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FORMULATION AND IN VITRO EVALUATION OF FUROSEMIDE FLOATING TABLETS

Shahid R. Shekh*, Ramesh R. Pagore, Rahul S. Radke, Mohd. Hasib Ahmed, Faiz Ahmed Khan

Karmayogi Tatyasaheb Bondre Institute of Pharmacy, Chikhli, Dist. Buldhana, Maharashtra (India) – 443201.

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***Corresponding Author: Shahid R. Shekh**
Karmayogi Tatyasaheb Bondre Institute of Pharmacy, Chikhli, Dist. Buldhana, Maharashtra (India) – 443201.
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ABSTRACT

The present study was undertaken to formulate and evaluate gastroretentive floating tablets of furosemide to enhance gastric residence time and achieve sustained drug release. Tablets were prepared by Wet Granulation method using hydrophilic polymers HPMC K4M and HPMC K15M at concentrations of 20%, 30%, and 40%. Six formulations (FT-1 to FT-6) were developed, sodium bicarbonate and citric acid were incorporated as gas-generating agents to provide buoyancy. Preformulation studies indicated good flow properties of the powder blend, suggesting good compressibility. FTIR analysis confirmed the compatibility of furosemide with selected polymers, as no significant changes in characteristic peaks were observed. Post-compression evaluation showed that all formulations possessed acceptable physicochemical properties. Hardness ranged from 5.2 ± 1.13 to 5.6 ± 1.11 kg/cm², thickness from 3.4 ± 0.3 mm to 3.9 ± 0.2 mm, and friability remained below 1%. Drug content uniformity was within 96.51 ± 0.28% to 99.8 ± 0.34%. The swelling index increased from 120 ± 2% to 230 ± 4%, indicating enhanced hydration with higher polymer concentration. Floating studies revealed a floating lag time range from 124 to 133 seconds and total floating time is increases up to 12 hours. In vitro drug release studies demonstrated sustained release over 12 hours. Overall, formulations containing higher concentrations of HPMC K15M (FT-6) exhibited better swelling, floating behavior, and controlled drug release. The study concludes that furosemide floating tablets can be effectively developed to improve gastric retention and therapeutic performance.

KEYWORDS : Furosemide, Floating tablets, Gastroretentive drug delivery system, HPMC K4M, HPMC K15M, etc.

INTRODUCTION

Oral drug delivery remains the most preferred and widely accepted route of drug administration because of its convenience, cost-effectiveness, patient compliance, and ease of manufacturing. However, conventional oral dosage forms often suffer from limitations such as short gastrointestinal residence time and unpredictable gastric emptying, which may result in reduced bioavailability of drugs exhibiting a narrow absorption window in the upper gastrointestinal tract.[1,2] To overcome these limitations, gastroretentive drug delivery systems (GRDDS) have been developed to prolong gastric residence time and enhance drug absorption and therapeutic efficacy. Among the various GRDDS approaches, floating drug delivery systems have gained considerable attention due to their ability to remain buoyant on gastric fluids for extended periods without affecting gastric emptying rate.[3] Floating drug delivery systems are low-density formulations that remain suspended in the stomach contents and release the drug in a controlled manner while floating on the gastric fluid surface. These systems improve gastric retention time and are particularly beneficial for drugs that are primarily absorbed from the stomach or proximal part of the small intestine, drugs that are unstable in alkaline pH, and drugs intended for local action in the stomach. Floating systems are generally classified into effervescent and non-effervescent systems, with effervescent systems utilizing gas-generating agents such as sodium bicarbonate and citric acid to impart buoyancy to the dosage form.[4-6] Furosemide is a potent loop diuretic widely used in the management of edema associated with congestive heart failure, hepatic cirrhosis, renal disorders, and hypertension. Despite its extensive clinical use, the oral bioavailability of furosemide is relatively low and highly variable, ranging from approximately 37–60%, primarily due to its poor solubility and limited absorption window located in the stomach and upper part of the small intestine. Furthermore, furosemide exhibits pH-dependent solubility and reduced absorption in the lower gastrointestinal tract, making it a suitable candidate for gastroretentive drug delivery systems. The development of floating tablets of furosemide offers several advantages, including prolonged gastric retention, improved dissolution in the acidic environment of the stomach, sustained drug release, enhanced bioavailability, reduced dosing frequency, and improved patient compliance. Various hydrophilic polymers such as Hydroxypropyl Methylcellulose polymers have been employed in the formulation of floating tablets to control drug release and maintain tablet buoyancy.[7,8] Therefore, the present study was undertaken to formulate and evaluate gastroretentive floating tablets of furosemide with the objective of improving gastric retention time, achieving sustained drug release, and enhancing the overall bioavailability of the drug. The formulated floating tablets were evaluated for pre-compression and post-compression parameters, buoyancy characteristics, swelling behavior, drug content uniformity, and in vitro drug release profile to identify an optimized formulation with desirable gastroretentive properties.[9,10]

