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Research Article

FORMULATION AND EVALUATION OF GASTRORETENTIVE FLOATING TABLETS OF ATENOLOL FOR HYPERTENSION MANAGEMENT: A PHARMACEUTICAL DEVELOPMENT STUDY

Shristi Patel[1], Rohit Ghoshi[1]*, Sunil K. Jain[1], Vivek Jain[1]

[1]Department of Pharmaceutics, Adina Institute of Pharmaceutical Sciences, Sagar (M.P.), India.

Corresponding Author*: Rohit Ghoshi, Department of Pharmaceutics, Adina Institute of Pharmaceutical Sciences, Sagar (M.P.), India.

Email ID: rohitghoshi30@gmail.com

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Abstract

Background: Atenolol, a cardioselective β_1-adrenergic blocker widely used in hypertension management, suffers from poor bioavailability (~50%) and short elimination half-life (6-7 hours) due to its narrow absorption window in the upper gastrointestinal tract. Conventional formulations require frequent dosing, leading to poor patient compliance.

Objective: To develop and evaluate gastroretentive floating tablets of atenolol using hydrophilic polymers to enhance gastric residence time, improve bioavailability, and achieve sustained drug release for improved hypertension management.

Methods: Six floating tablet formulations (F1-F6) containing 50 mg atenolol were prepared using wet granulation technique with varying concentrations of hydroxypropyl methylcellulose (HPMC 15cps, 60-90 mg), chitosan (25-60 mg), and guar gum (50-60 mg). Comprehensive preformulation studies included organoleptic evaluation, solubility analysis, and compatibility assessment. Tablets were evaluated for physical parameters (weight variation, hardness, friability, thickness), floating characteristics (lag time, total floating time), content uniformity, and in vitro dissolution over 12 hours in 0.1N HCl using USP apparatus II.

Results: All formulations demonstrated acceptable physical properties with weight variation within ±7.5%, hardness 2-3 kg/cm², friability 0.5%, and content uniformity 99.72±0.83%. Floating lag time was 5.2±0.3 minutes with total floating time exceeding 12 hours. In vitro dissolution studies revealed sustained drug release with F2 achieving optimal performance, releasing 98.1% drug over 12 hours. Flow properties indicated fair to good characteristics with bulk density 0.50 g/mL, tapped density 0.625 g/mL, angle of repose 29.2°, compressibility index 20%, and Hausner ratio 1.25.

Conclusion: Gastroretentive floating tablets of atenolol were successfully developed with F2 formulation demonstrating superior sustained release characteristics, prolonged gastric retention, and potential for improved bioavailability. This approach offers a promising strategy for enhanced hypertension management through reduced dosing frequency and improved patient compliance.

Keywords: Atenolol, Floating Tablets, Gastroretentive Drug Delivery, Hypertension, Sustained Release, Bioavailability Enhancement

1. Introduction

Hypertension affects approximately 1.13 billion people worldwide and represents the leading cause of cardiovascular mortality, contributing to over 10 million deaths annually. The condition is characterized by persistently elevated blood pressure (≥140/90 mmHg) and serves as a major modifiable risk factor for stroke, myocardial infarction, heart failure, and chronic kidney disease. Effective management requires sustained blood pressure control through appropriate pharmacological interventions, with β-adrenergic blockers serving as first-line therapy in specific patient populations[1][2].

Atenolol, a cardioselective β_1-adrenergic receptor antagonist, represents a cornerstone in hypertension management due to its favorable safety profile and proven cardiovascular benefits . The drug selectively blocks β_1-adrenergic receptors in cardiac tissue, reducing heart rate, myocardial contractility, and cardiac output, thereby lowering blood pressure . Additionally, atenolol inhibits renin release from juxtaglomerular cells, contributing to its antihypertensive efficacy through reduced angiotensin II formation[3,4].

Despite its therapeutic advantages, atenolol presents significant pharmacokinetic challenges that limit its clinical effectiveness. The drug exhibits poor oral bioavailability (approximately 50%) due to incomplete absorption from the gastrointestinal tract, with absorption primarily occurring in the upper small intestine through a saturable transport mechanism[5,6].

The elimination half-life of 6-7 hours necessitates multiple daily dosing, potentially compromising patient compliance and therapeutic outcomes[7,8].

The narrow absorption window of atenolol in the upper gastrointestinal tract makes it an ideal candidate for gastroretentive drug delivery systems[9,10].

Floating drug delivery systems (FDDS) represent an innovative approach to prolong gastric residence time by maintaining buoyancy on gastric contents without affecting gastric emptying rate[11,12].

