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FORMULATION AND OPTIMIZATION OF GASTRO-RETENTIVE FLOATING TABLETS OF ENALAPRIL MALEATE AND LOSARTAN FOR ENHANCED BIOAVAILABILITY AND THERAPEUTIC EFFICACY

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Abstract

The objective of this study was to formulate and optimize gastro-retentive floating tablets of Enalapril Maleate and Losartan to enhance their bioavailability and therapeutic efficacy. These drugs, commonly used in the management of hypertension and heart failure, suffer from limited solubility and rapid gastric emptying, which reduce their effectiveness. Gastro-retentive floating tablets were developed using hydroxypropyl methylcellulose (HPMC K4M) and guar gum as release-controlling agents, with sodium bicarbonate and citric acid as effervescent agents to ensure buoyancy. Twenty formulations were prepared using the direct compression method and evaluated for critical parameters, including hardness, friability, swelling index, floating lag time, total floating time, and in-*vitro* drug release.

Preformulation studies confirmed the compatibility of the drugs with excipients, with no chemical interactions detected using FTIR spectroscopy. The micrometric properties of the powder blends demonstrated excellent flowability and compressibility, ensuring suitability for tablet manufacturing. All formulations showed acceptable weight variation, hardness, and friability. The floating lag time ranged from 4.3 to 5.1 minutes, and total floating times exceeded 8 hours for all batches. Drug content ranged from 96.79% to 99.57%, reflecting uniformity and accuracy in dosing.

In-*vitro* dissolution studies revealed sustained release profiles, with optimized formulations achieving over 90% cumulative drug release within 12 hours. Batch F7 demonstrated the best overall performance, with a high swelling index, minimal floating lag time, prolonged floating duration, and consistent drug release. These findings indicate that gastro-retentive floating tablets of Enalapril Maleate and Losartan can effectively address challenges associated with poor bioavailability and rapid gastric emptying, offering a promising approach for improved therapeutic outcomes and patient compliance.

Keywords: Floating tablets, Enalapril Maleate, Losartan, Bioavailability, GRDDS.

Introduction

The gastrointestinal (GI) tract poses significant challenges to the effective delivery of many drugs, particularly those with low solubility and short half-lives. The development of gastro-retentive drug delivery systems

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(GRDDS) aims to address these issues by ensuring prolonged residence time in the stomach, enhancing drug bioavailability, and providing a controlled release of therapeutic agents. Among the various GRDDS, floating tablets have gained significant attention due to their ability to remain buoyant in the stomach, thereby allowing for extended drug release.

Enalapril Maleate and Losartan are commonly prescribed for the treatment of hypertension and heart failure. However, their bioavailability is often limited due to factors like low solubility and rapid gastric emptying. Gastro-retentive floating tablets offer a potential solution to these challenges by improving the drugs' residence time in the stomach, ensuring consistent absorption and therapeutic efficacy.

This study aims to design, formulate, and optimize floating tablets of Enalapril Maleate and Losartan. The primary goal is to develop a drug delivery system that ensures prolonged gastric residence time, which will enhance the bioavailability and therapeutic effectiveness of both drugs. By incorporating suitable polymers and excipients with floating and mucoadhesive properties, the study seeks to achieve controlled and sustained release profiles for these cardiovascular drugs, thereby improving patient outcomes and compliance.

Methodology

Materials, Chemicals, and Equipment

The study utilized Enalapril Maleate and Losartan as active pharmaceutical ingredients, with HPMC K4M and guar gum serving as drug release-controlling and swellable agents. Microcrystalline cellulose was used as a diluent, while sodium bicarbonate and citric acid acted as effervescent agents. Magnesium stearate and purified talc were employed as a lubricant and glidant, respectively. Equipment included a Contech precision balance, Ratnakar tablet press, Electrolab dissolution and friability testers, Shimadzu UV-1800 spectrophotometer, Monsato hardness tester, Bruker Alpha FTIR, and Amkette Analytics HPLC, ensuring precise formulation and analysis.

Evaluation and Characterization of Drugs

1. The physical characteristics of Enalapril Maleate and Losartan, including color, odor, and form, were examined.
2. Identification tests were conducted using IR spectroscopy, where KBr powder mixed with the drug was analyzed, and UV spectroscopy, using a 100 ppm solution scanned from 200–400 nm for absorption maxima.
3. Solubility was tested in distilled water and pH 1.2 buffer by ultrasonication and saturation equilibrium, followed by UV absorption measurement. The melting point was determined using the capillary method and Thiele’s tube.
4. Drug content was analyzed via HPLC with a mobile phase of methanol, buffer, and acetonitrile (65:30:5) at 249 nm, confirming drug purity and content with standard and sample solutions of 25 ppm in methanol.