MATERIALS AND METHODS

Materials

Furosemide was received as a gift sample from SM Pharma, Mumbai., India. All other materials used was of analytical grade and procured from commercial sources.

Methods

Formulation of Floating Tablets of Furosemide

The floating tablets of Furosemide were prepared by the Wet Granulation method using a gas-generating approach. Accurately weighed quantities of Furosemide, hydrophilic polymer HPMC K4M & HPMC K15M, sodium bicarbonate, and citric acid were passed through a #60 sieve to ensure uniform particle size. The sieved ingredients were then

blended thoroughly in a mortar to achieve a homogeneous mixture. Excipients such as microcrystalline cellulose were used as diluent and polyvinylpyrrolidone K30 as binder were added and mixed uniformly. Magnesium stearate and talc were subsequently incorporated as lubricants and glidants, respectively, and mixed gently to avoid over-lubrication.

The final blend was evaluated for pre-compression parameters and then compressed into tablets using a rotary tablet compression machine. The composition for floating tablets of Furosemide were shown in table 1.[11-14]

Table 1: Composition of Furosemide Floating Tablets.

Ingredient (mg)	FT-1	FT-2	FT-3	FT-4	FT-5	FT-6
Furosemide	80	80	80	80	80	80
Hpmc K4m	60	90	120	-	-	-
Hpmc K15m	-	-	-	60	90	120
Sodium Bicarbonate	30	30	30	30	30	30
Citric Acid	10	10	10	10	10	10
Pvp K30	15	15	15	15	15	15
Magnesium Stearate	3	3	3	3	3	3
Talc	3	3	3	3	3	3
Mcc	99	69	39	99	69	39
Isopropyl Alcohol	qs	qs	qs	qs	qs	qs
Total Weight	300	300	300	300	300	300

EVALUATION PARAMETER

Pre-compression Evaluation of Powder Blend

The powder blend was evaluated for its micromeritic properties prior to compression. Bulk density was determined by transferring a known quantity of powder passed through sieve #20 into a graduated measuring cylinder and measuring the untapped volume. Tapped density was determined by tapping the cylinder mechanically until a constant volume was obtained. The flow properties of the powder blend were assessed by calculating Hausner ratio and Carr's compressibility index using the values of bulk and tapped densities. The angle of repose was determined by the fixed funnel method, in which the powder blend was allowed to flow through a funnel fixed at a constant height to form a conical heap on a flat surface, and the height and radius of the heap were measured. Bulk density, tapped density, Hausner ratio, Carr's index, and angle of repose were calculated using the standard equations.[15,16]

Post-Compression Evaluation

Hardness Test

Hardness testing ensures that tablets can withstand handling, packaging, and transportation without breaking or crumbling, thereby maintaining their integrity and appearance throughout their shelf life. Tablet hardness was determined using a Pfizer hardness tester to evaluate the mechanical strength of the prepared tablets. The hardness was expressed in kg/cm^2.[17]

Thickness Test

Tablet thickness testing provides valuable feedback on the performance of tablet compression equipment and formulation parameters. Deviations in tablet thickness may indicate variations in raw material properties, compression pressure, or equipment calibration. The thickness of the prepared tablets was measured using Vernier caliper. It is expressed in mm.

Weight Variations

Twenty tablets were selected randomly and weighed individually. The average weight was calculated, and the results were compared with pharmacopeial limits for weight variation.[18]

Friability Test

Friability was determined using a Roche friabilator operated at 100 revolutions. The tablets were reweighed after the test, and percentage weight loss was calculated. A friability value below 1% was considered acceptable.