This technology enables sustained drug release in the optimal absorption region, potentially enhancing bioavailability and reducing dosing frequency[13,14].

Gastroretentive floating systems achieve buoyancy through various mechanisms, including gas generation by effervescent agents, low-density matrices formed by swellable polymers, or incorporation of hollow microspheres . Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC), chitosan, and natural gums create swellable matrices that reduce system density while controlling drug release through diffusion and matrix erosion[15,16].

The advantages of floating drug delivery systems for atenolol include enhanced bioavailability through prolonged gastric residence time, sustained drug release reducing dosing frequency, improved patient compliance, and reduced inter-patient variability in plasma drug concentrations[17,18].

Additionally, the approach may minimize adverse effects associated with peak plasma concentrations following immediate-release formulations[19,20].

The objective of this study was to develop and systematically evaluate gastroretentive floating tablets of atenolol using combinations of hydrophilic polymers to achieve optimal sustained release characteristics, prolonged gastric retention, and improved pharmaceutical properties for enhanced hypertension management[21,22].

2. Materials and Methods

2.1 Materials

Atenolol was obtained from pharmaceutical grade sources. Excipients included hydroxypropyl methylcellulose 15cps (HPMC 15cps), chitosan, guar gum, lactose monohydrate, magnesium stearate, and talc. All materials were of pharmaceutical grade and used as received. Analytical grade reagents including hydrochloric acid and distilled water were used for dissolution studies[23,24].

2.2 Drug Profile and Rationale

Atenolol ($C_{14}H_{22}N_2O_3$, molecular weight 266.336 g/

mol) is a white to almost white crystalline powder with melting point 152-155°C. The drug is sparingly soluble in water and exhibits pH-dependent solubility with enhanced dissolution in acidic conditions . Its physicochemical properties and absorption characteristics make it suitable for gastroretentive formulation approaches[25,26].

2.3 Preformulation Studies

Comprehensive preformulation studies were conducted to characterize drug and excipient properties. Organoleptic evaluation assessed color, odor, taste, and texture. Solubility studies determined drug solubility in various media. Melting point determination confirmed drug identity and purity. Drug-excipient compatibility was evaluated through physical observation and thermal analysis[27,28].

2.4 Flow Property Assessment

Granule flow properties were evaluated using established pharmacopeial methods. Bulk density and tapped density were determined using graduated cylinders with 100 taps. Angle of repose was measured using the fixed funnel method. Compressibility index (Carr's index) and Hausner ratio were calculated from density measurements[29,30].

2.5 Formulation Development

Six floating tablet formulations (F1-F6) were designed using wet granulation technique with systematic variation in polymer concentrations. Each tablet contained 50 mg atenolol with total tablet weight of 350 mg. Formulations varied in HPMC 15cps content (60-90 mg), chitosan concentration (25-60 mg), and guar gum levels (50-60 mg), while maintaining constant lubricant and glidant concentrations[31,32].

2.6 Tablet Preparation

Tablets were prepared using wet granulation method. Accurately weighed quantities of atenolol, polymers, and lactose were dry-mixed for 10 minutes. Purified water was added gradually to form coherent granules, which were passed through #16 mesh sieve. Granules were dried at 50°C until moisture content <2%, then passed through #20 mesh. Magnesium stearate and talc were added as lubricants before compression using 10mm round punches[33,34].

2.7 Physical Evaluation

Weight variation was determined using 20 tablets with acceptance criteria of ±7.5% deviation. Hardness was measured using Monsanto hardness tester targeting 2-3 kg/cm². Friability was assessed using Roche friabilator with acceptance limit ≤1%. Thickness was measured using Vernier calipers. Content uniformity was determined by analyzing individual tablets using validated HPLC method[35,36].

2.8 Floating Characteristics

Floating lag time and total floating time were determined in 900 mL of 0.1N HCl at 37±0.5°C. Tablets were observed for buoyancy, with floating lag time recorded as time to achieve surface floatation. Total floating time was monitored until tablets lost buoyancy or disintegrated[37].

2.9 In Vitro Dissolution Studies

Dissolution studies were conducted using USP Apparatus II (paddle method) in 900 mL of 0.1N HCl (pH 1.2) at 37±0.5°C with paddle speed 50 rpm. Samples were withdrawn at predetermined intervals over 12 hours and analyzed spectrophotometrically at 224 nm. Dissolution profiles were compared using model-independent approaches[38].

2.10 Release Kinetics

Drug release data were fitted to various mathematical models including zero-order, first-order, and Higuchi equations to determine release mechanisms. The Korsmeyer-Peppas model was applied to characterize diffusion and relaxation contributions to drug release[39].

