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Formulation and Evaluation of Gastroretentive Floating Tablets of Propranolol Hydrochloride

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Abstract

This study outlines a systematic framework for the design and evaluation of floating tablets containing Propranolol Hydrochloride, with the objective of enhancing the drug's bioavailability and therapeutic effectiveness. The tablets were prepared using the wet granulation technique to ensure sustained delivery of the active ingredient. Rapid gastrointestinal transit may lead to incomplete drug release from the delivery system before it reaches the absorption zone, which can result in decreased efficacy of the administered dose and, consequently, lower patient compliance. The gastroretentive floating tablets were specifically designed to provide the desired sustained and complete drug release over a prolonged period. Propranolol Hydrochloride gastroretentive floating tablets were formulated through the wet granulation method, utilizing different concentrations of Gellan Gum, Fenugreek Gum, and Karaya Gum. The optimized formulation (PF22) demonstrated a drug release of 99.17% over a 12-hour period, with a buoyancy lag time of 38 seconds. In vitro drug release kinetics were observed to follow both Zero order kinetics, and the potential mechanism for the release of Propranolol Hydrochloride from the optimized formulation may be ascribed to the super case II transport mechanism. The optimized formulation (PF22) exhibited no significant changes in physical appearance, drug content, floating lag time, or in vitro dissolution studies after being subjected to 75%±5% relative humidity at 40±2°C for a period of 6 months.

Keywords
Propranolol, Floating lag Time, Gastroretentive.

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INTRODUCTION

Propranolol Hydrochloride is a beta-adrenergic receptor antagonist used to treat hypertension. Propranolol Hydrochloride has a long duration of action as it is given once or twice daily depending on the indication. When patients abruptly stop taking propranolol Hydrochloride, they may experience exacerbations of angina and myocardial infarctions[1].

The process of gastric emptying for dosage forms is highly variable, and the capability to extend and regulate the emptying duration is a significant advantage for dosage forms that remain in the stomach longer than traditional dosage forms.

Designing controlled release systems to improve absorption and increase bioavailability presents several challenges [2, 3]. One such challenge is the difficulty in maintaining the dosage form within the targeted region of the gastrointestinal tract. The absorption of drugs from the gastrointestinal tract is a complex process influenced by numerous factors. It is well recognized that the degree of drug absorption in the gastrointestinal tract correlates with the duration of contact with the small intestinal mucosa. Therefore, the transit time in the small intestine is a crucial factor for drugs that are not fully absorbed. Controlled-release drug delivery systems (CRDDS) facilitate drug release at a specified, predictable, and regulated rate[4].

Various methods are presently employed to extend gastric residence times (GRT), such as floating drug delivery systems (FDDS), low-density raft systems that utilize alginate gels, bioadhesive or mucoadhesive systems, high-density systems, superporous hydrogels, and magnetic systems [5,6].

MATERIALS AND METHODS:

Materials:

The Propranolol Hydrochloride was obtained as a gift sample from splendid laboratories, Pune. Gellan Gum, Fenugreek Gum and Karaya Gum were obtained from Girijan Co-operative corp. Ltd, Hyderabad. Sodium bicarbonate, Citric acid, PVP-K30 was gifted from MSN Labs Ltd, Hyderabad. All other chemicals used were of analytical grade.

Methods:

Wet Granulation Method [6]

Floating tablets of Propranolol were formulated using the wet granulation method, incorporating varying concentrations of Gellan Gum, Fenugreek Gum, and Karaya Gum. All components were first sieved through a #85 mesh to achieve uniform particle size and thoroughly mixed. Granulation was performed using a binder solution composed of 5% PVP K30 in isopropyl alcohol. The resulting wet mass was then passed through a #12 mesh sieve and dried at 45°C for 2 hours. The prepared granules were finally compressed into tablets using a 9 mm flat-faced punch on a Cadmach tablet compression machine (Ahmedabad, India).

Table 1: Formulation trials of floating tablets of Propranolol using Fenugreek Gum

Ingredients (mg)	PF1	PF2	PF3	PF4	PF5	PF6	PF7	PF8
Drug	90	90	90	90	90	90	90	90
Fenugreek Gum	80	90	100	110	80	90	100	110
Sodium Bicarbonate	30	30	30	30	45	45	45	45
Citric acid	10	10	10	10	10	10	10	10
MCC	120	110	100	90	95	85	75	65
PVP K-30	10	10	10	10	10	10	10	10
Mg stearate	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5
Total weight	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**

MCC: Microcrystalline Cellulose; PVPK-30: Polyvinylpyrrolidone K-30.

