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Formulation Development and Characterization of Floating Drug Delivery System of Rosiglitazone Maleate

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ABSTRACT

In the current study, wet granulation with various concentrations and combinations of excipients like magnesium stearate as a lubricant, talc as glident, DCP as diluent, and PVP K 30 as a binder successfully produced floating tablets of rosiglitazone maleate. These excipients included HPMC K15M, xanthan gum, sodium bicarbonate, and tartaric acid as gas-generating agents. We investigated every pre-compressional parameter, including angle of repose, bulk density, and Carr's index. Drug content, hardness, friability, weight fluctuation, in-vitro dissolving experiments, floating qualities, and stability investigations were performed on the compressed tablets. According to in-vitro experiments, the release time increases up to 6, 8, and 10 hours, respectively, as the content of HPMC K15M in formulations F1, F2, and F3 is raised. For formulations F4, F5, and F6, adding xanthan gum raised the release to 7, 9, and 11 hours, respectively. In formulations F7, F8, and F9, the release was found to be increased up to 8, 10, and 12 hours, respectively, with the addition of HPMC K 15 M and Xanthan gum. F9 was discovered to be the finest formulation since it could maintain release for up to 12 hours. All formulations displayed "n" value for Peppa's plot in the range of 0.45 to 0.89, demonstrating anomalous transport (non-Fickian diffusion) as the method of drug release. The improved formulation (F9) was demonstrated to be stable and intact without any contact over the course of 90 days.

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INTRODUCTION

The design of oral control DDS should be primarily aimed at achieving greater predictability and increased bioavailability. Nowadays, most pharmaceutical scientists are involved in developing the ideal DDS. This ideal system should have the advantage of a single dose for the whole duration of treatment, and it should deliver the active drug directly to the specific site. Scientists have succeeded in developing a system, and it encourages them to develop control release systems [1]. Controlled release means that you can predict and repeat how

the drug is released, how much drug is in the target tissue, and how well the drug works by controlling how it is released in the body with a lower dose and less often. But this method has a lot of physiological problems, like not being able to hold and put the controlled drug delivery system in the right place in the GIT because of the way the stomach empties and moves [2]. Also, the human GIT, which takes an average of two to three hours to pass through the main absorption zone (the stomach and upper part of the intestine), can cause the drug delivery system to only partially release the drug, making the dose less effective. So, being able to control where a DDS goes in the GI tract is helpful for a number of important drugs that have a small window of absorption in the GI tract or don't stay stable. FDDS is a gastroretentive drug delivery system (GRDDS), which can prolong the gastric residence time (GRT) to produce an acceptable drug bioavailability [3]. FDDS is suitable for drugs with an absorption window in the stomach or the upper small intestine, for drugs that act locally in the stomach, and for drugs that are poorly soluble or unstable in the intestinal fluid [4].

Rosiglitazone maleate is an oral antidiabetic agent that acts primarily by increasing insulin sensitivity. It is effective only in the presence of insulin. It decreases insulin resistance at peripheral sites and in the liver. This results in insulin-dependent glucose disposal and reduced hepatic glucose output. The half-life of rosiglitazone maleate is 3–4 h, and it reaches a peak plasma concentration after 1 h. It is highly soluble in 0.1M HCl, and its solubility decreases with increasing pH over the physiological range [5]. Several methods have been reported that can be used to retain the dosage form in the stomach, which then results in the drug slowly spreading over the absorptive surface. A GRDDS will release the drug over an extended period in the stomach and upper gastrointestinal tract (GIT), thus enhancing the opportunity for absorption [6].

MATERIAL AND METHODS

Rosiglitazone Maleate was procured from Drugs India, Hyderabad, India. Sodium bicarbonate, Lactose, and Talc was obtained from Finar Chemicals, Ahmedabad, India.

Hydroxypropyl Methyl Cellulose (HPMCK15M) and Xanthan gum were procured from SD Fine Chemicals, Mumbai, India.

Tartaric acid was procured from Qualigen Chemicals, Mumbai, India. All other materials used and received were of analytical grade. The Rosiglitazone Maleate floating tablets were prepared by the wet granulation method.

