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Formulation Development and *In Vitro* Evaluation of Effervescent Floating Matrix Tablets of Rosuvastatin Calcium

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Abstract: The present study aimed to develop effervescent floating matrix tablets of Rosuvastatin calcium using direct compression with sodium bicarbonate as a gas-generating agent and polymers including HPMC K100M, Carbopol 934P, guar gum, and xanthan gum. Tablets were evaluated for pre-compression parameters, physical properties, buoyancy, and *in vitro* drug release. Optimization was performed by varying polymer type and concentration. FT-IR analysis confirmed no significant drug–excipient interactions. The optimized formulation (F10) showed sustained drug release up to 24 h (99.65% cumulative release) with a floating time exceeding10 h. Drug release followed the Higuchi model (R^2 = 0.996) and exhibited a non-Fickian diffusion mechanism.

Keywords: Effervescent floating tablets, Rosuvastatin calcium, CarbopoI 934P, Sustained release

INTRODUCTION

Conventional oral dosage forms are limited by variable gastrointestinal transit and short residence time at the absorption site, leading to incomplete drug absorption. Floating drug delivery systems (FDDS) overcome these limitations by remaining buoyant in gastric fluid, thereby prolonging gastric retention and enhancing bioavailability.[1,2] Rosuvastatin calcium, an HMG-CoA reductase inhibitor, shows low and variable oral bioavailability due to poor solubility, pH-dependent absorption, and first-pass metabolism.[3] As it is mainly absorbed in the upper gastro intestinal tract, gastro retentive systems such as effervescent floating matrix tablets are suitable to improve its therapeutic performance.[4]

Effervescent floating tablets utilize sodium bicarbonate to generate carbon dioxide for buoyancy, while hydrophilic polymers (HPMC K100M, Carbopol 934P, guar gum, and xanthan gum) control drug release and maintain tablet integrity. This study aimed to develop and

evaluate effervescent floating matrix tablets of rosuvastatin calcium by direct compression to achieve prolonged gastric retention and sustained drug release.[5]

MATERIALS AND METHODS

Materials

Rosuvastatin calcium was obtained as a gift sample from Dr. Reddy Lab, Hyderabad. Other reagents and solvents used were of analytical grade.

Methodology

Direct Compression Method for Rosuvastatin Calcium Floating Tablets

Effervescent floating tablets of rosuvastatin calcium were prepared by the direct compression method.[6] Rosuvastatin calcium, polymers (HPMC K100M, Carbopol 934P, guar gum, and xanthan gum), sodium bicarbonate, and other excipients were accurately weighed and passed through a #60 mesh sieve.[7,8] All ingredients, except magnesium stearate and talc, were blended to obtain a uniform mixture.[9,10] The lubricant and glidant were then added and mixed gently. The final blend was evaluated for pre-compression parameters and compressed into tablets using a single-punch tablet compression machine to obtain tablets of uniform weight and physical characteristics.[11-16]

TabIe 1: Composition of Rosuvastatin Calcium Floating Matrix Tablets (mg)

Name of the material	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Rosuvastatin calcium	40	40	40	40	40	40	40	40	40	40
Tri basic calcium phosphate	10	10	10	10	10	10	10	10	10	10
Xanthan gum	10	15	20	-	-	-	-	-	-	-
Guar gum	-	-	-	10	15	20	-	-	-	-
HPMC K4M	20	25	30	20	25	30	-	-	-	-
HPMC K100M	-	-	-	-	-	-	30	30	20	20
CarbopoI 934P	-	-	-	-	-	-	20	10	10	10
Sodium Bicarbonate	10	20	30	10	20	30	20	20	25	30
Citric acid	10	10	10	10	10	10	10	10	10	10
Magnesium stearate	5	5	5	5	5	5	5	5	5	5
TaIc	5	5	5	5	5	5	5	5	5	5
Iactose	40	20	-	40	20	-	20	30	35	30
TotaI tabIet weight	150 mg									

RESULTS AND DISCUSSION

Determination of λmax of Rosuvastatin by UV Spectrophotometric Method

Rosuvastatin calcium showed a maximum absorbance (λmax) at 244 nm, consistent with the reported reference value, as shown in Fig.1.