Drug Content Uniformity

Drug content was determined by dissolving tablets in 0.1 N HCl followed by suitable dilution and analysis using a UV-visible spectrophotometer at 274 nm. The drug content was calculated using the calibration curve of furosemide.[19]

Swelling Index

The swelling index of floating tablets is determined to evaluate the extent of hydration and matrix expansion upon contact with gastric fluid, which directly influences buoyancy and drug release behavior. The study is typically performed by accurately weighing a pre-dried tablet (W_0) and placing it in a suitable container containing a specified volume of dissolution medium, usually 0.1 N hydrochloric acid (pH 1.2), maintained at 37 ± 0.5 °C to simulate gastric conditions. At predetermined time intervals (e.g., 1, 2, 4, 6, and 8 hours), the tablet is carefully removed, excess surface liquid is gently blotted using filter paper without pressing the tablet, and the swollen tablet is reweighed (W_t). The swelling index (SI) is then calculated using the formula:[20]

$$SI(\%) = \frac{W_t - W_0}{W_0} \times 100$$

where W_0 is the initial weight of the tablet and W_t is the weight of the swollen tablet at time t. The experiment is generally conducted in triplicate.

Floating Lag Time

Floating lag time was determined as the time required for the tablet to emerge and float on the surface of the dissolution medium.

Total Floating Time

Total floating time was recorded as the duration for which the tablet remained continuously buoyant on the dissolution medium.[21]

In-Vitro Dissolution Study

In-vitro drug release studies were carried out using USP Type II (paddle) dissolution apparatus containing 900 mL of 0.1 N HCl maintained at 37 ± 0.5°C and stirred at 75 rpm. Samples were withdrawn at predetermined intervals up to 12 hours, replaced with fresh medium, and analyzed at 274 nm using a UV-visible spectrophotometer.[22]

Drug Release Kinetics

The analysis of release kinetics helps in understanding whether the drug is released in a concentration-dependent manner, time dependent manner, or through a diffusion-controlled or erosion-controlled mechanism. Kinetic modeling

also aids in predicting in-vivo drug performance and ensures batch-to batch consistency of the formulation. In the present study, the in-vitro dissolution data obtained for the formulated dosage forms were fitted into various mathematical models to elucidate the drug release behavior. The commonly employed kinetic models include zero-order, first-order, Higuchi and Korsmeyer Peppas, models. These models provide valuable information regarding the drug release mechanism and structural changes in the dosage form during dissolution.[23]

Stability Study

Accelerated stability studies of the optimized formulation were performed according to ICH guidelines at 40 ± 2°C and 75 ± 5% RH for three months. The formulation was evaluated before and after storage for appearance, hardness, floating characteristics, and in-vitro drug release.[24]

RESULTS AND DISCUSSION

Drug–Excipient Compatibility Studies

FTIR spectroscopy was performed to evaluate the compatibility of furosemide with the selected polymers, HPMC K4M and HPMC K15M. The FTIR spectrum of pure furosemide (figure 1) exhibited characteristic peaks corresponding to N–H stretching (3391–3345 cm^{-1}), O–H stretching (3254 cm^{-1}), amide C=O stretching (1666 cm^{-1}), aromatic C=C stretching (1558–1506 cm^{-1}), and sulfonamide S=O stretching (1321 and 1241 cm^{-1}). The physical mixtures of drug and polymers retained all characteristic peaks of furosemide with only minor shifts in peak positions and intensity variations. The absence of any significant disappearance or appearance of new peaks indicated the absence of chemical interaction between furosemide and the polymers, confirming their compatibility for the formulation of floating tablets.

