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FORMULATION & EVALUATION OF GASTRO RETENTIVE FLOATING SYSTEM OF PANTOPRAZOLE SODIUM

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ABSTRACT

Traditional sustained-release oral dosage forms frequently face challenges due to erratic gastrointestinal transit and brief periods of stomach retention. To counter these physiological barriers, gastroretentive drug delivery systems (GRDDS) have been engineered to intentionally prolong a medication's stay in the gastric environment. Among the various strategies utilized to achieve this extended retention, floating formulations remain one of the most widely adopted and effective approaches. This buoyancy significantly extends the gastric residence time (GRT), making it an ideal strategy for site-specific absorption and ultimately improving overall drug bioavailability. An attempt is created to organize bead of Pantoprazole Sodium using various grades of gelucire like Gelucire 48/01 and Gelucire 43/01. Among which gelucire 43/01 gave spherical bead. Percentage yield was found in a very range of 72.27±1.52 to 92.62±1.52. Percentage drug entrapment of drug was obtained with successful bead formation in a range of 80.09±0.043 to 95.07±0.045. Because of higher drug-lipid ratio the dimensions of bead slightly increased. The in vitro data indicated that pure drug showed 99.83% release within 2 hr. The drug release from the bead prepared in formulation F9 achieved 90.40±0.271% in 24 hr. As per model fitting methods the very best parametric statistic (R2) value was 0.978 through Higuchi model. Hence from all aspects it is concluded that the discharge of drug Pantoprazole Sodium will be controlled by proper designing of the formulation and selection of an acceptable method of preparation.

Keywords: Gastro-retentive system; floating beads; controlled release; pantoprazole sodium; bioavailability.

INTRODUCTION

Gastroretentive medication conveyance framework (GRDDS) is most encouraging framework concocted for accomplishing an extended medication conveyance profile inside the GIT. These framework stays inside the gastric locale for stretched out length prompting improved bioavailability, remedial productivity and diminished portion. Numerous pharmacokinetic favorable circumstances could even be seen like, upkeep of restorative levels, improvement of the medication dissolvability that is less soluble in high pH climate. [12]

Floating Drug Delivery System (FDDS) have been intended to hold the medication inside the stomach and are ideal for drugs with helpless solvency and low intestinal liquid steadiness. FDDS are low-thickness hydro-progressively worked structures with sufficient lightness to glide over the gastric substance and stay light inside the stomach for a significant stretch of time without influencing the gastric exhausting rate. With the release of the medication, the leftover framework is depleted from the stomach. These prompts expanded gastric length and solid authority over varieties in plasma drug fixation. An essential and reasonable way to deal with the acknowledgment of expanded gastric length for the dose type and persistent arrival of medications is given by the idea of light arrangement. [34]

The arrangement of FDDS extraordinarily clarifies its physiochemical movement and appearance in Figure1

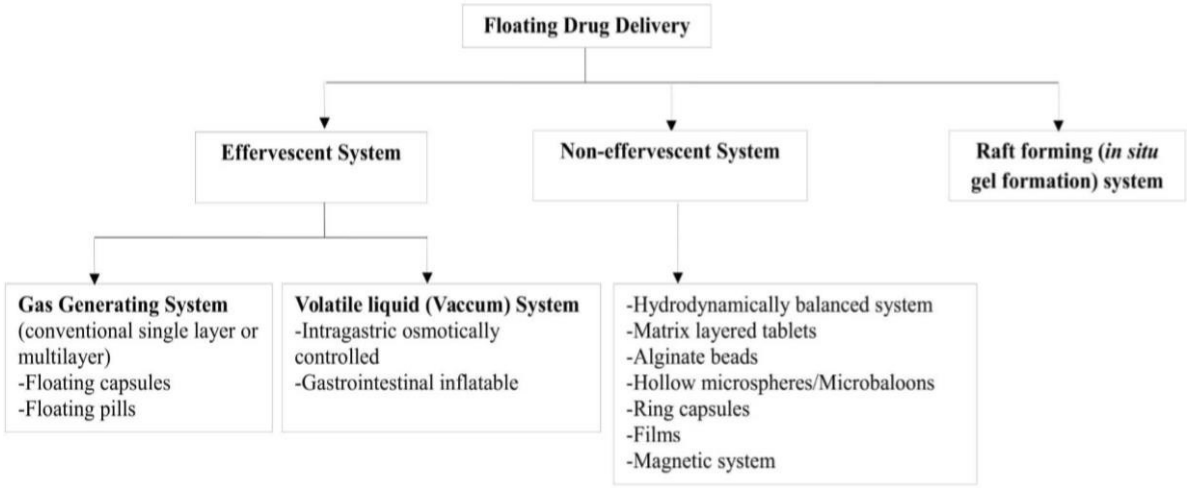


Figure 1: Classification of floating drug delivery system (FDDS)