Table 2: Formulation trials of floating tablets of Propranolol using Karaya Gum

Ingredients (mg)	PF9	PF10	PF11	PF12	PF13	PF14	PF15	PF16
Drug	90	90	90	90	90	90	90	90
Karaya Gum	75	85	95	105	75	85	95	105
Sodium Bicarbonate	30	30	30	30	45	45	45	45
Citric acid	10	10	10	10	10	10	10	10
MCC	125	115	105	95	85	75	65	55
PVP K-30	10	10	10	10	10	10	10	10
Mg stearate	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5
Total weight	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**

Table 3: Formulation trials of floating tablets of Propranolol using Gellan Gum

Ingredients (mg)	PF17	PF18	PF19	PF20	PF21	PF22	PF23	PF24
Drug	90	90	90	90	90	90	90	90
Gellan Gum	90	100	110	120	100	110	90	120
Sodium Bicarbonate	30	30	30	30	45	45	45	45
Citric acid	10	10	10	10	10	10	10	10
MCC	110	100	90	80	95	85	75	65
PVP K-30	10	10	10	10	10	10	10	10
Mg stearate	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5
Total weight	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**

MCC: Microcrystalline Cellulose; PVP K-30: Polyvinyl Pyrrolidone K-30.

Evaluation Parameters

Precompression parameters [7,8]

Before the compression process, the formulation powder blends were assessed for their bulk and tapped density, from which the compressibility index and Hausner's ratio were derived. Additionally, the flow properties of the powder blend were evaluated using the angle of repose.

Evaluation of Floating Tablets [9,10]

Post compression parameters: The prepared tablets were evaluated for quality control tests like weight variation, hardness, thickness, friability and content uniformity.

Weight variation: Ten tablets were selected randomly from each batch and weighed individually, calculating the average weight and comparing the individual tablet weight to the average. From this; percentage weight difference was calculated and then checked for USP specifications.

Hardness and friability: The Hardness (or) Crushing Strength(or)Tensile Strength of prepared tablets is said to be load required for cleft a tablet into tiny fragments when placed on edge of the hardness tester and its unit is Kg/cm^2. The sample size of the present parameter is THREE from each batch of the formulation.

$$\% \text{ Friability} = W_1 - W_2 / W_2 \times 100$$

Whereas friability of all batch formulations was predicted with aid of Roche Friabilator (Make: Electro lab, India) and computed using below formula;

Where;

W_1= Mass of tablet before friability W_2=Mass of the tablet after friability

***In vitro* buoyancy studies:** The in vitro buoyancy of the tablets was evaluated by measuring the floating lag time. Each tablet was placed in a 100 mL beaker containing 0.1N hydrochloric acid, and the time taken for the tablet to ascend and begin floating on the

surface was recorded as the floating lag time. The duration for which the tablet remained buoyant without sinking was noted as the total floating time.[10].

***In vitro* Dissolution Studies:**

Dissolution Apparatus	:	USP Dissolution Apparatus Type II (Paddle)
Dissolution Medium	:	0.1NHydrochloricAcid (pH1.2)
Dissolution Medium Volume	:	900ml
Temperature	:	37±0.2°C
Aliquot Volume	:	5ml
Replishing Volume	:	5ml
Speed	:	100rpm
Estimation	:	290 in UV-Spectrophotometer
Time Intervals (Hours)	:	1,2,3,4,6,8,10&12

Stability studies: Stability studies were performed in accordance with ICH guidelines by storing the formulations at 40 ± 2°C and 75 ± 5% relative humidity for a period of three months using a stability chamber (Thermo Lab, Mumbai). Samples were collected at specified time intervals—0, 30, 90, and 180 days—for evaluation. Key in vitro parameters such as drug content, floating lag time, and stability[12].

RESULTS AND DISCUSSION

In the current study, Propranolol, employed in the management of ulcers, has been utilized as an active pharmaceutical agent and regarded as a promising candidate for minimizing dose frequency, particularly in solid oral sustained release formulations, thereby enhancing patient compliance in ulcer treatment. This formulation is presented in the form of gastroretentive floating tablets to ensure the desired sustained and complete release over an extended duration.

Precompression Parameters

The results of precompression evaluation parameters are shown in (Table 4). All the precomression evaluation parameters were within the USP Pharmacopoeia limits.

