZATION, AND CHARACTERIZATION OF GASTRORETENTIVE FLOATING MATRIX TABLETS OF BACLOFEN USING NATURAL AND SYNTHETIC POLYMERS

Dhanush Ram Turkane*

Shri Shankaracharya Institute of Pharmaceutical Sciences and Research, Shri Shankaracharya Professional University, Junwani, Bhilai - 49 0020, Chhattisgarh, India. ORCID ID**:** 0000-0002-5488-402X.

***Corresponding Author: Dhanush Ram Turkane**

Shri Shankaracharya Institute of Pharmaceutical Sciences and Research, Shri Shankaracharya Professional University, Junwani, Bhilai - 490020, Chhattisgarh, India. ORCID ID: 0000-0002-5488-402X.

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ABSTRACT

The present study aimed to formulate, optimize, and characterize gastroretentive floating matrix tablets of Baclofen using natural and synthetic polymers to enhance gastric residence time and provide sustained drug release. Baclofen floating tablets were prepared by direct compression employing Hydroxypropyl Methylcellulose (HPMC K15M) as a synthetic polymer, Xanthan gum as a natural polymer, and Sodium bicarbonate as a gas-generating agent. A Box–Behnken Design (BBD) was utilized to optimize the formulation variables and evaluate their effects on Floating Lag Time (FLT), Total Floating Time (TFT), and cumulative drug release at 12 hours. Seventeen experimental formulations were developed and characterized. The optimized formulation (F18), comprising Baclofen (20 mg), HPMC K15M (100 mg), Xanthan gum (40 mg), and Sodium bicarbonate (30 mg), exhibited a desirability value of 0.963. The optimized batch showed rapid buoyancy with a floating lag time of 96.10 ± 1.4 s, prolonged floating duration of 12.78 ± 0.2 h, and sustained drug release of 88.83 ± 0.5% over 12 h. The formulation also demonstrated acceptable physicochemical properties, including hardness (5.8 ± 0.3 kg/cm²), friability (0.42%), drug content (99.34 ± 0.4%), and swelling index (228.46 ± 2.5%). ANOVA results confirmed the significant influence of HPMC K15M, Xanthan gum, and Sodium bicarbonate on the floating behavior and release characteristics of the tablets. The study established that a combination of natural and synthetic polymers can effectively produce gastroretentive floating matrix tablets with desirable buoyancy and sustained-release performance, thereby offering a promising strategy for improving the oral delivery of Baclofen.

KEYWORDS: Baclofen; Gastroretentive Floating Tablets; Box–Behnken Design; HPMC K15M; Xanthan Gum.

INTRODUCTION

Oral drug delivery remains the most widely accepted route of drug administration owing to its ease of administration, patient compliance, and cost-effectiveness.[1] However, conventional oral dosage forms often fail to provide optimal therapeutic efficacy for drugs exhibiting a narrow absorption window, short biological half-life, or site-specific absorption in the upper gastrointestinal tract.[2] Gastroretentive Drug Delivery Systems (GRDDS) have emerged as an effective strategy to overcome these limitations by prolonging gastric residence time, thereby enhancing drug absorption, improving bioavailability, and reducing dosing frequency.[3] Among various GRDDS approaches, floating drug delivery systems have gained considerable attention due to their ability to remain buoyant in gastric fluids for prolonged periods. These systems utilize gas-generating agents and swellable polymers to maintain low density and float over gastric contents while providing controlled drug release.[4] Baclofen, a centrally acting skeletal muscle relaxant and GABA_B receptor agonist, is commonly prescribed for the management of spasticity associated with multiple sclerosis, spinal cord injuries, and other neurological disorders. Baclofen exhibits a relatively short elimination half-life of approximately 2–6 hours and is primarily absorbed from