Pantoprazole is a medication utilized for the counteraction of stomach ulcers, transient treatment of erosive esophagitis identified with gastroesophageal reflux issue (GERD), protection of erosive esophagitis recuperation, and obsessive hypersecretory messes, including Zollinger-Ellison condition, initially promoted under the brand name Protonix. It can likewise be utilized to eliminate Helicobacter pylori alongside different medications. Other proton siphon inhibitors (PPIs) are comparable in strength (PPIs). It is accessible by infusion into a vein and by mouth. [5]

The purpose of this work was to formulate and test pantoprazole sodium Gelucire-based lipid Floating bead. Pantoprazole Sodium is extremely soluble and highly permeable, so recovering its effectiveness is a daunting challenge. Owing to its poor bioavailability (77 percent) and short half-life (1 h), its administration is favoured through intravenous (IV) routes, but it is provided through oral routes as multiple unit dosage type, such as floating microspheres, for non-invasive treatment, which effectively decreases the frequency of dosing.

Gelucires are a comparatively inexpensive family of waxy materials composed of mono-, di-and triglyceride mixtures, as well as fatty acid esters of poly(ethylene glycol). Gelucires are available with a variety of properties based on their hydrophilic lipophilic balance (HLB; 1-18) and melting point (33-65 ° C) range. In request to increment gastric maintenance time, the primary goals of the investigation are to improve solvency and to develop Pantoprazole Sodium coasting globule dependent on Gelucires. Furthermore, the details additionally balance or control the arrival of the medication for delayed activity. So, the objective was to develop pantoprazole floating beads to enhance entrapment of drug, to control release of drug and to improve patient compliance.[6]

MATERIAL AND METHODOLOGY

Materials

Table 1: List of Chemicals

S. No	Materials	Source
1	Pantoprazole Sodium	Marksan Pharma Ltd., Goa
2	Gelucire 43/01	Gattefosse
3	Gelucire 48/01	Gattefosse
4	Gelucire 50/13	Gattefosse
5	Iso propyl alcohol	Fisher Scientific India Pvt. Ltd.
6	Methanol	Fisher Scientific India Pvt. Ltd.
7	Potassium Dihydrogen orthophosphate	Thomas Baker
8	Disodium hydrogen orthophosphate	Thomas Baker

PRE-FORMULATION STUDIES

Melting point

A few quantities of the drug were inserted in a 10-15 mm long thin-walled capillary tube, around 1 mm in diameter inside and closed at one end. The capillary holding the sample was suspended to slowly and uniformly heat the samples, and the thermometer was positioned to verify the temperature. As the melting point of

the medication, the temperature range over which the sample is observed to melt is taken.

UV spectrum of Pantoprazole Sodium

Tw fold bar UV-noticeable spectrophotometer (Shimadzu, UV-1800, Japan) was utilized to know the λmax of medication. A 10 µg/ml arrangement of Pantoprazole Sodium in methanol was examined in the scope of 200-800 nm.

Standard Curve of Pantoprazole Sodium by UV-visible spectrophotometer

Methanol was used to prepare a regular stock solution of Pantoprazole Sodium (1mg/ml). To obtain different dilutions of 5-40 µg/ml, this solution was diluted with methanol. Using the UV-visible spectrophotometer, the absorption of these solutions was recorded at 290 nm against methanol as blank and the standard curve was plotted against concentration. The slope, straight line equation and correlation coefficient were obtained from the calibration curve intercept.