Postcompression Parameters

The results of postcompression evaluation parameters are shown in (Table 5). The Weight variation of all formulations witnessed to be in the limit allowed that is ± 5% of total tablet weight. The suitable hardness for compressed tablets is considered as a vital function for the end user. The deliberated crushing strength of fabricated tablets of formulations RF1-RF24 trended between 4.0-5.0kg/cm^2. The thickness of all the formulations ranges from 5.0-5.5 mm. The friability of all prepared formulation between 0.51-0.79 %, the friability properties limits are in between 0-1%. The drug content of all formulation is in between 95.11-99.34%, drug content depends on the angle of repose since the angle of repose indicates uniform flow nature of powder blend which makes the drug to evenly distribute in all the formulation and to maintain content uniformity in all batches. Tablets of all batches had floating lag time below 60 seconds regardless of viscosity and content of polymers because of evolution of CO_2 resulting from the interaction between sodium bicarbonate and dissolution medium, entrapment of gas inside the hydrated polymeric matrices enables the dosage form to float by lowering the density of the matrices. Total Floating time for the natural polymers' formulations were more than 12 hrs.

FTIR Studies:

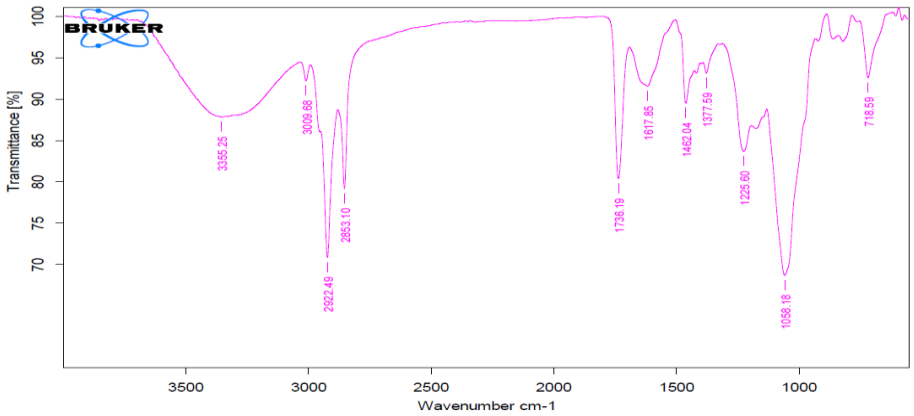


Figure 1: FTIR Spectrum of Pure Drug Propranolol Hychloride

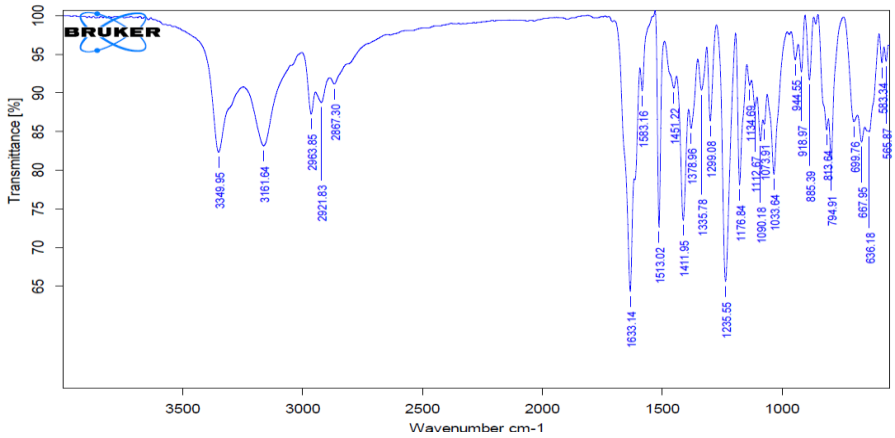


Figure 2: FTIR Spectrum of Propranolol Hydrochloride and Gellan Gum

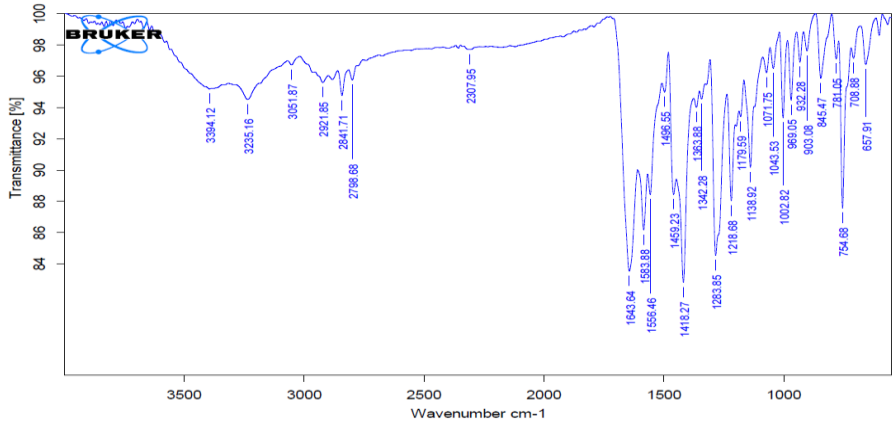


Figure 3: FTIR spectrum of Propranolol hydrochloride and Karaya Gum

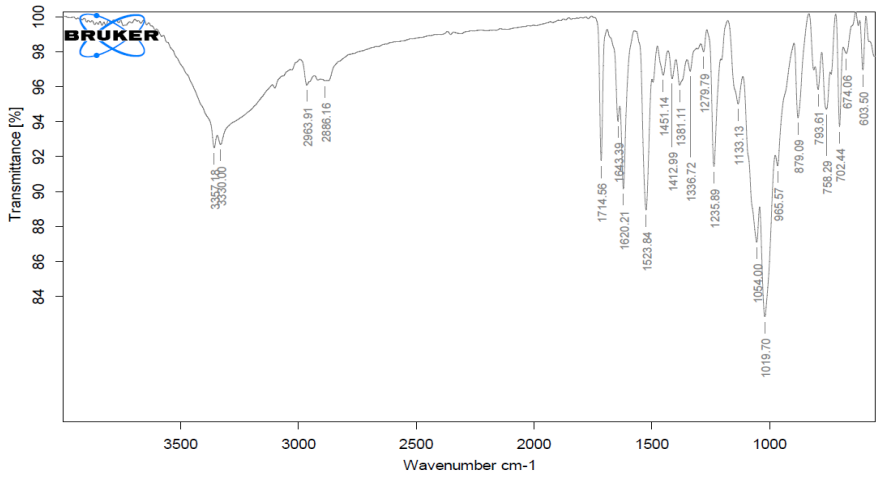


Figure 4: FTIR spectrum of Propranolol hydrochloride and Fenugreek Gum

DSC Studies:

