Journal of Pharma Research
Available online through
www.jprinfo.com
Vol. 15 Issues 04, 2026 ISSN: 2319-5622

Research Article

FORMULATION AND IN VITRO EVALUATION OF SILYMARIN GASTRORETENTIVE FLOATING TABLET

Eda Deeksha[1], Anumula Rama Rao[2], M. Sugandha Parimala[3], Chandrasekhara Rao Baru[4], M. Ashwini[5], Sushma Desai [6*]

[1]Student, Department of Pharmaceutics, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, India-500075.
[2]Associate Professor, Department of Pharmacology, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, India-500075.
[3,5]Assistant Professor, Department of Pharmaceutics, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, India-500075.
[4]Professor and Principal, Department of Pharmaceutics, Chilkur Balaji College of Pharmacy, Aziznagar, Hyderabad, Telangana, India-500075.
[6]Research Scholar, Department of Pharmaceutics, GITAM School of Pharmacy, GITAM (Deemed to be) University, Rudraram, Patancheru, Sangareddy district, Hyderabad, Telangana, India-502329.

Received on: 02-07-2026 **Accepted & Published on: 20-08-2026**

ABSTRACT

Objective: *The study aimed to develop and evaluate gastro-retentive floating tablets of silymarin, a hepatoprotective agent, to enhance its bioavailability and therapeutic efficacy by prolonging its gastric residence time.*

Methods: *Gastro-retentive floating tablets of silymarin were formulated using a combination of hydrogel polymers (e.g., Hydroxypropyl Methylcellulose (HPMC) and Chitosan) and gas-generating agents (sodium bicarbonate and citric acid). The tablets were prepared using direct compression techniques. The formulated tablets were then subjected to a series of in vitro evaluations to assess their floating behavior, drug release profile, and physical properties.*

Results: *The in vitro floating studies demonstrated that the tablets achieved a buoyancy lag time of less than 30 minutes and maintained floatation for over 12 hours in simulated gastric fluid (SGF). The drug release studies indicated a controlled and sustained release of silymarin over a 12-hour period, following zero-order or Higuchi kinetics, which suggests a steady and consistent release rate. Additionally, the tablets exhibited desirable physical characteristics, including appropriate hardness, friability, and uniform drug content.*

Conclusion: *The developed gastro-retentive floating tablets of silymarin successfully met the intended formulation goals, showing effective floating behavior and prolonged drug release. This formulation strategy is expected to enhance the bioavailability and therapeutic efficacy of silymarin by improving its gastric residence time.*

Keywords: *Gastroretentive drug delivery systems, silymarin, floating behavior, bioavailability.*

INTRODUCTION

Oral controlled release drug delivery has recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. Drugs that are easily absorbed from gastrointestinal tract (GIT) and have short half-lives are eliminated quickly from the systemic circulation. Frequent dosing of these drugs is required to achieve suitable therapeutic activity. After oral administration, such a drug delivery would be retained in the stomach and release the drug in a controlled manner, so that the drug could be supplied continuously to its absorption sites in the gastrointestinal tract (GIT)[1.] Prolonged gastric retention improves bioavailability, increases the duration of drug release, reduces drug waste, and improves the drug solubility that are less soluble in a high pH environment2. Gastroretentive drug delivery is an approach to prolong gastric residence time, thereby targeting site-specific drug release in the upper gastrointestinal tract (GIT) for local or systemic effects. Gastroretentive dosage forms can remain in the gastric region for long periods and hence significantly prolong the gastric retention time (GRT) of drugs. Over the last few decades, several

Corresponding author:
Sushma Desai
Research Scholar, Department of Pharmaceutics, Gitam School of Pharmacy, Rudraram, Patencheru, Hyderabad, India-502329
Email: d.sushmapharma@gmail.com
DOI: https://doi.org/10.5281/zenodo.22098401

gastroretentive drug delivery approaches being designed and developed, including: high density (sinking) systems that is retained in the bottom of the stomach[3] , low density (floating) systems that causes buoyancy in gastric fluid[4,5,6], mucoadhesive systems that causes bioadhesion to stomach mucosa[7], unfoldable, extendible, or swellable systems which limits emptying of the dosage forms through the pyloric sphincter of stomach[8,9] superporous hydrogel systems[10] magnetic systems[11]etc. The current review deals with floating type gastroretentine drug delivery system.

Basic gastrointestinal tract physiology: The stomach is divided into three regions anatomically fundus, body, and antrum pylorus. The proximal part is the fundus and the body acts as a reservoir for undigested material, whereas the antrum is the main site for mixing motions and acts as a pump for gastric emptying by propelling actions. Gastric emptying occurs during fasting as well as fed states but the pattern of motility is distinct in the 2 states. During the fasting state an inter-digestive series of electrical events take place, which cycle through both stomach and intestine every 2 to 3 hours. This is called the inter-digestive myoelectric cycle or migrating myoelectric cycle (MMC), which is divided into following 4 phases as

Phase I- no obstructions observed for a time span of 30-60 min.