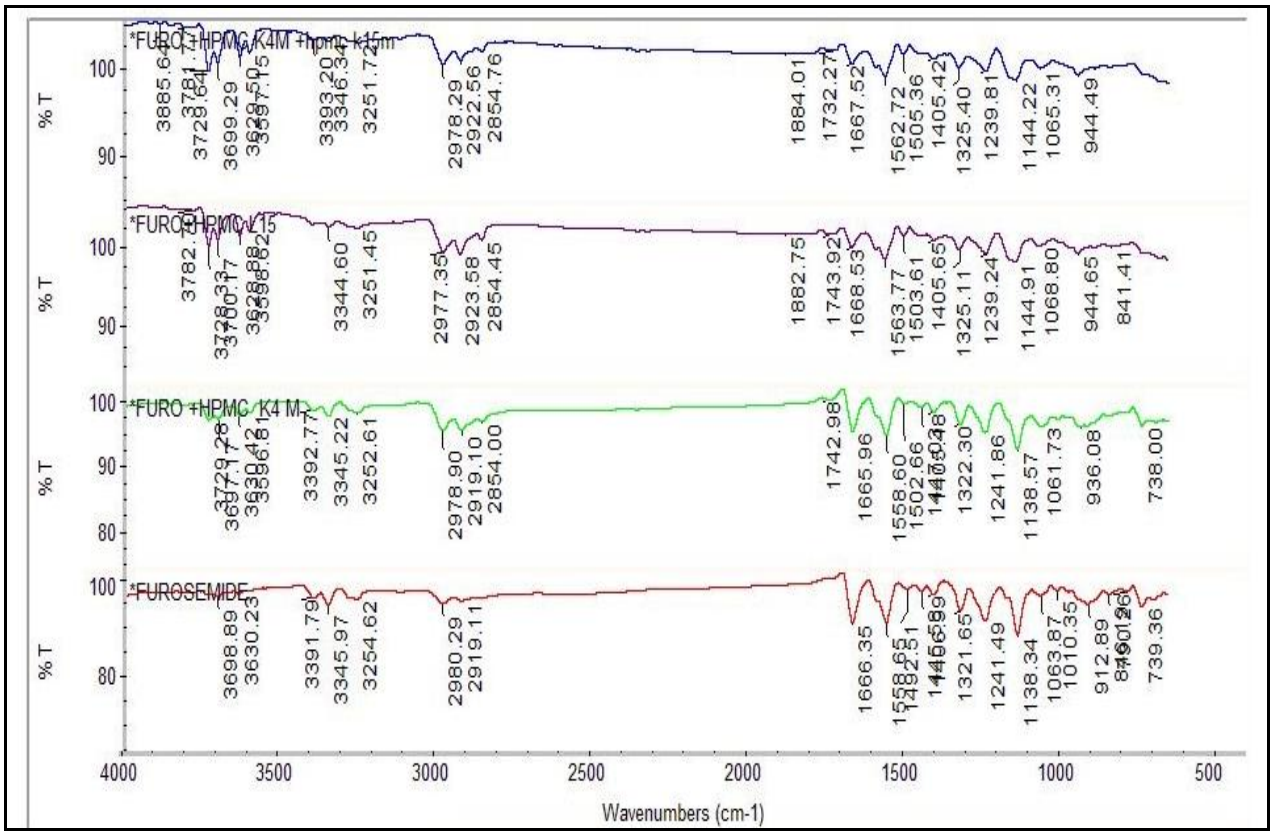

Figure 1: FTIR Overlay Spectra of Drug Furosemide and its Physical Mixture.

Pre-compression Evaluation of Powder Blend

The powder blends prepared for the formulation of furosemide floating tablets were evaluated for their micromeritic properties to assess flowability and compressibility. The bulk density and tapped density values ranged from 0.51±0.04 to 0.59±0.02 g/cm³ and 0.66±0.03 to 0.73±0.05 g/cm³, respectively, indicating satisfactory packing characteristics of the blends. The Hausner's ratio values were found between 1.21±0.07 and 1.35±0.02, while Carr's compressibility index ranged from 12.5±0.8% to 17.2±0.8%, suggesting good to fair flow properties. The angle of repose values ranged from 25.9±0.06° to 28.1±0.01°, confirming good flowability of all formulations. Overall, the micromeritic parameters were within acceptable limits, indicating that the powder blends possessed suitable flow and compression characteristics for the preparation of floating tablets.

Table 2: Post-Compression Evaluation Parameters of Furosemide Floating Tablets.

Batch	Hardness (Kg/Cm^2)	Thickness (mm)	Weight Variation (mg)	Friability (%)	Drug Content (%)	Floating Lag Time (Sec)	Total Floating Time (Hrs)
FT-1	5.4±1.13	3.4±0.3	298±2	0.62±0.08	96.51±0.28	124±10	08±0.65
FT-2	5.5±0.87	3.5±0.2	301±3	0.58±0.11	97.8 ±0.46	132±06	10±0.54
FT-3	5.6±1.11	3.6±0.4	300±2	0.55±0.13	98.6 ±0.67	133±08	11±0.47
FT-4	5.5±1.23	3.7±0.1	299±2	0.50±0.09	99.2 ±0.54	130±11	12±0.32
FT-5	5.5±1.03	3.8±0.3	302±3	0.48±0.12	99.5 ±0.23	128±04	12±0.28
FT-6	5.5±0.78	3.9±0.2	300±2	0.45±0.15	99.8 ±0.34	126±02	12±0.21

