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Research Article

Development and Evaluation of Raft-Forming Rosiglitazone Maleate Tablets for Enhanced Drug Delivery

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ABSTRACT

This research aimed to enhance patient satisfaction by improving the absorption and effectiveness of Rosiglitazone Maleate. Floating tablets were developed using a raft-forming method. Compatibility assessments, including physical observation and FTIR analysis, confirmed minimal drug-polymer interaction. Nine formulations were prepared using varying ratios of HPMC K15M, Guar gum, Chitosan, sodium bicarbonate (effervescent agent), sodium alginate (viscous gel-forming agent), and MCC (diluent). The tablets were evaluated for weight variation (345.09–352.72 mg), hardness (< 5 kg/cm^2), thickness (3.0–3.8 mm), friability, drug content uniformity, floating lag time, and *in-vitro* drug release. All formulations exhibited favorable floating properties. Formulation F7 demonstrated 91.68% drug release over 12 hours. Sodium bicarbonate and sodium alginate primarily influenced buoyancy lag time, while HPMC K15M and Guar gum significantly affected drug release. These findings suggest that raft-forming rosiglitazone maleate tablets offer a promising approach to improving drug absorption, effectiveness, and patient satisfaction.

Keywords: Rosiglitazone maleate, Raft forming tablets, Guar gum, HPMC, Sodium alginate, Sustained release.

INTRODUCTION

While oral administration remains the preferred drug delivery route, limited gastric retention time hinders maximizing drug absorption from the stomach, often leading to suboptimal therapeutic efficacy. Floating, or gastro retentive, drug delivery systems offer a solution by prolonging gastric residence time. These systems, less dense than gastric fluids, maintain buoyancy in the stomach without impacting gastric emptying.[1] This sustained presence facilitates controlled drug release over an extended period, leading to improved absorption and more stable plasma drug concentrations. Upon completion of drug release, the residual system is eliminated from the stomach[2]. This approach is particularly advantageous for drugs with low solubility or susceptibility to degradation in the intestinal environment. This approach is particularly beneficial for drugs exhibiting site-specific absorption in the upper gastrointestinal tract.

A key advantage of GRDDS is their ability to localize drug release in the upper GIT, which can improve bioavailability for drugs with narrow absorption windows in this region[3]. Additionally, GRDDS can reduce fluctuations in plasma drug concentrations, resulting in more consistent therapeutic effects and potentially reducing side effects associated with peak plasma levels[4]. For drugs susceptible to degradation in the colon, GRDDS offers protection by limiting exposure to this environment. However, GRDDS are generally not suitable for drugs that are poorly absorbed from the stomach or that irritate the gastric mucosa[5].

Several different approaches have been explored for achieving gastroretention, including floating systems, swelling/expanding systems, bioadhesive systems, and high-density systems. These systems utilize a variety of polymers, effervescent agents, and other excipients to control buoyancy, drug release, and residence time in the stomach[6].

Raft-forming systems enhance gastric retention time, leading to improved drug absorption and reduced drug waste. This is particularly beneficial for drugs with low solubility in high pH environments, as the extended gastric residence allows for greater dissolution[4]. The localized drug delivery to the stomach and proximal small intestine offers therapeutic advantages. These systems also simplify administration, reduce dosing frequency, and improve patient adherence and comfort. Various stimuli, including pH changes, temperature adjustments, and solvent replacement, can trigger raft formation[7].

Developing raft-forming drug delivery systems involves using various natural and synthetic polymers, such as gellan gum, alginic acid, xyloglucan, pectin, chitosan, and polycaprolactone[8]. These systems improve drug bioavailability compared to traditional liquid dosage forms due to the bioadhesive properties of the polymers. The resulting lighter raft either floats on the stomach contents or adheres to the gastric mucosa, leading to prolonged gastric retention and extended drug release within the gastrointestinal tract[9].

The rationale for designing gastroretentive drug delivery systems for antidiabetic medications stems from the severity and prevalence of diabetes, a life-threatening disease with frequent complications. Effective management of type II diabetes often necessitates continuous administration of antidiabetic drugs to regulate blood glucose levels[10]. Gastro retentive formulations offer a targeted approach for delivering these medications to the upper gastrointestinal tract, improving patient adherence and optimizing disease management. This localized delivery can enhance drug absorption and reduce systemic side effects, contributing to better glycemic control and overall patient outcomes[11].