Phase II- lasting for a time span of 20-40 min gastric fluid begins to discharge.

Phase III- intense distal and proximal contractions observed lasting for a time span of 10-20 min.

Phase IV - time span of 0-5 min with very short transitory period in MMC 12.

Need for Gastroretention:

- Drugs that are absorbed from the proximal part of the gastrointestinal tract (GIT).
- Drugs that are less soluble or that degrade at the alkaline pH.
- Drugs that are absorbed due to variable gastric emptying time.
- Local or sustained drug delivery to the stomach and proximal small intestine to treat certain conditions.
- Particularly useful for the treatment of peptic ulcers caused by H.Pylori infections.

Factors controlling gastric retention of dosage forms: There are several factors that can affect gastric emptying of an oral dosage form which include density, size and shape of dosage form, feeding state, biological factors such as age, gender, posture, body mass index, disease state etc.

a. Effect of Dosage Form Size & Shape: Small size tablets are emptied from the stomach during the digestive phase while large size units are expelled during the house keeping waves found that floating unit with a diameter equal or less than 7.5 mm had larger gastric residence time (GRT) compared to non-floating units but the GRT was similar for floating and non-floating units having a large diameter of 9.9 mm. They found that GRT of non-floating units were much more variable and highly dependent on their size which are in the order of small < medium < large units. Moreover, in supine subjects, size influences GRT of floating and non- floating form. Tetrahedron and ring-shaped devices have a better GRT compared with other shapes [13,14].

b. Density: The density of a dosage form also affects the gastric emptying rate and determines the location of the system in the stomach. Dosage forms having a density lower than the gastric contents can float to the surface, while high density systems sink to bottom of the stomach 16. Both positions may isolate the dosage system from the pylorus. A density of < 1.0 gm/ cm3 is required to exhibit floating property[15].

c. Gender, Posture & Age: Generally, females have slower gastric emptying rates than male. The effect of posture does not have any significant difference in the mean gastric retention time (GRT) for individuals in upright, ambulatory and supine state. In case of elderly people, gastric emptying is slowed down[16].

d. Effect of Food & Specific Gravity: To float FDDS in the stomach, the density of dosage form should be less than gastric content i.e.1.0 g/cm3. Since, the bulk density of a dosage form is not a sole measure to describe its buoyant capabilities because the magnitude of floating strength may vary as a function of time and gradually decrease after immersing dosage form into fluid because of development of its hydrodynamic equilibrium. Various studies have shown the intake of food as main determinant of gastric emptying rather than food. Presence of food is the most important factor effect GRT than buoyancy. GRT has significantly increased under fed conditions since onset of MMC is delayed. Studies show that GRT for both floating and non-floating single units are shorter in fasted subjects (less than 2 h), but significantly prolonged after meal (around 4 hour).

e. Nature of Meal & Frequency of Food: Feeding of indigestible polymers or fatty acid salts can change the motility pattern of the stomach to fed state, to increase gastric emptying rate and prolonging the drug release. Diets rich in protein and fat can increase GRT by 4-10 h [16-20].

f. Type of Formulation: Multiple unit formulation shows a more predictable release profile and insignificant impairing of performance due to failure of units, allow co-administration of units with different release profile or containing incompatible substances and permit a large margin of safety against dosage form failure compared with single unit dosage form [21-27].

Future Potential: Floating dosage form offers various future potential as evident from several recent publications. The reduced fluctuations in the plasma level of drug results from delayed gastric emptying. Drugs that have poor bioavailability because of their limited absorption to the upper gastrointestinal

tract can be delivered efficiently thereby maximizing their absorption and improving their absolute bioavailability. Buoyant delivery system is considered as a beneficial strategy for the treatment of gastric and duodenal cancers.

• The floating concept can also be utilized in the development of various anti-reflux formulations.
• Developing a controlled release system for the drugs, which are potential to treat the Parkinson's disease.
• To explore the eradication of Helico-bactor pylori by using the narrow spectrum antibodies [28-31].

Floating Drug Delivery Systems: A floating dosage form is useful for drugs acting locally in the proximal gastrointestinal tract. These systems are also useful for drugs that are poorly soluble (or) unstable in intestinal fluids. The floating properties of these systems help to retain in the stomach for a long time. Various attempts have been made to develop floating systems, which float on the gastric contents and release drug molecules for the desired time. After the release of a drug, the remnants of the system are emptied from the stomach. Based on the mechanism of buoyancy, two different technologies have been used in development of floating drug delivery systems.

These include:
a) Effervescent system.
b) Non- Effervescent system.