Preparation of rosiglitazone maleate floating tablets

The composition of different formulations of Rosiglitazone maleate floating tablets is shown in Table 1. The ingredients were weighed accurately and mixed thoroughly. Granulation was done with a solution of PVP K-30 in sufficient isopropyl alcohol. The granules (40 mesh) were dried in conventional hot air oven at 45°C. Drying of the granules was stopped when the sample taken from the oven reached a loss on drying (LOD) value of 1 to 3%, as measured by a moisture balance at 105°C [7]. The dried granules were sized through 40/60 mesh, lubricated with magnesium stearate (2% w/w) and purified talc (1 % w/w) and then compressed.

Evaluations of micrometric properties

The prepared granules were evaluated for its micrometric properties such as bulk, tapped density, angle of repose and Carr's index [8].

Post-compressional parameters

Thickness and diameter

Control of physical dimensions of the tablet such as thickness and diameter is essential for consumer acceptance and tablet uniformity. The thickness and diameter of the tablet was measured using vernier calipers. It is measured in mm [9, 10].

Hardness

For each formulation, the hardness of tablets was determined using the Pfizer hardness tester. The value was noted in kg/cm^2 [11].

Friability

Tablet strength was tested by Roche friabilator. Preweighed tablets were allowed for 100 revolutions in 4 min and were deducted. The percentage weight loss was calculated by reweighing the tablets [12]. The % friability was then calculated by

$$\%\ Friability = ((Initial\ weight - Final\ weight)/ Initial\ weight) \times 100$$

Weight variation

Randomly selected twenty tablets were weighed individually and together in a single pan balance. The average weight was noted and standard deviation calculated. The tablet passes the test if not more than two tablets fall outside the percentage limit and none of the tablet differs by more than double percentage limit [13]. IP limit for weight variation in case of tablets weighing upto 120 mg is ± 10%, 120 mg to 300 mg is ± 7.5% and more than 300 mg is ±

5%.

$$\%\ Weight\ variation = ((Average\ weight - Individual\ weight)/ Average\ weight) \times 100$$

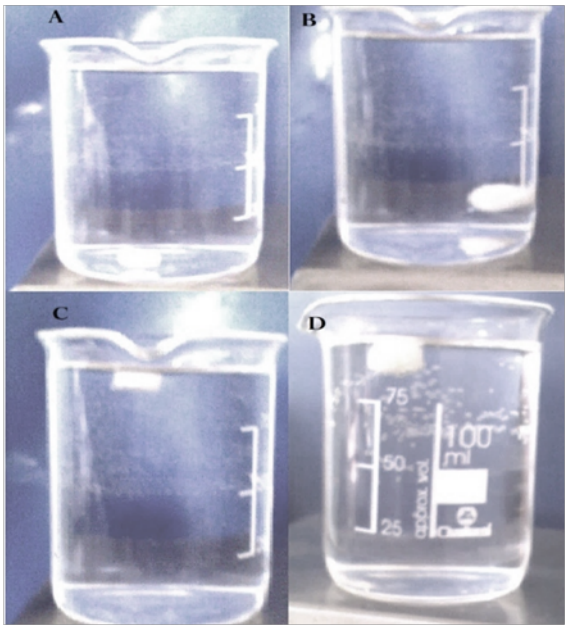

Figure 1: In-vitro BLT of F9 A) Initial B) At 25 Sec C) 74 Sec D) At 12 hours

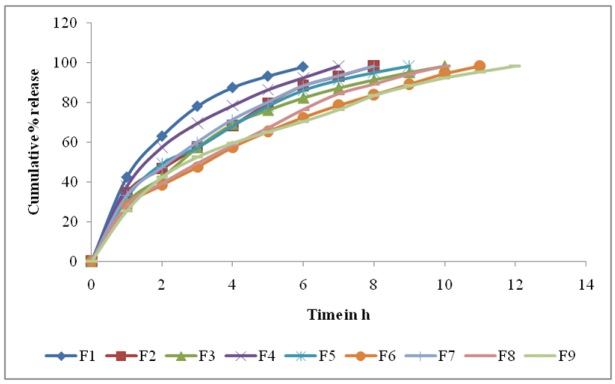

Figure 2: Comparative in-vitro release of formulations F1-F9

Drug Content

Twenty tablets were powdered in a mortar. Weighed accurately the quantity equivalent to 100 mg of Rosiglitazone maleate and transferred to a 100 ml volumetric flask containing few ml of 0.1M HCL and shake for some time and make up the volume up to 100 ml with 0.1M HCL. Pipette out 10 ml from the I stock solution into another 100 ml volumetric flask and make up the volume with 0.1M HCL (i.e. 100 μg/ml). From the above solution withdraw 1ml quantity (as per Beer's range 5-30 μg/ml) and the volume was made up to 10 ml with

