

Formulation and Characterization of Flurbiprofen Floating Microballons as A Gastroretentive Drug Delivery System

Manjunath B Pyati^{1*}, Ashwini Rajendra² and Gagana C R³

^{1* 2,3} Department of Pharmaceutics, National College of Pharmacy, Shivamogga 577201, Karnataka, India.

**Corresponding Author: manjunathpyati2001@gmail.com*

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ABSTRACT

The experiment was intended to prepare and evaluate the Flurbiprofen loaded floating microballoons as a gastric retention-based drug delivery approach to maintain extended gastric retention period and offer sustained drug release. Flurbiprofen, is a non-steroidal anti-inflammatory drug, was loaded into floating microballoons using the polymers ethyl cellulose and HPMC K4M as release-retarding polymers using solvent evaporation technique. The obtained formulations were characterised by FTIR to assess the compatibility, encapsulation efficiency, percentage yield, drug content, particle size, floating lag time, buoyancy, and in-vitro drug release. The selected formulation was subjected to scanning electron microscopy (SEM) to study the surface morphology. The outcome of FTIR analysis displayed good compatibility between Flurbiprofen and the excipients. All the prepared formulations showed satisfactory floating properties with zero floating lag time and floating duration greater than 12 h. Among the prepared formulations, formulation F8 showed the highest encapsulation efficiency of 92.25 ± 0.06 % and drug content of 44.84 ± 0.14 mg, with sustained drug release up to 9 h. The SEM analysis verified the formation of spherical microballoons with a porous structure. Overall, the results indicated that Flurbiprofen loaded floating microballoons can give a effective gastroretentive drug delivery system, providing prolonged gastric residence and extended drug release, which led to increase the therapeutic effectiveness and reduce dosing frequency.

Keywords: Ethyl cellulose, Flurbiprofen, Floating microballoons, gastro-retentive drug delivery system, HPMC K4M, solvent evaporation, sustained release.

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INTRODUCTION

The oral route is among the most selected and widely accepted routes of drug administration because it is suitable, non-invasive, and increased patient convenience. The therapeutic effectiveness of orally administered drugs depends up on achieving adequate drug absorption from gastrointestinal (GI) tract. Despite this, conventional oral dosage forms are often need to be taken several times in a day to maintain the drug levels in the body, which can reduce the patient compliance. Controlled-release oral drug delivery approach has demonstrated to reduce this issue; they are still impacted by variations in gastric emptying and uneven drug absorption. To overcome with these limitations, this system has been formulated to increase the residence time within the stomach, improve drug absorption, and offer sustained drug release, resulting in better therapeutic outcomes and improved patient adherence [1,2].

GRDDS are developed to stay in the gastric region over an extended period. This reduces the dosing frequency, which improves the patient acceptance. Many techniques are

used to improve the retention of drug in the stomach. These include mucoadhesive (bioadhesive) systems, high-density system, expandable (swelling) system, magnetic system, raft-forming systems, super-porous hydrogels, low-density systems, and floating ion-exchange resin systems [3]. Floating drug delivery systems (FDDS) are low density drug delivery systems that remain float on the stomach contents and remains in the stomach for more duration. Their buoyancy facilitates prolonged gastric retention, permitting the drug to be released at a controlled and predetermined rate while reducing variations in drug concentration [4]. The FDDS offer a many advantage over conventional oral dosage forms, primarily which prolongs gastric residence time (GRT), provides controlled and sustained drug release, enables site-specific drug delivery, reduces gastric irritation. Despite these advantages, FDDS have certain disadvantages like, not suitable for some drugs that are difficult to dissolve or unstable in acid nature of the stomach, gastric retention may change depending on aspects such as food intake and gastric movement, which can affect drug release, and drugs that cause discomfort the gastric lining are not favourable for