Gastro-retentive floating dosage form provides various future potential. Delayed gastric emptying time results in the decreased fluctuations in the plasma level of drug. Drugs that have poor bioavailability because of their limited absorption to the upper gastrointestinal tract can be delivered efficiently thereby maximizing their absorption and improving their absolute bioavailability. Buoyant delivery system is considered an advantageous approach for the treatment of gastric and duodenal cancers. The floating concept can also be utilized in the development of various anti-reflux formulations. Developing a controlled release system for the drugs, which are potential to treat the Parkinson's disease. This system can also be useful to discover the eradication of Helicobacter pylori by using the narrow spectrum antibodies. Day after day the FDDS shows more promise for a bright future32,33.

2. MATERIALS AND METHODOLOGY:

2.1 Materials: silymarin drugs purchased from SuraLabs, Hyderabad. Talc, Eudragit RSPO was purchased from Degussa India Ltd. (Mumbai, India). HPMC K 100 was purchased from Arvind Remedies Ltd, Tamil nadu, India.Chitosan was purchased from Merck Specialities Pvt Ltd, Mumbai, India.Citric acid purchased from Laser Chemicals, Ahmedabad, India. Sodium bicarbonate was purchased from Merck Specialities Pvt Ltd, Mumbai, India. Micro crystalline cellulose was purchased from Merck Specialities Pvt Ltd, Mumbai, India. Magnesium Stearate was purchased from Apex Chemicals, Ahmedabad, India. Talc was purchased from S.D. Fine Chem., Mumbai, India.

2.2 Methodology:

2.2.1 Drug – Excipient compatibility studies : Fourier Transform Infrared (FTIR) spectroscopy: The compatibility between the pure drug and excipients was detected by FTIR spectra obtained on Bruker FTIR Germany (Alpha T).
The solid powder sample directly place on yellow crystal which was made up of ZnSe.
The spectra were recorded over the wave number of 4000 cm-1 to 550 cm-1.

2.2.1.1 Determination of absorption maxima: A solution containing the concentration 10 µg/ mL drug was prepared in 0.1N HCL UV spectrum was taken using Double beam UV/VIS spectrophotometer. The solution was scanned in the range of 200 – 400 nm.

2.2.1.2 Preparation calibration curve: 10mg Silymarin pure drug was dissolved in 10ml of methanol (stock solution1) from stock solution 1ml of solution was taken and made up with10ml of 0.1N HCL (100µg/ml). From this 1ml was taken and made up with 10 ml of 0.1N HCL (10µg/ml). The above solution was subsequently diluted with 0.1N HCL to obtain series of dilutions Containing 2, 4, 6, 8, 10µg /ml of per ml of solution. The absorbance of the above dilutions was measured at 288 nm by using UV-Spectrophotometer taking 0.1N HCL as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight- line Linearity of standard curve was assessed from the square of correlation coefficient (R2) which determined by least-square linear regression analysis.

2.2.1.3 Pre-formulation parameters: The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

2.2.1.3.1 Angle of repose: The frictional force in a loose powder can be measured by the angle of repose. It is defined as the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, is in equilibrium with the gravitational force. The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height (h), above a graph paper that is placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose was calculated using the following formula:

Tan θ = h / r Tan θ = Angle of repose
h = Height of the cone, r = Radius of the cone base

Table 1: Angle of Repose values (as per USP)

Angle of Repose	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

The bulk density was calculated using the formula:
Bulk Density = M / Vo
Where, M = weight of sample
Vo = apparent volume of powder

2.2.1.3.2 Tapped density: After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurement is less than 2 % and then tapped volume, V measured, to the nearest graduated unit. The tapped density was calculated, in gm per L, using the formula:
Tap = M / V
Where, Tap= Tapped Density
M = Weight of sample
V= Tapped volume of powder

2.2.1.3.3 Measures of powder compressibility: The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measures of the relative importance of interparticulate interactions. In a free-flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value.

For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:

Carr's Index = [(tap - b) / tap] × 100
Where, b = Bulk Density
Tap = Tapped Density

2.2.1.4 Formulation development of floating Tablets:

Procedure for direct compression method:

Drug and all other ingredients were individually passed through sieve no. 60. All the ingredients were mixed thoroughly by triturating up to 15 min. The powder mixture was lubricated with talc. The tablets were prepared by using direct compression method by using 9mm punch.

Table 2: Formulation composition for Floating tablets

Ingredients (mg)	FORMULATION CODE								
	S1	S2	S3	S4	S5	S6	S7	S8	S9
Silymarin	70	70	70	70	70	70	70	70	70
Eudragit RSPO	35	70	105	-	-	-	-	-	-
HPMC K 100	-	-	-	35	70	105	-	-	-
Chitosan	-	-	-	-	-	-	35	70	105
Citric acid	20	20	20	20	20	20	20	20	20
Sodium bicarbonate	10	10	10	10	10	10	10	10	10
Micro crystalline cellulose	155	120	85	155	120	85	155	120	85
Magnesium Stearate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Total Weight	300	300	300	300	300	300	300	300	300

2.2.1.5 Evaluation of post compression parameters for prepared Tablets: The designed compression tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

2.2.1.6 Weight variation test: To study the weight variation, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviate by more than twice the percentage. The mean and deviation were determined. The percent deviation was calculated using the following formula.

