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Design and *In Vitro* Characterization of Domperidone Effervescent Floating Tablets

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ABSTRACT
The objective of the present research is to develop an ideal floating drug delivery system using domperidone to increase the gastric residence time in the stomach and evaluate the in vitro quality control tests of prepared tablet formulation. Materials and Methods: In this study Domperidone effervescent floating tablets were prepared using xanthan gum, HPMC K_4M as polymers, gas releasing agent sodium bicarbonate, acidifying agent's citric acid, stearic acid, talc and magnesium stearate was used as flow promoters. Wet granulation technique was employed and compressed by using a tablet rotary compression machine. Before compression, the granular material was evaluated for angle of repose, bulk density, tapped density, carr's index and hausner's ratio. After punching the tablets are subjected to weight variation, hardness, friability, drug content, floating lag time, duration of buoyancy and cumulative percent drug release. The formulations were optimised for different concentrations of HPMC K4M, Xanthan gum and their formulations. The Optimised formulation was subjected to stability studies and characterised by FTIR. Results and Discussions: All the prepared tablets showed good in vitro buoyancy for >9 to>24 hr. the optimized formulation showed cumulative percent drug release 99.8±0.14, buoyancy lag time of 43±0.09 and duration of buoyancy >24±0.3. The release kinetics of optimized formulation showed zero order with non-fickian diffusion. Conclusion: Out of nine formulations, F6 has 80mg of xanthan gum was considered as the best formulation based on buoyancy, swelling studies and the drug release mechanism corresponds to zero order and non-fickian diffusion.
Keywords: *Domperidone, Effervescent floating tablets, HPMC K_4M, Xanthan gum, In vitro evaluation.*

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INTRODUCTION

Domperidone is a benzimidazole derivative and is a specific dopamine-2 receptor Antagonist, is mainly used as anti-sickness medicine [1]. Floating systems are low density systems that have sufficient buoyancy to float through the gastric contents and remain buoyant in the stomach for a longer period of time. FDDS has a bulk densityless than gastric fluids [2]. Remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time[3]. In an effervescent drug delivery system, CO_2 is evolved once dose type comes up-to-date with viscous fluid, hydrogen carbonate, acid or hydroxy acid is employed for gas generation during this approach. In this process carbonic acid gas is sometimes entrapped by gel forming or swellable material like hydroxypropyl methylcellulose (HPMC) [4]. Domperidone belongs to class II drug as per biopharmaceutical classification system which is having poor solubility and high permeability. Domperidone is absorbed orally about 15 percent [6]. Domperidone shows first pass effect in liver and gastro-intestinal metabolism. It helps to stop feeling or being sick, nausea or vomiting. Domperidone increases the level of prolactin hormone which is involved in breast milk production.It helps to improve milk supply. Antiemetics are a group of drugs that are used to control nausea and vomiting. Nausea and vomiting are common symptomswith multiple causes including cancer, pregnancy[8].

Multiple-dose treatment leads to the build of parent drugs and active metabolites, which results in extreme muscle fatigue, respiratory depression, and sedation [2]. Domperidone conventional dosage form has increased dosing frequency, which leads to plasma peak fluctuation. Therefore, this is given through the gastro retentive system in a controlled release manner, decreasing the accumulation of a drug by maintaining plasma blood concentration within the therapeutic window[3]. This floating drug delivery system remains in the stomach for several hours, which results in prolonged gastric-retention and reduces fluctuation of doses. Floating drug delivery systems can also be given as local delivery to

specific regions like the stomach and proximal small intestine. It shows good bioavailability, better therapeutic activity and substantial advantages to patients [5]. Pavan Kumar et al (2013)., formulated and evaluated effervescent floating tablets by using Minocycline hydrochloride. They concluded that gastro retentive floating tablets of Minocycline HCl were successfully developed in the form of floating tablets to improve the bioavailability and to reduce dosing[4]. Hemant Sahu et al (2011)., prepared an effervescent floating tablet by using levofloxacin. They observed that the formulation showed sufficient release for a prolonged period, the dose can be reduced and incomplete absorption of the drug can be avoided [3].