3. Results

3.1 Preformulation Studies

Atenolol appeared as white crystalline powder, odorless, with characteristic bitter taste and melting point 152-155°C, confirming drug identity and

purity. Solubility studies revealed sparingly soluble nature in water with enhanced dissolution in acidic conditions. All excipients demonstrated acceptable organoleptic properties and showed no incompatibility with the drug substance (Table 1) .

3.2 Flow Properties

Granule flow properties indicated acceptable characteristics for tablet compression. Bulk density was 0.50 g/mL with tapped density 0.625 g/mL, yielding compressibility index of 20% and Hausner ratio of 1.25. Angle of repose measured 29.2°, indicating good flow properties suitable for uniform die filling during tablet compression (Table 2).

3.3 Formulation Composition

Six formulations were developed with systematic variation in polymer concentrations while maintaining drug content at 50 mg per tablet. Formulation F2 contained the highest HPMC concentration (90 mg) with moderate chitosan (30 mg) and guar gum (50 mg) levels. The composition design enabled evaluation of individual and synergistic polymer effects on floating and release characteristics (Table 3).

Table 1. Preformulation Study Results

Substance	Color	Odor	Solubility	Melting_Point	Compatibility
Atenolol	White crystalline powder	Odorless	Sparingly soluble	152-155Â°C	Compatible
HPMC 15cps	White fibrous powder	Odorless	Swells forms gel	>180Â°C (softens)	Compatible
Chitosan	White/off White powder	Odorless to slight odor	Slightly soluble in acidic	Decomposes >220Â°C	Compatible
Guar Gum	Light brownish powder	Odorless	Insoluble	~200Â°C (decomposes)	Compatible
Lactose	White crystalline powder	Odorless	Slightly soluble	~202Â°C	Compatible
Mg stearate	White greasy powder	Slight characteristic	Insoluble	~88-90Â°C	Compatible

Table 2. Flow Property Assessment

Parameter	Value	Interpretation
Bulk density	0.50 g/mL	Good bulk density
Tapped density	0.625 g/mL	Good packing property
Angle of repose	29.2Â°	Good flow
Compressibility index	20%	Fair flow
Hausner ratio	1.25	Good flow

Table 3. Tablet Formulation Composition

Ingredient	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	Function
Atenolol	50	50	50	50	50	50	Active ingredient
HPMC 15cps	80	90	70	60	85	75	Sustained-release polymer
Chitosan	40	30	50	60	25	35	Bioadhesive/release retardant
Guar Gum	60	50	60	50	60	55	Matrix former/swelling agent
Lactose	105	110	100	110	110	115	Diluent/filler
Mg-stearate	7.5	7.5	7.5	7.5	7.5	7.5	Lubricant
Talc	7.5	7.5	7.5	7.5	7.5	7.5	Glidant

3.4 Physical Evaluation

All formulations demonstrated acceptable physical properties meeting pharmacopeial standards. Weight variation remained within ±7.5% for all batches, hardness values ranged 2-3 kg/cm², and friability was consistently <1%. Thickness uniformity was maintained at 5.2±0.1 mm. Content uniformity averaged 99.72±0.83% with acceptance value 2.27, well below the limit of 15 (Table 4).

3.5 Floating Characteristics

All formulations achieved successful floatation with varying lag times. Floating lag time averaged 5.2±0.3 minutes, attributed to hydration time required for polymer swelling and matrix formation. Total floating time exceeded 12 hours for all formulations, indicating sustained buoyancy throughout the intended release period. The absence of gas-generating agents resulted in slightly longer lag times compared to effervescent systems.

3.6 Dissolution Studies

In vitro dissolution studies revealed sustained drug release profiles over 12 hours for all formulations. Release rates varied with polymer composition, with F2 demonstrating optimal characteristics releasing 98.1% drug at 12 hours. F1 showed fastest release (99.2% at 12 hours) while F4 exhibited most sustained profile (89.6% at 12 hours). All formulations maintained floating behavior throughout dissolution testing (Table 5).

3.7 Release Kinetics

Mathematical modeling revealed that drug release followed anomalous transport mechanisms with release exponents between 0.45 and 0.89, indicating combined diffusion and polymer relaxation. Higuchi model showed good correlation ($r^2 > 0.95$) for most formulations, confirming diffusion-controlled release from swelling matrices.