Preformulation Studies

Preformulation studies serve as the foundation for the rational development of drug formulations, focusing on understanding drug properties and compatibility with excipients. Drug-excipient compatibility was evaluated using FTIR spectroscopy, covering a range of 4000 to 400 cm^{-1}, to detect potential interactions, and pH testing was conducted using aqueous solutions. Flow properties of granules were assessed through Hausner's ratio, with values below 1.2 indicating free-flowing powders, and the angle of repose, measured using the funnel method, categorized flow characteristics, with $\theta < 25°$ denoting excellent flow. Bulk and tapped densities were calculated to evaluate granule packing behavior, with compressibility index (Carr’s Index) further characterizing flowability. Granules with a compressibility index below 15% exhibited good flow, ensuring suitability for tablet manufacturing.

Developing formulations of floating tablets of Enalapril Maleate and Losartan, utilizing HPMC K4M and Guar gum

Floating tablets of Enalapril Maleate and Losartan were formulated using HPMC K4M and guar gum as release-controlling agents. A total of 20 batches, each weighing 225 mg, were prepared using the direct compression method. The excipients and polymers were blended uniformly, passed through sieves, and lubricated with talc and magnesium stearate before being compressed into tablets using a tablet punching machine. The formulations varied in concentrations of HPMC K4M and guar gum to evaluate their impact on drug release and floating properties. Sodium bicarbonate and citric acid were included as effervescent agents, while microcrystalline cellulose served as a diluent to achieve the desired tablet properties.

Table 1 - Formulation Composition

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1.	Enalapril Maleate	10	10	10	10	10	10	10	10	10	10
2.	Losartan	50	50	50	50	50	50	50	50	50	50
3.	HPMC K4M	--	--	--	--	--	100	120	130	80	60
4.	Guar Gum	60	75	80	90	100	--	--	--	--	--
5.	Sodium bicarbonate	45	50	--	--	40	25	--	--	35	45
6.	Citric acid	--	--	15	20	--	--	25	20	--	--
7.	Avicel (MCC)	56	36	66	51	21	36	16	11	46	56
8.	Talc	2	2	2	2	2	2	2	2	2	2
9.	Magnesium stearate	2	2	2	2	2	2	2	2	2	2
Total weight (mg)		**225**	**225**	**225**	**225**	**225**	**225**	**225**	**225**	**225**	**225**

Evaluation of Floating Matrix Tablets

The evaluation of floating matrix tablets included various parameters to ensure quality and performance. Weight uniformity was assessed for 20 tablets, with percentage deviations checked as per IP standards. Hardness, measured using a Monsanto tester, was expressed in kg/cm². Friability, indicating tablet strength, was tested with a Friabilator, calculating weight loss after 100 revolutions. Swelling index was determined by soaking tablets in HCl solution (pH 1.2) at 37±0.5°C for 8 hours, measuring weight changes. Floating studies evaluated buoyancy lag time (BLT) and total floating time (TFT) in HCl solution (pH 1.2) under similar conditions. Dissolution studies were performed using USP Type II apparatus in simulated gastric fluid (pH 1.2), analyzing drug release via HPLC at 249 nm. These tests confirmed the tablets' uniformity, strength, swelling behavior, buoyancy, and sustained drug release.

Results and Discussion

Drug Evaluation

The evaluation and characterization of Enalapril Maleate and Losartan were conducted using various techniques to confirm their identity, purity, and physicochemical properties.

Descriptive Tests revealed that Enalapril Maleate is a white powder, while Losartan is a light-yellow fine powder, consistent with their reported descriptions.

Identification Tests were performed using **IR spectroscopy** and **UV spectroscopy**. The IR spectra of Enalapril Maleate exhibited characteristic peaks at 3445.22 cm^{-1} (O-H stretching), 2937 cm^{-1} (C-H stretching), 1726 cm^{-1} (C=O stretching), and 1616 cm^{-1} (N-H bending), confirming its functional groups. Similarly,

Losartan displayed peaks at 2953 cm^{-1} (C-H stretching), 2304 cm^{-1} (N=N-N stretching), and 1662 cm^{-1} (C=O stretching), among others, aligning with its chemical structure.