Rosiglitazone maleate's short half-life (3–4 hours), rapid achievement of peak plasma concentration (within 1 hour), and pH-dependent solubility (high in acidic environments, decreasing with increasing pH) make it a suitable candidate for a raft-forming drug delivery system[12]. By prolonging gastric residence time, such a system can potentially improve the absorption and bioavailability of rosiglitazone maleate, thereby enhancing its therapeutic efficacy. This approach addresses the challenge of maintaining consistent drug levels for optimal management of type II diabetes.

MATERIALS AND METHODS

Rosiglitazone maleate was generously provided by Jigs Chemical Ltd. Microcrystalline cellulose, calcium carbonate, sodium alginate, and HPMCK15M were sourced from LOBA Ltd. Guar gum, chitosan, sodium bicarbonate, talc, and magnesium stearate were obtained from S.D. Fine Chemical Ltd. All other reagents were of analytical grade.

METHODOLOGY

Preparation of Calibration Curve

A precise amount of 100 mg of rosiglitazone maleate was dissolved in 0.1N HCl and diluted to a volume of 100 mL, resulting in a stock solution with a concentration of 1000 µg/mL [13]. Following this, 10 mL from the stock solution was further diluted to 100 mL using 0.1N HCl to obtain a stock solution with a 100 µg/mL concentration. This new stock solution was then divided into aliquots ranging from 0.2 to 2.0 mL, each placed into various volumetric flasks and adjusted to volume with 0.1N HCl. The solutions were filtered through Whatman filter paper no.1 before being analyzed at λmax 318 nm using a UV-visible spectrophotometer.[13] The blank solution consisted of 0.1N HCl. A standard curve was established by plotting the absorbance against concentration.

Formulation of floating raft forming tablets of Rosiglitazone Maleate

The floating raft-forming tablets containing rosiglitazone maleate were formulated using direct compression (Table 1).[14] The tablet manufacturing process included various stages: straining, blending, lubrication, and compression. Microcrystalline cellulose was used as a binding agent, while HPMC K15M was a synthetic hydrophilic polymer. In addition, natural hydrophilic polymers like Guar gum and chitosan were employed along with sodium alginate acting as a thickening gel-forming agent and sodium bicarbonate serving as an effervescent-producing agent.[15] Talc was used for dilution purposes, whereas magnesium stearate was a lubricating element in the formulation. Finally, utilizing a rotary tablet punching machine led to the compaction of the powder blend into 350 mg tablet.

Precompression Characterization

The bulk density was determined by employing a bulk density apparatus. About 25 g of the powder was accurately weighed and transferred into a measuring cylinder to determine its volume and weight. The determination of tapped density was conducted using a Tapped density apparatus. A total of 25 g of the powder were precisely measured and transferred into a measuring cylinder. The volumetric measurement of the powder after 200 taps and the total mass of the powder were documented.[16]

The angle of repose is defined as the maximum angle that can be formed between the surface of a pile of powder and the horizontal plane. The fixed funnel technique was utilized, wherein a funnel was positioned with its tip at a predetermined height (H) above a flat horizontal surface covered with graph paper. The particulate substance was introduced into the funnel and allowed to flow until it accumulated in a conical shape, stopping just short of the apex. The experiments were conducted both before and after the introduction of lubricant/glidant. Following that, the angle of repose (q) was determined based on reference.[17]

The compressibility index is a crucial parameter calculated based on the bulk and tap densities. A substance with values below 20 to 30% is classified as a free-flowing material. The compressibility percentage of the bulk drug was determined based on the measured apparent bulk density and tapped density. Hausner's ratio measures the flow properties of a powder, which is determined by dividing the tapped density by the bulk density.

Post Compression Parameters

Hardness

The Monsanto tester, a device commonly used in pharmaceutical quality control, was employed to quantitatively assess the hardness of a set of ten tablets.[18] The tablet's resistance to transportation and breakage during storage and handling before usage depends on its hardness, which was quantified in kg/cm^2. The tablet's durability, in terms of its ability to withstand transportation, storage conditions, and handling prior to usage, depends on its strength. The measurement was expressed in kilograms per square centimeter (kg/cm^2). Five tablets were taken randomly, and their strength was assessed. The average strength of the five tablets was recorded.[19]

Friability (F)

The Roche friability apparatus was utilized to evaluate the susceptibility of the prepared tablets, quantified as a percentage (%). The procedure entailed the determination of the initial weight of 10 tablets, followed by their placement into the friability.[20] The experiment was conducted by operating the equipment at a rotational speed of 25 revolutions per minute (rpm) for four minutes. Following this, the tablets were re-weighed to determine the friability percentage.