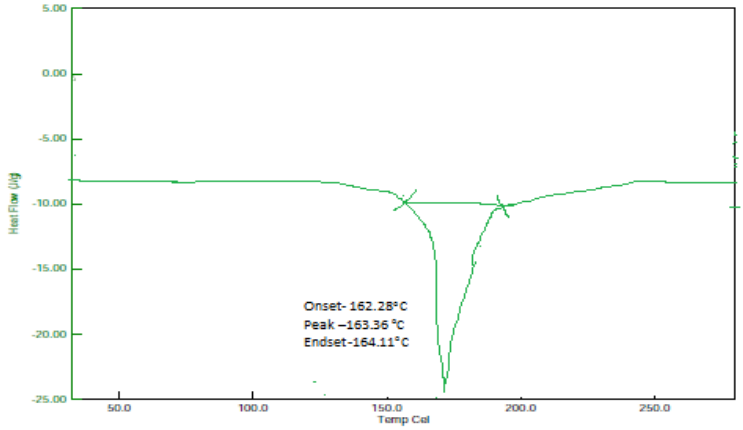


Figure 5: DSC Thermogram of Propranolol Hydrochloride

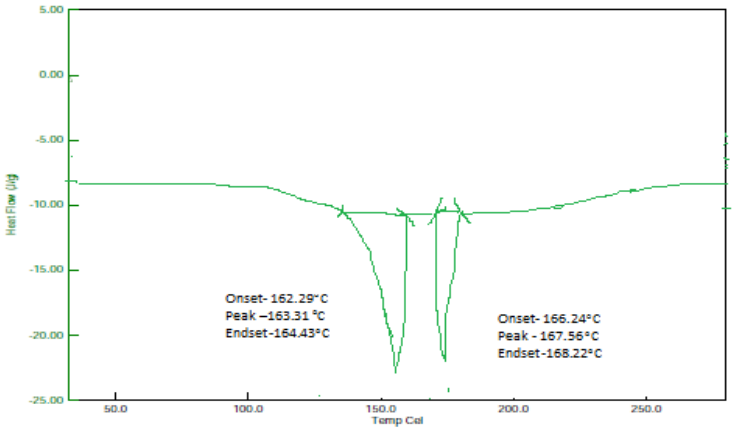


Figure 6: DSC Thermogram of Propranolol Hydrochloride with Gellan Gum

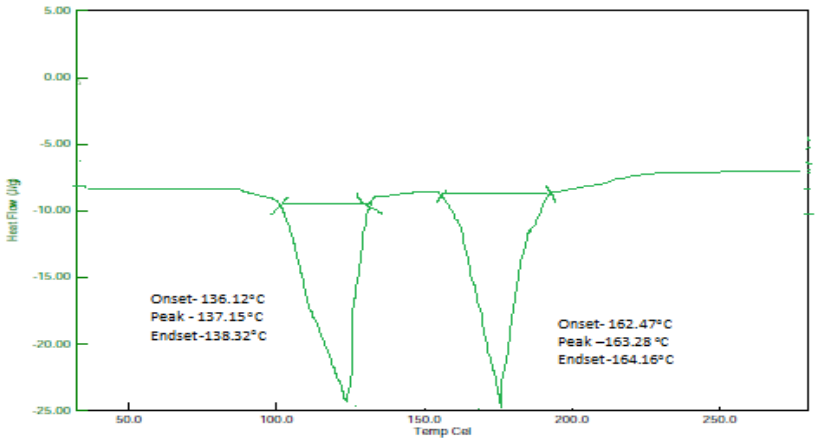


Figure 7: DSC Thermogram of Propranolol Hydrochloride with Karaya Gum

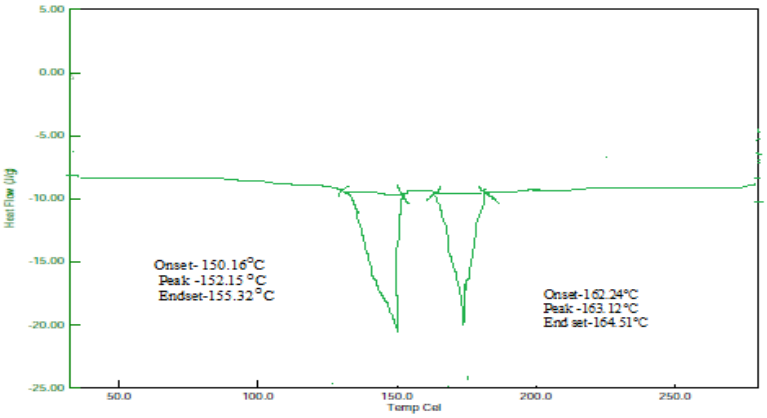
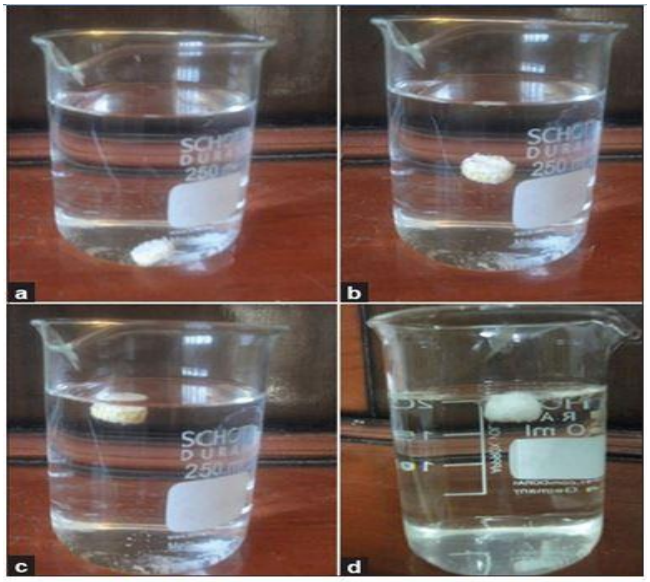