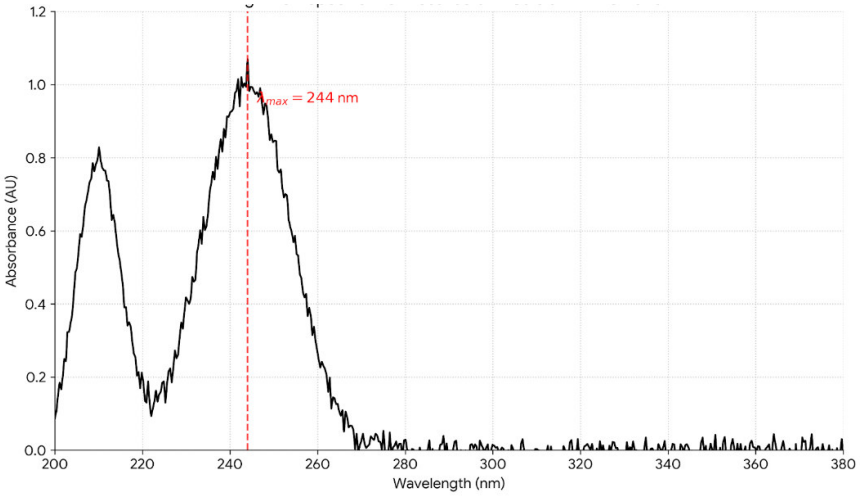

Fig 1: U.V. spectrum of Rosuvastatin calcium in methanol

Calibration curve of Rosuvastatin calcium:

The HPLC method demonstrated excellent linearity and correlation between peak area and analyte concentration, as shown in table 1.

TabIe 2: Calibration of Rosuvastatin calcium by HPLC Method

Nominal Concentration (µg/mI)	Avg Peak area	Practical concentration (µg/mI)	Accuracy (%)
25	1186360	25.01	100.08
30	1421245	29.98	99.96
40	1895067	40.01	100.03
50	2369727	50.05	100.10
60	2847064	60.14	100.25
70	3324742	70.25	100.36
75	3530504	74.60	99.47