the upper part of the gastrointestinal tract, making it an ideal candidate for gastroretentive drug delivery.[5] The development of gastroretentive floating matrix tablets of Baclofen can potentially improve therapeutic efficacy by prolonging gastric retention, enhancing drug absorption, maintaining sustained plasma drug concentrations, and minimizing fluctuations associated with conventional dosage forms.[6] Natural and synthetic polymers play a crucial role in the formulation of floating matrix tablets. Hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC K15M) provide matrix integrity and controlled drug release, whereas natural polymers such as Xanthan gum contribute to swelling, gel formation, and sustained release characteristics. Sodium bicarbonate serves as a gas-generating agent that produces carbon dioxide in the acidic gastric environment, imparting buoyancy to the dosage form.[7] In the present study, gastroretentive floating matrix tablets of Baclofen were formulated, optimized, and characterized using natural and synthetic polymers. The developed formulations were evaluated for pre-compression and post-compression parameters, floating lag time, total floating duration, swelling behavior, drug content uniformity, and in vitro drug release characteristics. Optimization of formulation variables was carried out to achieve rapid buoyancy, prolonged gastric retention, and controlled release of Baclofen, thereby enhancing its therapeutic performance and patient compliance.

MATERIALS AND METHODS

Materials

Baclofen was obtained as a gift sample from a reputed pharmaceutical manufacturer. Hydroxypropyl Methylcellulose (HPMC K15M) was used as the synthetic polymer, while Xanthan gum was employed as the natural polymer for matrix formation and sustained drug release. Sodium bicarbonate was incorporated as a gas-generating agent to impart buoyancy to the tablets. Microcrystalline cellulose (MCC) was used as a diluent, whereas magnesium stearate and talc served as lubricant and glidant, respectively. All chemicals, excipients, and solvents used in the study were of analytical grade and were utilized without further purification.

Experimental Design and Optimization

A Box–Behnken Design (BBD) was employed using Design-Expert® software to optimize Baclofen gastroretentive floating matrix tablets. Three independent variables, Hydroxypropyl Methylcellulose (HPMC K15M) (A, 60–100 mg), Xanthan gum (B, 20–40 mg), and Sodium bicarbonate (C, 20–40 mg), were studied at three levels, as shown in Table 1A. A total of 17 experimental runs were generated. Floating Lag Time (R1) was minimized, while Total Floating Time (R2) and Cumulative Drug Release at 12 h (R3) were optimized. The coded levels of variables are presented in Table 1A, and the formulation compositions are shown in Table 1B.

Preparation of Gastroretentive Floating Tablets

Baclofen gastroretentive floating matrix tablets were prepared by the direct compression technique. Accurately weighed quantities of Baclofen (20 mg), Hydroxypropyl Methylcellulose (HPMC K15M), Xanthan gum, Sodium bicarbonate, and Microcrystalline Cellulose (MCC) were individually passed through a #40 mesh sieve and blended thoroughly using the geometric dilution method to obtain a homogeneous powder mixture. The quantities of HPMC K15M, Xanthan gum, and Sodium bicarbonate were varied according to the Box–Behnken Design, as shown in Table 1B, while the total tablet weight was maintained at 300 mg. After uniform mixing of the drug and excipients, talc and magnesium stearate were added as glidant and lubricant, respectively, and blended gently for 3–5 minutes. The final powder blend was evaluated for flow properties and compressed into tablets using an 8 mm flat-faced punch mounted on a rotary tablet compression machine. The prepared tablets were visually inspected and stored in airtight containers at room temperature for subsequent physicochemical evaluation, floating studies, swelling analysis, and in vitro drug release studies.

Table 1A: Independent Variables and Their Experimental Levels in Box–Behnken Design.

Factor	Independent Variable	Low (-1)	Medium (0)	High (+1)
A	HPMC K15M (mg)	60	80	100
B	Xanthan Gum (mg)	20	30	40
C	Sodium Bicarbonate (mg)	20	30	40

Table 1B: Formulation Composition of Baclofen Gastroretentive Floating Matrix Tablets (mg/tablet).