Solubility Studies

Excess quantities of the substance were taken into thoroughly washed test tubes containing 1 ml of various solvents (methanol, ethanol, acetone, chloroform, 0.1N HCl, water, PBS pH 6.8 and 7.4) for the quantitative solubility analysis and the test tubes were tightly closed. These test tubes were shaken for 24 h at room temperature in a water shower shaker. 15,000 rpm were centrifuged after 24 h each sample and withdrawal of supernatant. After that, supernatant was filtered and filtrates were diluted correctly and spectrophotometrically assessed. [7]

Partition Coefficient of Drug

The partition coefficient determination study was performed by using shake flask method. Excess amounts of the drug (Pantoprazole Sodium) dissolved in 10 ml of two solvents (n-octanol: Water) together (1:1) and placed for 24 h. After 24 h, the two layers were separated and centrifuge for 15 mins at 15,000 rpm. The absorbance was taken in UV spectrophotometer at the respective λ_{max} after appropriate dilution.[7]

Drug-excipients Compatibility Study by FTIR

FT-IR determined the compatibility of drugs with excipients. FTIR has been used as a method to identify any physical and chemical drug-excipient interaction. Drugs and different excipients were extensively combined in a 1:1 ratio. Samples were scanned within the range of 4000 cm-1 by FTIR. To check any incompatibility and physical changes, the spectrum of pure drugs and drugs with excipients was compared.[8]

Preparations of Gelucire Floating Beads of Pantoprazole Sodium

Lipid (Gelucire 43/01/ Gelucire 48/13) was melted at 60 °C and gradually the finely powdered drug was applied to form dispersion with uniform mixing.[20] The resulting dispersion was dropped into 100 ml of pre-chilled (4 C) IPA at a rate of 5 ml/min through a 23-guage syringe needle (0.65 mm internal diameter). There was a distance of 5 cm from the needle tip to the IPA. The contents were stirred with a magnetic stirrer for 15 min at 100 rpm. After filtration via What man filter paper (# 41), the beads were collected, washed three times with distilled water and then

dried to their constant weight in a vacuum desiccator for 24 h to ensure full solvent removal. As a dispersion medium, vehicles such as isopropyl alcohol were used. [91012]

Figure 2: Method of preparation of Gelucire beads of Pantoprazole Sodium

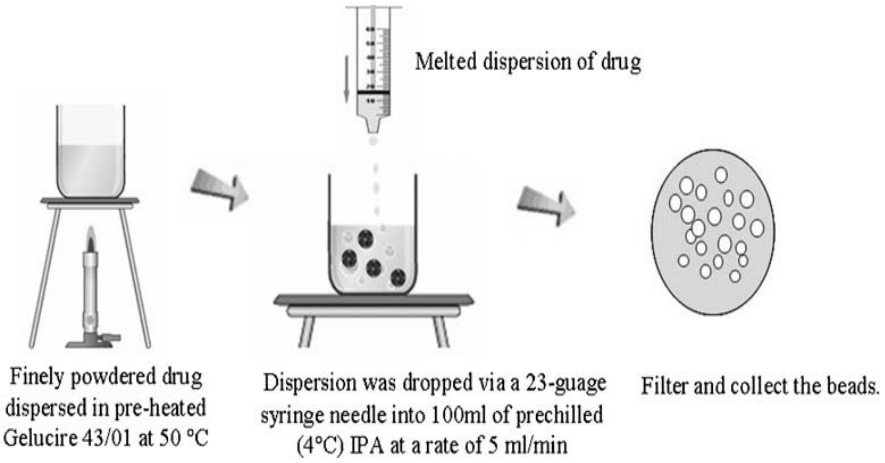


Table 2: Composition of different bead formulations containing Pantoprazole Sodium

S.N	Formulation Code	Drug (mg)	Gelucire 43/01 (mg)	Gelucire 48/13 (mg)	Isopropanol (ml)
1	F1	100	-	500	100
2	F2	100	-	1000	100
3	F3	100	-	1500	100
4	F4	100	-	2000	100
5	F5	100	-	3000	100
6	F6	100	500	-	100
7	F7	100	1000	-	100
8	F8	100	1500	-	100
9	F9	100	2000	-	100
10	F10	100	3000	-	100
11	F11	10	50	-	100
12	F12	10	1000	-	100

Evaluation of Gelucire floating bead of Pantoprazole Sodium

Production yield

The prepared beads were collected and weighed. The measured weight was divided by the total weight of all the excipients and drug. The % yield was calculated.

