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Research Article

Formulation And Evaluation of Floating Drug Delivery System of Benazepril

Divyashree P.[1], Nagendra R.[2], Nanditha V. V.[3], Venkatesh[4], K. Hanumanthachar Joshi[5]

[1,2,3,4]*Department of Pharmaceutics, Sarada Vilas College of Pharmacy Mysuru, Karnataka, India.*
[5]*Department of Pharmacognosy, Sarada Vilas College of Pharmacy Mysuru, Karnataka, India*

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ABSTRACT

The research focuses on developing a floating drug delivery system for Benazepril, aimed at enhancing its absorption and prolonging gastric residence time, thereby improving bioavailability. Floating drug delivery systems (FDDS) maintain buoyancy in gastric fluids, allowing for extended action and reduced dosing frequency. The formulation of floating tablets utilized Carbopol 940, Guar gum, and HPMC K100M as polymers through direct compression, resulting in nine Formulations (F1-F9). Preformulation parameters adhered to pharmacopoeial standards, and FTIR studies confirmed no incompatibility between the drug and polymers. Post-compression evaluations included weight variation, hardness, friability, thickness, drug content, in vitro buoyancy, and dissolution studies. The micromeritic properties were satisfactory, with formulation F9 exhibiting optimal in vitro buoyancy lag time and floating duration. This Formulation F9 achieved a 98.3% drug release over 12 hours, demonstrating superior control over the release rate compared to others. Stability data indicated no significant changes in parameters over time. Therefore, Formulation F9 is recognized as stable and effective in significantly increasing gastric residence time for Benazepril, thus enhancing its bioavailability.

INTRODUCTION

Tremendous advances have been seen in oral controlled drug delivery systems in the last two decades. In the development of oral controlled drug delivery system, one of the main challenges is to modify the GI transit time. Gastric emptying of pharmaceuticals is highly variable and is dependent on the dosage form and the fed/fasted state of the stomach. Normal gastric residence times usually range between 5 minutes and 2 hours. Drugs having a short half-life are eliminated quickly from the blood circulation. Various oral

***Corresponding Author:** Nagendra R.
Address: *Department of Pharmaceutics, Sarada Vilas College of Pharmacy Mysuru, Karnataka, India*
Email : nagendrar16@gmail.com
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controlled delivery systems like gastro retention dosage forms have been designed to overcome this problem and release the drug to maintain its plasma concentration for a longer period of time.[1] It includes various advantages like, the principle of HBS can be used for any particular medicament or class of medicament. The HBS formulations are not restricted to medicaments, which are principally absorbed from the stomach. The HBS are advantageous for drugs absorbed through the stomach e.g. ferrous salts and for drugs meant for local action in the stomach and treatment of peptic ulcer disease e.g. antacids. The efficacy of the medicaments administered utilizing the sustained release principle of HBS has been found to be independent of the site of absorption of the particular medicaments.[2] Formulation of floating drug delivery system for antihypertensive medications is of great use in the case of drugs with lower bioavailability. Nowadays, a variety of methods have been employed to extend the residency period, including systems that expand and swell, polymeric bioadhesive systems, self modified form systems etc. Benazepril is an ACE Inhibitor used to treat high blood pressure and heart failure. It is primarily dissolved and absorbed from the upper part of the GI tract. Hence, the main objective of this study is to formulate and evaluate Benazepril floating tablets which will remain buoyant in the stomach for an extended period thereby increasing the bioavailability and improved therapeutic effect.[3]

MATERIALS AND METHODS:

Benazepril, a gift sample from Yarrow chem Mumbai, HPMC K100M and Carbopol 940 Obtained from Otto Chemika-Biochemika reagents Mumbai, Guar gum obtained from Loba Chemie Pvt Ltd Mumbai. All other the chemicals were of analytical grade.

Formulation Development of Benazepril Floating Tablets:

Table 1: Formulation trails of Benazepril floating tablets (F1 – F9)

Sl.no	INGREDIENTS	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Benazepril	200	200	200	200	200	200	200	200	200
2	Carbopol 940	50	100	150	-	-	-	-	-	-
3	Guar gum	-	-	-	50	100	150	-	-	-
4	HPMC K100M	-	-	-	-	-	-	50	100	150
5	Sodium bicarbonate	80	80	80	80	80	80	80	80	80
6	Magnesium stearate	5	5	5	5	5	5	5	5	5
7	Talc	5	5	5	5	5	5	5	5	5
8	Lactose	140	90	40	140	90	40	140	90	40
9	Citirc acid	20	20	20	20	20	20	20	20	20
Total weight in mg		500	500	500	500	500	500	500	500	500

Direct compression was used to prepare nine formulations of floating drug delivery systems (FDDS) for Benazepril, labeled F1 to F9. All ingredients were (Table 1) accurately weighed, and the drug was mixed with polymers and excipients in ascending order of weight. The mixture was blended for 20 minutes for uniformity, followed by a brief 1-minute mixing with magnesium stearate for lubrication. Finally, 500 mg of the powder mix was accurately weighed and compressed using a single punch machine with 12 mm flat-surface punches.