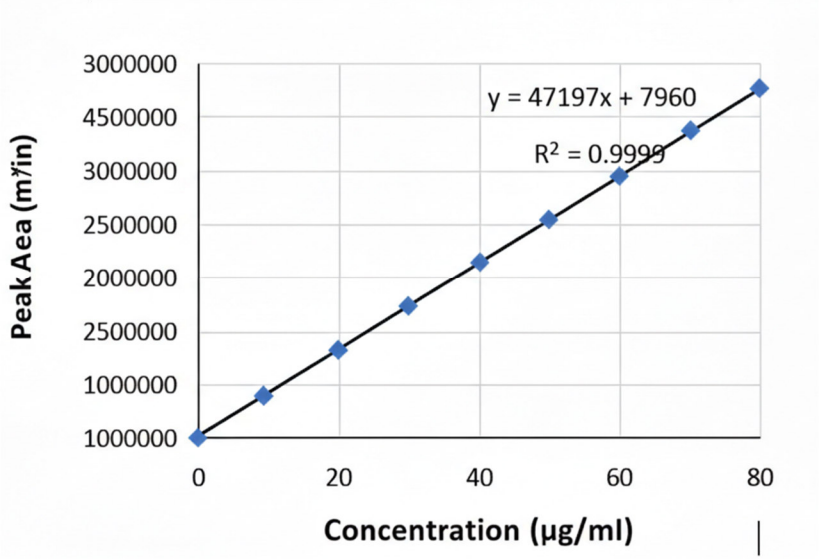

Fig.2: Calibration curve of Rosuvastatin calcium in methanol at 244 nm

Evaluation parameters

Pre-compression parameters

Table 3: Pre-compression parameters of powder blend

Formulation Code	Blend Characterization				
	Bulk density (BD) (g/cc)	Tapped density (TD) (g/cc)	Compressibility Index (%)	Hausner's ratio	Angle of repose
F1	0.468 ±0.009	0.586 ±0.013	20.13 ± 1.49	1.25 ± 0.03	24.55 ±1.53
F2	0.464 ±0.004	0.583 ±0.012	20.41 ± 1.64	1.25 ± 0.04	28.98 ±1.25
F3	0.464 ±0.003	0.584 ±0.015	20.54 ± 1.34	1.26 ± 0.04	29.85 ±1.44
F4	0.472 ±0.005	0.589 ±0.014	19.86 ± 0.76	1.24 ± 0.08	25.30 ±1.45
F5	0.466 ±0.006	0.584 ±0.017	20.20 ± 0.87	1.25 ± 0.06	28.97 ±1.58
F6	0.469 ±0.004	0.588 ±0.001	20.23 ± 1.36	1.25 ± 0.04	29.13 ±1.23
F7	0.490 ±0.009	0.594 ±0.013	17.50 ± 1.49	1.21 ± 0.06	29.85 ±1.44
F8	0.486 ±0.003	0.586 ±0.015	17.06 ± 1.34	1.21 ± 0.08	25.98 ±1.57
F9	0.486 ±0.004	0.578 ±0.012	15.67 ± 1.62	1.18 ± 0.04	24.41 ±1.53
F10	0.484 ±0.004	0.581 ±0.013	16.69 ± 1.64	1.20 ± 0.04	24.55 ±1.53

Tablet powder blend was subjected to various pre-compression parameters. The angle of repose values was showed from 24.55 to 29.13; it indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.46-0.48 (gm/cm3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.58-0.59 showing the powder has good flow properties. The compressibility index of all the formulations was found to be ranging from 17.06 to 20.54 which showed that the powder has good flow properties. All the formulations were showed the hausner ratio ranging from 1.16 to 1.25 indicating the powder has good flow properties.

Post Compression Parameters for tablets

Table 4: Post Compression Parameters of Tablets

FormuIation Code	PhysicaI properties		
	Weight variation (mg)	Hardness (Kg/cm^2)	Diameter (mm)
F1	150 ± 0.46	4.8± 0.34	7 ± 0.01
F2	150 ± 0.64	4.3± 0.15	7 ± 0.12
F3	150 ± 0.48	4.2 ± 0.44	7 ± 0.14
F4	150 ± 0.60	5.6 ± 013	7 ± 0.14
F5	150 ± 0.38	5.6 ± 0.34	7 ± 0.23
F6	150 ± 0.64	5.9 ± 0.15	7 ± 0.26
F7	150 ± 0.55	5.9 ± 0.23	7 ± 0.18
F8	150 ± 0.54	5.3 ± 0.17	7 ± 0.10
F9	150 ± 0.53	5.2 ± 0.14	7 ± 0.04
F10	150 ± 0.42	5.2± 0.49	7 ± 0.08

TabIe 5: Physical characteristics of Rosuvastatin calcium floating matrix Tablets

Formulation Code	Physical properties		
	Thickness (mm)	Friability (%)	Drug content (mg)
F1	3.19 ± 0.01	0.339 ± 0.011	39.65
F2	3.17 ± 0.14	0.352 ± 0.014	39.26
F3	3.20 ± 0.08	0.410 ± 0.012	39.24
F4	3.14 ± 0.04	0.328 ± 0.016	38.31
F5	3.16 ± 0.06	0.340 ± 0.01	38.18
F6	3.21 ± 0.13	0.350 ± 0.24	38.97
F7	3.15 ± 0.17	0.225 ± 0.42	39.83
F8	3.16 ± 0.06	0.246 ± 0.23	39.27
F9	3.22 ± 0.05	0.251 ± 0.15	39.40
F10	3.23 ± 0.03	0.286 ± 0.38	39.52

Weight variation and thickness

All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown in table 3. The average tablet weight of all the formulations was found to be between 150.03 to 150.03. The maximum allowed percentage weight variation for tablets weighing >100.5 mg is 1.5% and no formulations are not exceeding this limit. Thus all the formulations were found to comply with the standards given In I.P. And thickness of all the formulations was also complying with the standards that were found to be between 3.14 to 3.21.