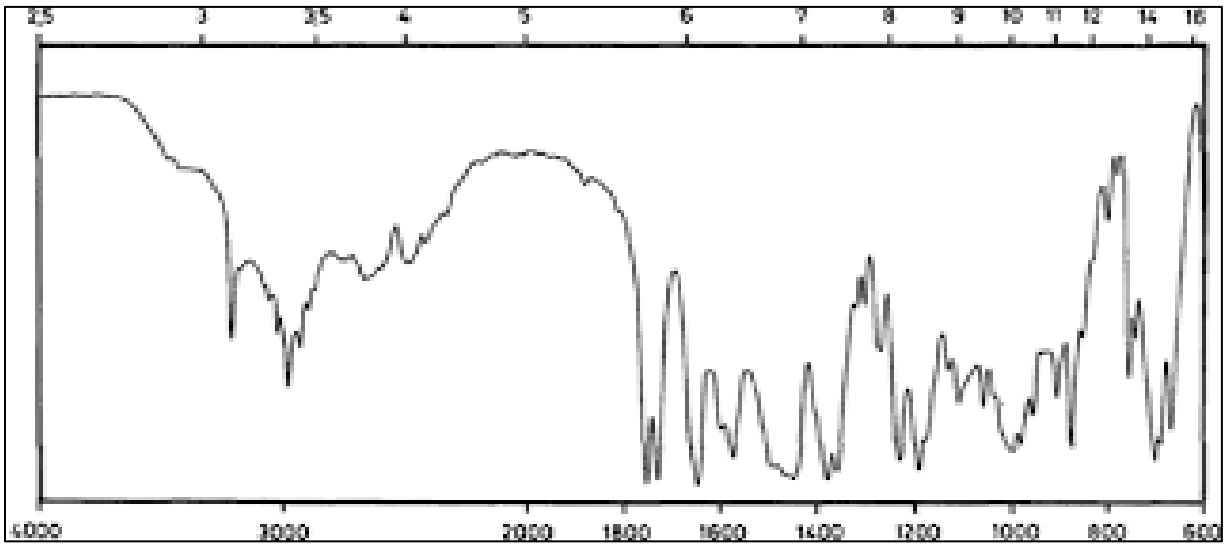

Figure 1: IR Spectra of Enalapril Maleate

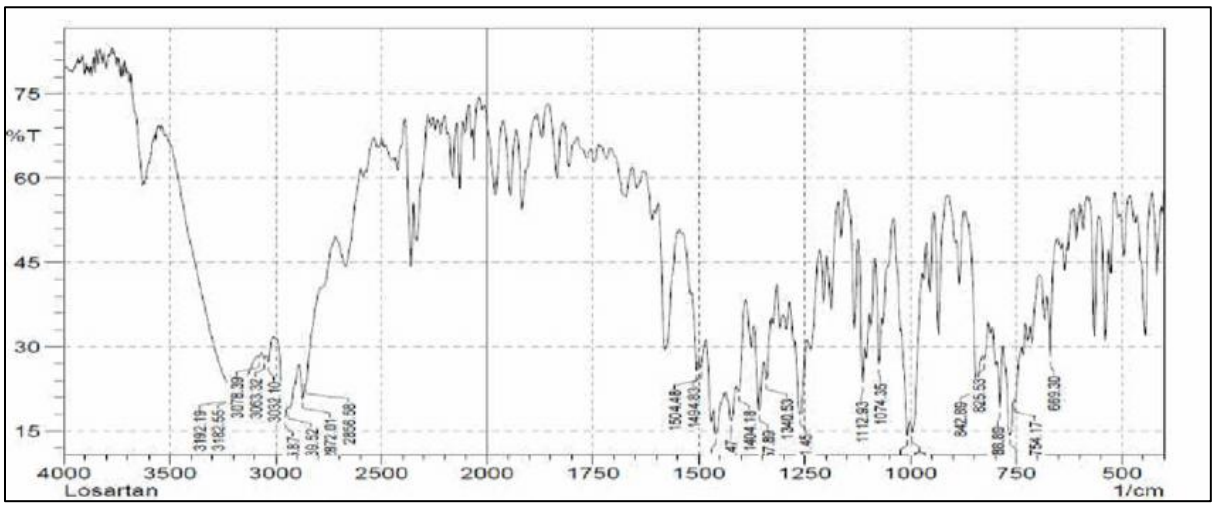

Figure 2: IR Spectra of Losartan

UV spectroscopic analysis showed absorption maxima (λmax) at 221 nm for Enalapril Maleate and 205 nm for Losartan, verifying their unique UV absorption properties. These results establish their identity and purity, with methanol serving as a suitable solvent that does not interfere with UV absorbance.