Weight variation test

The weight of the tablet was determined in order to ensure the accurate dosage of the drug. A total of 20 tablets were chosen

Table 1: Composition of RFTs of rosiglitazone maleate

Ingredients (mg)	*Formulation code*								
	F1	*F2*	*F3*	*F4*	*F5*	*F6*	*F7*	*F8*	*F9*
Rosiglitazone maleate	8	8	8	8	8	8	8	8	8
Microcrystalline cellulose	165	115	85	165	115	85	165	115	85
Sodium alginate	70	70	90	70	70	90	70	70	90
HPMC K15M	60	110	110	-	-	-	-	-	-
Guar gum	-	-	-	60	110	110	-	-	-
Chitosan	-	-	-	-	-	-	60	110	110
Sodium bicarbonate	40	40	50	40	40	50	40	40	50
Magnesium stearate	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Talc	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Tablet weight (mg)	350	350	350	350	350	350	350	350	350

randomly from each formulation, and their weights were measured using an electronic balance. The mean tablet weight was subsequently computed and compared to the individual tablet weights for variability.[21]

Thickness

Thickness was assessed using a calibrated vernier caliper to determine the thickness of the tablets. Five randomly selected tablets from each formulation were individually measured for thickness.[22]

%Drug content

The drug quantity in the manufactured tablets was accurately quantified and subsequently pulverized using a pestle and mortar. A tablet containing a measured amount of powdered cefotaxime, specifically 400 mg, was added to a volumetric flask. The tablet was dissolved in 60 mL of a solution containing 0.1N HCl and subjected to sonication for 15 minutes. The volume was subsequently modified to achieve a total of 100 mL. Following that, the samples underwent analysis utilizing a UV-visible spectrophotometer to ascertain the drug concentration in each sample.[23]

In-vitro Buoyancy Studies

The floating lag time was calculated to determine the *in-vitro* buoyancy of the dosage form. This involved measuring the duration of the introduction of the dosage form into simulated gastric fluid and its subsequent buoyancy and monitoring how long it remained afloat. The tablets were placed in a 100 mL beaker with 0.1 N HCl, and the time taken for them to rise to the surface and float was recorded as part of determining their floating lag time.[24]

In-vitro Dissolution Studies of RFTs

The tablets underwent dissolution using a paddle apparatus in a 900 mL solution of 0.1N hydrochloric acid (HCl) as the dissolution medium. The dissolution process occurred at 37 ± 0.5°C, with the paddle rotating at 50 rpm. Over 5 mL aliquots were extracted at designated time points and substituted with an equivalent volume of fresh medium. The withdrawn samples were then diluted to 10 mL with 0.1N HCl, filtered, and analyzed on a UV spectrophotometer at a wavelength of approximately 318 nm using a blank solution consisting of merely the solvent itself (i.e., the same concentration used for dissolving). The cumulative percentage of drug release was subsequently calculated using a constructed calibration curve [25].

Raft strength measurement

A tablet powder containing the equivalent doses of a single unit dose was introduced into a 150 mL solution of 0.1N hydrochloric acid. The mixture was then maintained at 37°C inside a glass beaker with a volume capacity of 250 mL. Each raft was constructed around an L-shaped wire probe with a diameter of 1.2 mm. The wire probe was held vertically inside the beaker for 30 minutes of raft formation. The strength of the rafts was assessed using a modified balance method, where water was added gradually to the pan until the weight required to break the raft was recorded.[26]

Stability Studies

The research was carried out on the most suitable formulation, selected based on dissolution studies and in accordance with ICH guidelines. The recommended conditions for accelerated stability studies include maintaining a temperature of 40 ± 2°C, a relative humidity of 75 ± 5%, and a duration of 3 months. Furthermore, the system's stability was assessed at a temperature of 25 ± 2°C and a relative humidity of 60 ± 5%. Sampling took place at intervals of 1, 2, and 3 months. A stability chamber was used to conduct the study. Changes in the appearance and drug content of the stored raft-forming tablets were examined over this period as well as after three months.[27,28]

RESULTS AND DISCUSSION

Calibration Curve of Drug

A calibration curve was prepared in a solution of 0.1N hydrochloric acid at a specific wavelength of 318 nm. The curve was then subjected to linear regression analysis to determine the correlation coefficient, which was very close to one. This data suggests a strong linear relationship between 2 to 20 µg/mL concentrations (Figure 1). Therefore, it can be concluded that drugs follow Beer-Lambert law within this specified range.