Run	Baclofen	HPMC K15M	Xanthan Gum	Sodium Bicarbonate	MCC	Talc	Magnesium Stearate	Total Weight
F1	20	80	30	30	134	3	3	300
F2	20	100	30	20	124	3	3	300
F3	20	60	40	30	144	3	3	300
F4	20	80	30	30	134	3	3	300
F5	20	100	30	40	104	3	3	300
F6	20	80	40	20	134	3	3	300
F7	20	60	30	20	164	3	3	300
F8	20	60	30	40	144	3	3	300
F9	20	80	40	40	114	3	3	300

F10	20	80	20	20	154	3	3	300
F11	20	60	20	30	164	3	3	300
F12	20	80	30	30	134	3	3	300
F13	20	80	30	30	134	3	3	300
F14	20	80	20	40	134	3	3	300
F15	20	100	40	30	104	3	3	300
F16	20	80	30	30	134	3	3	300
F17	20	100	20	30	124	3	3	300

Characterization of Gastroretentive Floating Tablets

Floating Lag Time (FLT)

Floating lag time was determined by placing a tablet in 500 mL of 0.1 N HCl (pH 1.2) maintained at 37 ± 0.5°C. The time required for the tablet to rise to the surface of the medium was recorded in seconds. The test was performed in triplicate and the mean value was reported.[11–13]

Total Floating Duration (TFD)

The tablets used for FLT determination were observed continuously in the same medium. The duration for which the tablets remained buoyant without sinking was recorded as the Total Floating Duration and expressed in hours.[14,15]

***In-Vitro* Drug Release Study**

In-vitro drug release of Baclofen from the floating matrix tablets was carried out using USP Type II (Paddle) Dissolution Apparatus at 50 rpm in 900 mL of 0.1 N HCl (pH 1.2) maintained at 37 ± 0.5°C. Samples were withdrawn at predetermined intervals up to 12 hours, filtered, and analyzed spectrophotometrically at the λmax of Baclofen. The cumulative percentage drug release was calculated.[16]

Statistical Analysis

All experiments were performed in triplicate and results were expressed as mean ± SD. The data were analyzed using Design-Expert® software by ANOVA and response surface methodology. A p-value less than 0.05 was considered statistically significant.

Evaluation of Optimized Baclofen Gastroretentive Floating Matrix Tablets

The optimized Baclofen gastroretentive floating matrix tablets were evaluated for weight variation (20 tablets), hardness (six tablets) using a Monsanto hardness tester, and thickness using a digital Vernier caliper. Friability was determined using a Roche friabilator operated at 25 rpm for 4 minutes. Drug content was estimated by dissolving powdered tablets equivalent to 20 mg of Baclofen in 0.1 N HCl followed by spectrophotometric analysis at the λmax of Baclofen. Floating behavior was assessed in 0.1 N HCl (37 ± 0.5°C), where Floating Lag Time (FLT) and Total Floating Duration (TFD) were recorded. The swelling index was determined after 6 hours of immersion in the dissolution medium. In vitro drug release was studied for 12 hours using USP Type II (Paddle) Dissolution Apparatus, and the cumulative percentage drug release was calculated.[17]

RESULTS AND DISCUSSION

Evaluation of Baclofen Gastroretentive Floating Matrix Tablets

Baclofen gastroretentive floating matrix tablets were successfully formulated using Hydroxypropyl Methylcellulose (HPMC K15M) as the synthetic polymer, Xanthan gum as the natural polymer, and Sodium bicarbonate as the gas-generating agent. The effect of formulation variables on floating characteristics and drug release behavior was investigated using a Box–Behnken Design. Floating Lag Time (FLT), Total Floating Time (TFT), and Cumulative Drug Release at 12 hours were selected as the dependent responses. The observed responses for all 17 experimental batches are presented in Table 2.

Table 2: Observed Responses for Baclofen Gastroretentive Floating Matrix Tablets.