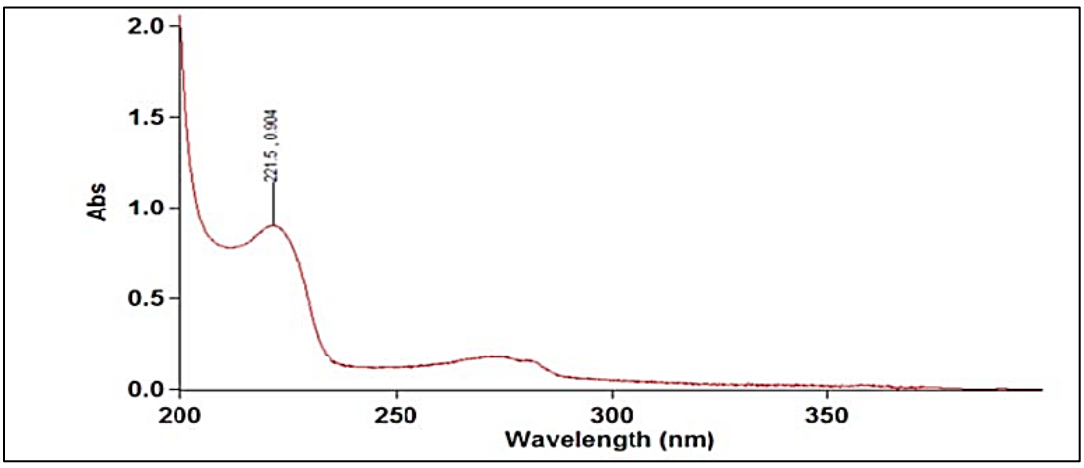

Figure 3: UV Spectra of Enalapril Maleate

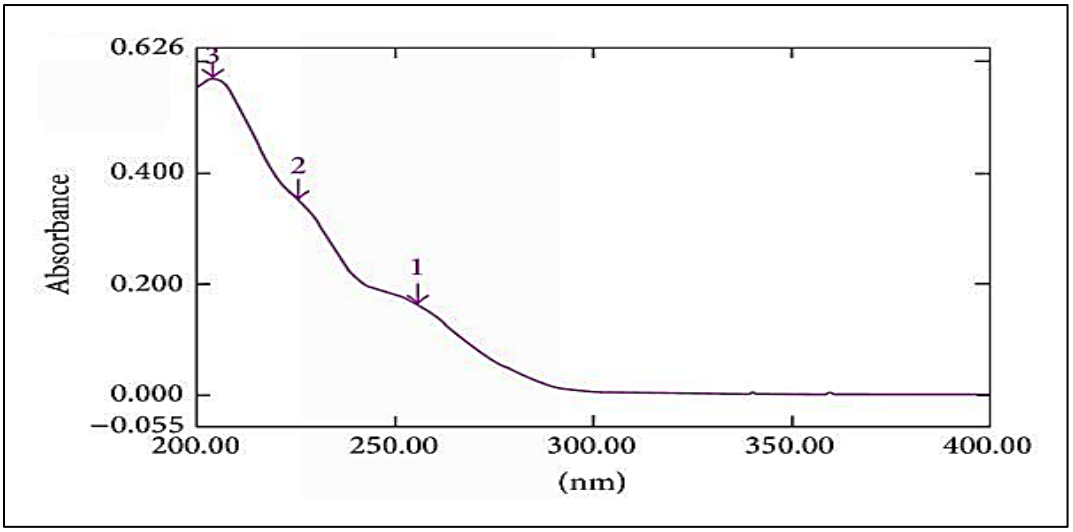

Figure 4: UV Spectra of Losartan

Solubility Studies demonstrated that Enalapril Maleate is sparingly soluble in water, soluble in methanol, and slightly soluble in pH 1.2 buffer, indicating limited dissolution in aqueous and acidic environments. This may necessitate formulation strategies to enhance solubility and bioavailability. In contrast, Losartan exhibited higher solubility, being freely soluble in water and soluble in methanol and pH 1.2 buffer, suggesting better dissolution and absorption under physiological conditions.

The **melting point analysis** confirmed the purity of both drugs. The observed melting points for Enalapril Maleate (144°C) and Losartan (184°C) matched the reported values, indicating the absence of impurities or degradation.