**Author for Correspondence: manjunathpyati2001@gmail.com*

formulation as FDDS [5]. Microballoons are small, spherical particulate system with particle diameter in the micrometer varying from 1 to 1000 μm , consists of natural or synthetic polymers. In this system, the drug might be either evenly dispersed in the polymer matrix or surrounded by a polymeric shell. microballoons are generally used as controlled drug delivery carriers, as they can protect the drug, make more stable, and ensure sustained or targeted release of the drug. There are multiple forms of microballoons such as floating microballoons, magnetic microballoons, bioadhesive microballoons, radioactive microballoons, and polymeric microballoons [6,7]. Floating microballoons are non-effervescent gastro-retentive drug delivery systems formulated to extend the residence time of drugs in the stomach due their low density, hollow structure, providing controlled drug release. Floating microballoons are also commonly called as hollow microballoons, micro balloons, or floating microballoons [8].

Flurbiprofen is a BCS class II drug, with low solubility, high permeability and an effective nonsteroidal anti-inflammatory drug (NSAIDs) used in the therapy of acute and chronic rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis. Flurbiprofen is a part of phenyl alkanolic acid class of drugs and shows its therapeutic effects by reducing the cyclooxygenase (COX) enzyme. This suppression minimizes the synthesis of prostaglandins, the key mediators responsible for inflammation, pain, swelling, and fever. Flurbiprofen is appropriate drug for prolonged drug release because of its short half- life, (3-6 hours) which requires frequent dosing.

An extended release formulation can expand the drug release, reduce dosing frequency, and increase patient compliance [9].

Flurbiprofen dosage form given through oral route of administration, with normal adult doses ranging from 50–100 mg per dose, depending on the therapeutic use and administration schedule. After the administration, immediately the drug taken up from the GIT with an oral bio availability of 90–100%. It passes through hepatic metabolism, mainly due to CYP2C9-mediated hydroxylation, followed by conjugation to inactive metabolites and its first-pass effect is relatively reduced because of its high systemic bioavailability. After the administration, within 1–2 hours plasma concentrations of the drug achieved. It is fairly high oral bioavailability and short elimination half-life make it appropriate candidate for gastro-retentive drug delivery systems formulated to prolong gastric residence and provide sustained drug release [10].

MATERIALS AND METHODS

MATERIALS

Flurbiprofen was received from Yarrow chemical products. Ethyl cellulose is obtained from Hi Media laboratories Pvt. Ltd, Mumbai. Hydroxy propoxy methyl cellulose K4M was purchased from Ozone International. All other excipients were of analytical grade which was used.

METHODOLOGY

Determination of Melting Point of Flurbiprofen:

A small quantity of Flurbiprofen pure drug was finely powdered and loaded it into a clean, dry capillary tube. The Flurbiprofen pure drug was filled uniformly at the base of the capillary tube to a height 2-3 mm. The capillary tube was placed in a melting point apparatus, and the temperature was increased uniformly. The temperature at which the Flurbiprofen drug started melting and the temperature at which it completely melted were noted. The recorded melting point value was examined relative to a reported melting point of Flurbiprofen to confirms the nature and purity of the drug.

Calibration Curve of Flurbiprofen:

Accurately weighed the desired amount of Flurbiprofen (50 mg) and poured to 50 ml volumetric flask, solubilized in methanol and makeup the volume till 50 ml to get a stock solution A (1000 $\mu\text{g}/\text{mL}$). From the stock solution A, 1 mL was pipetted out and transferred into 50 ml volumetric flask and diluted to volume using 50 mL phosphate buffer solution (pH 6.8) to get stock solution B (i.e. 20 $\mu\text{g}/\text{mL}$) From the stock solution B, subsequent dilutions were performed by using phosphate buffer solution (pH 6.8) to get the solutions ranging from 2 – 20 $\mu\text{g}/\text{mL}$ concentration. The absorption maxima of the samples were analyzed by using UV-Visible spectrophotometer (UV 1601, Shimadzu, Japan) at 247 nm against suitable blank. The study was conducted in triplicate and values are represented as mean $\pm$ SD (n = 3).