Preformulation studies:

FTIR study:[4]

FTIR was used to identify if there is any drug excipient interaction. FTIR studies were

performed on drug, polymer and optimized formulation. Samples were analyzed by potassium bromide pellet method in an IR spectrophotometer in the region between 4000-400 cm^{-1}.

Standard curve of Benazepril:[5]

A Standard Solution of Benazepril was prepared by dissolving accurately weighed 100 mg of Benazepril with little quantity of 0.1N HCl solution, in a 100 ml volumetric flask. The volume was made up to 100 ml with 0.1N HCl, to obtain a stock solution of 1000µg/ml. From the above solution several dilutions are made to obtain 2, 4, 6, 8, 10 (µg/ml) solutions. The absorbance of the drug solutions were estimated at λ_{max} 242nm.

Precompression parameters of powder blends:

1. **Angle of repose:**[6]

Angle of repose is defined as the maximum angle possible between the surface of the pile of powder and the horizontal plane. The angle of repose is designated by θ. It was determined by funnel method. The powder blend was passed through funnel so that it forms a pile. The height (h) of the pile and the radius of the pile (r) were measured and angle of repose was calculated using following formula

$\theta = \tan^{-1}(h/r)$

2. **Bulk density & Tapped density:**[7]

Bulk and tapped densities were measured by using 10 ml of graduated cylinder. The sample poured in cylinder was tapped mechanically for 100 times, then tapped volume was noted down and bulk density and tapped density were calculated using following formula,

$$Bulk\ Density = \frac{Mass\ of\ powder}{Volume\ of\ powder(Bulk)}$$

$$Tapped\ Density = \frac{Mass\ of\ powder}{Volume\ of\ powder(Tapped)}$$

3. **Compressibility index:**[8]

CI of the powder was determined from the bulk and tapped density as follows,

$$Percentage\ Compressibility\ index = 100 \times \frac{Tapped\ density - Bulk\ density}{Tapped\ density}$$

4. **Hausner's ratio:**

It was calculated as,

$$Hausner's\ ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

Post-Compression Evaluation:

1. **Weight variation test**:[9]

20 tablets were chosen at random and each one was weighted. It was determined what the typical tablet weighed. The variations between the individual tablet weights and the average weight were compared.

2. **Thickness** :

Thickness of the tablet was measured by using vernier caliper. Tablet thickness should be controlled within a ± 5% variation of standard value. Thickness values were expressed in millimetre.

3. **Hardness test:**[10]

Tablet hardness has been defined as the force required for breaking or cracking or crushing a tablet in a diametric compression test. A tablet was placed in between two anvils of the hardness tester (Monsanto type), force was applied to the anvils and the crushing strength that caused the tablet to break was recorded.

4. **Content uniformity:**[11]

It is the quantity that is contained in each formulation for tablets. Tablets from the formulation were taken and dropped into a beaker of 100ml 0.1N HCl. The same sample (approximately 1ml) was removed after 24 hours or when the medication has entirely been released, diluted to 10 ml with 0.1N HCL, and the absorbance was measured at 242nm using a UV spectrometer. Calculations of drug release were made using the usual graph.

5. **Friability:**[12]

A sample of pre weighted 20 tablets was placed in Roche friabilator which was then operated for 100

revolutions i.e. 4 mins. The tablets were then dusted and reweighed. Percent friability (%F) was calculated as follows, % F= (loss in weight / initial weight) x 100.

6. Swelling Index:[13]

0.1 N HCl solution having pH 1.2 was used to determination of the swelling index of tablets at room

at room temperature. Weight of the tablets after the swollen was determined at specific time intervals. The Swelling index was calculated using following formula,

$$\text{Swelling index} = \frac{W_t - W_0}{W_0}$$

Where, W_0= initial weight of tablet, W_t = weight of the tablet in t (time)

7. *In-vitro* Buoyancy Study:[14]

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 the duration of the time the tablet constantly floats on the dissolution medium was noted as the Total Floating Time respectively

(TFT).