Percentage Drug Entrapment

The sodium substance of Pantoprazole in Gelucire dabs was dictated by a precisely gauged amount (20 mg) of medication stacked globules pummeled in a perfect dry glass mortar and brooded in 20 mL of mimicked gastric liquid (SGF, pH 1.2) at room temperature for 24 hours for full medication extraction. The suspension was centrifuged (Remi, India) at 5000 rpm for 15 min. The unmistakable supernatant arrangement was measured spectrophotometrically (UV-1800 spectrophotometer, Shimadzu, Japan) for drug content at 290 nm after reasonable weakening. The analysis was acted in three-fold. [11]

Particle Size

A micrometer was used to determine the average particle size of the beads and to measure that the average particle size of 100 beads. Scanning electron microscopy has visualized the surface morphology of selected beads.[17]

Floating Behaviors of Beads

In the simulated gastric fluid (0.1 N HCl) at room temperature, floating beads (a number) were mounted. In this solution, the beads were put. The ratio of sinking and floating beads was determined after 8 h. [1316]

In-Vitro Drug Release Study

In a USP Type I basket dissolution apparatus, the release of drugs from floating beads was calculated. In the dissolution rate apparatus, 900 ml of the simulated gastric fluid was applied to a weighed quantity of beads equal to 10 mg of substance. At a rotation rate of 50 rpm, the dissolution fluid was maintained at 37±0.5°C. During the drug release analysis, optimal sink conditions prevailed. At defined intervals, 5 ml of sample was withdrawn and passed through a 0.25-µm membrane filter, and the initial dissolution fluid volume was retained by adding 5 ml of fresh dissolution fluid after each withdrawal. Samples were analyzed at 290nm with a UV-visible spectrophotometer. [14,15]

Drug release kinetics

The methods dependent on the model are based on various mathematical functions that define the release profile. The release profiles were evaluated based on the derived model parameters once a suitable function has been chosen.[19] The data obtained from *in vitro studies* were plotted in different kinetic models.

RESULTS AND DISCUSSION

PREFORMULATION

Melting Point:

It was observed that the melting point of Pantoprazole Sodium is 142.25±0.015^{0}C which is in the pure drug category. Therefore, the drug assay was free of impurities of some kind.

UV Spectroscopy

Determination of absorption maxima in methanol

For quantitative examination of the compound, a double beam UV-visible spectrophotometer was used. In the 200-400 nm region, a 30 µg/ml solution of Pantoprazole Sodium in methanol was scanned. The outcome of the Pantoprazole Sodium UV spectrum is seen in Figure 3.

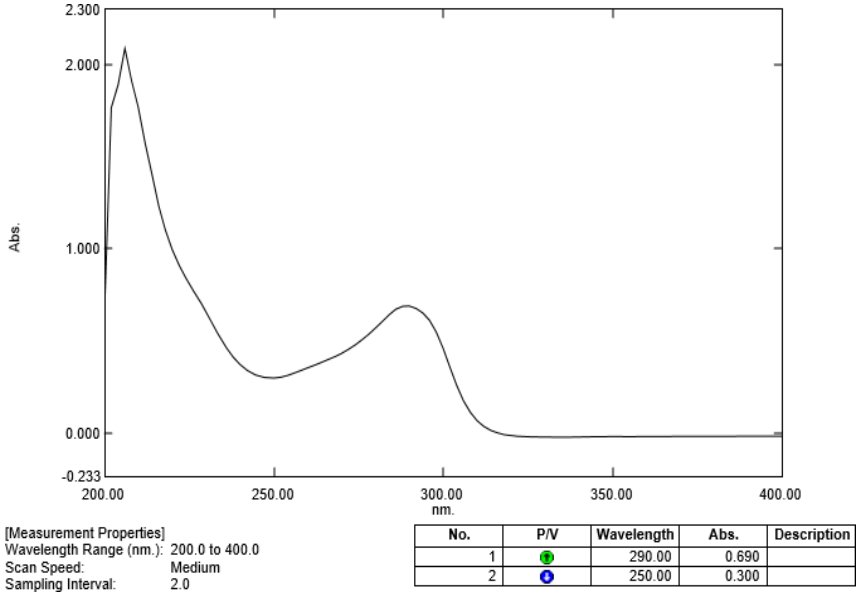


Figure 3: UV Spectrum of Pantoprazole Sodium in methanol

The overall wavelength of Pantoprazole Sodium was close to that found in literature at 290 nm.