MATERIAL AND METHODS

Domperidone was kindly supplied as a gift sample from srikrishna pharmaceuticals limited, Hyderabad, India. HPMC K4M and Xanthan gum supplied by Research-Lab Fine Industries, Mumbai, India.Sodium bicarbonate, Citric acid was supplied by Merck specialities Pvt Ltd, Mumbai, India. Talc, Magnesium stearate and Avicel PH 101 supplied by SD fine chem Ltd., Hyderabad, India. Analytical grade chemicals and distilled water were used for experimental studies.

PREPARATION OF FLOATING EFFERVESCENT TABLETS OF DOMPERIDONE:

Various formulations of Domperidone floating effervescent tablets were prepared using HPMC K4M, xanthan gum (swelling and rate-controlling polymers), sodium bicarbonate(gas releasing agent), citric acid, stearic acid (acidifying agent), talc and magnesium stearate(lubricant) in various ratios. All the ingredients and Domperidone were weighed and mixed in the ascending order of their weights, then added isopropyl alcohol in small quantities to make wet mass and passed through sieve No.12 to get uniform sized wet granules. Then these granules are dried at 60°C in a hot air oven for sufficient period of time after drying the granules were passed through sieve No.22. Talc and Magnesium Stearate was added and punched by using a 16-station rotary tablet compression machine with flat 10mm punches.

Precompression Parameters: Before compression process, granules were subjected to pre compression parameters (flow properties) such as angle of repose, bulk density, tapped density, hausner's ratio and carr's compressibility index.

Post compression parameters: After compression, tablets were subjected to tablet diameter, thickness, weight variation, hardness, friability, drug content, swelling index, buoyancy lag time, duration of buoyancy, cumulative percentage *in vitro* drug release.

The optimised formulation is subjected to stability studies and characterization using FT-IR.

Weight variation: A group of 20 tablets were taken from each formulation randomly selected and weighed using an electronic balance (Mettler-Toledo, Switzerland) and the average weight of the tablets was determined. The individual tablet weights were compared with average weight [9,10]

Percentage weight variation = (Average weight-initial weight/Average weight) x100

Hardness of tablets: The hardness of the tablet was measured by tablet hardness tester (Monsanto hardness tester, India) [7,11].

Friability: It is a measurement of the mechanical strength of a tablet. For this purpose, Fabrilator (Roche friabilatorAnalab, India). A pre-weighed group of 20 tablets was charged in the fabrilator and subjected to 100 revolutions (USP). The dusted tablets were then reweighed. Compressed tablets must not drop more than 1% of their weight [8].

It is expressed by

$$F= W_{initial}-W_{final} / W_{initial} \times 100$$

Drug content:

20 tablets were randomly selected and weighed. The average weight was noted. Tablets were crushed in a mortar, powder equivalent to 10mg of domperidone was taken, shaken and diluted with 0.1N HCl in 100 ml volumetric flask. Filter the solution and do the necessary dilutions using 0.1NHCl to get 5 µg/ml of domperidone. Measure the absorbance of the resulting solution at 284 nm using a double beam UV spectrophotometer (Lab India UV 3200) [6].

Swelling index:

Tablets were weighed individually and placed in a glass beaker, containing 200 ml of 0.1 N HCl, placed in a water bath at 37 ºC ± 0.5 ºC. At fixed time intervals, the tablets were removed and the excess surface liquid was carefully removed using tissue paper. The swollen tablets were then re-weighed. The percentage swelling Index (SI) was calculated using the formula [8].

$$(SI\%) = W_{final}-W_{Initial}/W_{final} \times 100$$

Buoyancy lag time

Three tablets were taken randomly and placed in a beaker containing 200 mL of 0.1 N HCl with a temperature at 37±0.5 ºC using a water bath. The time required for the tablet to rise from the bottom of the beaker to the surface and float was determined [7].

Duration of buoyancy

The time during which the tablet remains buoyant, was recorded to be the Floating Lag Time (FLT) and the duration of time in which the tablet constantly floated is called Total floating time [11,12].

Cumulative percentage *in vitro* drug release

USP dissolution apparatus type II was used (Lab India DS8000) for *in vitro* drug release of domperidone. 900ml of 0.1 N HCl was used as a dissolution medium and the paddle was rotated at 100 rpm for 24hr. 10ml of the sample from each basket was withdrawn at predetermined time intervals and the same 10 ml was replaced with fresh 0.1 N HCl as medium to maintain the sink conditions. The collected samples at different intervals were analysed at 284 nm using a double beam UV spectrophotometer (Lab India UV 3200). The dissolution study data from optimized formulation was subjected to release kinetics [12].