8. *In-vitro* Dissolution Study:[15]

Benazepril floating tablets were kept in a 0.1N HCl (900 ml) dissolution buffer for the first two hours while being run at a temperature of 37°C and 50 rpm. Then, as a dissolving medium, 900 ml of pH 6.8 phosphate buffer was utilised. Always use freshly produced dissolving medium. The usage of paddle devices. Every 2, 4, 6, 8, 10 and 12 hours , 10ml of the dissolution medium were pipetted out and the volume was changed by substituting 10 ml of 0.1N HCl or pH 6.8 phosphate buffer. At 242nm, a UV spectrometer was used to evaluate the samples that were gathered.

9. Stability studies:[16]

The optimized formulation were packed in aluminium pouch and subjected to accelerated stability studies at 40±2°C/75%RH for a period of three months. Samples from the formulation which were kept for examination and withdrawn at definite time intervals and evaluated for their drug release and drug content.

Results and Discussion:

FTIR studies:

Drug polymer compatibility studies were carried out using Fourier Transform Infra Red spectroscopy to establish or rule out any possible interaction of Benazepril with the polymers used in the formulation. The FT-IR spectra of the formulations were compared with the FT-IR spectra of the pure drug. The results are shown in fig 1-4, indicating that the characteristic absorption peaks due to pure Benazepril have appeared in the formulated tablets, without any significant change in their position after successful formulation, indicating the absence of any chemical interaction between Benazepril and Polymers.