HPLC Analysis further validated the purity and content of the drugs. Enalapril Maleate showed a drug content of 99.65%, and Losartan displayed 98.92%, demonstrating high purity and minimal impurities. Chromatographic analysis was performed using a mobile phase of acetonitrile, methanol, and potassium phosphate buffer (pH 3.8) in a ratio of 30:50:20, with a flow rate of 1 mL/min and detection at 249 nm.

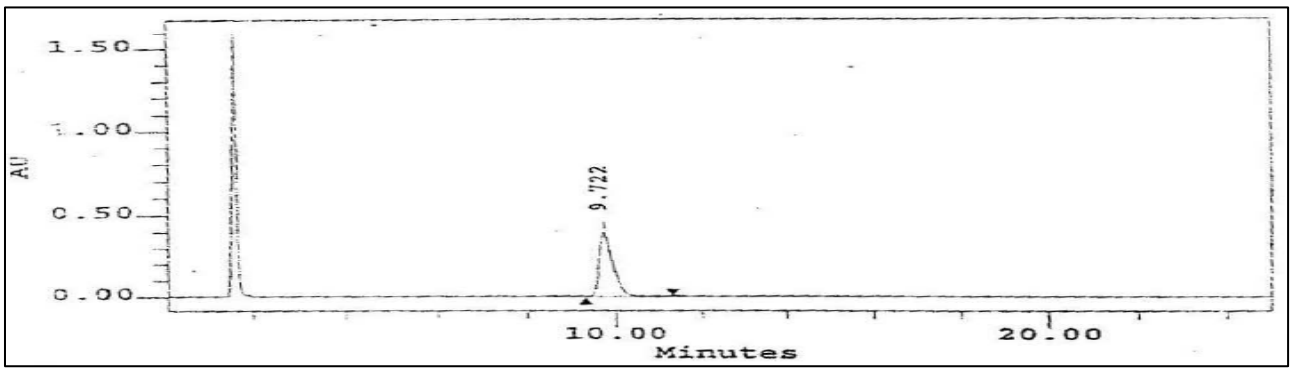

Figure 5: Chromatogram of Enalapril Maleate Pure drug

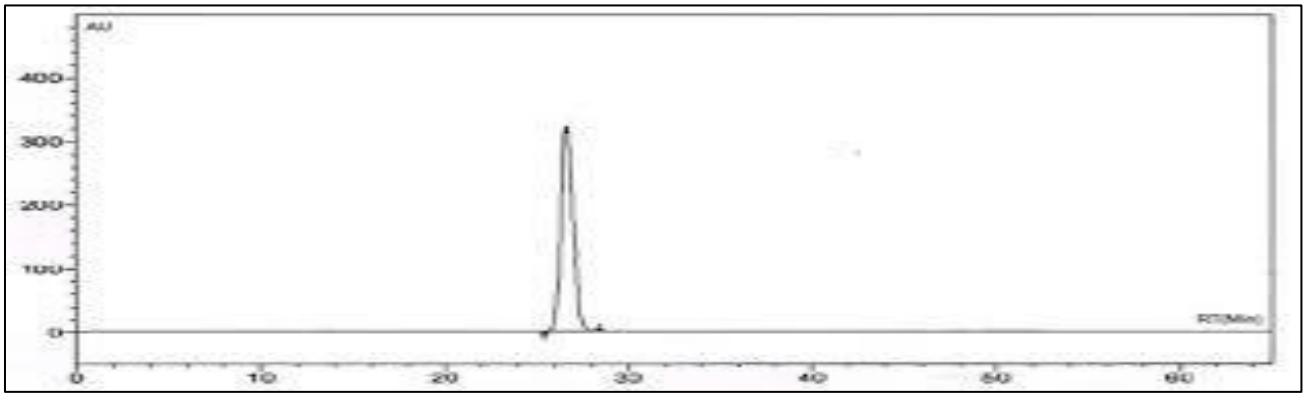

Figure 6 - Chromatogram of Losartan Pure drug

Preformulation Studies

Preformulation studies are essential for the rational development of dosage forms, providing a foundation for the formulation process. These studies focused on the drug-excipient compatibility, pH behavior, and micrometric evaluation of powder blends.

Drug-Excipient Compatibility

Drug-excipient compatibility was evaluated using Fourier Transform Infrared (FTIR) spectroscopy and pH analysis. FTIR spectra of Enalapril Maleate, Losartan, and their combinations with various excipients, including HPMC K4M, Guar Gum, MCC, Citric Acid, Sodium Bicarbonate, Magnesium Stearate, and Talc, showed no significant shifts or disappearance of characteristic peaks, indicating the absence of chemical interactions. The pH evaluation demonstrated that the excipients exhibited a pH range of 4.2 (citric acid) to 7.2 (magnesium stearate), which aligns well with the stability requirements of both drugs. Enalapril Maleate and Losartan were stable within this pH range, showing no signs of degradation or precipitation, ensuring their compatibility with the selected excipients. This stability supports their incorporation into formulations and highlights the potential of excipients like HPMC K4M and MCC to maintain a stable microenvironment in the final dosage form.