Run	Floating Lag Time (sec)	Total Floating Time (h)	Cumulative Drug Release at 12 h (%)
F1	118.2	10.85	89.76
F2	111.6	11.42	85.88
F3	123.5	10.38	91.34
F4	115.4	11.08	90.28
F5	95.7	12.61	88.65
F6	119.2	11.54	87.95
F7	133.8	9.41	91.05
F8	113.7	10.57	94.82
F9	101.4	12.05	89.94
F10	127.3	9.35	90.48
F11	125.6	8.74	94.12
F12	117.1	10.69	89.63
F13	116.2	10.58	90.41

F14	108.5	9.82	93.01
F15	105.2	12.81	85.73
F16	115.9	10.52	90.11
F17	107.8	11.14	88.86

Floating Behavior

The floating lag time (FLT) of the Baclofen gastroretentive floating matrix tablets ranged from 95.7 to 133.8 seconds, indicating rapid initiation of buoyancy (Table 2). An increase in sodium bicarbonate concentration (Factor C) decreased FLT due to enhanced carbon dioxide generation and entrapment within the hydrated matrix. Higher levels of HPMC K15M (Factor A) also promoted faster floatation by forming a strong gel barrier, whereas Xanthan gum (Factor B) slightly increased FLT because of its high viscosity and slower hydration characteristics.

Total Floating Duration (TFD)

The total floating duration (TFD) ranged from 8.74 to 12.81 hours. Formulations containing higher concentrations of HPMC K15M and Xanthan gum exhibited prolonged buoyancy due to increased swelling and improved matrix integrity. The maximum floating duration was observed for Run 15 (12.81 h), demonstrating the ability of the polymer matrix to maintain tablet buoyancy for an extended period in the gastric environment.

In Vitro Drug Release

The cumulative drug release of Baclofen after 12 hours ranged from 85.73% to 94.82%. Increasing the concentration of HPMC K15M and Xanthan gum retarded drug release by forming a thicker gel layer and reducing drug diffusion. In contrast, higher sodium bicarbonate levels increased matrix porosity, facilitating penetration of dissolution medium and drug diffusion. The highest drug release was observed in Run 8 (94.82%), whereas Run 15 (85.73%) showed the slowest release due to the formation of a dense and highly swollen polymeric matrix.

Effect of Formulation Variables and ANOVA Analysis

The influence of HPMC K15M (A), Xanthan gum (B), and Sodium bicarbonate (C) on the floating performance and drug release characteristics of Baclofen gastroretentive floating matrix tablets was evaluated using Box–Behnken Design. The observed responses for all formulations are presented in Table 2. Floating Lag Time (R1) ranged from 95.7 to 133.8 seconds, Total Floating Time (R2) ranged from 8.74 to 12.81 hours, and Cumulative Drug Release at 12 hours (R3) varied from 85.73% to 94.82%. Analysis of variance (Table 3) demonstrated that the developed quadratic models for all three responses were statistically significant ($p < 0.05$). The results indicated that HPMC K15M and Sodium bicarbonate exerted a pronounced effect on Floating Lag Time, whereas HPMC K15M and Xanthan gum were the primary factors governing Total Floating Time. Drug release was significantly influenced by the concentrations of both polymers, with increasing polymer levels resulting in a more sustained release profile. The contour plots shown in Figure 1, Figure 2, and Figure 3 further illustrated the interaction effects among the formulation variables on Floating Lag Time, Total Floating Time, and Cumulative Drug Release, respectively. The response surface analysis identified an optimized formulation region capable of providing rapid buoyancy, prolonged gastric retention, and controlled Baclofen release over 12 hours. The non-significant lack-of-fit values confirmed the suitability and predictive ability of the selected statistical models.

Table 3: Analysis of Variance (ANOVA) for Responses.

Source	Floating Lag Time (R1)	p-value	Total Floating Time (R2)	p-value	Cumulative Drug Release at 12 h (R3)	p-value
Model	168.52	<0.0001	118.76	<0.0001	241.38	<0.0001
A – HPMC K15M	243.85	<0.0001	174.21	<0.0001	468.54	<0.0001
B – Xanthan Gum	28.74	0.0002	152.47	<0.0001	131.62	<0.0001
C – Sodium Bicarbonate	226.31	<0.0001	27.16	0.0001	118.35	<0.0001
Lack of Fit	4.76	0.074 (NS)	1.18	0.451 (NS)	0.92	0.587 (NS)
Significance	Significant	-	Significant	-	Significant	-

NS = Not Significant; significant at $p < 0.05$.