Hardness Test

The hardness test of furosemide floating tablets (FT-1 to FT-6) demonstrated satisfactory mechanical strength across all formulations. The hardness values were found to be in the range of 5.4 ± 1.13 to 5.6 ± 1.11 kg/cm², indicating uniform tablet compaction. Among the batches, FT-3 exhibited the highest hardness (5.6 ± 1.11 kg/cm²), while FT-1 showed the lowest value (5.4 ± 1.13 kg/cm²). The remaining batches (FT-2, FT-4, FT-5, and FT-6) displayed comparable hardness values of approximately 5.5 kg/cm² with minimal standard deviation, suggesting consistent compression during tablet formulation. These results confirm that all batches possessed adequate mechanical integrity to withstand handling, packaging, and transportation without significant breakage.

Thickness

The thickness of the formulated floating tablets (FT-1 to FT-6) was measured to ensure uniformity in tablet size, which is important for consistent drug release and packaging. The observed thickness values ranged from 3.4 ± 0.3 mm to 3.9 ± 0.2 mm. FT-1 showed the lowest thickness (3.4 ± 0.3 mm), while FT-6 exhibited the highest thickness (3.9 ± 0.2 mm). A slight and consistent increase in thickness was observed from FT-1 to FT-6, which may be attributed to the gradual increase in polymer concentration and compression characteristics of the formulations. Overall, all formulations were within acceptable limits, confirming satisfactory tablet thickness.

Weight Variation

The weight variation of the prepared floating tablets (FT-1 to FT-6) was determined to evaluate the uniformity of tablet weight. The results showed that the average tablet weights ranged from 298 ± 2 mg to 302 ± 3 mg. The variations in weight were minimal across all batches, indicating uniform die filling during the compression process. All batches complied with the acceptable pharmacopoeial limits for weight variation, demonstrating good uniformity and reliability of the tablet manufacturing process.

Friability

The friability values were found to range from 0.62 ± 0.08% to 0.45 ± 0.15%. Among the batches, FT-1 exhibited the highest friability (0.62 ± 0.08%), while FT-6 showed the lowest value (0.45 ± 0.15%). A decreasing trend in friability was observed from FT-1 to FT-6, indicating an improvement in mechanical strength, which may be attributed to increased polymer concentration and better binding properties. All formulations showed friability values below 1%, which is within the acceptable pharmacopoeial limit, confirming that the tablets possess adequate mechanical integrity and are suitable for further evaluation.

Drug Content Uniformity

The drug content uniformity of the prepared floating tablets (FT-1 to FT-6) was evaluated to ensure uniform distribution of the drug within each formulation. The results indicated that the drug content ranged from 96.51 ± 0.28% to 99.8 ± 0.34%. All formulations were found to be within acceptable pharmacopoeial limits, confirming uniform drug distribution and reliability of the formulation process.

Swelling Index

The swelling index of the formulated floating tablets (FT-1 to FT-6) was determined to evaluate their hydration behavior and matrix expansion limit, which are critical for maintaining buoyancy and controlling drug release. The results showed that the swelling index ranged from 120 ± 2% to 230 ± 4% after 8 hours. Among the formulations, FT-1 exhibited the lowest swelling index (120 ± 2%), while FT-6 showed the highest swelling (230 ± 4%). A progressive increase in swelling was observed from FT-1 to FT-6, which may be attributed to the higher concentration of hydrophilic polymers such as HPMC, leading to greater water uptake and gel formation. The results suggest that all formulations possessed good swelling characteristics, contributing to prolonged gastric retention and sustained drug release.

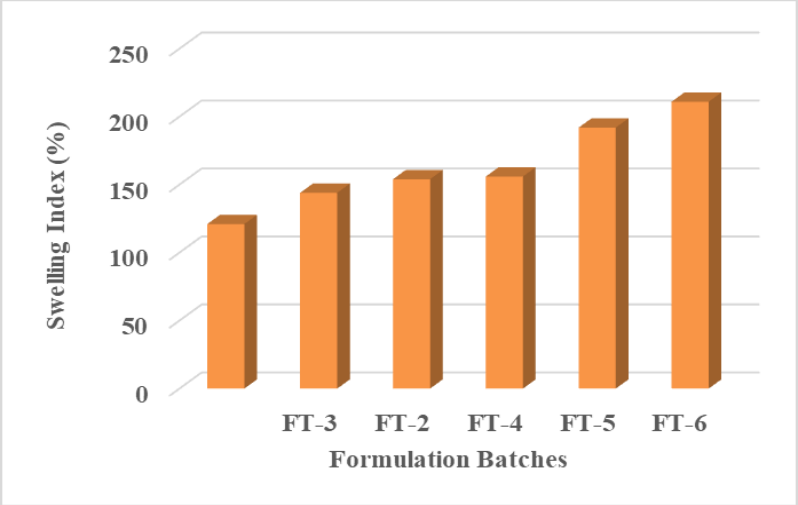

Figure 2: Swelling Index Of Formulation Batches (FT-1 to FT-6).