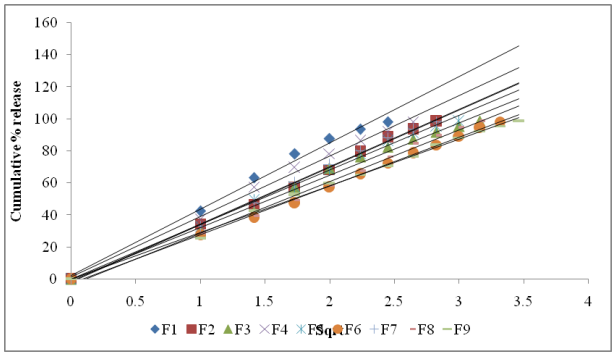

Figure 3: Comparative Higuchi's plot of formulations F1-F9

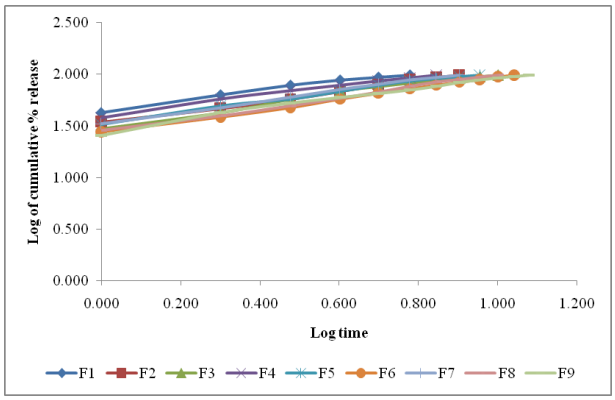

Figure 4: Comparative Peppas's plot of formulations F1-F9

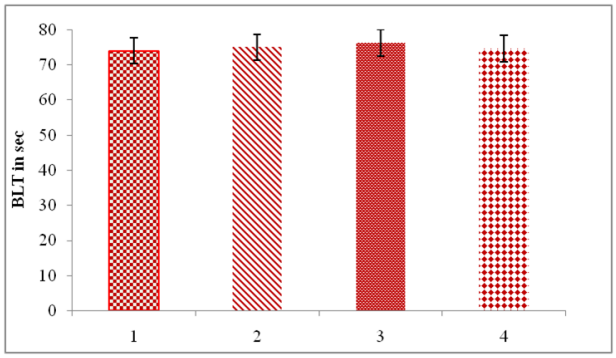

Figure 5: Comparison of stability studies by BLT of formulation F9 1. BLT before storage 2. BLT at ± 25^{0}C ± 2^{0}C / 60% ± 5% RH 3. BLT at ± 30^{0}C ± 2^{0}C / 65% ± 5% RH 4. BLT at ± 40^{0}C ± 2^{0}C /75% ± 5% RH

0.1 M Hcl [14]. The absorbance was measured spectrophotometrically at 318 nm using 0.1 M HCL as blank.

Floating property

The in-vitro buoyancy was determined by the floating lag time. The tablets were placed in 100 mL beaker containing 0.1M HCL. The time required for the tablet to rise to the surface for floating was determined as the In-vitro buoyancy lag time (BLT) and

Table 1: Composition of different formulations of Rosiglitazone maleate floating tablets

Ingredientsin mg	F1	F2	F3	F4	F5	F6	F7	F8	F9
Rosiglitazone Maleate	9	9	9	9	9	9	9	9	9
HPMC K 15 M	45	54	63	-	-	-	30	22.5	15
Xanthan gum	-	-	-	45	54	63	15	22.5	30
Sodium bicarbonate	20	20	20	20	20	20	20	20	20
Tartaric acid	10	10	10	10	10	10	10	10	10
PVP-K-30	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
Dicalcium phosphate	57	48	39	57	48	39	57	48	39
Magnesium Stearate	3	3	3	3	3	3	3	3	3
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Total weight in mg	150	150	150	150	150	150	150	150	150