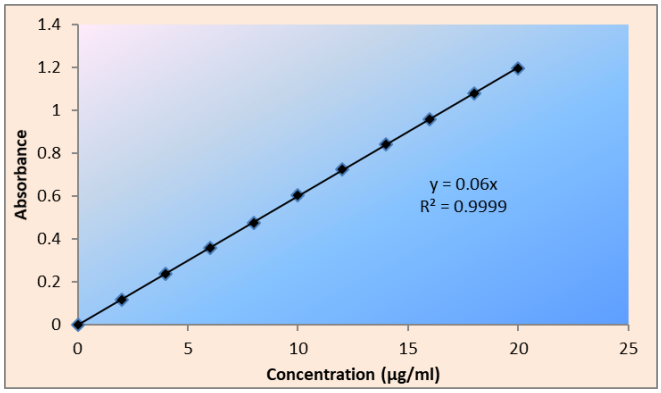

Figure 1: Calibration curve of RZM in 0.1N HCl at 318 nm

Precompression characterization of formulation blend

Precompression assessments were conducted to verify the flow characteristics of the powder mixture. The favorable flow properties of the powder blend are essential for producing high-quality tablets and facilitating the tableting process. Bulk density measurements were performed to evaluate the free-flowing nature of the powder blend, with all formulations exhibiting bulk densities ranging from 0.36 to 0.45 g/cm^3 (Table 2). These results confirm that all formulations had excellent flow properties.

Tapped densities were also determined to analyze the free-flowing behavior of the powder blends, with values ranging from 0.45 to 0.56 g/cm^3 across all formulations, indicating good flow properties for each one. Furthermore, measuring the angle of repose provided insight into frictional forces within loose powders, which affect their flow properties; in this study, the angle of repose for all formulations fell within a range of 25°5' to 29°6'. These findings indicate that all formulations possess favorable flow characteristics based on these parameters (Table 2).

The compressibility index provided a measure of the material's flowability. The compressibility index for all formulations varies from 8.69 to 30.35, indicating favorable flow properties for the powder blends across all formulations. Hausner's ratio served as an indirect indicator of powder flow behavior, with values ranging from 1.09 to 1.43 for the powder blends of all formulations observed in the results except for F1, F2, and F8 (Table 2).

Evaluation of Raft Forming Tablets

Hardness

The hardness test for tablets is an important measure of their resistance to abrasion and breakage under various conditions such as storage, processing, and handling prior to use. The results indicated that the hardness of all formulations was less than 5 kg/cm^2 (Table 3).

Friability test

The friability assessment was conducted to verify the tablet's mechanical robustness, preventing surface damage during packaging, handling, transit, and storage. A friability of less than 1% signified strong mechanical resistance. The findings suggest that all formulations exhibited a friability below 1%, demonstrating successful compliance with the test requirements (Table 3).

Table 2: Precompression characterization of formulation blend

Formula code	*parameters*				
	Angle of Repose (θ)	*BD (g/mL)*	*TD (g/mL)*	*CI (%)*	*HR*
F1	28.2	0.36	0.49	26.53	1.36
F2	25.5	0.39	0.56	30.35	1.43
F3	28.1	0.39	0.48	18.75	1.23
F4	29.6	0.42	0.46	8.69	1.09
F5	25.7	0.40	0.46	13.04	1.15
F6	27.2	0.38	0.45	15.55	1.18
F7	27.8	0.39	0.46	15.21	1.17
F8	27.1	0.41	0.53	22.64	1.29
F9	27.4	0.45	0.54	16.66	1.20

Weight variation test

The tablets of each formulation underwent a weight variation test to confirm their consistent weight, indicating an even distribution of powder blends. The results showed that the tablets for all formulations ranged from 345.09 to 352.72 mg, staying within the specified limit of ± 5% set by IP standards. This compliance demonstrates that all formulations meet the required standard according to IP guidelines(Table 3).

Thickness of the tablets

Tablet thickness plays a key role in providing visual appeal, safeguarding against external damage, and ensuring consistent filling of powder blends. The tablets across all formulations exhibited a thickness ranging from 3.0 to 3.8 mm (Table 3).

%Drug content

All formulations underwent evaluation to estimate the drug content in 0.1N HCl tablet samples, following the procedure outlined in the methodology section. The drug content values for all formulations ranged from 98 to 99%. The drug content was analyzed at a wavelength of 318 nm (Table 3).

In-vitro Buoyancy Studies

The overall formulation exhibited excellent floating lag time and total floating time. The floating lag time and total floating time of the tablets are primarily influenced by the type of polymer used and their concentration, as detailed in Table 4.