Stability studies: Optimised formulation was subjected to accelerated stability studies by retaining the tablets in a stability chamber kept at 40 ±2 °C and 75% ±5% RH for 3 months as per ICH guidelines. Tablets were checked for hardness, friability, buoyancy lag time, duration of buoyancy, swelling index, and drug content every month for 3 months.

RESULTS AND DISCUSSION:

In this present study, Domperidone effervescent floating tablets were developed to treat nausea and vomiting. Nine domperidone effervescent floating formulations were prepared using various concentrations of gel forming polymers like HPMC K4M, xanthan gum(swelling and rate-controlling polymers), sodium bicarbonate(gas releasing agent), citric acid, stearic acid (acidifying agent), talc and magnesium stearate(lubricants) in various ratios.

Table1: Formulation of Effervescent floating tablets of Domperidone

Formulation Code	Drug (mg)	HPMC K4M (mg)	Xanthan gum (mg)	Sodium bicarbonate (mg)	Citric acid (mg)	Stearic acid (mg)	Avicel PH 101 (mg)	Talc (mg)	Magnesium stearate (mg)	Total weight (mg)
F_1	30	40	-	50	40	10	68	6	6	250
F_2	30	60	-	50	40	10	48	6	6	250
F_3	30	80	-	50	40	10	28	6	6	250
F_4	30	-	40	50	40	10	68	6	6	250
F_5	30	-	60	50	40	10	48	6	6	250
F_6	30	-	80	50	40	10	28	6	6	250
F_7	30	20	20	50	40	10	68	6	6	250
F_8	30	30	30	50	40	10	48	6	6	250
F_9	30	40	40	50	40	10	28	6	6	250

Pre compression parameters: All nine (F1 to F9) granular formulations were evaluated for pre compressional parameters. Angle of repose ≤31.7±0.14° assuring that the flow properties were good for all the formulations. Apart from this, Carr's index and Hausner's ratio were ≤15.3±0.15 % and ≤ 1.18±0.15 respectively for all the nine formulations and showed good mixing, flowability and compressibility as shown in table.

Table 2: Pre compression parameters of granules (F1 to F9) (n=3, mean ±SD)

Formulation Code	Angle of repose (°)	Bulk density(g/cc)	Tapped density(g/cc)	Compressibility index (%)	Hausner's ratio
F1	30.2±0.15	0.22±0.12	0.25±0.31	13.6±0.03	1.13±0.03
F2	31.3±0.13	0.26±0.07	0.29±0.33	11.5±0.21	1.11±0.24
F3	30.3±0.13	0.22±0.15	0.26±0.29	13.6±0.13	1.18±0.15
F4	31.3±0.11	0.30±0.16	0.34±0.11	13.3±0.02	1.13±0.05
F5	30.7±0.10	0.26±0.12	0.30±0.13	15.3±0.15	1.15±0.22
F6	30.3±0.13	0.25±0.01	0.29±0.12	12±0.06	1.16±0.15
F7	30.6±0.15	0.25±0.13	0.28±0.13	12±0.04	1.12±0.17
F8	31.7±0.14	0.30±0.22	0.34±0.11	13.3±0.16	1.13±0.19
F9	30.6±0.16	0.25±0.11	0.28±0.13	10.7±0.12	1.12±0.21

Statistical significance ($p<0.05$)

Post compression parameters: The prepared tablets from each formulation are white, circular, odourless which were analysed for thickness, diameter, weight variation, hardness, friability, buoyancy

lag time, duration of buoyancy, swelling index, *in vitro* dissolution and drug content showed in table-3and table 4**.** The diameter and thickness of all the tablet formulations were almost uniform. The average weight of the tablet in all formulations ranged from 249±0.09 mg to 254 ±0.02 mg. All the tablets formulated in this study met the USP needs for weight variation (USP 31) and in all the formulations had<2% deviation**.** The hardness of the tablets ranged from 3.8±0.02 to 4.0±0.11kg/cm^2 which indicated good mechanical strength during compression. The percentage friability for all nine formulations ranged from to 0.15±0.01 to 0.35±0.12 demonstrating the friability was within the acceptable limits (USP 31), indicating that the tablets are not brittle and can handle without difficulty. All the formulations were checked for drug content uniformity. The uniformity of drug results was good among various batches of tablets and the percent of drug content for all formulations was found to be greater than 98.56±0.08. The results also indicated acceptable and uniform dispersion of drugs in all tablet formulations shown in Table 3.