Figure 8: DSC Thermogram of Propranolol Hydrochloride with Fenugreek Gum



(A) After 10 Seconds (B) After 36 Seconds

(C) After 1 Hour (D) After 12 Hours

Figure 9: Propranolol floating lag Time

Table 4: Physical properties of prepared powder blends of the floating tablet

Formulation code	Bulk density (g/cc)	Tapped density (g/cc)	Angle of repose (θ)	Carr's index (%)	Hausner ratio
PF1	0.53±0.19	0.62±0.15	24.38±0.44	09.27±1.12	1.12±0.24
PF2	0.56±0.16	0.62±0.17	22.65±0.31	08.29±1.42	1.11±0.10
PF3	0.58±0.17	0.63±0.21	26.57±0.41	10.42±0.8	1.13±0.20
PF4	0.57±0.25	0.66±0.25	25.88±0.55	11.36±0.6	1.14±0.24
PF5	0.58±0.18	0.64±0.18	22.52±0.0.57	12.24±0.12	1.12±0.32
PF6	0.57±0.20	0.65±0.20	25.37±0.30	11.29±0.25	1.13±0.30
PF7	0.54±0.14	0.65±0.16	22.59±0.57	10.36±0.31	1.12±0.20
PF8	0.57±0.16	0.67±0.17	23.69±0.60	09.14±0.24	1.14±0.25
PF9	0.55±0.18	0.61±0.19	25.53±0.44	09.47±1.15	1.14±0.70
PF10	0.61±0.25	0.65±0.18	21.64±0.31	13.48±1.3	1.15±0.20
PF11	0.51±0.17	0.67±0.16	22.35±0.37	14.25±1.5	1.13±0.16
PF12	0.54±0.16	0.65±0.20	25.91±1.70	11.33±1.25	1.12±0.12
PF13	0.53±0.12	0.67±0.14	22.13±0.21	11.27±1.57	1.13±0.17
PF14	0.56±0.13	0.65±0.17	22.49±0.57	10.21±1.55	1.14±0.15
PF15	0.52±0.18	0.62±0.16	24.76±0.77	10.48±1.5	1.15±0.15
PF16	0.53±0.13	0.63±0.15	23.49±0.80	09.61±1.3	1.15±0.18
PF17	0.56±0.13	0.65±0.19	25.49±1.86	13.44±1.09	1.12±0.15
PF18	0.54±0.16	0.64±0.20	23.25±0.75	14.91±1.20	1.14±0.15
PF19	0.55±0.18	0.63±0.16	26.66±0.67	12.46±1.45	1.13±0.15
PF20	0.58±0.17	0.65±0.17	23.74±1.57	13.13±1.45	1.15±0.17
PF21	0.55±0.13	0.64±0.18	25.36±1.70	11.79±1.07	1.16±0.20
PF22	0.56±0.19	0.66±0.18	20.14±0.50	09.67±1.55	1.09±0.14
PF23	0.55±0.14	0.64±0.21	26.45±0.37	10.67±1.25	1.14±0.35
PF24	0.54±0.16	0.64±0.12	25.56±0.31	09.68±1.35	1.14±0.15

Table 5: Physicochemical parameters of Propranolol Floating tablets

Formulation	*Weight variation (mg)	#Thickness (mm)	#Hardness (Kg/Cm^2)	#Friability (%)	#Content uniformity (%)	Floating lag time (sec)	Total floating time (hrs)
PF1	350.18±5.20	5.1±1.17	4.1±0.16	0.52±0.08	98.23±1.23	55	>12
PF2	349.23±3.24	5.0±1.15	4.0±0.37	0.53±0.09	96.04±1.03	56	>12
PF3	348.08±3.15	5.1±1.23	4.3±0.14	0.67±0.07	97.56±0.94	54	>12
PF4	351.09±4.70	5.2±1.89	4.2±0.12	0.54±0.05	97.11±0.63	48	>12
PF5	351.89±3.50	5.1±1.47	4.1±0.17	0.62±0.07	96.23±0.81	53	>12
PF6	350.34±5.20	5.2±1.31	4.2±0.19	0.65±0.09	95.45±0.32	48	>12
PF7	350.23±4.60	5.0±1.51	4.0±0.14	0.55±0.02	96.11±1.17	49	>12
PF8	349.12±3.50	5.2±1.36	4.2±0.16	0.68±0.02	97.23±0.45	54	>12
PF9	350.23±2.48	5.2±1.49	4.2±0.12	0.55±0.02	98.13±1.17	58	>12
PF10	350.24±4.20	5.1±1.55	4.1±0.23	0.78±0.07	97.23±0.49	56	>12
PF11	351.45±3.97	5.1±1.80	4.4±0.12	0.73±0.05	96.97±0.95	53	>12
PF12	352.03±2.54	5.4±1.25	4.6±0.18	0.74±0.08	95.45±0.35	48	>12
PF13	351.04±6.30	5.5±1.70	4.8±0.19	0.53±0.09	97.85±0.24	46	>12