Preparation of the Pantoprazole Sodium Calibration Curve

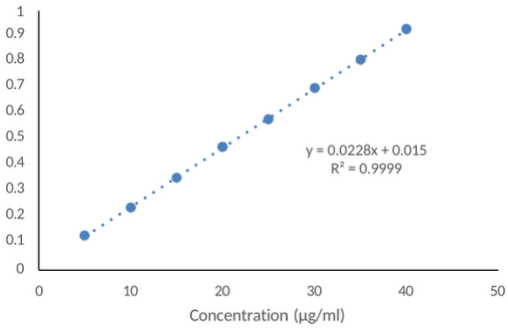


Figure 4: Pantoprazole Sodium calibration curve in methanol

The calibration curve for Pantoprazole Sodium was obtained by using the 5 to 40 µg/ml concentration of Pantoprazole Sodium in methanol. The absorbance was measured at 290 nm. The calibration curve of Pantoprazole Sodium as shows in graph indicated the regression equation Y=0.0228x-0.015 and R^2 value 0.999, which shows good linearity.

Solubility Studies

The solubility of the substance in different solvents was completed all together to test. The compound was tested using a UV spectrophotometer at 290 nm.

Table 3: Solubility tests with multiple solvents with Pantoprazole Sodium

Sr.no	Solvent	Solubility in (mg/ml)
1	SGF Buffer	16.102±0.066
2	Chloroform	37.471±0.452
3	Ethanol	59.144±0.664
4	Methanol	91.608±0.434
5	Water	136.536±0.905
6	Acetone	200.304±0.434

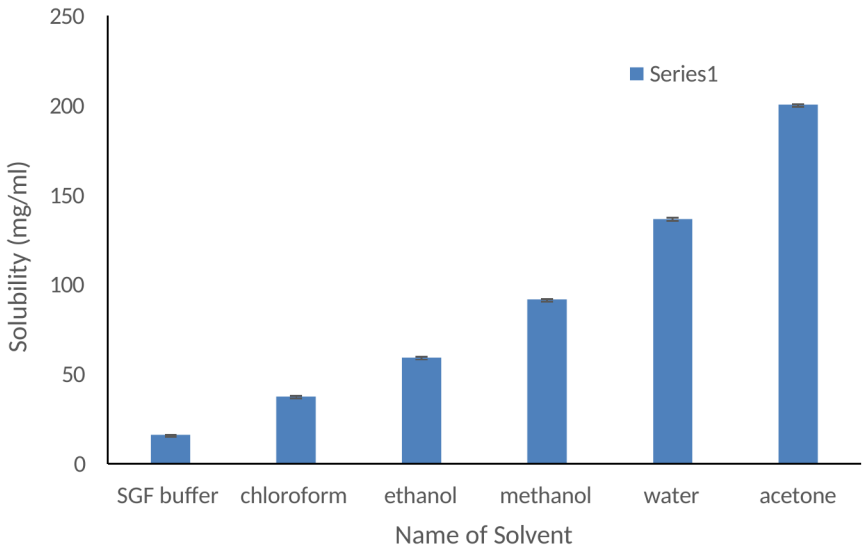


Figure 5: Solubility study of drug in different solvents

It is clearly seen from the above evidence that Pantoprazole Sodium is strongly soluble in ethanol, methanol, water and acetone.

Partition Coefficient

The Pantoprazole Sodium partition coefficient in n-octanol: water was observed to be 3.541 ± 0.004, suggesting that the lipophilic structure of the substance is close to the literature.

FTIR Studies

Pantoprazole Sodium's major IR absorption peaks were found in the spectrum of Pantoprazole Sodium at 3071.89 cm-1 (N-H Stretching), 1586.19 cm-1 (C-O Stretching),

1031.18 cm-1 (C-F Stretching), 1162.09 cm-1 (C=S Stretching), 822.93 cm-1 (sp2 C-O aromatic ether stretch). The purity and validity of the Pantoprazole Sodium was verified by these observed principal peaks.

Table 4: FTIR interpretation of Pantoprazole Sodium.