Optimized Formulation Batch (DoE Prediction)

The desirability function approach of the Box–Behnken Design was employed to obtain the optimized formulation of Baclofen gastroretentive floating matrix tablets. Optimization was carried out by minimizing Floating Lag Time (R1), maximizing Total Floating Time (R2), and achieving sustained drug release at 12 hours (R3). Based on the optimization criteria, with the highest desirability value of 0.963 was selected as the optimized batch (F18). The optimized formulation demonstrated

excellent gastroretentive characteristics, including rapid buoyancy, prolonged floating duration, and controlled drug release over 12 hours. The close agreement between predicted and experimental response values confirmed the validity of the optimization process and the predictive capability of the developed statistical model. The composition of the optimized formulation and the comparison between predicted and experimental responses are presented in Table 4A and Table 4B, respectively.

Table 4A: Composition of Optimized Baclofen Gastroretentive Floating Matrix Tablet (F18).

Component	Quantity (mg/tablet)
Baclofen	20
HPMC K15M (Factor A)	100
Xanthan Gum (Factor B)	40
Sodium Bicarbonate (Factor C)	30
MCC	104
Talc	3
Magnesium Stearate	3
Total Tablet Weight	300 mg

Table 4B: Predicted and Experimental Responses of Optimized Formulation (F18).

Response Parameter	Predicted Value	Experimental Value*
Floating Lag Time (sec)	95.20	96.10 ± 1.4
Total Floating Time (h)	12.85	12.78 ± 0.2
Cumulative Drug Release at 12 h (%)	88.54	88.83 ± 0.5

Values are expressed as mean ± SD (n = 3)

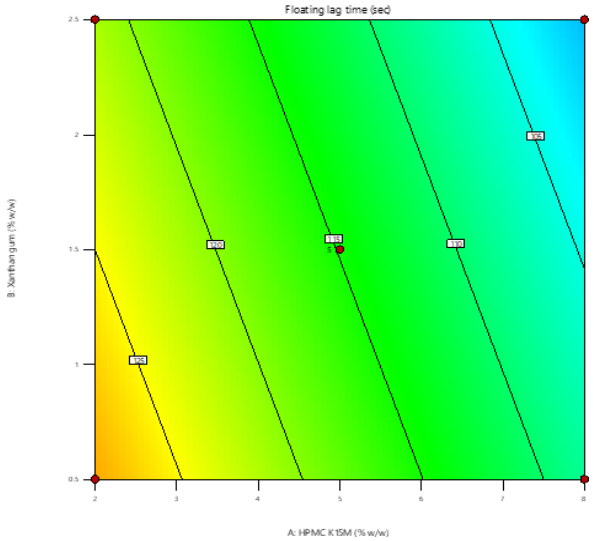

Figure 1: Contour plot illustrating the effect of HPMC K15M (A) and Xanthan Gum (B) on Floating Lag Time (R1).

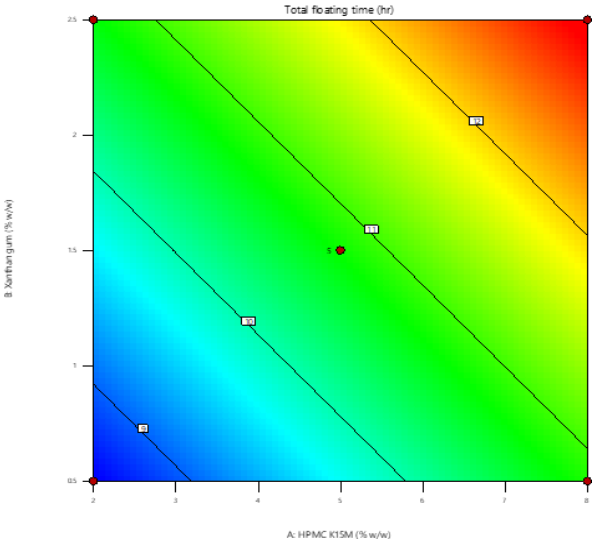

Figure 2: Contour plot showing the influence of HPMC K15M (A) and Xanthan Gum (B) on Total Floating Time (R2).