Preparation method for floating microballoons:

Flurbiprofen incorporated floating microballoons were formulated by using solvent evaporation method. In this procedure drug and polymers were solubilized in 10 mL of organic phase that is dichloromethane in 50 ml beaker. PVA aqueous solution of 0.46 % 150 mL was taken as aqueous phase and it was positioned on mechanical stirrer at 700 rpm and then the organic phase was incorporated slowly drop by drop to the aqueous medium. The above prepared emulsion was kept on mechanical stirrer at 700 rpm for 2 hrs and temperature at 40 °C was kept constant throughout the procedure. After hardening of floating microballoons, the mixture of the solution was filtered off by using filter paper (Whatman) and floating microballoons were collected and subjected to washing with distilled water. Then obtained floating microballoons were dried overnight at 40 °C. The prepared floating microballoons were kept in an air tight container in a desiccator.

Table 1: Formulation table of Flurbiprofen floating microballons

Components	F1	F2	F3	F4	F5	F6	F7	F8	F9
Flurbiprofen (mg)	50	50	50	50	50	50	50	50	50
Ethyl cellulose (mg)	200	200	200	300	300	400	400	500	500
HPMC K4M	-	75	100	75	100	75	100	75	100
0.46% PVA (mL)	150	150	150	150	150	150	150	150	150
DCM (mL)	10	10	10	10	10	10	10	10	10
Speed (rpm)	700	700	700	700	700	700	700	700	700

Evaluation of Flurbiprofen loaded floating Microballons:**Compatibility study:**

The compatibility between drug substance and polymer was assessed by FTIR. The FTIR spectra of selected formulation and excipients were evaluated with the FTIR spectra of the pure drug. The distinctive peaks of the drug were obtained by scanning in between the 400- 4000 cm⁻¹ by using FTIR spectrophotometer. (Bruker ALPHA II FTIR spectrometer India Scientific Pvt. Ltd., India).

$$\text{Percentage yield} = \frac{\text{Particle yield}}{\text{Weight of all ingredients added in the preparation}} \times 100$$

The studies were conducted in triplicate and the outcomes are given a mean $\pm$ S.D (n=3).

Estimation of drug content

The drug content was determined by crushing the floating microballons in a mortar-pestle apparatus and then the

$$\text{Drug content} = \frac{\text{Actual amount of drug in the formulation}}{\text{Theoretical amount of drug in the formulation}} \times 100$$

The studies were performed in triplicate and the findings are given a mean $\pm$ S.D (n=3).

Drug encapsulation efficiency

The drug content was detected by crushing the floating microballons in a mortar-pestle apparatus and then the crushed floating microballons were transferred into 50

$$\text{Encapsulation efficiency} = \frac{\text{Actual amount of drug encapsulated}}{\text{Theoretical amount of drug used}} \times 100$$

The studies were conducted in triplicate and the findings are given a mean $\pm$ S.D (n=3).

Particle size determination

The particle diameter of the Flurbiprofen microballons was initially assessed using an optical microscope (Binocular Microscope, Vass Scientific Labs, Bangalore, India) fitted with a calibrated eyepiece micrometre at a magnification of 40X. The mean particle diameter was calculated from the measurement of approximately 100 microballons.

Floating behaviour:**A. Floating lag time**

The time needed for the microballons to come over the surface of the medium after being placed in the dissolution medium and start floating.

B. Percentage buoyancy

It was assayed using USP dissolution apparatus II (Paddle type). The microballons were kept in the vessel and the paddles were rotated at speed of 50 rpm in 900 mL of 0.1N

Physicochemical evaluation:**Percentage yield**

It is determined by accurately weighed floating microballons divided by sum of the weights of all solids including drug added during the preparation of floating microballons and multiplied by 100. The formula for determining percentage yield is as follows ^[11].

crushed floating microballons were transferred into 50 mL of volumetric flask containing methanol and kept it for 48 hrs of shaking. After 48 hrs the solution was filtered using filter paper (Whatman) suitably diluted. It was then analysed using UV spectrophotometer (1601, Shimadzu, Kyoto, Japan) using suitable blank at 247 nm ^[12].

mL of volumetric flask containing methanol and kept it for 48 hrs of shaking. After 48 hrs it was separated by filtration using filter paper (Whatman) suitably diluted. It was then analysed using UV spectrophotometer (1601, Shimadzu, Kyoto, Japan) using suitable blank at 247 nm ^[12].