Reported (cm^{-1})	Observed(cm^{-1})	Characteristics Peaks
2941.3	2943.07	Aliphatic C–H Vibrations
1590.02	1586.19	C–N Stretching
1304.61	1301.05	C–F Stretching
1041.37	1162.09	S-O Absorption Peak

Table 5: Interpretation of FTIR spectrum of Gelucire 43/01.

Reported (cm^{-1})	Observed (cm^{-1})	Functional group
1741	1739.64	C=O ester group stretching
1172	1172.22	C–O stretch of primary alcohols
1100	1103.69	C–O stretch of secondary alcohols

Table 6: Interpretation of FTIR spectrum of Physical mixture

Reported (cm^{-1})	Observed (cm^{-1})	Functional group
2941	2916.94	Aliphatic C–H Vibrations
1590	1587.76	C–N Stretching
1041	1035.45	S–O Absorption Peak
1741	1738.55	C=O ester group stretching
1172	1171.40	C–O stretch of primary alcohols
1100	1102.99	C–O stretch of secondary alcohols

Both the spectrum peaks showed that in the above spectra, along with excipient peaks, corresponding drug peaks are present. Therefore in this combination, no contact was noted.

Floating Bead Preparation of Gelucire

In the present inquiry, Gelucire 43/01 was used to prepare a multiparticulate conveyance arrangement of Pantoprazole Sodium fit for giving controlled delivery. It was seen that the readiness cycle for dots was straightforward and reproducible.

Evaluation of Floating Bead

Appearance of Bead

Table 7: Appearance of different Gelucire based beads

S. No	Formulation Code	Appearance
1	F1	Bead Not produced
2	F2	Bead Not produced
3	F3	Bead Not produced
4	F4	Bead Not produced
5	F5	Bead Not produced
6	F6	Formation of Spherical Bead
7	F7	Formation of Spherical Bead
8	F8	Formation of Spherical Bead
9	F9	Formation of Spherical Bead
10	F10	Formation of Spherical Bead
11	F11	Irregular shape produced
12	F12	Bead Not produced

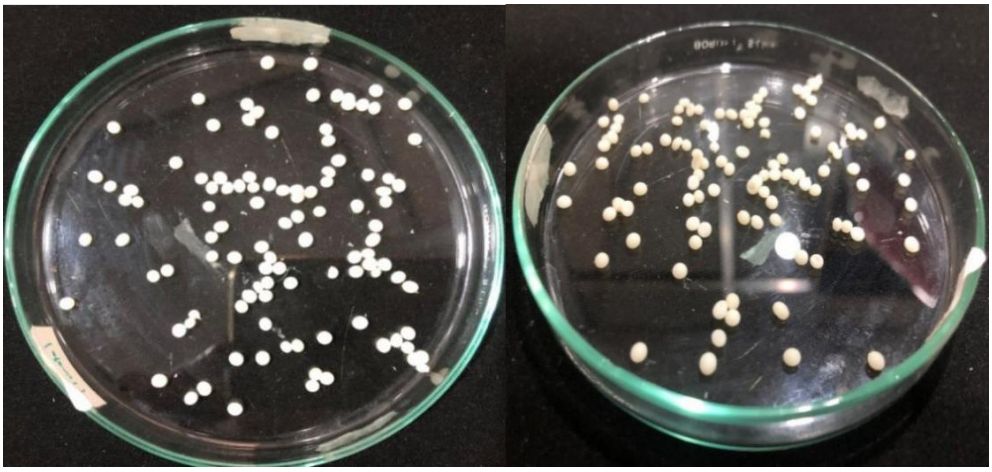


Figure 6: Pantoprazole Sodium loaded Gelucire floating bead

It was found that Gelucire 43/01 and isopropanol has formed spherical shape beads. Beads were not formed when the high ratio of lipid as well as low ratio of lipid was used. Uniform and compact beads were formed with IPA when we used Gelucire 43/01 and IPA was used as surface active agent and cross-linking agent. So, might be these properties play an important role in uniform bead formation.

Yield Percentage

Percentage yield was calculated of the formulation which was found successful in bead formation with floating ability in gastric medium. The yield thus calculated was found in a range of 72.27±1.52 to 92.62±1.52 with the maximum yield possessed by F10 formulation, which was 92.62±1.52.