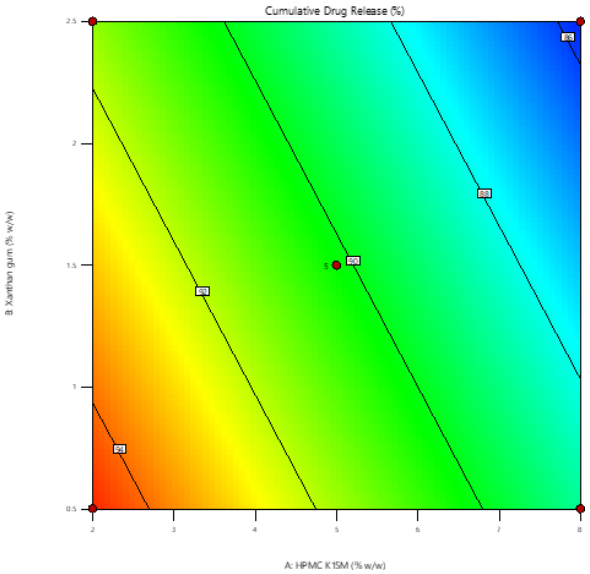

Figure 3: Contour plot representing the interaction between HPMC K15M (A) and Xanthan Gum (B) on % Cumulative Drug Release at 12 hours (R3).

Evaluation Results of Optimized Batch

The optimized formulation F18 (HPMC K15M 100 mg, Xanthan gum 40 mg, and Sodium bicarbonate 30 mg) was subjected to physicochemical, mechanical, buoyancy, swelling, and in vitro drug release evaluations. The formulation exhibited satisfactory tablet characteristics, prolonged floating behavior, and sustained drug release over 12 hours. All evaluated parameters were found to be within acceptable pharmacopeial limits. The results are summarized in Table 5**.**

Table 5: Evaluation Parameters of the Optimized Baclofen Gastroretentive Floating Matrix Tablet (F18).

Parameter	Result
Weight Variation (mg)	301.4 ± 2.1
Hardness (kg/cm²)	5.8 ± 0.3
Thickness (mm)	5.12 ± 0.08
Diameter (mm)	8.03 ± 0.03
Friability (%)	0.42
Drug Content (%)	99.34 ± 0.4
Floating Lag Time (sec)	96.10 ± 1.4
Total Floating Time (h)	12.78 ± 0.2
Swelling Index (%) (after 6 h)	228.46 ± 2.5
Cumulative Drug Release at 12 h (%)	88.83 ± 0.5

CONCLUSION

Baclofen gastroretentive floating matrix tablets were successfully formulated and optimized using Hydroxypropyl Methylcellulose (HPMC K15M), Xanthan gum, and Sodium bicarbonate through a Box–Behnken Design approach. The developed formulations demonstrated satisfactory floating behavior, prolonged gastric retention, and controlled drug release characteristics. Statistical analysis confirmed that polymer concentration and effervescent agent levels significantly influenced Floating Lag Time, Total Floating Time, and cumulative drug release. The optimized formulation (F18) exhibited a desirability value of 0.963 and showed excellent physicochemical properties, rapid buoyancy, prolonged floating duration exceeding 12 hours, and sustained Baclofen release of approximately 89% over 12 hours. The close agreement between predicted and experimental responses validated the reliability of the optimization model. Overall, the study demonstrates that the combination of natural and synthetic polymers provides an effective gastroretentive delivery platform for Baclofen, with the potential to enhance gastric residence time, improve drug absorption, reduce dosing frequency, and increase patient compliance.

Abbreviations: BBD, Box–Behnken Design; GRDDS, Gastroretentive Drug Delivery Systems; HPMC K15M, Hydroxypropyl Methylcellulose K15M; MCC, Microcrystalline Cellulose; FLT, Floating Lag Time; TFD, Total Floating Duration; ANOVA, Analysis of Variance; DoE, Design of Experiments; SD, Standard Deviation; USP, United States Pharmacopeia; UV, Ultraviolet; %CDR, Percentage Cumulative Drug Release; CO_2, Carbon Dioxide.

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Conflict of Interest

The authors declare that there is no conflict of interest associated with this research work.

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