Table 3: Post Compression evaluation parameters (n=3, mean ±SD)

Formulation code	Weight variation (mg)	Hardness (Kg/cm^2)	Friability (%)	Drug content(%)
F1	251±0.17	4.0±0.11	0.15±0.01	99.08±0.21
F2	250±0.02	3.9±0.08	0.19±0.10	99.41±0.21
F3	249±0.09	4.0±0.11	0.35±0.12	99.23±0.09
F4	250±0.02	3.9±0.07	0.33±0.01	98.94±0.07
F5	251±0.12	3.9±0.03	0.32±0.08	98.56±0.08
F6	251±0.13	3.9±0.08	0.17±0.01	99.84±0.15
F7	251±0.04	3.9±0.01	0.37±0.11	99.23±0.13
F8	250±0.11	3.8±0.02	0.37±0.08	99.24±0.13
F9	251±0.02	3.9±0.07	0.35±0.07	99.37±0.17

Statistical significance ($p<0.05$)

In-vitro buoyancy studies

In-vitro buoyancy studies were performed to evaluate the duration of buoyancy and buoyancy lag time in the presence of various rate-controlling polymers. The duration of buoyancy varied from >9±0.23hr to >24±0.04hr and buoyancy lag time varied from 60±0.04sec to >120±0.03 sec for all the nine formulations. F6 formulation exhibited a short buoyancy lag time of 43±0.09 sec as well as a high swelling index of 29.2±0.05. Xanthan gum is a natural, swellable, sustainable polymer having zero order drug release. When this natural xanthan gum is present along with sodium bicarbonate and citric acid, upon influx into the stomach, carbon dioxide is released, causing the formulation to float in the stomach, thereby improving the bioavailability of the drug with substantial benefits, further drug wastage was reduced. *In vitro* buoyancy study data is represented in Figure 1 and Table 4.

Swelling index

The hydration ability of the formulation may have a significant result on tablet buoyancy and release kinetics. The swelling behaviour of a tablet depends on the swellable polymers present in the formula. The formulations F1, F2, and F3 have 40mg, 60mg and 80mg of HPMC K4M. An increase in the concentration of HPMC K4M showed an increase in the viscosity of the gel layer and an increase in the time for water to reach the inner core of the tablet. F1 to F3 formulations showed swelling indices of 2.1±0.03, 2.06±0.12, and 1.98±0.12 respectively. Formulations F4, F5 and F6 showed swelling indices of 19.1±0.13, 22.6±0.14 and 29.2±0.05 respectively. Formulations F7, F8, and F9 showed swelling indices of 16.2±0.12, 18.3±0.11 and 19.4±0.06 respectively. The formulation F6 showed the highest swelling index (29.2±0.05) among all nine formulations and contained 80mg of xanthan gum per tablet. It is observed that as the percentage of xanthan gum in formulation is increased the swelling rate of formulation also increased as shown in Table 4.

***In vitro* drug release studies**

Formulations F1, F2 and F3 had HPMC K4M at 40mg, 60mg and 80mg, while formulations F4, F5 and F6 were prepared using xanthan gum 40mg, 60mg and 80mg and formulations F7, F8 and F9 were prepared using in combinations both xanthan gum and HPMC K4M as 20mg, 30mg and 40mg each in each formulation respectively shown in Figure 2. Cumulative percent release for 24 h for F1 to F9 ranges from 91.8±0.36 to 99.8±0.14. Among all nine formulations, F6 showed the maximum percentage of drug release 98.75±0.24 % within 24 hours. As the concentration of xanthan gum increases in formulations showed greater release for prolonged periods at higher rates. Hence F6 formulation containing xanthan gum as 80 mg was considered to be optimised formulation.

Figure 1: Photograph taken during *in vitro* buonany studies of F1 to F9 formulations in 200ml of 0.1NHCl after 12 hours.