Table 8: Percentage yield of different Gelucire beads containing Pantoprazole Sodium

S.No.	Formulation Code	Percentage Yield
1	F6	72.27±1.52
2	F7	87.06±2.51
3	F8	77.91±2.51
4	F9	87.30±2.08
5	F10	92.62±1.52

Percentage Drug Entrapment

9It was found from table 3.13 that the percentage of drug capture of all formulations was found to be between 80.09±0.043 and 95.07±0.045. These findings explain that lipid accumulation has been found to have a major impact on the percent trapping ability of beads.

Table 9: Percentage Drug Entrapment of different Gelucire based bead containing Pantoprazole Sodium

S.No.	Formulation Code	Percentage drug entrapment
1	F6	81.25±0.045
2	F7	80.09±0.043
3	F8	84.81±0.033
4	F9	95.84±0.033
5	F10	95.07±0.045

The value is seen as mean ± SD; n = 3

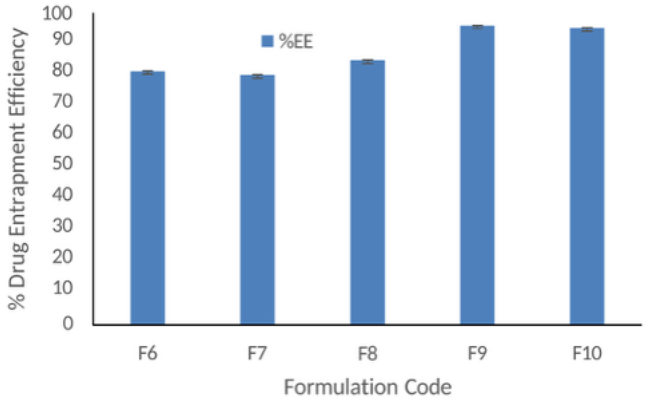


Figure 7: Percentage drug entrapment of Pantoprazole Sodium loaded floating beads

Particle Size

The particle size varies from 0.827±0.45 to 1.81±0.74 mm for all beads found. The result revealed that particle size increased marginally as the lipid concentration increased. The beads that were shaped were sufficiently hard and spherical in shape.

Table 10: Particle size of different Gelucire based bead containing Pantoprazole Sodium

Sr. No.	Formulation Code	Particle Size (mm)
1	F6	0.827±0.45
2	F7	0.938±0.28
3	F8	1.242±0.83
4	F9	1.469±0.18

Sr. No.	Formulation Code	Particle Size (mm)
5	F10	1.810±0.74

In-vitro Floating study

The findings show that all formulations stay floating for up to 8 hours, reflecting the beads' excellent floating capacity (table 3.14). The density of Gelucire 43/01 (true density 0.0856 g/cm3) also plays an important role in the floating potential of beads, aside from hydrophobicity. Formulation F9 was chosen for further in-vitro drug release tests on the basis of the effects of the above parameters.

Table 11: Percentage floating of different Gelucire based beads

S.No.	Formulation Code	Percentage Floating
1	F6	95% floating
2	F7	100% floating
3	F8	100% floating
4	F9	100% floating
5	F10	95% floating

Analysis of *In-vitro* Drug Release

The in-vitro release of the lipid-based floating bead drug was found to be lower relative to the pure drug that demonstrated the effect of Gelucire's lipid matrix on the property of drug release. Table 19 revealed that pure drug release in vitro showed 100 percent release within 2 hours. A biphasic continuous release pattern was seen in formulations and an initial burst release of Pantoprazole Sodium was obtained from F9. In addition, Pantoprazole Sodium release profiles from beads made from Gelucire 43/01 revealed that the Gelucire 43/01 used provided a continuous release of Pantoprazole Sodium. It was observed from the *in-vitro* drug release analysis that the formulation of F10 displayed lower drug release relative to pure products.