Hardness and friability

All the formulations were evaluated for their hardness, using monsan to hardness tester and the results are shown in table 3. The average hardness for all the formulations was found to be between (4.2 to 5.9) Kg/cm2 which was found to be acceptable. Friability was determined to estimate the ability of the tablets to withstand the abrasion during packing, handling and transporting. All the formulations were evaluated for their percentage friability using roche friabilator and the results were shown in table 3. The average percentage friability for all the formulations was between 0.24 and 0.35, which was found to be within the limit.

Drug content

All the formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown in table 4. The drug content values for all the formulations were found to be in the range of (95.78 to 99.61). According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the FDT formulations comply with the standards given in IP.

Floating behaviour of Rosuvastatin calcium Floating Matrix Tablets

Effect of Gas-Generating Agent (Sodium Bicarbonate) on Floating Lag Time and Duration

The gastric floating systems were formulated using sodium bicarbonate as a gas-forming agent within a hydrogel matrix of HPMC K100M, Carbopol 934P, xanthan gum, and guar gum. Buoyancy studies showed that most formulations remained afloat for over 10 hours (Table 5, Fig. 5), indicating effective gas entrapment by the polymer matrix. Increased tablet porosity reduced density, enabling prolonged flotation in 0.1 N HCl. In the stomach, carbon dioxide released by gastric acid is trapped within the gel, lowering the tablet's specific gravity and allowing it to float. Extended gastric residence improves rosuvastatin absorption, as it is mainly absorbed in the stomach and upper intestine, with floating lag time being a critical performance factor.

Floating lag times for formulations F1–F10 ranged from 86 to 54 seconds, with decreasing times observed as sodium bicarbonate content increased. Higher levels of sodium bicarbonate generate more effervescence, enhancing pore formation and matrix hydration, which accelerates tablet buoyancy.

Consequently, formulations with higher sodium bicarbonate (e.g., F10) exhibited shorter floating lag times than those with lower amounts.

Table 6: Floating Behaviour of Tablets with Sodium Bicarbonate

Formulation Code	Parameter		
	Amount of $NaHCO_3$	Floating Lag time (sec)	Floating duration (Hrs)
F1	10	86	> 10
F2	20	77	> 10
F3	30	64	> 10
F4	10	84	> 10
F5	20	73	> 10
F6	30	62	> 10
F7	20	58	> 10
F8	20	63	> 10
F9	25	60	> 10
F10	30	54	> 10

Swelling Behaviour

The hydration ability of the formulation affects tablet buoyancy, adhesion of swellable polymers (HPMC K100M, Carbopol 934P, xanthan gum, guar gum) with the medium, and drug release kinetics. The medium uptake of the matrices was found to depend on the polymer type (Figure 5). Formulation F3 showed the highest swelling throughout the study, likely due to the high affinity of xanthan gum for the medium, reaching a maximum swelling index of 243.69 after 8 h. The maximum swelling indices of formulations F1–F10 were 199.86, 225.39, 243.69, 181.57, 195.49, 218.38, 135.25, 117.74, 119.56, and 125.32, respectively (Table 7). Formulations F9 and F10 showed the lowest swelling, likely due to the lower affinity of Carbopol 934 for the medium.

Fig 3: Photographs of formulation F10 during in vitro buoyancy study in 200 mL of 0.1 N HCl at different time intervals

Hydrogels swell due to the presence of hydrophilic functional groups that absorb water, causing polymer network expansion and ordering of polymer chains. Swelling equilibrium (maximum swelling) is reached when osmotic forces are balanced by the polymer network's restrictive forces. Continued water penetration forms a concentrated polymer gel layer, increasing the dimensions of the swollen tablet, a process referred to as swelling.

TabIe 7: Swelliing Index of tablets

Formulation Code	Time (Hrs)				
	1	2	4	6	8
F1	58.46	89.38	141.65	189.52	199.86
F2	68.75	97.47	163.41	213.76	225.39
F3	79.43	119.59	177.66	228.53	243.69
F4	32.74	70.87	132.94	174.88	181.57
F5	54.63	86.36	141.88	183.36	195.49
F6	67.71	99.47	157.59	198.58	218.38
F7	49.83	67.69	104.71	121.77	135.25
F8	36.55	52.31	89.43	99.50	117.74
F9	34.79	55.27	83.33	104.26	119.56
F10	37.47	56.76	84.47	101.51	125.32