PF14	348.23±5.35	5.1±1.56	4.2±0.13	0.76±0.02	96.98±0.13	57	>12
PF15	349.34±3.25	5.5±1.70	4.6±0.18	0.72±0.20	97.25±1.21	55	>12
PF16	350.12±2.55	5.1±1.40	4.2±0.28	0.76±0.9	98.45±1.30	58	>12
PF17	351.23±4.50	5.5±1.17	4.7±0.14	0.75±0.04	96.34±1.31	59	>12
PF18	351.67±3.30	5.5±1.40	4.6±0.15	0.81±0.03	97.56±1.36	58	>12
PF19	349.13±2.45	5.0±1.17	4.0±0.17	0.83±0.01	98.29±1.31	54	>12
PF20	349.45±4.55	5.3±1.96	4.5±0.14	0.64±0.03	98.18±1.36	49	>12
PF21	348.12±2.70	5.2±1.50	4.3±0.13	0.65±0.03	97.27±1.30	58	>12
PF22	**350.45±4.80**	**5.0±1.63**	**5.0±0.12**	**0.73±0.015**	**99.34±1.16**	**36**	**>12**
PF23	350.23±4.55	5.3±1.78	4.8±0.18	0.72±0.04	96.14±1.46	66	>12
PF24	350.12±4.60	5.41±1.86	4.7±0.17	0.74±0.06	98.16±0.56	54	>12

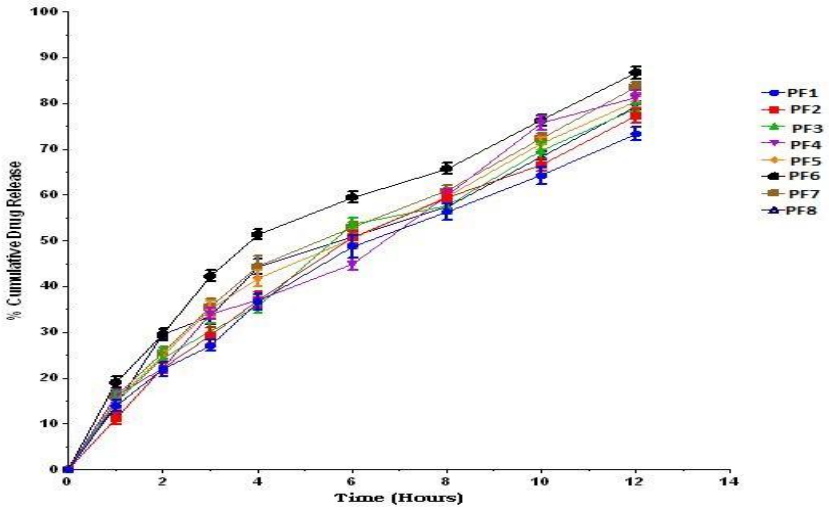


Figure 10: Comparison of *in vitro* Percentage drug release of Propranolol floating tablet formulations PF1-PF8

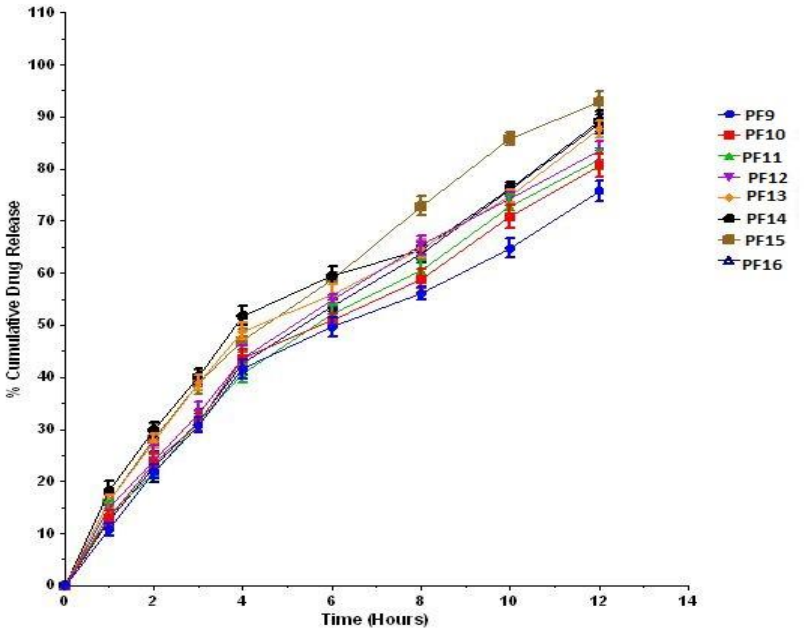


Figure 11: Comparison of *in vitro* Percentage drug release of Propranolol floating tablet formulations PF9-PF16