Table 2: Micrometric properties of formulations F1 – F9

Formulations codes	Bulk density (g/cc) ± SD	Tapped density (g/cc) ± SD	The angle of repose (θ) ± SD	Carr's index ± SD
F1	0.486 ± 0.011	0.564 ± 0.041	20.1± 0.7	13.82 ± 0.74
F2	0.483 ± 0.005	0.578 ± 0.096	21.7± 1.0	15.91 ± 0.52
F3	0.468 ± 0.113	0.568 ± 0.013	23.7± 0.4	17.60 ± 0.79
F4	0.442 ± 0.035	0.521 ± 0.038	21.5± 0.8	15.16 ± 0.32
F5	0.443 ± 0.147	0.531 ± 0.052	22.3± 0.3	16.57 ± 0.27
F6	0.453 ± 0.012	0.547 ± 0.016	23.2± 1.2	17.18 ± 0.13
F7	0.478 ± 0.034	0.567 ± 0.013	21.7± 1.1	15.69 ± 0.32
F8	0.473 ± 0.092	0.569 ± 0.912	23.8± 0.9	16.87 ± 0.56
F9	0.457 ± 0.001	0.556 ± 0.821	23.9± 0.4	17.80 ± 0.83

Table 3: Post-compression parameters of Formulations F1 –F9

Formulation code	Thickness ± SD (mm)	Hardness ± SD (kg/cm2)	Friability (%) ± SD	Average weight variation ± SD	
F1	2.80 ± 0.021	3.9 ± 0.1	0.359 ± 0.05	0.149 ± 0.577	95.78 ± 0.007
F2	2.82 ± 0.034	4.2 ± 0.1	0.678 ± 0.02	0.149 ± 1.527	95.45 ± 0.002
F3	2.80 ± 0.012	4.1 ± 0.1	0.420 ± 0.08	0.148 ± 0.577	95.7 4± 0.005
F4	2.81 ± 0.001	4.2 ± 0.1	0.399 ± 0.03	0.151 ± 0.821	95.76 ± 0.006
F5	2.83 ± 0.005	4.2 ± 0.1	0.566 ± 0.01	0.152 ± 0.634	95.57 ± 0.004
F6	2.80 ± 0.011	4.3 ± 0.1	0.481 ± 0.06	0.149 ± 1.231	96.63 ± 0.001
F7	2.82 ± 0.013	4.2 ± 0.1	0.644 ± 0.09	0.149 ± 0.912	96.47 ± 0.006
F8	2.81 ± 0.016	4.1 ± 0.1	0.455 ± 0.03	0.151 ± 0.577	97.16 ±0.008
F9	2.80 ± 0.003	4.3 ± 0.1	0.483 ± 0.05	0.149 ± 1.527	99.91 ± 0.005

Table 4: Diffusion characteristics of Formulations F1-F9

Formulation code	Correlation coefficient values (r)		Diffusion exponent value (n)
	Zero Order	Higuchi's Model	
F1	0.929376	0.995235	0.472
F2	0.963228	0.998375	0.524
F3	0.943896	0.995509	0.535
F4	0.939058	0.997878	0.485
F5	0.949809	0.998018	0.512
F6	0.96799	0.998974	0.544
F7	0.958494	0.998954	0.535
F8	0.971315	0.99744	0.561
F9	0.95336	0.99844	0.524

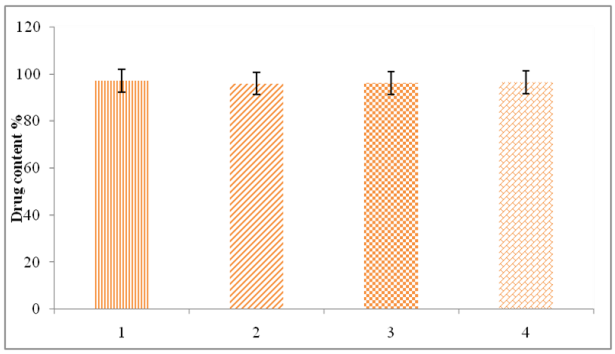

Figure 6: Comparison of stability studies by % drugcontent of formulation F9 1. Percent drug content before storage 2. Percent drug content at 25^{0}C ± 2^{0}C / 60% ±5% RH 3. Percent drug content at 30^{0}C ± 2^{0}C / 65% ± 5% RH 4. Percent drug content at 40^{0}C ± 2^{0}C / 75% ± 5% RH