Table4: *In vitro* buoyancy studies and swelling index of Domperidone Effervescent floating tablets (n=3, mean ± SD)

Formulation code	Buoyancy lag time (sec)	Duration of buoyancy (hr)	Swelling Index (%)
F1	70±0.13	>9±0.23	2.1±0.03
F2	73±0.03	>10±.21	2.06±0.12
F3	79±0.08	>12±0.20	1.98±0.12
F4	66±0.21	15±0.03	19.1±0.13
F5	60±0.04	18±0.12	22.6±0.14
F6	43±0.09	>24±0.03	29.2±0.05
F7	60±0.13	>24±0.04	16.2±0.12
F8	90±0.08	>24±0.03	18..3±0.11
F9	120±0.03	>24±0.02	19.4±0.06

Statistical significance ($p<0.05$)

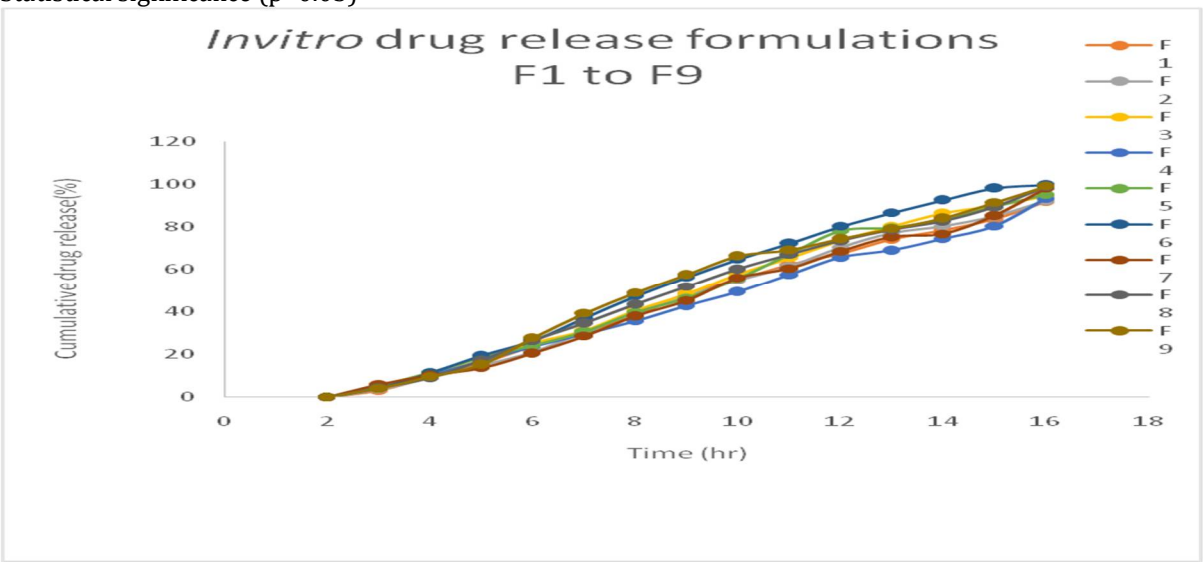


Figure 2 *In vitro* drug release studies

Application of Release Rate Kinetics to Dissolution Data

From the *in vitro* dissolution data, the optimised formulation F6 was further tested for the mechanism of drug release kinetics. The data were fitted into Zero order, First order, Higuchi and Korsmeyerpeppas mathematical models to study the drug release mechanism. The drug release mechanism was inferred to be zero order and Non-Fickian diffusion in the sense that drug release was independent of the concentration of drug, and the mechanism of drug release in F6 is swelling or relaxation of the polymer chain.