Floating Lag Time and Total Floating Duration

The floating lag time and total floating time (TFT) of furosemide floating tablets (FT-1 to FT-6) were evaluated to assess their buoyancy behavior and suitability for gastroretentive drug delivery. The floating lag time for all formulations was found to be within the range of 124 ± 10 to 133 ± 8 seconds, indicating a rapid onset of buoyancy.

The total floating time of all batches was observed to be satisfactory, ranging from 8 ± 0.65 to 12 ± 0.21 hours. Batch FT-6, the optimized formulation, exhibited an ideal balance with a relatively short floating lag time (126 ± 2 sec) and maximum total floating time (12 ± 0.21 hrs) with minimal variability. This suggests efficient gas generation and retention, along with a robust gel barrier formed by the polymer, which helps maintain tablet buoyancy for an extended period. The results show that all formulations possessed acceptable floating characteristics.

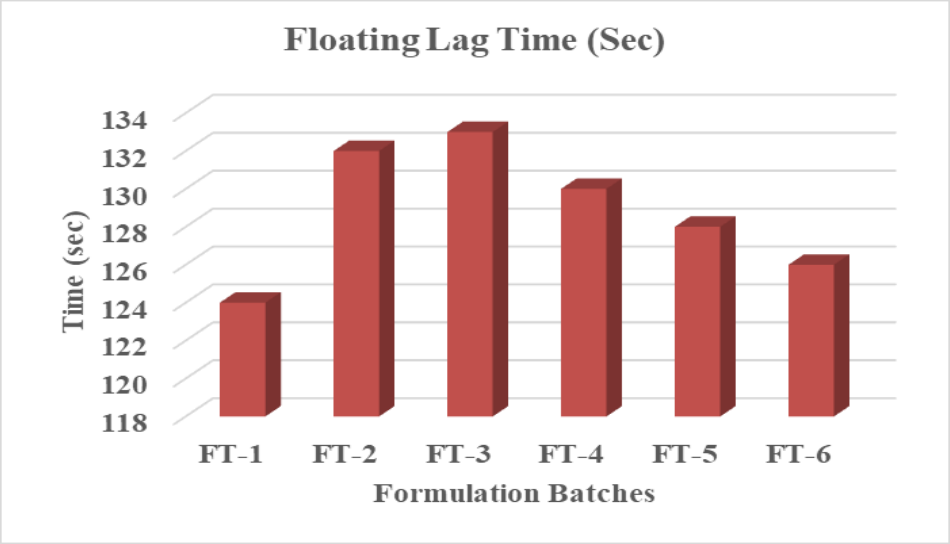

Figure 3: Floating Lag Time Of Formulation Batches.

In-Vitro Dissolution Study

The in vitro dissolution studies of Furosemide Floating Tablets formulations FT-1 to FT-6 demonstrated varied drug release profiles over the study period. FT-1 and FT-2 showed relatively faster drug release, achieving near-complete release within 8–10 hours, indicating less controlled release behavior. FT-3 and FT-4 exhibited moderate and sustained release patterns. Among all formulations, FT-6 showed the most desirable sustained release pattern with a gradual and controlled drug release, achieving approximately complete release at 12 hours, thereby confirming it as the optimized formulation.