Table 4. Physical Evaluation Parameters

Parameter	Result	Acceptance_Criteria	Status
Weight variation	Â±5-7.5%	Â±5% (USP), Â±7.5% (IP)	Passed
Hardness	2-3 kg/cmÂ²	2-3 kg/cmÂ²	Passed
Friability	0.50%	â‰¤1%	Passed
Thickness	5.2Â±0.1 mm	Uniform thickness	Passed
Content uniformity	99.72Â±0.83%	85-115%	Passed
Floating lag time	5.2Â±0.3 min	<10 min	Passed
Total floating time	>12 hours	>8 hours	Passed

Table 5. Dissolution Study Results

Time_hours	F1_percent	F2_percent	F3_percent	F4_percent
0	0	0	0	0
0.5	12.4	10.3	8.6	6.1
1	22.6	18.7	16.2	11.9
2	35.8	30.1	25.6	19.7
3	48.1	42.6	36.4	28.5
4	59.3	54.7	47.1	38.3
6	74.2	70.9	61.5	51.7
8	87.6	84.5	74.8	66.2
10	96.3	92.8	87.3	78.4
12	99.2	98.1	95.7	89.6

4. Discussion

The successful development of gastroretentive floating tablets of atenolol addresses significant therapeutic challenges associated with conventional immediate-release formulations. The comprehensive preformulation studies confirmed drug-excipient compatibility and established optimal processing parameters for tablet manufacture[40].

The selection of HPMC 15cps, chitosan, and guar gum as matrix-forming polymers was based on their proven efficacy in gastroretentive systems and complementary functional properties. HPMC provides rapid hydration and gel formation, chitosan offers bioadhesive properties enhancing gastric retention, while guar gum contributes to matrix strength and controlled release[41].

Formulation F2 emerged as optimal based on comprehensive evaluation parameters. The combination of 90 mg HPMC 15cps, 30 mg chitosan, and 50 mg guar gum achieved ideal balance between floating characteristics and sustained release. The higher HPMC concentration facilitated rapid matrix hydration and buoyancy while moderate chitosan levels provided adequate bioadhesive properties without compromising release rate.

The floating lag time of 5.2±0.3 minutes, though slightly higher than effervescent systems, remains clinically acceptable and reflects the time required for polymer hydration and matrix swelling. The extended total floating time (>12 hours) ensures sustained gastric retention throughout the intended dosing interval, potentially improving bioavailability through prolonged drug exposure to the absorption site.

The sustained release profiles demonstrated successful rate modulation with F2 achieving near-complete release (98.1%) over 12 hours. This release pattern is ideal for atenolol therapy, providing sustained therapeutic levels while minimizing peak-related adverse effects. The anomalous transport mechanism indicates combined diffusion and matrix erosion, typical of hydrophilic matrix systems.

The physical properties of all formulations met pharmacopeial standards, confirming robust manufacturing processes. The acceptable flow properties facilitated uniform tablet compression, while mechanical strength parameters ensure product integrity during handling and storage.

The gastroretentive approach offers significant advantages for atenolol therapy including reduced dosing frequency from twice-daily to once-daily administration, improved patient compliance, enhanced bioavailability through optimal absorption window utilization, and reduced plasma concentration fluctuations.

Study limitations include absence of in vivo bioavailability data and long-term stability assessment. Future research should focus on comparative bioavailability studies, optimization of floating lag time through effervescent agents, and comprehensive stability evaluation under accelerated conditions.

The development strategy employed systematic formulation optimization with robust evaluation methodology. The use of natural and semi-synthetic polymers ensures safety and regulatory acceptance while achieving desired pharmaceutical performance[42].

5. Conclusion

This study successfully demonstrates the development and evaluation of gastroretentive floating tablets of atenolol using combinations of hydrophilic polymers. Formulation F2, containing 90 mg HPMC 15cps, 30 mg chitosan, and 50 mg guar gum, exhibited optimal performance with sustained drug release (98.1% over 12 hours), acceptable floating characteristics (lag time 5.2±0.3 minutes, total floating time >12 hours), and robust physical properties.

The wet granulation technique proved effective for tablet manufacture, yielding products meeting all pharmacopeial standards. The sustained release profiles and prolonged gastric retention achieved through this approach offer significant potential for

improved atenolol bioavailability and therapeutic outcomes in hypertension management.

The floating drug delivery system addresses key limitations of conventional atenolol formulations by reducing dosing frequency, potentially improving patient compliance, and providing sustained therapeutic levels. This research contributes to advancing gastroretentive drug delivery technology and supports development of patient-centric pharmaceutical solutions for cardiovascular therapeutics.

Future clinical studies are warranted to establish bioequivalence, confirm therapeutic benefits, and optimize formulation parameters for commercial development. The principles established in this work can be extended to other cardiovascular drugs with similar absorption characteristics, expanding the impact of gastroretentive drug delivery in cardiovascular medicine.

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8. Conflicts of Interest

The authors declare no competing financial interests or personal relationships that could have influenced this work.

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