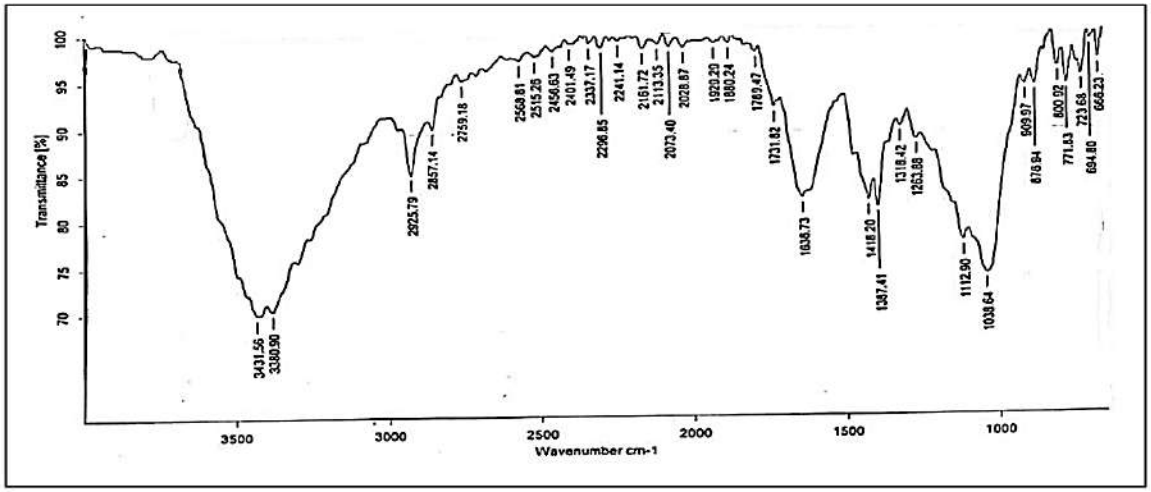

Figure 1 : FTIR Spectra of Benazepril

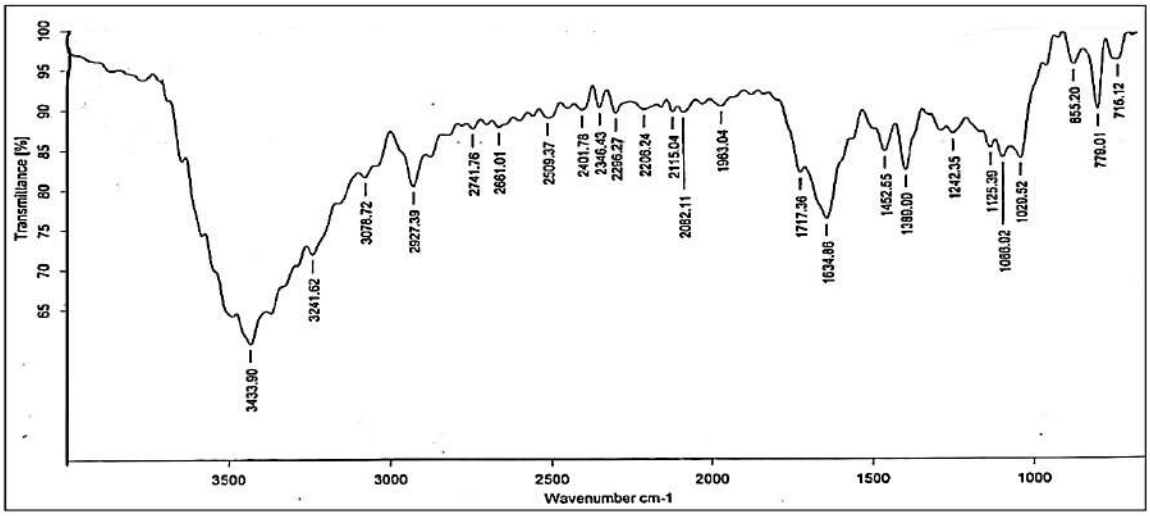

Figure 2 : FTIR Spectra of Benazepril + Carbopol 940

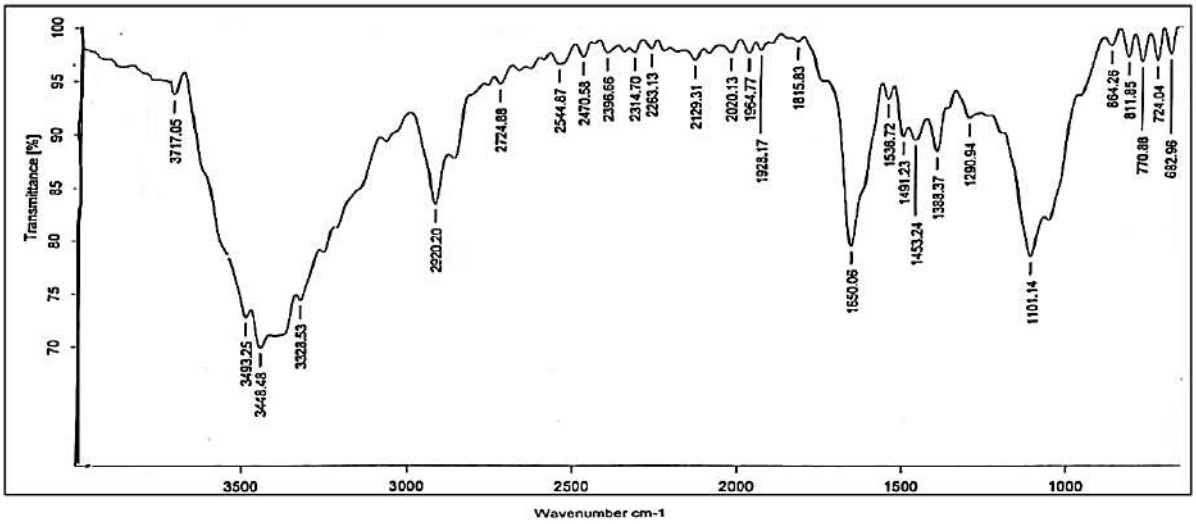

Figure 3: FTIR Spectra of Benazepril + Guar gum

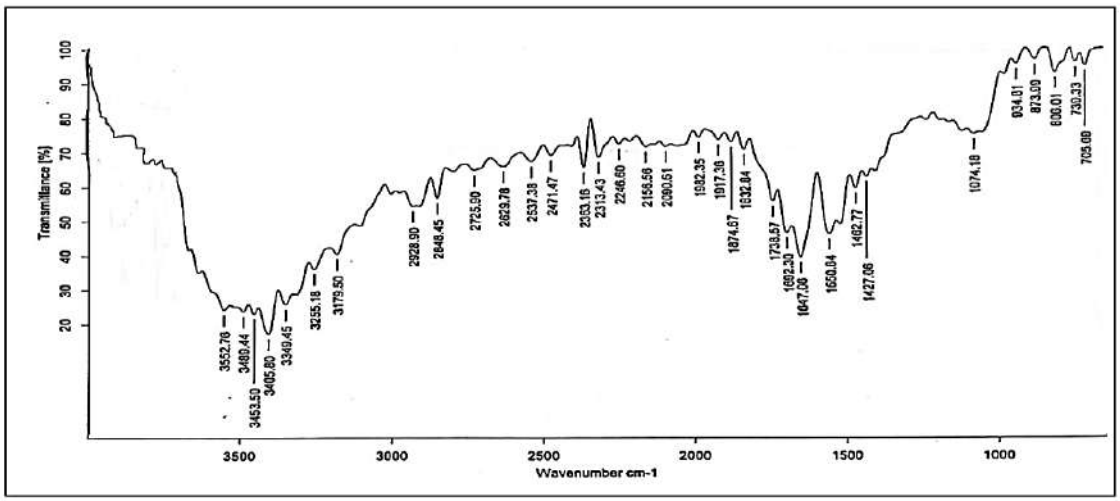

Figure 4: FTIR Spectra of Benazepril + HPMC K100M

Table 2: FTIR absorption spectra of different functional groups of drug and drug polymer mixture