% Deviation = (Individual weight – Average weight / Average weight) × 100

Table 3: Pharmacopoeia specifications for tablet

Weight variation Average weight of tablet (mg) (I.P)	Average weight of tablet (mg) (U.S.P)	Maximum percentage difference allowed
Less than 80	Less than 130	10
80-250	130-324	7.5
More than	More than 324	5

2.2.1.7 Hardness: Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. For each formulation, the hardness of three tablets was determined using Monsanto hardness tester and the average is calculated and presented with deviation.

2.2.1.8 Thickness: Tablet thickness is an important characteristic in reproducing appearance. Tablet thickness is an important characteristic in reproducing appearance. Average

thickness for core and coated tablets is calculated and presented with deviation.

2.2.1.9 Friability: It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. Pre-weighed tablets were placed in the friabilator. The tablets were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the tablets were re- weighed, and loss in the weight of tablet is the measure of friability and is expressed in percentage as

% Friability = [(W1-W2) / W1] × 100

Where, W1 = Initial weight of tablets

W2 = Weight of the tablets after testing

2.2.2 Determination of drug content: Both compression-coated tablets were tested for their drug content. Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of SILYMARIN were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with water. The solution was suitably diluted, and the absorption was determined by UV –Visible spectrophotometer. The drug concentration was calculated from the calibration curve.

2.2.3 In vitro Buoyancy studies: The in vitro buoyancy was determined by floating lag time, and total floating time. The tablets were placed in a 100ml beaker containing 0.1N HCL. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and duration of time the tablet constantly floats on the dissolution medium was noted as

Total Floating Time respectively (TFT).

In vitro drug release studies and the Dissolution parameters:

Apparatus -- USP-II, Paddle Method

Dissolution Medium -- 0.1 N HCL

RPM -- 50

Sampling intervals (h) -- 1,2,3,4,5,6,7,8,9,10,11,12

Temperature -- 37°c + 0.5°c

Procedure: 900ml 0f 0.1 HCL was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37°c + 0.5°c. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 12 hours and then the medium 0.1 N HCL was taken and process was continued from 0 to 12 h at 50 rpm. At definite time intervals of 5 ml of the receptor's fluid was withdrawn, filtered and again 5ml receptor fluid was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at 288 nm using UV-spectrophotometer.

2.2.4 Application of Release Rate Kinetics to Dissolution Data:

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Zero order release rate kinetics: To study the zero–order release kinetics the release rate data fitted to the following equation.

F = Ko t

Where, 'F' is the drug release at time 't', and 'Ko' is the zero-order release rate constant. The plot of % drug release versus time is linear.

First order release rate kinetics: The release rate data are fitted to the following equation.

Log (100-F) = kt

A plot of log cumulative percent of drug remaining to be released vs. time is plotted then it gives first order release.

Higuchi release model: To study the Higuchi release kinetics, the release rate data were fitted to the following equation.

F = k t1/2

Where, 'k' is the Higuchi constant.

In Higuchi model, a plot of % drug release versus square root of time is linear.

Korsmeyer and Peppas release model: The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to Korsmeyer- Peppas equation. The exponent 'n' indicates the mechanism of drug release calculated through the slope of the straight Line.

$Mt/ M\infty = K\ tn$

Where, Mt/ M∞ is fraction of drug released at time 't', k represents a constant, and 'n' is the diffusional exponent, which characterizes the type of release mechanism during the dissolution process. For non-Fickian release, the value of n falls between 0.5 and 1.0; while in case of Fickian diffusion, n = 0.5; for zero-order release (case I I transport), n=1; and for supercase

II transport, n > 1. In this model, a plot of log (Mt/ M∞) versus log (time) is linear.

3. RESULTS AND DISCUSSION

3.1. Drug – Excipients compatibility studies

Fourier Transform-Infrared Spectroscopy: There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions. Silymarin also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug.

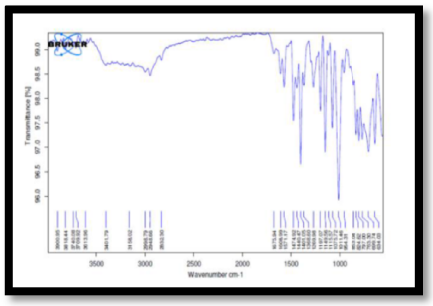


Fig 1: FTIR OF PURE DRUG

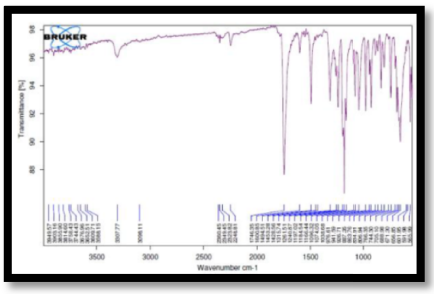


Fig 2: FTIR OF OPTIMIZED FORMULATION

3.2 Determination of absorption maxima: The standard curve is based on the spectrophotometer. The maximum absorption was observed at 288nm. Calibration curve given in Figure 1.