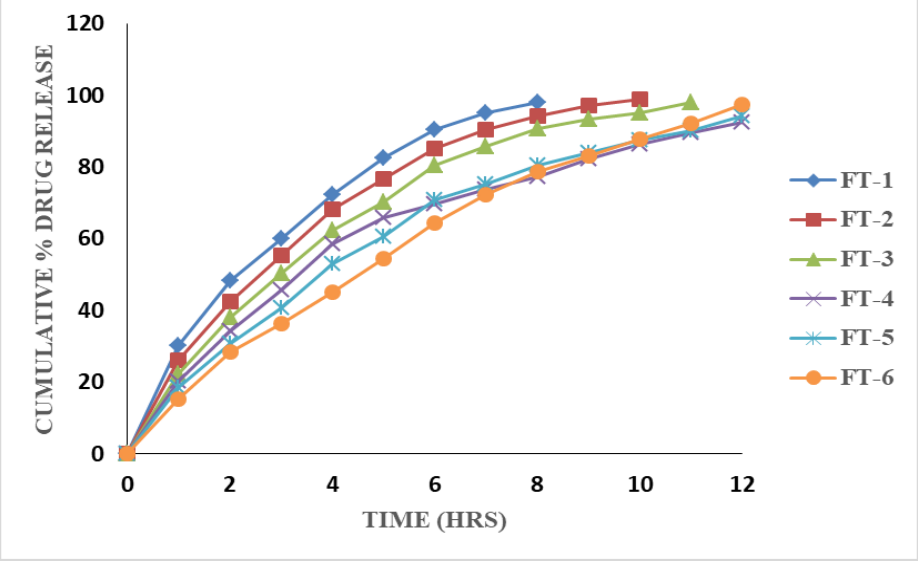

Figure 4: Comparative In-vitro Dissolution Profile of Furosemide Floatinf Tablets Formulaion.

Drug Release Kinetics Study

The drug release kinetics of the optimized formulation FT6 were evaluated using various mathematical models to determine the mechanism of drug release. The regression coefficient (R^2) values for zero-order, first-order, Higuchi, and Korsmeyer–Peppas models were found to be 0.969, 0.908, 0.978, and 0.995, respectively. Among these, the highest R^2 value was observed for the Korsmeyer–Peppas model, indicating it as the best fitting model for the drug release behavior of FT6. The release exponent (n) value of 0.742 suggests a non-Fickian (anomalous) diffusion mechanism, indicating that the drug release is governed by a combination of both diffusion and polymer relaxation (erosion) processes. This confirms that the formulation exhibits controlled drug release characteristics suitable for sustained delivery.

Stability Study

The optimized formulation batch FT-6 of Furosemide floating tablets was evaluated for stability under accelerated conditions (40 ± 2°C / 75 ± 5% RH), and the results were compared with the initial (pre-stability) data. The hardness of the tablets showed a slight decrease from 5.5 ± 0.78 kg/cm² to 5.4 ± 0.22 kg/cm², which remains within acceptable limits, indicating that the mechanical strength of the tablets was largely unaffected. The floating lag time exhibited a minimal increase from 126 ± 02 seconds to 128 ± 03 seconds, suggesting that the gas-generating capability and hydration behavior of the formulation were preserved. The total floating time remained unchanged at 12 hours, confirming the stability of the floating mechanism. Drug content was found to decrease marginally from 99.8 ± 0.34% to 99.5 ± 0.12%, which is within acceptable pharmacopeial limits, indicating uniform drug distribution and stability.

Furthermore, the in vitro drug release showed a marginal decrease from 97.52 ± 0.91% to 96.80 ± 0.86% over 12 hours, indicating that the sustained release characteristics of the formulation were maintained without significant alteration. The results confirm that the optimized batch FT-6 possesses good stability with no significant variation in performance parameters & the negligible changes observed in all evaluated parameters confirm that the optimized batch FT-6 possesses good stability and retains its desired physicochemical and functional properties under accelerated storage conditions.

CONCLUSION

The present investigation successfully developed gastroretentive floating tablets of furosemide using HPMC K4M and HPMC K15M as matrix-forming polymers through the direct compression technique. The prepared powder blends exhibited satisfactory flow and compressibility characteristics, confirming their suitability for tablet manufacture. FTIR studies demonstrated the absence of significant drug–excipient interactions, indicating the compatibility and stability of furosemide with the selected polymers. The formulated tablets showed acceptable post-compression properties, including hardness, friability, thickness, weight variation, and drug content uniformity. Floating studies revealed short floating lag times and prolonged buoyancy, suggesting effective gastroretentive behavior of the formulations. In vitro dissolution studies demonstrated sustained drug release over a period of 12 hours, with the release profile being significantly influenced by the type and concentration of polymer employed. Formulations containing higher concentrations of HPMC K15M exhibited superior swelling characteristics, floating behavior, and controlled drug release. Overall, the developed furosemide floating tablets offer a promising gastroretentive delivery system for improving gastric residence time and enhancing the therapeutic efficacy of furosemide.

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