Raft Strength

The strength of the tablet raft was affected by the presence of sodium alginate and HPMC K15M. The raft's strength notably rose as the content of sodium alginate increased from 1 to 12 g (F3, F6, F9), indicating the development of a more robust hydrogel network. However, incorporating 100 g of HPMC K100M into formulation (F2, F3) decreased the raft strength by about 25%, suggesting interference with the alginate gel network (Table 5).

In-vitro drug release of RFTs

The dissolution testing of RZM raft-forming tablets was conducted using 0.1N HCl as the dissolving agent. Drug release investigations for each batch (F1–F9) were carried out over 12 hours in the same

Table 3: Post-compression parameters of RZM loaded RFTs

Formula code	*Hardness (kg/cm^2)*	*Thickness (mm)*	*Weight variation (mg)*	*Friability (%)*	*(%) Drug content*
F1	3.9 ± 0.4	3.0 ± 0.4	349.41 ± 0.32	0.20 ± 0.17	98.23
F2	4.3 ± 0.2	3.1 ± 0.1	345.09 ± 0.57	0.12 ± 0.15	99.52
F3	4.1 ± 0.4	3.8 ± 0.2	350.57 ± 0.26	0.35 ± 0.14	98.48
F4	4.4 ± 0.5	3.4 ± 0.3	346.46 ± 0.39	0.29 ± 0.12	99.01
F5	3.9 ± 0.3	3.7 ± 0.2	346.33 ± 0.23	0.30 ± 0.16	98.26
F6	4.0 ± 0.4	3.5 ± 0.1	347.25 ± 0.62	0.35 ± 0.14	99.11
F7	4.2 ± 0.3	3.8 ± 0.3	352.72 ± 0.47	0.42 ± 0.13	99.10
F8	4.4 ± 0.4	3.9 ± 0.3	349.01 ± 0.28	0.45 ± 0.18	98.65
F9	3.9 ± 0.4	3.3 ± 0.2	446.32 ± 0.43	0.43 ± 0.16	98.47

medium, and samples were periodically withdrawn for analysis using a UV-visible spectrophotometer. The percentage of drug released was determined based on the average amount of gastroretentive RZM present in each respective formulation and plotted against time to generate cumulative percentage drug release profiles for floating RFTs of RZM (Table 6 and Figures 2, 3, 4).

Stability Study

Formulation F7 underwent stability testing for 1 to 3 months and the tablets were examined for drug content. The effects of various storage

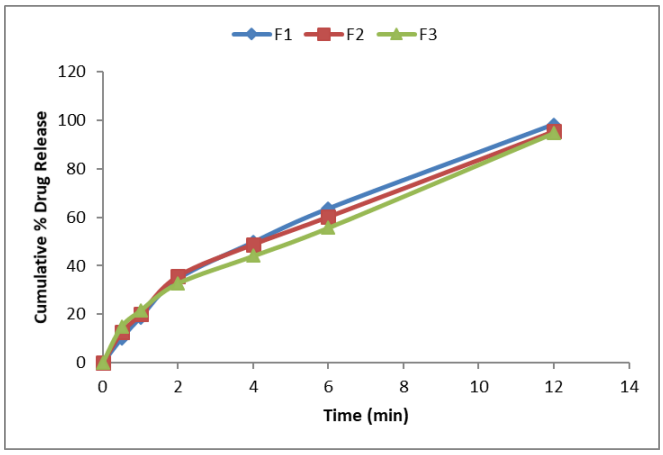

Figure 2: Comparative drug release from formulations F1-F3

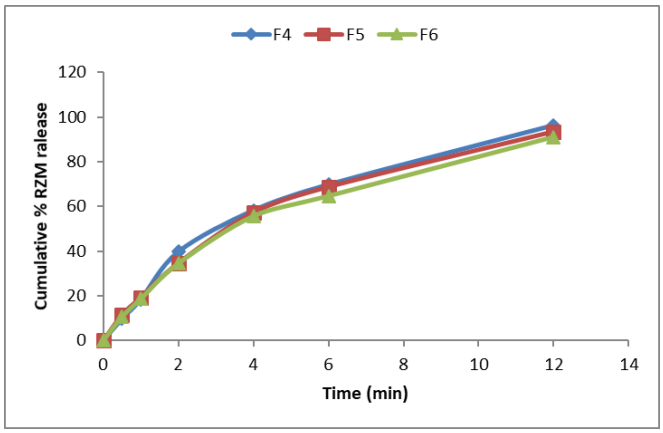

Figure 3: Comparative drug release from formulations F4-F6

Table 4: Floating lag time of the raft-forming tablets

Formulation code	*Floating lag time (sec)*	*Total floating time (hr)*
F1	23	12
F2	36	12
F3	28	12
F4	42	12
F5	10	10
F6	16	10
F7	18	12
F8	26	12
F9	31	12