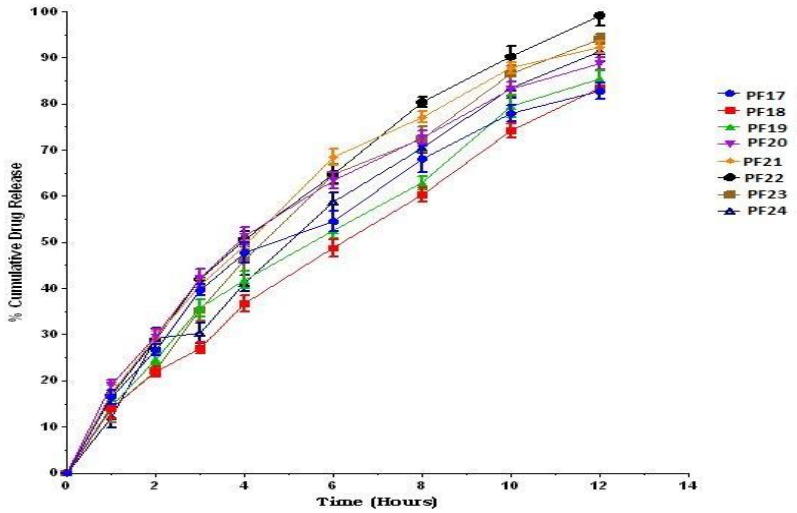


Figure 12: Comparison of *in vitro* Percentage drug release of Propranolol floating tablet formulations PF17-PF24

All tablet formulations exhibited weight variation limit of ±5% of the average tablet weight. Adequate hardness is crucial for the mechanical strength and usability of compressed tablets; the measured hardness for formulations DF1 to DF24 ranged between 4.0 and 5.0 kg/cm². The thickness of the tablets across all batches was consistent, falling between 4.1 and 4.5 mm.

Friability values for all formulations were within the acceptable range of 0–1%, with observed values ranging from 0.53% to 0.79%, indicating good mechanical resistance. Drug content across the formulations varied from 94.23% to 99.68%. The uniformity in drug content is likely attributed to the good flow properties of the powder blends, as indicated by a suitable angle of repose, which facilitates even distribution of the drug during tablet compression.

Floating lag times for all batches were below 60 seconds, regardless of the type and concentration of polymers used. This rapid buoyancy is due to carbon dioxide generation from the reaction between sodium bicarbonate and the dissolution medium. The gas becomes trapped within the hydrated polymer matrix, reducing the matrix density and enabling flotation. The total floating duration for formulations containing natural polymers exceeded 12 hours, demonstrating sustained buoyancy performance.

Mathematical treatment of optimized formula of Propranolol floating tablets

In vitro dissolution testing plays a crucial role in drug development, especially for assessing bioequivalence. Several models exist to describe drug dissolution profiles, where the amount of drug dissolved is a function of time and is related to the dosage form. To quantitatively analyze the data from dissolution tests, a generic equation is often employed to mathematically interpret the dissolution curve, taking into account parameters specific to the formulation.

For water-soluble drugs incorporated into a matrix, release typically occurs via diffusion. In contrast, for poorly water-soluble drugs, the matrix's self-erosion becomes the primary mechanism for release. By comparing experimental release data to established mathematical models, the dissolution process can be better understood and quantitatively described.

CONCLUSION

In the current study, it can be inferred that Propranolol floating tablets represent an innovative and promising method for delivering Propranolol in the treatment of gastric ulcers. The optimized formulation PF22 incorporates Gellan Gum along with a gas-generating agent. When comparing the in-vitro release profile of Propranolol from the optimized formulation PF22 to that of the marketed product, it was observed that PF22 exhibited a drug release of 99.17±1.86 % over 12 hours, while the marketed product released 95.12±2.28 % of the drug within just 1 hour. The primary mechanism governing drug release adheres to zero order kinetics and non-Fickian transport, which involves a combination of diffusion and erosion. This indicates that both water diffusion and polymer rearrangement play a crucial role in the drug release process. The release rate constant for the optimized formulation PF22 was sufficiently low, thereby extending the duration of drug delivery. This finding is promising, as an extended gastric residence time is a critical factor for

enhancing the bioavailability of drugs contained in prolonged or sustained release dosage forms.

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