Table 12: Comparison of F9 and Pure Drug Percentage of Drug Release

Time (h)	Percent Drug release in Pure suspension	Percent drug Formulation release (F9)
0	0	0
0.25	78.82±0.830	49.64±0.271

Time (h)	Percent Drug release in Pure suspension	Percent drug Formulation release (F9)
0.5	86.79±0.543	57.25±0.271
0.75	90.77±2.057	60.51±0.270
1	93.85±0.543	65.13±0.269
2	99.83±0.543	73.37±0.156
3	-	79.99±0.156
4	-	83.61±0.271
6	-	85.69±0.156
8	-	87.41±0.271
12	-	88.77±0.271
18	-	89.59±0.271
24	-	90.40±0.271

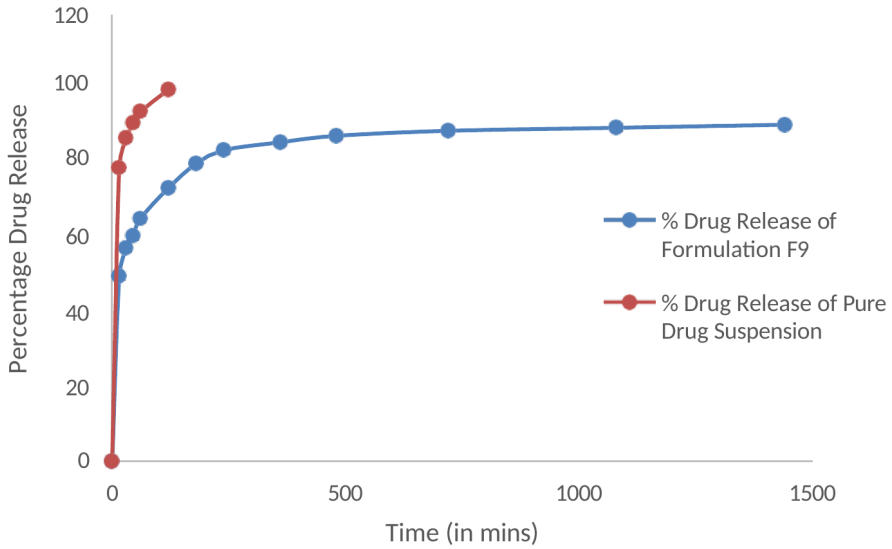


Figure 8: In-Vitro release of Pantoprazole Sodium floating beads

In-vitro drug release kinetics

Different release kinetics models including zero order, first order, Higuchi and Korsmeyer-Peppas were introduced to explain the process by which the drug was released from the

Pantoprazole Sodium floating beads F9 formulation.

Table 13: Kinetic equation parameter of F9 batch

Batch name	Zero order release kinetics Results		First order release kinetics Results		Higuchi release kinetics Results		Peppas release kinetics Results	
	R^2	K_0	R^2	K_0	R^2	K_0	R^2	K_0
F9	0.854	0.6294	0.954	-0.0178	0.981	3.517	0.978	0.0425

The higuchi model was found to match the release data better (R^2=0.989). This indicates that molecules of Pantoprazole Sodium were loaded into the bead and there was no contact between the drug and the formulation substance. From the findings, it could be inferred that the compound was released through a sustainable process from the bead.

CONCLUSION

Gastroretentive floating drug delivery systems (GFDDS) are particularly valuable for medications that are primarily absorbed in the duodenum and upper jejunum. As a cost-effective class of excipients, Gelucires offer excellent potential for these lipid-based formulations. In this study, pantoprazole sodium beads were formulated using different grades of Gelucire, specifically Gelucire 48/01 and Gelucire 43/01. Gelucire 43/01 successfully produced highly spherical beads through a preparation process that was both straightforward and highly reproducible. The formulation demonstrated a strong percentage yield ranging from 72.27 ± 1.52% to 92.62 ± 1.52%, with an impressive drug entrapment efficiency between 80.09 ± 0.043% and 95.07 ± 0.045% across all successful batches. As is common in multiparticulate systems, higher drug-to-lipid ratios resulted in a slight increase in bead size, with average diameters ranging from 0.827±0.45 to 1.81±0.74 mm. *In vitro* dissolution data highlighted the efficacy of the extended-release system. The optimized bead formulation (F9) provided sustained delivery, releasing 90.40 ± 0.271% of the drug over a 24-hour period. Kinetic modeling indicated that the release profile best fit the Higuchi model ($R^2 = 0.978$), suggesting a diffusion-controlled release mechanism. Ultimately, Gelucire 43/01 demonstrated significant promise as a reliable and effective carrier for the development of multiparticulate gastroretentive formulations.

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