Table 4: Observations for graph of Silymarin in 0.1N HCL

Concentration (µg/ml)	Absorbance(nm)
0	0
2	0.119
4	0.222
6	0.339
8	0.447
10	0.556

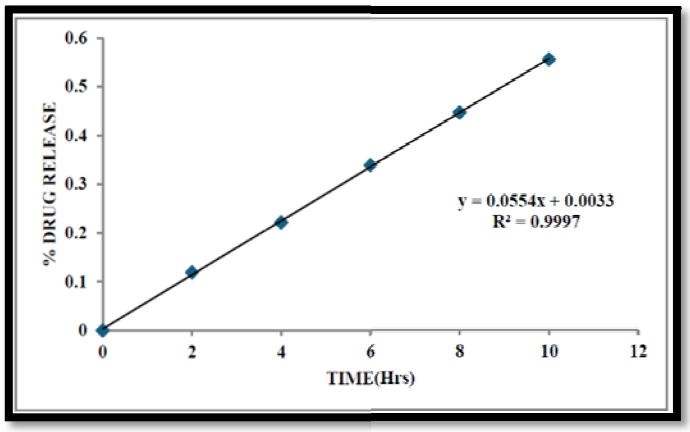


Fig 3 Calibration Graph of Silymarin in 0.1N HCL (pH 1.2)

Standard graph of Silymarin was plotted as per the procedure in experimental method and its linearity is shown in Table 8.1 and Fig 8.1. The standard graph of Silymarin showed good linearity with R2 of 0.999, which indicates that it obeys "Beer- Lamberts" law.

Table 5: Pre-formulation parameters of powder blend:

Formulation Code	Angle of Repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's Ratio
S1	21.22±0.62	0.445±0.067	0.487±0.065	8.62±0.15	1.094±0.46
S2	22.24±0.59	0.421±0.048	0.478±0.055	11.92±0.76	1.135±0.86
S3	21.12±0.58	0.417±0.075	0.471±0.054	11.46±0.45	1.129±0.62
S4	23.21±0.74	0.470±0.015	0.502±0.065	6.37±0.26	1.068±0.54
S5	22.92±0.38	0.425±0.025	0.485±0.025	12.37±0.35	1.141±0.19
S6	29.94±0.47	0.578±0.046	0.620±0.035	6.77±0.75	1.072±0.23
S7	27.33±0.56	0.570±0.035	0.616±0.065	7.46±0.36	1.087±0.59
S8	26.97±0.43	0.530±0.054	0.598±0.054	11.37±0.45	1.122±0.48

Fig 4 Floating Time of Formulations S1-S9.

Table 6: Dissolution data of Floating tablets -In vitro drug release studies

Time	% OF DRUG RELEASE								
(H)	S1	S2	S3	S4	S5	S6	S7	S8	S9
0	0	0	0	0	0	0	0	0	0
1	18.59	20.21	19.82	16.18	19.95	25.19	27.45	21.34	18.63
2	21.67	23.78	20.71	25.99	23.21	32.57	29.17	26.68	22.51
3	23.13	27.04	25.38	33.67	29.17	37.83	33.28	29.19	27.28
4	26.05	37.65	27.05	41.25	37.86	42.95	37.09	34.58	31.76
5	37.39	41.11	36.91	52.91	41.51	49.61	44.37	42.12	39.42
6	46.51	43.81	39.72	58.47	45.99	56.27	48.42	49.35	42.71
7	49.98	47.14	49.29	63.06	56.71	61.08	57.91	61.99	55.87
8	52.37	53.23	57.22	69.52	62.52	72.89	63.89	67.02	61.99
9	56.18	59.94	62.41	74.51	72.97	79.46	74.12	71.58	66.25
10	71.31	61.07	69.03	78.07	79.38	85.84	81.57	78.71	72.36
11	79.69	76.61	82.11	83.13	88.24	92.51	89.36	84.09	79.83
12	91.37	89.12	92.32	92.86	95.51	99.43	94.55	91.31	89.11

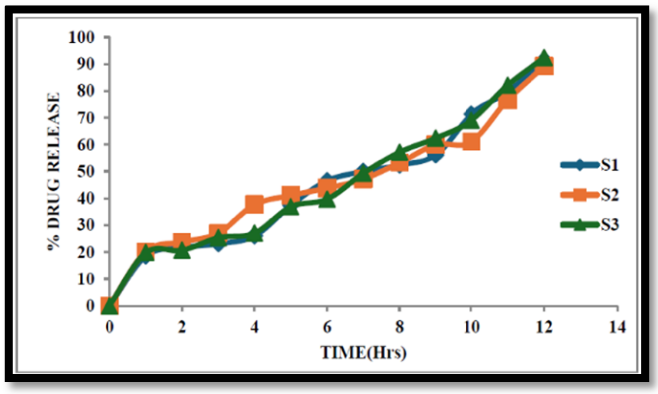


Fig 5: Dissolution profile data of formulations (S1-S3) containing Eudragit RSPO polymer