Functional group	Drug (cm^{-1})	Drug+Carbopol 940	Drug+ Gaur gum	Drug+ HPMC K100M
Acid O-H stretching	3431.56	3433.90	3443.48	3453.50
N-H stretching	2925.79	2927.39	2920.20	2928.90
C-H stretching	2759.18	2741.76	2724.88	2725.90
C-N stretching	2456.63	2401.78	2470.58	2471.47
Acid C=O stretching	1731.82	1717.36	1735.45	1738.57

Standard graph of Benazepril:

Standard calibration curve of Benazepril was drawn by plotting absorbance v/s concentration. The λ_{max} of Benazepril in 0.1N HCl was determined to be 242 nm as shown in Figure 5. The absorbance values are tabulated in Table 3. It was found that the solution of Benazepril in methanol show linearity (R^2 =0.9989) in absorbance at concentration of 2-10(µg/ml) and obey Beer Lamberts Law.

Table 3: Standard plot of Benazepril

Concentration (µg/ml)	Absorbance
0	0
2	0.195±0.003
4	0.420±0.001
6	0.615±0.001
8	0.801±0.002
10	0.986±0.002

All values represented as mean ± standard deviation (n=3)

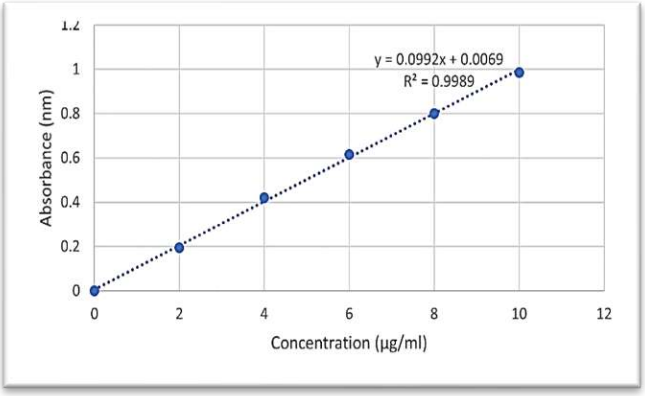

Figure 5: Standard Calibration curve of Benazepril

Precompression parameters of powder blends:

The prepared blend of the formulations was evaluated for the parameters like Angle of repose, Bulk density, Tap density, Compressibility

index and Hausner's ratio. After the addition of glidants. The results have shown in the table 4.

Table 4: Characteristics of final blend of Benazepil Floating tablets.

Formulations Code	Angle of repose (θ)	Bulk density (g/ml)	Tapped density (g/ml)	Compressibility index (%)	Hausner's ratio
F1	$22.17^0 \pm 0.15$	0.515 ± 0.15	0.522 ± 0.08	13.15 ± 0.24	1.10 ± 0.17
F2	$26.11^0 \pm 0.12$	0.471 ± 0.11	0.476 ± 0.12	16.23 ± 0.64	1.21 ± 0.18
F3	$25.31^0 \pm 0.23$	0.505 ± 0.05	0.527 ± 0.15	14.26 ± 0.24	1.15 ± 0.15
F4	$23.31^0 \pm 0.14$	0.519 ± 0.13	0.522 ± 0.02	12.36 ± 0.33	1.09 ± 0.14
F5	$24.27^0 \pm 0.22$	0.492 ± 0.21	0.497 ± 0.03	17.42 ± 0.28	1.12 ± 0.12
F6	$24.67^0 \pm 0.15$	0.481 ± 0.16	0.511 ± 0.14	18.09 ± 0.33	1.07 ± 0.16
F7	$25.71^0 \pm 0.13$	0.515 ± 0.14	0.522 ± 0.06	13.15 ± 0.22	1.10 ± 0.10
F8	$23.31^0 \pm 0.16$	0.522 ± 0.13	0.519 ± 0.02	12.36 ± 0.32	1.09 ± 0.11
F9	$26.21^0 \pm 0.11$	0.496 ± 0.16	0.499 ± 0.03	17.42 ± 0.28	1.12 ± 0.18

All values represented as mean ± standard deviation (n=3)

The pre- compression parameters obtained for all formulations was tableted in the table 5 . The value of angle of repose was found to be in the range of $22.17^0 \pm 0.15$ to $26.21^0 \pm 0.12$. This indicates good flow property of powder blend. The bulk density and tapped density values ranged from 0.471±0.11 to 0.522±0.13 g/ml for bulk density and 0.476±0.12 to 0.527±0.15 g/ml for tapped density respectively So, it shows that all formulations having good flow properties and packability. The values of Compressibility Index & Hausner's ratio ranged from 12.36 and 18.09 % and 1.07 and 1.21, respectively. This showed that the powder combination has good flow properties and hence all parameters were within the limit as per IP specifications.