In-Vitro Drug Release Studies

Drug release profiles were successfully tailored based on the type and concentration of polymers used. Tablets containing guar gum and xanthan gum, alone or in combination, eroded faster and dissolved completely within 14–16 hours, whereas HPMC-containing tablets remained intact and provided sustained release up to 20–24 hours. The effects of HPMC K100M, Carbopol 934P, xanthan gum, and guar gum on rosuvastatin release from floating tablets in 0.1 N HCl (pH 1.2) at 37 ± 0.5 °C are shown in Figures 6–8. All formulations controlled drug release effectively, with the rate depending on polymer type and concentration. At 12 hours, percentage drug release for F1–F10 was 83 ± 1.63, 81 ± 1.19, 79 ± 1.39, 80 ± 0.89, 78 ± 1.39, 63 ± 1.19, 37 ± 1.62, 47 ± 1.63, 65 ± 1.69, and 67 ± 1.28%, respectively. At 20 hours, release was 99 ± 1.06, 99 ± 1.25, 95 ± 1.32, 99 ± 1.63, 93 ± 0.89, 85 ± 1.39, 55 ± 1.55, 73 ± 1.83, 87 ± 1.25, and 88 ± 1.42%, respectively. At 24 hours, F3, F5, F6, F7, F8, F9, and F10 showed 99 ± 0.89, 99 ± 1.25, 93 ± 1.42, 68 ± 1.63, 84 ± 1.19, 99 ± 1.55, and 99 ± 1.69% drug release, respectively.

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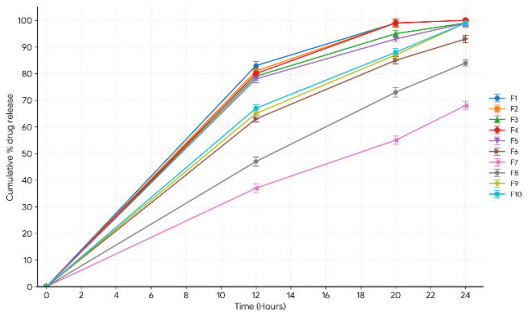

Fig 4: *In-Vitro* Drug Release Profiles of Rosuvastatin Floating Tablets (F1–F10)

Comparative Dissolution Profiles

Effect of Xanthan Gum and HPMC K4M Polymer Mixture on Rosuvastatin Calcium Floating Matrix Tablets

Formulations F1, F2, and F3, containing 20%, 26%, and 33% of the Xanthan gum–HPMC K4M polymer mixture, exhibited good swelling. However, only F3 effectively controlled drug release for 24 hours.

Effect of Guar Gum and HPMC K4M Polymer Mixture on Rosuvastatin Calcium Floating Matrix Tablets

Formulations F4, F5, and F6, containing 20%, 26%, and 33% of the Guar gum–HPMC K4M polymer mixture, exhibited good swelling and floating duration (>10 h). Among these, only F5 effectively controlled drug release for 24 hours, while F6 released approximately 85% of the drug at 24 hours. These results indicate that, for formulations F1–F6, increasing polymer concentration or viscosity reduces the drug release rate.

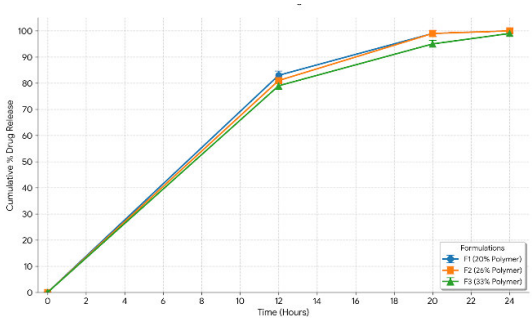

Fig 5: Comparative Dissolution Profiles – Effect of Xanthan Gum and HPMC K4M Mixture

Effect of HPMC K100M and Carbopol 934P Polymer Mixture on Rosuvastatin Calcium Floating Matrix Tablets

Formulations F7–F10, containing 33%, 26%, 20%, and 20% of the polymer mixture of HPMC K100M and Carbopol 934P, showed lower drug diffusivity. Formulations F9 and F10, with lower polymer content, successfully controlled drug release for 24 hours. The high viscosity of Carbopol 934P and HPMC K100M promotes the formation of a viscous gel upon contact with aqueous fluids, which retards drug release. According to korsmeyor and Peppas, drug release from HPMC–Carbopol matrices occurs sequentially: (i) steep water concentration gradients form at the polymer–water interface, leading to water imbibition; (ii) polymer swelling alters polymer and drug concentrations and expands the matrix; (iii) the drug dissolves and diffuses out due to concentration gradients; (iv) increased water content raises the drug diffusion coefficient.