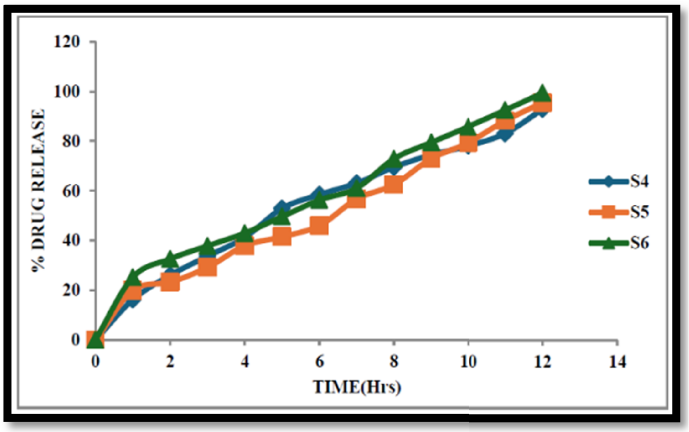


Fig 6: Dissolution profile data of formulations (S4-S6) containing HPMC K100

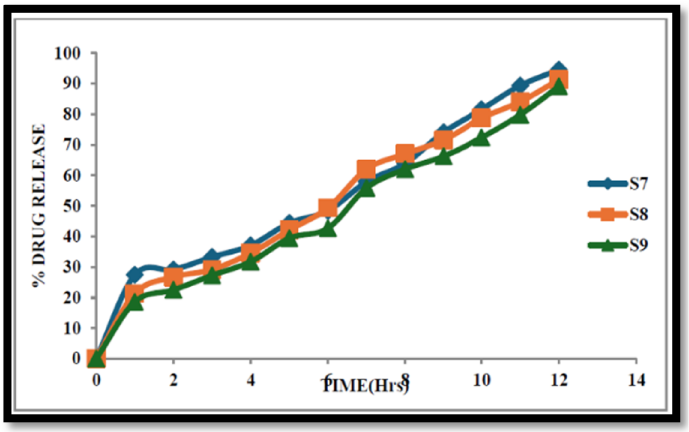
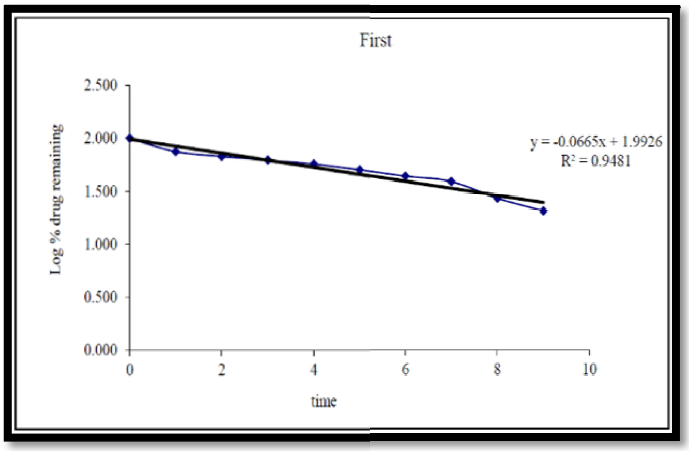
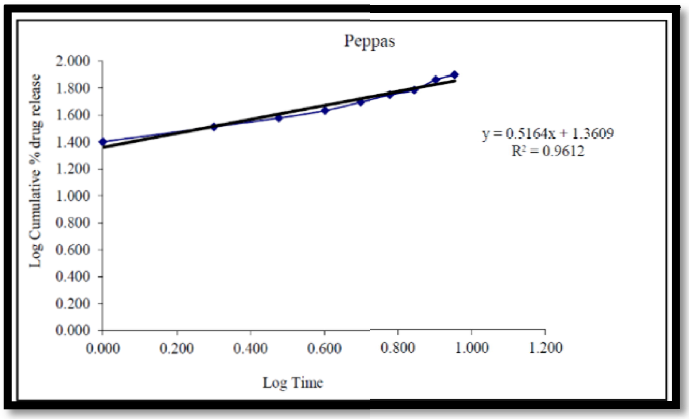


Fig 7: Dissolution profile data of formulations (S7-S9) containing chitosan.