Post-Compression Evaluation:

The prepared floating tablets were evaluated for Average weight variation, Hardness, Friability, Drug content and Thickness all the studies were performed and the results have shown in the table 5.

Table 5: Post compression of Benazepril floating tablets

Formulations Code	Average weight (mg)	Hardness (kg)	Friability (%)	Drug content (%)	Thickness (mm)
F1	500.4 ± 0.12	5.9 ± 0.26	0.59±0.15	99.98 ± 0.18	4.13± 0.34
F2	500.2 ± 0.22	6.2 ± 0.25	0.68±0.12	99.21 ± 0.20	4.91 ± 0.23
F3	499.6 ± 0.24	6.3 ± 0.21	0.58±0.17	99.67 ± 0.12	4.84 ± 0.14
F4	500.3 ± 0.31	5.9 ± 0.23	0.59±0.15	99.32 ± 0.14	4.88 ± 0.21
F5	500.6 ± 0.21	6.3 ± 0.13	0.62±0.19	99.65 ± 0.18	4.87 ± 0.21
F6	500.9 ± 0.23	6.1 ± 0.20	0.59±0.15	99.89 ± 0.22	4.34 ± 0.14
F7	500.2 ± 0.26	5.9 ± 0.26	0.68±0.12	99.21 ± 0.20	4.91 ± 0.23
F8	499.6 ± 0.18	6.2 ± 0.21	0.58±0.14	99.67 ± 0.12	4.84 ± 0.13
F9	500.2 ± 0.21	6.3 ± 0.25	0.68±0.12	99.21 ± 0.20	4.91 ± 0.23

All values represented as mean ± standard deviation (n=3)

The pre- compression parameters obtained for all formulations was tableted in the table 5. Tablet weights ranged from 499.6±0.18 to 500.9±0.23 in all formulations. The standard deviation was within 5% of the mean. The hardness of the formulated tablets ranged from 5.9±0.23 to 6.3±0.25, this ensures the good handling characteristics of all the batches. The range of

friability readings was 0.58±0.14 to 0.68±0.12, which was well within the limit. Benazepril concentration ranged from 99.21±0.20 % to 99.98±0.18 % in all tablets, which were within permissible levels. Tablet thickness was consistent, ranging from 4.91 ± 0.23 to 4.13± 0.34 mm. The results showed that the thickness of all formulated tablets was found to be uniform. Based on the results obtained from all post compression parameters all the formulations were in within the limits as per the IP.

Swelling Index:

The Percentage swelling index of all formulations results were given in table 6 and graphically shown in Figure 6.

Table 6: Swelling index (%) of Formulations

Time (hrs)	Formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	26.6±0.1	23.3±0.4	22.8±0.1	40.7±0.3	37.2±0.2	36.4±0.4	17.8±0.3	19.4±0.3	22.1±0.2
2	87.4±0.3	74.7±0.6	41.2±0.4	73.2±0.3	74.5±0.1	68.1±0.2	34.7±0.1	36.1±0.6	36.5±0.1
4	158.8±06	149.7±02	65.7±0.6	163.7±0.4	160.3±0.2	130.7±0.4	59.4±0.2	64.2±0.4	72.3±0.6
6	-	154.5±03	114.8±01	-	-	154.2±0.1	89.2±0.1	98.2±0.2	112.7±0.2
8	-	-	133.4±0.1	-	-	-	122.3±0.4	114.5±0.1	128.7±0.1
10	-	-	-	-	-	-	-	126.9±0.6	132.3±0.4
12	-	-	-	-	-	-	-	-	135.1±0.1

All values represented as mean ± standard deviation (n=3)