Formulations with a synergistic effect of HPMC K100M and Carbopol 934P form strong gel networks that act as surface barriers, reducing burst release. Considering the goals of achieving rapid floating, prolonged buoyancy, extended gastric retention, and sustained drug release, formulation F9 was selected for further studies. Formulation F10, with the highest gas-forming agent content, showed faster drug release and shorter floating lag time than F9, as increased effervescence accelerates pore formation, matrix hydration, and drug release.

Drug Release Kinetics of Rosuvastatin Calcium Floating Matrix Tablets

Drug release data for all formulations were analyzed using zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. Linear regression results, including regression coefficients (R^2), are summarized in Table 31 and Figures 12–16. Comparison of R^2 values showed that zero-order plots (0.913–0.995) had a better fit than first-order plots (0.856–0.985), indicating that drug release from all formulations followed zero-order kinetics. The Higuchi model also showed good linearity (R^2 = 0.985–0.996), suggesting diffusion as the predominant mechanism controlling drug release. Korsmeyer–Peppas analysis for the optimized formulation F10 ($0.45 < n < 0.89$) indicated non-Fickian (anomalous) release. Specifically, for F10, R^2 values were: zero-order 0.965, first-order 0.872, Higuchi 0.992, and Korsmeyer–Peppas 0.838, confirming that F10 exhibits zero-order, diffusion-controlled release.

Table 8: Regression Coefficient (R^2) Values for Drug Release from Various Kinetic Models and Release Exponent (n) from Korsmeyer–Peppas

FormuIation Code	kinetic modeIs					
	Zero order	First order	Higuchi	Korsmeyer-Peppas		Hixson-croweII
	R^2	R^2	R^2	R^2	n	R^2
F1	0.939	0.935	0.990	0.987	0.746	0.994
F2	0.948	0.919	0.992	0.985	0.812	0.996
F3	0.913	0.965	0.981	0.976	0.802	0.988
F4	0.955	0.897	0.992	0.991	0.773	0.994
F5	0.919	0.942	0.982	0.976	0.837	0.989
F6	0.957	0.979	0.996	0.985	0.862	0.996
F7	0.993	0.985	0.979	0.989	1.093	0.995
F8	0.995	0.951	0.997	0.996	0.945	0.989
F9	0.966	0.856	0.998	0.988	0.877	0.990
F10	0.996	0.872	0.992	0.993	0.838	0.993