Table 2: pH of Drug and Excipients Datasheet

Excipient	Enalapril Maleate and Losartan
HPMC K4M	5.9
Talc	6.1
Magnesium Stearate	7.2
Guar gum	6.8
Sodium bicarbonate	4.9
Citric Acid	4.2
MCC	6.9

Micrometric Evaluation

Micrometric properties of powder blends, including bulk density, tap density, Carr's index, Hausner's ratio, and angle of repose, were assessed to evaluate flowability and compressibility. Bulk density ranged from 0.33 to 0.49 g/cm³, while tap density values varied between 0.716 and 0.767 g/mL, indicating efficient packing across all batches. Carr's index values, which measure compressibility, ranged from 11.935% to 14.236%, reflecting excellent flow characteristics. Similarly, Hausner's ratio values ranged from 1.226 to 1.285, further confirming good to excellent flowability. The angle of repose values were consistently below 30° (24.1°–25.1°), indicating satisfactory flow properties.

Table 3: Preformulation parameters for powder blend

Batch	Bulk Density (gm/cm)	Tap Density (gm/mL)	Carr's Index	Hausner's Ratio	Angle of Repose
F1	0.48±0.046	0.744±0.056	13.357±0.73	1.247±0.03	24.7±0.64
F2	0.49±0.059	0.726±0.045	13.935±0.71	1.227±0.06	24.1±0.49
F3	0.35±0.076	0.719±0.067	13.236±0.64	1.285±0.05	24.4±0.38
F4	0.42±0.025	0.753±0.049	13.945±0.36	1.246±0.07	25.1±0.35
F5	0.33±0.048	0.733±0.041	13.457±0.32	1.264±0.07	24.4±0.58
F6	0.45±0.076	0.731±0.036	13.276±0.25	1.226±0.07	24.9±0.53
F7	0.46±0.071	0.739±0.036	12.276±0.25	1.226±0.07	24.9±0.53
F8	0.39±0.005	0.716±0.067	14.236±0.64	1.285±0.05	24.4±0.38
F9	0..46±0.043	0.767±0.056	12.357±0.73	1.247±0.03	24.7±0.64
F10	0.43±0.044	0.723±0.045	11.935±0.71	1.227±0.06	24.1±0.49

Batch-wise analysis revealed uniform and balanced micrometric properties across all formulations. For instance, F1 demonstrated excellent flow characteristics with a bulk density of 0.48 g/cm³, a Carr's index of 13.357%, and an angle of repose of 24.7°. Similarly, F2 and F10 exhibited optimal properties, with Carr's index values of 13.935% and 11.935%, respectively, and low angles of repose. Notably, F7 showed the best performance, with a Carr's index of 12.276% and a Hausner's ratio of 1.226, reflecting exceptional flowability and compressibility.

Physico-chemical evaluation of the tablets

The physico-chemical evaluation of the tablets revealed that the key parameters, including hardness, friability, weight variation, swelling index, floating lag time, floating duration, and drug content, met acceptable pharmacopeial standards, ensuring the formulation's quality and potential therapeutic efficacy.

Table 4: Physio-chemical evaluation of Tablet

Batch	Hardness (Kg/cm²)	Friability (%)	Weight Variation	Swelling Index 12 hr	Floating Lag Time (min)	Floating Time	Drug Content (%)
F1	4.6±0.03	0.27±0.04	223±1.42	96.89±0.754	4.7±0.35	>10 hr	96.79±0.26
F2	4.3±0.07	0.28±0.06	226±1.24	92.12±0.346	4.9±0.14	>8 hr	98.67±0.12
F3	4.2±0.04	0.23±0.03	221±1.64	91.35±0.156	4.8±0.24	>10 hr	98.86±0.19
F4	4.7±0.05	0.27±0.05	221±1.43	94.42±0.535	4.7±0.13	>8 hr	99.15±0.26
F5	4.4±0.03	0.29±0.06	224±1.13	96.65±0.764	4.6±0.15	>10 hr	99.57±0.25
F6	4.2±0.01	0.25±0.04	223±1.64	94.34±0.963	4.4±0.27	>10 hr	97.35±0.22
F7	4.4±0.03	0.22±0.46	221±5.35	97.24±0.567	4.3±0.13	>9 hr	99.28±0.24
F8	4.6±0.04	0.22±0.04	220±3.35	93.46±0.723	4.9±0.12	>10 hr	98.36±0.23
F9	4.5±0.01	0.23±0.07	229±3.62	96.53±1.353	5.0±0.24	>10 hr	98.31±0.13
F10	4.4±0.08	0.24±0.01	222±7.95	93.64±1.134	5.1±0.14	>10 hr	99.35±0.34