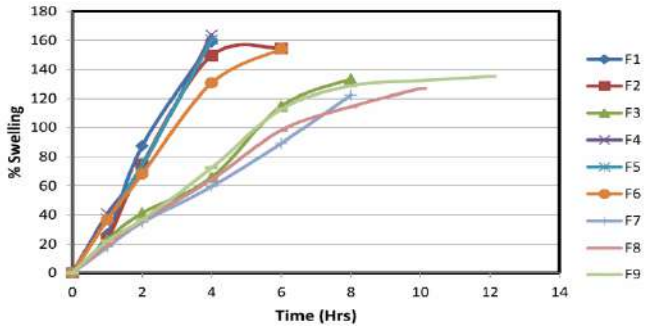

Figure 6: Graph for comparison of swelling index of all the formulation

Swelling index for all the formulations was carried out in the 0.1N HCl. The formulations showed different indices in the swelling media and it is shown in the table 6. Tablets containing HPMC K100M (F9) showed maximum swelling in 12 hr with sharp increase up to 8 hr this may due to increased concentration of HPMC K100M which retain water and form thick swollen mass.

***In-vitro* buoyancy studies:**

All the formulations were tested for floating properties like Floating lag time and Floating duration. The results of the *In vitro* buoyancy study were shown in table 7.

Table 7: Buoyancy studies of Formulations

Formulations code	Floating lag time (sec)	Floating duration (hrs)
F1	52.2±0.4	4.5±0.1
F2	58.1±0.2	6.1±0.4
F3	76.3±0.1	8.2±0.5
F4	29.2±0.5	4.5±0.2
F5	36.4±0.1	5.2±0.6
F6	34.6±0.3	6.5±0.2
F7	34.1±0.2	9.1±0.1
F8	32.4±0.6	10.1±0.2
F9	39.2±0.1	12.0±0.4

All values represented as mean ± standard deviation (n=3)

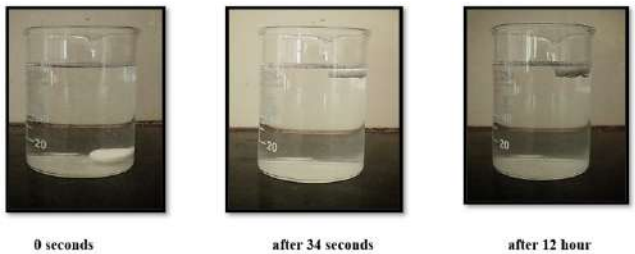

Figure 7: In vitro buoyancy studies of optimized Formulation

The *In-vitro* floating behavior of the tablets was studied by placing them in beaker containing 0.1 N HCl (pH 1.2). The gas generating agents immediately evolves carbon dioxide in presence of

HCl solution generating sufficient porosity which helped the dosage unit to float. Formulation F1-F3 prepared with carbopol 940 started floating after 52.2 seconds and remains buoyant for 8 hr till they were completely eroded. On the other hand formulation F4-F6 prepared with Guar gum which shows a floating time of 6.5 hrs and formulation of F7-F9 prepared with HPMC K100M show decrease in floating lag time to 34 seconds and increased floating duration time to 12 hrs. This might be due to high viscosity polymer HPMC K100M maintains the integrity of the tablets for longer duration by reducing the effect of erosion thus resulting in increase in floating time. The results are shown in table 7. Thus it can be concluded that the batch containing HPMC polymers showed good floating lag time and total floating time.

In-Vitro drug release studies:

In-vitro drug release studies were carried out using USP dissolution apparatus II at 50 rpm. The dissolution medium consisted of 900 ml of pH 1.2 acid buffer (0.1N HCl), maintained at 37.5ºC . The drug release at different time intervals was measured using an uv spectrophotometer at 242 nm.

Table 8: *In-vitro* dissolution test of Benazepril Floating tablet.

Time (hrs)	Formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	24.8±0.4	22.9±0.3	20.6±0.1	38.3±0.2	32.2±0.1	27.5±0.3	23.4±0.1	22.4±0.2	18.8±0.4
2	58.1±0.2	55.2±0.5	48.2±0.8	62.1±0.4	45.3±0.3	41.1±0.6	39.8±0.3	31.1±0.1	24.1±0.7
4	96.5±0.1	71.1±0.8	69.1±0.3	98.1±0.7	94.1±0.2	76.7±0.2	67.8± 0.2	53.6±0.6	43.6±0.2
6	-	96.1±0.1	78.9±0.2	-	-	96.1±0.8	82.1±0.4	65.2±0.4	61.8±0.1
8	-	-	98.3±0.3	-	-	-	97.1±0.6	76.5±0.2	72.4±0.6
10	-	-	-	-	-	-	-	98.7±0.1	83.5±0.4
12	-	-	-	-	-	-	-	-	98.3±0.2

All values represented as mean ± standard deviation (n=3)