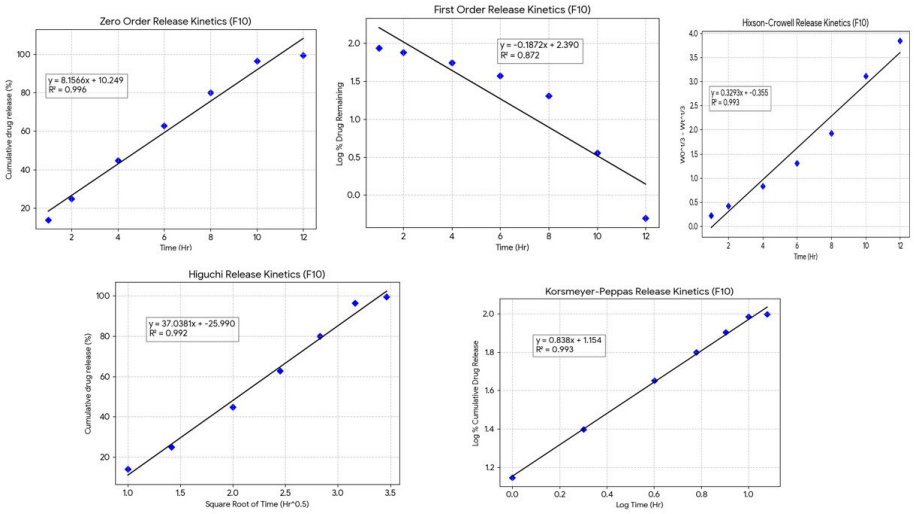

Fig 6: *In-vitro* Drug Release Kinetics for Formulation F10

Stability studies

Stability studies for the optimized formulation F10 were conducted at 25 °C/65% RH, 25 °C/70% RH, 40 °C/65% RH, and 40 °C/70% RH over a defined period. Tablets were evaluated for physical appearance, weight variation, hardness, diameter, friability, drug content, floating lag time, and duration of buoyancy. The results (Table 9) indicated that F10 remained stable under all tested storage conditions.

TabIe 9: Stability studies for optimized formulation (F10)

Parameters	Duration		
	After 15 days	After 30 days	After 45 days
Physical appearance	No change	No change	No change
Weight variation (mg)	150 ± 1.26	150 ± 1.44	149 ± 0.86
Hardness (Kg/cm²)	5.2 ± 0.89	5.1 ± 1.18	4.9 ± 0.45
Diameter (mm)	7 ± 0.08	7 ± 0.16	6.9 ± 0.03
Friability (%)	0.286 ± 0.82	0.431 ± 0.03	0.524 ± 0.12
% Drug content at 25⁰C/65%RH	99.46 ± 0.43	98.86 ± 0.62	98.73 ± 0.91
% Drug content at 25⁰C/70%RH	99.26 ± 0.26	98.42 ± 0.18	98.25 ± 0.28

% Drug content at 40^{0}C/65%RH	98.88 ± 0.21	98.34 ± 0.32	98.16 ± 0.44
% Drug content at 40^{0}C/70%RH	98.36 ± 0.32	98.16 ± 0.41	97.89 ± 0.16
Buoyancy Lag time (sec)	55 ± 1.23	56 ± 2.20	56 ± 3.13
Duration of Buoyancy (Hrs)	> 10	> 10	> 10

Summary

In the present study, controlled-release effervescent floating matrix tablets of rosuvastatin calcium were prepared by direct compression using HPMC K100M, Carbopol 934P, xanthan gum, and guar gum as release-retarding polymers. The formulations were evaluated for hardness, friability, weight variation, drug content uniformity, floating lag time and duration, swelling index, and in vitro drug release. Tablet hardness was maintained at ≈4–5 kg/cm², thickness ≈3.2 mm, and weight ≈150 ± 0.66 mg. All batches complied with pharmacopeial specifications for weight variation, drug content (99.65–101.40%), and friability (<1%), indicating good mechanical strength and content uniformity. Floating lag times for formulations F1–F10 were 86, 77, 64, 84, 73, 62, 58, 63, 60, and 54 seconds, respectively. Decreased floating lag time with increasing sodium bicarbonate content was attributed to faster medium penetration and gel formation.*In vitro* drug release studies over 24 hours showed that at 12 hours, drug release from F1–F10 ranged from 37 ± 1.62% to 83 ± 1.63%, at 20 hours from 55 ± 1.55% to 99 ± 1.63%, and at 24 hours from 68 ± 1.63% to 99 ± 1.69% (Tables 10 & 11). The results indicate that increasing the concentration of HPMC K100M, Carbopol 934P, xanthan gum, and guar gum reduces the drug release rate, providing sustained release over 24 hours.

CONCLUSION

Rosuvastatin calcium floating matrix tablets were developed and evaluated, with polymer concentration optimized to extend gastric residence time up to 24 h. Sustained drug release up to 20 h was achieved using HPMC K4M–Xanthan gum (1:1.5) and HPMC K4M–Guar gum combinations, though with longer floating lag times. The HPMC K100M–Carbopol 934P (2:1) combination provided an optimal balance of buoyancy, swelling, and controlled drug release. The optimized formulation F10 demonstrated sustained release up to 24 h, following zero-order kinetics ($R^2 = 0.996$), and was selected for further studies.

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