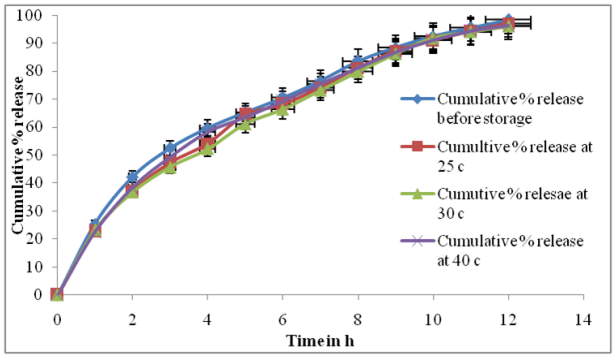

Figure 7: Comparison of stability studies by in-vitro drug release of formulation F9 1. Cumulative percent drug release before storage 2. Cumulative percent drug release at 25^{0}C 3. Cumulative percent drug release at 30^{0}C 4. Cumulative percent drug release 40^{0}C

further floating duration of all tablets was determined by visual observation [15].

In-vitro release studies

The release rate of Rosiglitazone Maleate from floating tablets was determined using USP dissolution testing apparatus II (Paddle type) [16]. The dissolution test was performed using 900 ml of 0.1M HCL at 37 ± 0.5°C and 50 rpm. A sample (10 ml) of the solution was withdrawn from the dissolution apparatus hourly for 12 hours, and the samples were replaced with a fresh dissolution medium. The samples were passed through Whatman filter paper, and the absorbance of these solutions was measured at 318 nm. The dissolution profiles of the formulations were analyzed by plotting drug release versus time. The results of the in-vitro release profile obtained for all the formulations were plotted in modes of data treatment like cumulative % drug released versus time (zero-order kinetic model), Cumulative % drug released versus square route of time (Higuchi's model), and Log percentage cumulative release versus log time. (Korsemeyer-Peppas model) [17].

Stability studies

A study of the stability of pharmaceutical products is essential. These studies were designed to increase the rate of chemical or physical degradation of the drug substance or product by using exaggerated storage conditions [18]. Stability studies are important to prevent the economic repercussions of marketing an unstable product since subsequent withdrawal and reformulation may lead to considerable financial loss. From the point of view of patient safety, it is important that the patient receive a uniform dose of the drug throughout the shelf life of the product [19]. The optimized formulation F9 was stored at different storage conditions at elevated temperatures such as 25^{0}C / ± /2^{0}C / 60% / ± / 5%

RH, 30^0C /± / 2^0C / 65% /±/ 5% RH and 40^0 C/ ± / 2^0C / 75% ± / 5% RH for 3 months. The samples were withdrawn at the end of 3 months and checked for BLT, drug content, and in-vitro drug release studies.

RESULTS AND DISCUSSION

Gastro retentive systems have the potential to remain in the gastric region for several hours, considerably extending the residence time of drugs in the stomach. Prolonged gastric retention increases bioavailability, decreases drug waste, and increases the solubility of drugs that are less soluble in an environment with a high pH. It has applications for the local delivery of drugs to the stomach and small intestines. The purpose of the study was to formulate and characterise Rosiglitazone Maleate floating tablets using the wet granulation technique with HPMC K15M, Xanthan gum, and sodium bicarbonate as polymers, tartaric acid and sodium bicarbonate as gas generating agents, and DCP as a diluent, and then conduct stability studies to determine the optimal formulation. The tablets were prepared with excipients that are generally accepted and compatible with Rosiglitazone maleate. Floating tablets containing Rosiglitazone maleate, sodium bicarbonate, tartaric acid, DCP, and various polymers (HPMC K15M and Xanthan gum) were prepared and evaluated in the present study. In addition, rosiglitazone maleate has a very brief half-life (3–4 hours) and its solubility decreases with increasing physiological pH, which makes it an ideal candidate for formulation into a floating dosage form to prolong the GRT. Flow properties serve an essential role in the pharmaceutical industry, particularly in tablet formulation. The bulk density of the formulation granules ranged from 0.442 to 0.578 g/cc, while the tapped density ranged from 0.521 to 0.578 g/cc, indicating that the powder was not substantial. The angle of repose of the drug powder was between 20.1 and 23.9 degrees, indicating that the particles flowed well. Carr's index ranged from 13.82 to 17.80, indicating that the compressibility of the tablet granules is favourable. The obtained parameters for precompression are listed in Table 2.