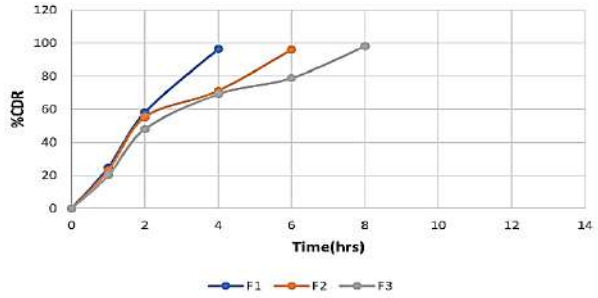

Figure 8: *In-vitro* dissolution profile of F1 to F3 Formulations

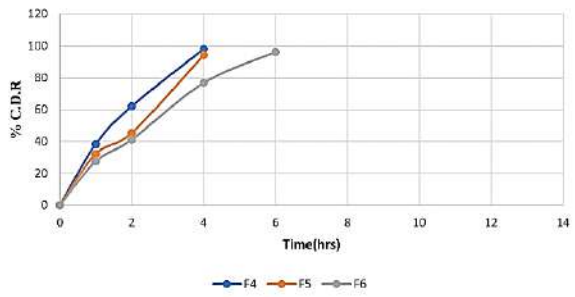

Figure 9: *In-vitro* dissolution profile of F4 to F6 Formulations

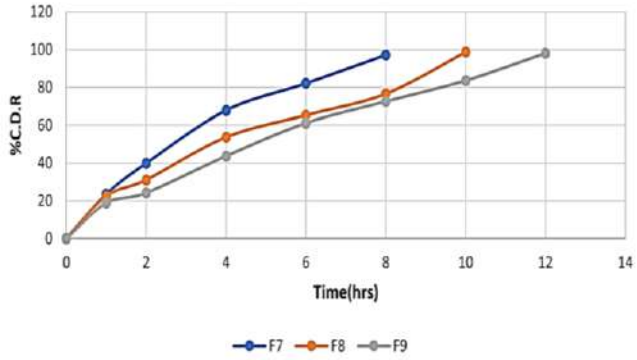

Figure 10: *In-vitro* dissolution profile of F7 to F9 Formulations

The drug release from the formulations F1-F3 prepared with Carbopol 940 was found to be 96.5, 93.1 and 98.3%, where as formulation F4- F6 prepared with Guar gum was found to be 98.1, 94.1, 96.1 at the end of 4 & 6 hours. Formulations F7-F9 prepared with HPMCK100M was found to be 97.1, 98.7, 98.3% showed reasonable drug release of formulation in F9. As per the results of dissolution study the formulations F1-F9 the drug

release was sustained for 4 to 12hr. In order to check the 100% dissolution release profile, formulations were subjected to dissolution studies for 12 hours. Among the nine formulations, F9 was best and shows 98.3% drug release in the end of 12 hours. It is evident from the *in-vitro* dissolution data that increase in HPMC K100M concentration decreases the release rate this might be due to increase in diffusional path length, which the drug molecule may have to travel. So, formulation F9 was selected as the optimized formulation. The results are shown in table 8.

Stability Studies:

Accelerated stability studies were carried out with optimized formulation (F9) with the conditions of 40° C ± 2° C / 75 % ± 5 % RH as per ICH guidelines over 3 months and determine the parameters like Drug content and *In-vitro* drug release of the tablets at specified time intervals (monthly once). The study results were shown in table 9 and there were no changes observed in Drug content, *In-vitro* drug release studies during storage of the optimized formulation and hence the optimized formulation was found to be stable.

Table 9: Stability studies with optimized Formulation

Test	Initial	1st month	2nd month	3rd month
Drug content (%)	99.21±0.2(%)	99.10±0.1(%)	99.09±0.2(%)	99.06±0.4(%)
In-vitro Drug release (%)	98.31±0.2(%)	98.28±1.2(%)	98.20±1.4(%)	98.01±0.6(%)

All values represented as mean ± standard deviation (n=3)

CONCLUSION

The study successfully developed a floating drug delivery system for Benazepril, enhancing its absorption and prolonging gastric residence time to improve bioavailability. Utilizing Carbopol 940, Guar gum, and HPMC K100M, nine formulations (F1-F9) were created via direct compression, adhering to pharmacopoeial standards. Formulation F9 exhibited optimal buoyancy and achieved a 98.3% drug release over 12 hours, demonstrating superior control over the release rate. Stability studies confirmed no significant changes in formulation parameters, indicating stability. This approach effectively increases gastric residence time, thereby enhancing Benazepril's bioavailability.

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