The hardness of the tablets ranged from 4.2 to 4.7 kg/cm², with all batches falling within acceptable limits for mechanical strength. Batch F4 exhibited the highest hardness (4.7 kg/cm²), while F3 and F6 showed slightly lower values (4.2 kg/cm²). These results confirm that the tablets possess adequate mechanical integrity, ensuring they remain intact during handling and transportation. Friability tests further supported this observation, with all batches showing excellent resistance to crumbling. The friability values ranged from 0.22% to 0.29%, well below the acceptable limit of ≤1%. Notably, batches F7 and F8 demonstrated the lowest friability (0.22%), reflecting superior resistance to abrasion.

The weight variation of the tablets was consistent, ranging from 220 to 229 mg, meeting pharmacopeial requirements. This uniformity ensures precise dosing across all batches. Batch F9 showed the highest average weight (229 mg), while F8 exhibited the lowest (220 mg). The swelling index, which influences both drug release and buoyancy, ranged from 91.35% to 97.24% over 12 hours. Batch F7 exhibited the highest swelling index (97.24%), ensuring prolonged buoyancy and sustained drug release, while F3 demonstrated a relatively lower swelling index (91.35%), potentially affecting its release profile.

The floating lag time, a critical parameter for gastro-retentive formulations, ranged from 4.3 to 5.1 minutes. Batch F7 achieved the shortest lag time (4.3 minutes), indicating efficient buoyancy, while F10 exhibited a slightly longer lag time (5.1 minutes). Importantly, all batches achieved floating times exceeding 8 hours, with most (e.g., F1, F3, F5, F6, F8–F10) remaining buoyant for over 10 hours. This prolonged floating duration ensures effective gastric retention, which is essential for sustained drug delivery in gastro-retentive systems. The drug content across batches ranged from 96.79% to 99.57%, reflecting uniformity and compliance with

pharmacopeial standards. Batch F5 demonstrated the highest drug content (99.57%), ensuring optimal dosing accuracy, while F1 showed the lowest drug content (96.79%), still within acceptable limits.

In-*vitro* Drug Release Study

The in-*vitro* drug release profiles of batches F1 to F10 were assessed over 12 hours, showcasing effective sustained-release characteristics.

Table 5: Percent Cumulative drug release of Batches F1 to F10

Batch	Cumulative Drug release at 1 hr	Cumulative Drug release at 2 hr	Cumulative Drug release at 4 hr	Cumulative Drug release at 8 hr	Cumulative Drug release at 10 hr	Cumulative Drug release at 12 hr
F1	24.24±0.233	41.24±0.735	58.24±1.244	76.88±0.567	88.56±1.357	94.48±0.748
F2	26.64±0.236	34.24±0.636	56.36±1.753	73.24±0.245	89.34±1.754	95.53±0.986
F3	27.46±0.535	47.52±0.574	58.56±1.357	78.97±0.543	86.86±1.457	93.35±0.346
F4	22.35±0.235	38.45±0.735	59.34±1.754	72.07±0.753	85.75±1.724	92.55±0.864
F5	24.85±0.457	35.76±0.852	56.86±1.457	71.43±0.357	88.45±1.524	95.88±0.567
F6	29.45±0.544	41.67±0.257	55.75±1.724	79.24±0.932	86.94±0.843	94.45±0.735
F7	20.93±0.567	38.45±0.735	58.45±1.524	78.64±0.556	84.24±0.233	95.76±0.852
F8	30.41±0.969	55.5±0.377	66.01±0.357	75.27±0.924	81.24±0.735	96.01±0.357
F9	30.05±1.539	48.01±0.357	58.40±0.246	73.75±0.934	84.24±0.636	94.41±0.733
F10	20.12±0.831	44.41±0.733	54.31±1.378	79.53±0.986	87.52±0.574	93.31±1.378