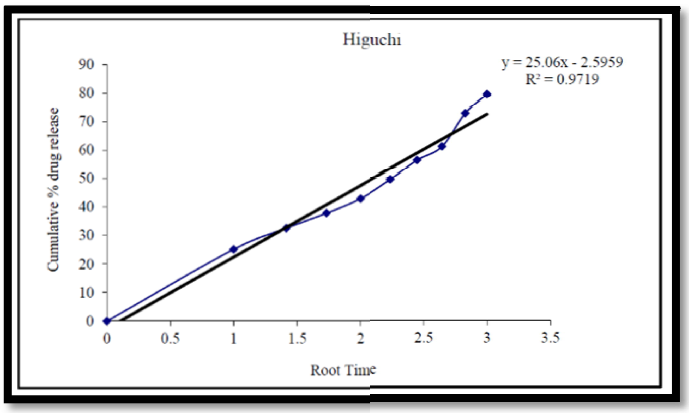
All the formulations prepared with Eudragit RSPO (S1-S3) retarded the drug release up to 12 hours and showed maximum of 92.32 %. Whereas the formulations (S4-S6) prepared with HPMC K 100 retarded the drug release up to 12 hours and showed maximum of 99.43% and the formulations (S7-9) prepared with Chitosan showed retarded the drug release up to 12 hours and showed maximum of 94.55% in 12 hours with good retardation. Hence from the above dissolution data it was concluded that S6 formulation was considered as optimized formulation because good drug release (99.43%) in 12 hours. Optimised formulation S6 was kept for release kinetic studies. From the above graphs it was evident that the formulation S6 was followed Higuchi release kinetics mechanism.



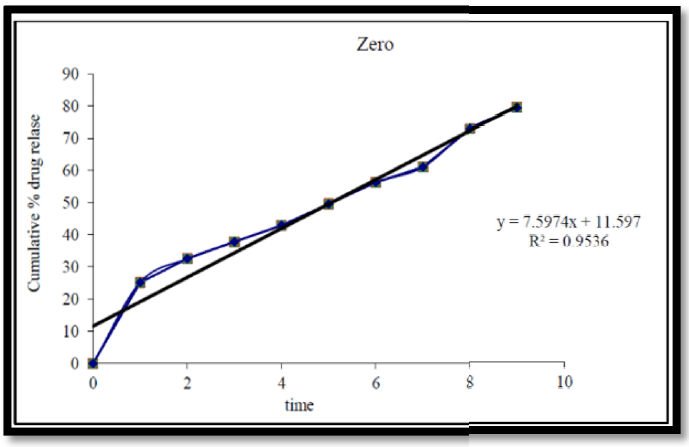
(a)



(b)



(c)



(d)

Fig 8 (a-c) Drug Release Kinetic graphs of Optimized Formulation S6.

CONCLUSION

The formulated and evaluations studies performed on floating type of solid oral gastroretentive dosage forms have showed acceptable results compiling with I.P standards for solid oral dosage forms. with the in-vitro release studies and kinetic release studies the drug release followed Higuchi model suggesting a sustained effect and post compression evaluations study report the objective of enhancing the Silymarin drug bioavailability gastroretention has been achieved with the hydrogel polymers HPMC and Guar gum.

References:

1. Streubel A, Siepmann J, Bodmeier R. Gastroretentive drug delivery system. Expert Opin Drug Deliv, 2006; 3(2): 217- 33.

2. Garg R, Gupta GD. Progress in controlled gastroretentive delivery systems. Trop. J Pharm Res, 2008; 7(3): 1055-66.

3. Rouge N, Allemann E, Gex-Fabry M, Balant L, Cole ET, Buri P, Doelker E. Comparative pharmacokinetic study of a floating multiple-unit capsule, a high density multipleunit capsule and an immediate-release tablet containing 25 mg atenolol. Pharm Acta Helbetiae, 1998; 73: 81-7.

4. Streubel A, Siepmann J, Bodmeier R. Multiple unit Gastroretentive drug delivery: a new preparation method for low density microparticles. J Microencapsul, 2003; 20: 329-47.

5. Goole J, Vanderbist F, Aruighi K. Development and evaluation of new multiple-unit levodopa sustained-release floating dosage forms. Int J Pharm, 2007; 334: 35-41.

6. Shrma S, Pawar A. Low density multiparticulate system for pulsatile release of meloxicam. Int J Pharm, 2006; 313: 150-58.

7. Santus G, Lazzarini G, Bottoni G, Sandefer EP, Page RC, Doll WJ, Ryo UY, Digenis GA. An in vitro- in vivo investigation of oral bioadhesive controlled release furosemide formulations. Eur J Pharm Biopharm 1997; 44: 39-52.

8. Klausner EA, Lavy E, Friedman M, Hoffman A. Expandable gastroretentive dosage forms. J Control Release 2003; 90: 143-62.

9. Deshpande AA, Shah N, Rhodes CT, Malik W. Development of a novel controlled-release system for gastric retention. Pharm Res 1997; 14: 815-19.