The weight variation of prepared tablets was evaluated, and the percentage deviation from the mean weight was found to be within the official limits. The friability of the formulations was determined to be between 0.359 and 0.678%, which is within the official requirement. The tablet's thickness indicates that the filling was uniform. The thickness of the batch from F1 to F9 was determined to be 2.80 to 2.83 millimetres, and the hardness was determined to be between 3.9 and 4.3 kilogrammes per square centimetre, indicating excellent mechanical strength. All of the formulations have adequate drug content. Using a 0.1M HCL solution with a pH of 37, buoyancy studies were conducted; the tablets floated and remained buoyant without disintegrating. Figure 1 depicts the outcomes of in-vitro BLT, and the duration of floating for each set of prepared tablets was up to 12 hours. All formulations underwent in-vitro dissolution testing using a USP type II tablet dissolution tester with a basket at 50 rpm and 900 ml of 0.1M HCL as the dissolution medium. At six hours, the formulation F1 containing the drug and HPMC (1:5) demonstrated a cumulative percentage release of 98.14 percent. The objective of the formulation is to create Rosiglitazone Maleate tablets with a 12-hour sustained release. The formulation F2 containing the drug and HPMC (1:6) demonstrated a cumulative release of 98.55 percent after eight hours. The increased formulation F3 containing the drug and HPMC (1:7) showed a cumulative release of 98.6% after 10 hours. In the F4, F5, and F6 formulations, an attempt was made to attain the objective by substituting Xanthan gum for HPMC. At 7 hours, the formulation F4 containing the drug and Xanthan gum (1:5) demonstrated a cumulative percentage release of 98.34%. The F5 formulation containing the drug and Xanthan gum (1:6) was increased to sustain the release for 12 hours and showed a cumulative release of 98.47% at the end of the ninth hour. The F6 formulation containing Drug: Xanthan gum (1:7) was increased to sustain the release for 12 hours and showed a cumulative release of 98.3% after 11 hours. Attempts were made to optimise the release by combining HPMC and Xanthan gum in varying proportions. At 8 hours, the formulation F7 containing a 2:1 mixture of HPMC and Xanthan gum showed a cumulative percentage release of 98.3%. Formulation F8 HPMC: Xanthan gum (1:1) demonstrated a cumulative release of 98.3% after ten hours. At the end of 12 hours, the formulation F9 containing HPMC: Xanthan gum (1:2) showed a cumulative release of 98.38%. It was discovered that Formulation F9 met the objective. Different equations and kinetic models were used to explain the release kinetics of Rosiglitazone maleate from the floating tablets by fitting in-vitro release data. A zero-order equation, the Higuchi model, and the Peppa model were used as kinetic models. The obtained results in these formulations were plotted according to the following model treatments: Specifically, cumulative percentage of drug release against time (zero order)depicts the outcomes of in-vitro BLT, and the duration of floating for each set of prepared tablets was up to