Table 5: Raft strength of the prepared raft-forming tablets

Formulation code	*Raft strength (g)*
F1	6.0 ± 0.0
F2	5.07 ± 0.2
F3	8.0 ± 0.4
F4	6.8 ± 1.3
F5	10.5 ± 1.0
F6	12.4 ± 0.5
F7	7.9 ± 0.9
F8	9.2 ± 0.3
F9	10.1 ± 0.7

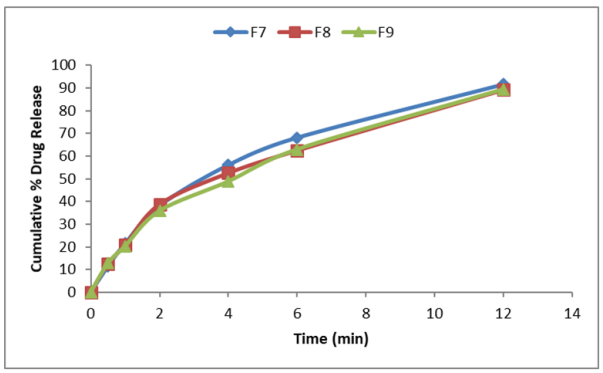

Figure 4: Comparative drug release from formulations F7-F9

Table 6: *In-vitro* drug release from RFTs of rosiglitazone maleate

Dissolution time (hours)	*Cumulative %drug release*								
	F1	*F2*	*F3*	*F4*	*F5*	*F6*	*F7*	*F8*	*F9*
0	0	0	0	0	0	0	0	0	0
0.5	10.11	12.47	14.81	9.8	11.52	10.65	11.43	12.56	12.71
1	18.77	19.96	21.52	18.44	19.32	18.65	21.45	20.77	20.35
2	34.66	35.78	32.83	39.74	34.68	34.48	38.14	38.77	35.81
4	49.72	48.88	44.12	58.23	57.27	55.62	56.08	52.56	48.76
6	63.61	60.23	55.73	69.76	68.76	64.65	68.15	62.51	62.89
12	98.26	95.42	94.82	96.28	93.47	90.96	91.68	89.25	89.33

Table 7: Stability studies at different conditions (F7)

Storage Conditions	*Formulation (F7)*	*Observations on storage for drug content (%)*			
		Initial	*1 month*	*2 months*	*3 months*
25 ± 2°C and 60 ± 5% RH	%Drug content	100%	100%	99.73 ± 1.6	99.54 ± 1.3%
40 ± 2°C and 75 ± 5% RH	%Drug content	100%	99.65 ± 2.7	99.38 ± 3.1	99.14 ± 1.6%

Values are mean ± SD (n = 3)

conditions on formulation F7 were assessed to identify any alterations in the final formulation. The findings are presented in Table 7.

CONCLUSION

The experimental findings indicate that sodium bicarbonate and sodium alginate significantly influence the delay in buoyancy, while HPMC K15M and Guar gum notably impact drug release. *In-vitro*, release tests of rosiglitazone maleate floating raft tablets revealed that the controlled release profile was observed with the F7 formulation over 12 hours. This study suggests promising potential for developing controlled-release tablets of rosiglitazone maleate using raft-forming technology. In conclusion, the precompression assessments and stability testing have provided valuable insights into the formulations' flow properties and drug release characteristics. The favorable flow properties observed in the powder blend, as indicated by bulk density measurements, tapped densities, and angle of repose, confirm the potential for producing high-quality tablets. Furthermore, the findings from the *in-vitro* release tests demonstrate the promising potential for developing controlled-release tablets of rosiglitazone maleate using raft-forming technology. These results highlight the significance of the study in advancing the development of pharmaceutical formulations with enhanced flow characteristics and controlled drug release profiles.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTIONS

Writing, review and editing: Ashish Kumar Parashar; Study concept: Vandana Arora Sethi; Data interpretation: Lalit Kumar Tyagi. All authors have read and approved the manuscript.

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Declaration of the use of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used Grammarly for the purpose of language enhancement and error checking.

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