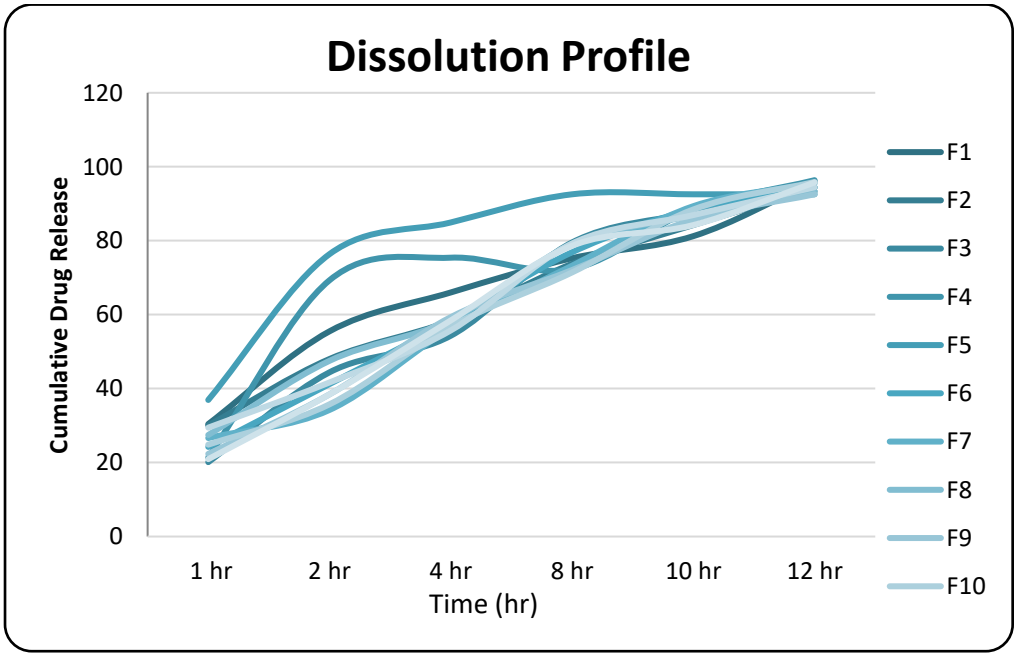

Figure 7: Dissolution Profile

At 1 hour, the release ranged from 20.12% (F10) to 30.41% (F8), with F8 exhibiting the fastest initial release and F10 the slowest. By 4 hours, F8 maintained the highest cumulative release (66.01%), while F10 released the least (54.31%). At 8 hours, most batches surpassed 70% release, with F10 achieving 79.53% and F5 the lowest at 71.43%.

By 12 hours, all batches exceeded 92% release, with F8 reaching the highest (96.01%) and F4 the lowest (92.55%). Batch F8 demonstrated rapid and sustained release, ideal for immediate therapeutic availability, while F10 provided controlled release for prolonged effects. Batches F5, F6, and F7 displayed balanced

profiles. The results confirm that polymer composition and matrix design significantly impact drug release, with all formulations meeting the criteria for effective gastro-retentive drug delivery systems.

Conclusion

The study successfully designed, formulated, and optimized floating tablets of Enalapril Maleate and Losartan, addressing the need for sustained gastric residence time and enhanced bioavailability. By employing suitable excipients like HPMC K4M, Guar gum, and effervescent agents such as sodium bicarbonate and citric acid, we were able to develop a dosage form that not only ensured prolonged floating but also facilitated controlled drug release, which is critical for effective cardiovascular treatment.

The formulation was evaluated comprehensively, with results confirming the tablets' optimal physico-chemical properties, including uniform drug content, excellent mechanical strength, low friability, and consistent swelling and floating behaviors. Additionally, the in-*vitro* dissolution studies demonstrated that the floating tablets could achieve sustained release over 12 hours, with varying release rates across formulations. Importantly, formulations such as F7 and F5 showed the most promising performance in terms of drug release profiles, buoyancy, and stability.

The findings highlight the potential of floating drug delivery systems in improving patient compliance, especially for chronic conditions requiring consistent therapeutic plasma concentrations. The study also underscores the importance of careful selection of excipients and the optimization of tablet formulation to balance drug release and gastro-retentive properties effectively.

In conclusion, the developed floating tablets of Enalapril Maleate and Losartan hold promise as a viable approach for the sustained treatment of cardiovascular diseases, enhancing both the efficacy and safety profiles of the drugs. Further studies on long-term stability and in-*vivo* testing will be essential to confirm the clinical applicability of the formulation.

Conflict of Interest

We declare that we do not have conflict of interest.

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