12 hours. All formulations underwent in-vitro dissolution testing using a USP type II tablet dissolution tester with a basket at 50 rpm and 900 ml of 0.1M HCL as the dissolution medium. At six hours, the formulation F1 containing the drug and HPMC (1:5) demonstrated a cumulative percentage release of 98.14 percent. The objective of the formulation is to create Rosiglitazone Maleate tablets with a 12-hour sustained release. The formulation F2 containing the drug and HPMC (1:6) demonstrated a cumulative release of 98.55 percent after eight hours. The increased formulation F3 containing the drug and HPMC (1:7) showed a cumulative release of 98.6% after 10 hours. In the F4, F5, and F6 formulations, an attempt was made to attain the objective by substituting Xanthan gum for HPMC. At 7 hours, the formulation F4 containing the drug and Xanthan gum (1:5) demonstrated a cumulative percentage release of 98.34%. The F5 formulation containing the drug and Xanthan gum (1:6) was increased to sustain the release for 12 hours and showed a cumulative release of 98.47% at the end of the ninth hour. The F6 formulation containing Drug: Xanthan gum (1:7) was increased to sustain the release for 12 hours and showed a cumulative release of 98.3% after 11 hours. Attempts were made to optimise the release by combining HPMC and Xanthan gum in varying proportions. At 8 hours, the formulation F7 containing a 2:1 mixture of HPMC and Xanthan gum showed a cumulative percentage release of 98.3%. Formulation F8 HPMC: Xanthan gum (1:1) demonstrated a cumulative release of 98.3% after ten hours. At the end of 12 hours, the formulation F9 containing HPMC: Xanthan gum (1:2) showed a cumulative release of 98.38%. It was discovered that Formulation F9 met the objective. Different equations and kinetic models were used to explain the release kinetics of Rosiglitazone maleate from the floating tablets by fitting in-vitro release data. A zero-order equation, the Higuchi model, and the Peppa model were used as kinetic models. The obtained results in these formulations were plotted according to the following model treatments: Specifically, cumulative percentage of drug release against time (zero order) (Figure 2), cumulative percentage of drug release against square root of time (Higuchi's) (Figure 3), and log cumulative percentage of drug release against log time (Peppa's) (Figure 4). All formulations exhibited an "n" value in the range of 0.45 to 0.89 for Peppa's plot, indicating anomalous transport (non-Fickian diffusion mechanism) and zero-order drug release. Table 3 presents the diffusion characteristics of all formulations.

The stability studies were performed on optimized formulation F9 at 25°C ± 2°C / 60% ± 5% RH, 30°C ± 2°C / 65% ± 5% RH, 40°C ± 2°C / 75% ± 5% RH and analyzed for BLT, drug content, and in-vitro dissolution studies in 0.1M HCL. As shown in Figures 5, 6 and 7, no significant difference was observed for the above parameters, and the optimized formulation F9 was stable (Table 4).

CONCLUSION

The concept of formulating floating tablets containing Rosiglitazone maleate offers a suitable, practical approach to achieving a prolonged therapeutic effect by continuously releasing the medication over an extended period of time. In this study, Rosiglitazone Maleate floating tablets were made by wet granulation using different concentrations and combinations of polymers like HPMC K15M, Xanthan gum, sodium bicarbonate, and tartaric acid as gas-generating agents and other excipients like magnesium stearate as a lubricant, talc as a glident, DCP as a diluent, and PVP K 30 as a binder. All the Pre-compressional parameters, like angle of repose, bulk density, and Carr's index, were studied. The compressed tablets were subjected to drug content, hardness, friability, weight variation, in-vitro dissolution studies, floating properties, and stability studies. Floating tablets of Rosiglitazone Maleate prepared using hydrophilic swellable polymer (HPMC K15M), natural gum (Xanthan gum), sodium bicarbonate, tartaric acid, magnesium stearate, talc, and DCP by wet granulation method were found to be good without chipping, capping, or sticking. The drug content was uniform in all the tablet formulations, indicating uniform distribution of the drug within the matrices. From in-vitro buoyancy studies, it was concluded that all formulations exhibited satisfactory floatation ability and remained buoyant for more than 12 hours. In-vitro studies conclude that as the concentration of HPMC K15M is increased in formulations F1, F2, and F3, there is an increase in release time of up to 6, 8, and 10 hours, respectively. With Xanthan gum in formulations F4, F5, and F6, release was found to be increased up to 7, 9, and 11 hours, respectively. With the combination of HPMC K 15 M and Xanthan gum in formulations F7, F8, and F9, release was found to be increased up to 8, 10, and 12 hours, respectively. By sustaining release for up to 12 hours, F9 was found to be the best formulation. All formulations showed 'n' value in the range of 0.45–0.89 for Peppa's plot, indicating that the drug release was by anomalous transport (non-Fickian diffusion). The stability studies carried out for 90 days showed that the optimized formulation (F9) was stable and intact without any interaction. The final optimized formulation (F9) was found to

comply with all the properties of tablets, and the formulations were satisfactory.

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Conflict of interest

No.

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