10. Park K. Enzyme-digestible swelling as platforms for longterm oral drug delivery: synthesis and characterization. Biomaterials 1988; 9: 435.

11. Fujimori J, Machida Y, Nagai T. Preparation of a magneticallyresponsive tablet and configuration of its gastric residence in beagle dogs. STP Pharma Sci 1994; 4: 425-30.

12. S.U. Zate, P.I. Kothawade, G.H. Mahale, K.P. Kapse, S.P. Anantwar. Gastroretentive Bioadhesive Drug Delivery System: A Review. International Journal of PharmTech Research Res. 2(2); 2010: 1227-1235.

13. Desai S, Bolton S. A floating controlled release drug delivery system: in vitro- in vivo evaluation.Pharm Res.1993;10:1321-1325. PubMed DOI: 10.1023/A:1018921830385.

14. Singh BN, Kim KH. Floating drug delivery systems: an approach to oral controlled drug delivery via gastric retention. J Control Release. 2000;63:235-259. PubMed DOI: 10.1016/S0168-3659(99)00204-7.

15. Arrora S, Ali J, Khar RK, Baboota S. Floatng drug delivery systems: A review. AAPS Pharm Sci Tech 2005; 6(3): 372-90.

16. Mojaverian P, Vlasses PH, Kellner PE, Rocci Jr ML. Effects of gender, posture and age on gastric residence time of an indigestible solid: Pharmaceutical considerations. Pharm Res 1988; 10: 639-44.

17. Banker GS, Rhodes CT.Modern Pharmaceutics.3rd ed.: Marcel Dekker; New York 1996. 678-721.

18. Howard C.Ansel "Pharmaceutical Dosage Form and Drug Delivery Systems", (7th edition), 229-243.

19. Debjit Bhowmik, Chiranjib.B, Margret Chandira, B. Jayakar, K.P.Sampath Kumar. Floating Drug Delivery System: A Review. Der Pharmacia Lettre. 1(2); 2009: 199-218.

20. Vinod K.R., Santhosh Vasa, Anbuazaghan S, David Banji1, Padmasri A, Sandhya S. Approaches for Gastroretentive Drug Delivery Systems. 1(2); 2010: 589-601.

21. Hilton AK, Deasy PB. In vitro and in vivo evaluation of an oral sustained release floating dosage form of amoxicillin trihydrate. Int J Pharm 1992; 86: 79-88.

22. Garg R, Gupta GD. Progress in controlled gastroretentive delivery systems. Trop. J Pharm Res 2008; 7(3): 1055-66.

23. Whiteland L, Fell JT, Collett JH. Development of gastroretentive dosage form. Eur J Pharm Sci 1996; 4(suppl.): S182.

24. Badoni A, Gnanarajan G, Ojha A. Review on gastro retentive drug delivery system. The Pharma Innovation 2012; 1:32-42.

25. Mishra V, Singh A. Gastroretentive drug delivery system. International Journal of Pharmaceutical & Research Sciences 2013; 2:779-793.

26. Vinod et al. Approaches for gastrotentive drug delivery system. International Journal of Applied Biology and Pharmaceutical Technology 2010; 1:589-601.

27. Bhowmik D. Floating drug delivery system- A review. Der Pharmacia Lettre 2009; 1:199-218.

28. Sharma Ankur Raj, Khan Afroz. Gastroretentive Drug Delivery System: An Approach to Enhance Gastric Retention for Prolonged Drug Release. IJPSR 2014; 5(4):1095-1106.

29. Nayak KP, Upadhyay P. Gastroretentive drug delivery systems and recent approaches: A review. Journal of Pharmaceutical Research and Opinion 2012; 2:1-8.

30. Kagan L, Hoffman A. Selection of drug candidates for gastroretentive dosage forms: Pharmacokinetics following continuous intragastric mode of administration in a rat model. European Journal of Pharmaceutics and Biopharmaceutics 2008; 69:238–246.

31. Reddy BV, Navaneetha K. Gastroretentive drug delivery system- A review. Journal of Global Trends in Pharmaceutical Sciences 2013; 4:018-1033.

32. Vasa S, Banji D. Approaches for gastrotentive drug delivery systems. International Journal of Applied Biology and Pharmaceutical Technology 2010; 1:589-601.

33. Ishwarya Vinod Ghadge, Sakshi Anna Gharat, Swapnil Dilip Phalak, Vishal Sharad Bodke. Formulation and evaluation of floating tablet of esomeprazole by using natural gums. May 2024 World Journal of Advanced Research and Reviews 22(2):1895-1907.

How to cite this article:
Sushma Desai*, FORMULATION AND IN VITRO EVALUATION OF SILYMARIN GASTRORETENTIVE FLOATING TABLET
J Pharma Res, 2026; 15(04): 26-34. DOI: https://doi.org/10.5281/zenodo.22098401

Conflict of interest: The authors have declared that no conflict of interest exists.
Source of support: Nil