TABLE 5: MATHEMATICAL KINETIC MODEL APPLIED TO *IN VITRO* RELEASE DATA OF F6

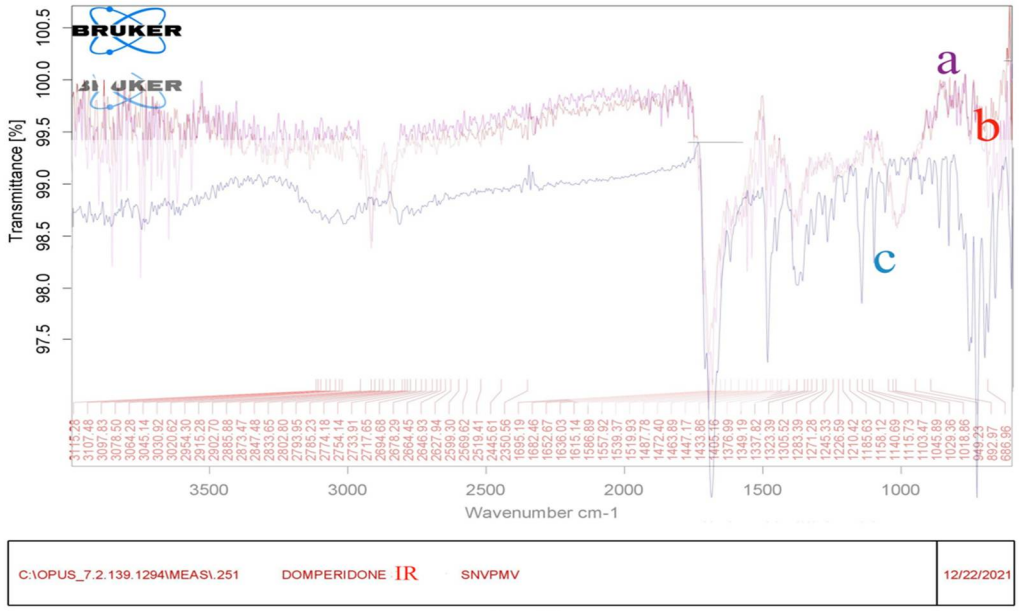
Formulation Code	Zero order R2	First order R2	Higuchi kinetics R2	Korsmeyerpeppas	
				N	R2
F6	0.9976	0.8862	0.9699	0.98	0.9893

CHARACTERIZATION OF DOMPERIDONE EFFERVESCENT FLOATING TABLETS

FOURIER TRANSFORM INFRARED SPECTROSCOPY (FT-IR) STUDIES

FTIR spectra of Placebo tablets, Domperidone effervescent floating tablets and Domperidone standard were shown in Figure 3.The significant all peaks of domperidone were present in the entire spectrum obtained between drug and excipients. The FTIR spectra showed that there are no significant changes in chemical integrity of drug formulation.

Figure 3: FTIR spectras of a) Domeridone effervescent floating tablet formulation b) Placebo tablet c) Domperidone standard.



Evaluation of Stability Studies

The effect of storage of optimised formulation F6 at 40 ±2°C and 75%±5% RH for 90 days and analysed for hardness, friability, buoyancy lag time, duration of buoyancy, swelling index and drug content. The percent drug content did not vary much, staying in the range of 99.80±0.14 to 99.85±0.13% from day 1 upto 90 days. Hardness, friability, and swelling index stayed close to initial values. The tablets remain buoyant for more than 24hrs throughout the testing period.

TABLE 6: STABILITY STUDIES OF OPTIMISED FORMULATION F6(n=6, mean±SD)

Day of testing	Hardness (Kg/cm2)	Friability (%)	Buoyancy lag time (sec)	Duration of buoyancy (h)	Swelling index (%)	Drug content (%)
Day 1	3.9±0.08	0.17±0.01	43±0.09	>24±0.03	29.2±0.05	99.84±0.15
Day 30	3.9±0.43	0.16±0.02	43±0.32	>24±0.45	29.5±0.1	99.80±0.14
Day 60	3.9±0.45	0.17±0. 05	43±0.29	>24±0.32	29.5±0.09	99.85±0.13
Day 90	3.92 ±0.15	0.15±0.08	43±0.28	>24±0.23	29.5±0.11	99.82±0.24

Statistical significance (P<0.05)

CONCLUSION

Domperidone effervescent floating tablets were prepared using HPMC K4M and xanthan gum as polymers in various proportions. Wet granulation method was proceeded using isopropyl alcohol as binder. The results of present research showed that the tablet containing domperidone alone cannot effectively

maintain its release rates for 24hrs. In present study this problem can be minimised by using xanthan gum in various proportions, which helps in increasing the viscosity of the dissolution fluid, thereby prolonging the release of the drug at higher release rates for 24 hours. Among all nine formulations, the F6 formulation containing 80 mg of xanthan gum was considered the best formulation based on buoyancy and swelling studies. From the present study, it was concluded that the formulation F6 has shown high swelling or relaxation of polymers. The drug release mechanisms of F6 formulation corresponds to zero order and non-fickian diffusion behaviour.

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Conflict of interest: The authors declare that there is no conflict of Interest.

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