HCl containing 10 % alcohol, temperature was regulated at 37 $\pm$ 0.5 °C. Then percentage of floating microballons after predetermined time (24 h), the microballons that floated over an upper surface of the medium and those settled at the base of the vessel were separated and dried separately After drying both are weighed separately. The buoyancy of the floating microballons determined by applying flowing equation ^[13].

$$\% \text{ Buoyancy} = \frac{W_f}{(W_f + W_s)} \times 100$$

Where, W_f and W_s are the mass of the floating and settled microballons respectively. The studies were done in triplicate and results are given as mean +SD (n=3).

Surface morphology:

SEM examination was employed to assess the particle diameter analysis and surface morphology of the microballons. The selected microballons were exposed to sputter coating with an electrically conductive metal, such as gold. This analysis revealed that the Flurbiprofen in polymers is in a spherical shape (SEM, JSM-IT500).

In-vitro dissolution studies:

The release of Flurbiprofen from the floating microballons were measured using the USP Apparatus II (paddle type). The specified amount of floating microballons was added into 900 mL of dissolution media (0.1 N HCl). After 2 hours, the microballons were shifted to a phosphate buffer solution of (pH 6.8). The temperature was set at a 37 ± 0.5 °C, and the medium was stirred at a speed of 50 rpm. At predetermined time intervals, 5 mL aliquots were withdrawn and the samples were separated by filtration using filter paper (Whatman). The amount of drug was analyzed using a UV spectrophotometer (UV-1601, Shimadzu, Kyoto, Japan) at 247 nm. All formulations were conducted in triplicate, and outcome are given as mean +SD (n=3).

Drug release kinetics

The in-vitro release data of the formulation were analysed using various models to describe the kinetics of the drug release.

Zero order kinetics:

$$Q_t = Q_0 - K_0 t$$

Where,

Q_t represent amount of drug- release at time 't', Q_0 indicates initial drug and K_0 shows Zero order release constant

First order kinetics:

$$\log C = \log C_0 - K_t$$

Where,

C represents drug retained at time 't', C_0 indicates initial drug amount and K_t represent first- order release constant

Higuchi model:

Release of the drug from matrix by diffusion has been described by Higuchi's classical diffusion equation.

$$Q = Kt^{1/2}$$

The graph was plotted square root of time v/s % cumulative drug release.

Korsmeyer- Peppas's model:

It indicates the study mechanism of how the drug liberated from the matrix formulation which also describes the behaviour of polymeric system.

$$M_t / M_\infty = Kt^n$$

Where,

M_t / M_∞ represents fraction amount released at time t, K indicates release constant (h^{-1}) and n represents release exponent.

Table 2: Mechanism of drug release as per Korsmeyer- Peppas's model

n-value	Mechanism of drug release
$n = 0.45$	Fickian release
$0.45 < n < 0.89$	Non-Fickian release
$n > 0.89$	Case II transport

Stability study:

The formulation was evaluated for its stability under specified storing conditions at different temperature 5-8°C, 27°C and 42°C for 90 days. The samples were withdrawn at regular time intervals and evaluated for changes in drug content, floating ability, physical appearance, entrapment efficiency, and in-vitro drug release. The results received after storage were contrasted with the initial values. The evaluated parameters remained statistically un changed throughout the stability period, which suggest that the selected Flurbiprofen floating microballons were stable under the selected storage conditions.

RESULTS AND DISCUSSION:**Melting Point of Flurbiprofen:**

The obtained value of melting point of the pure Flurbiprofen was 117°C, which is consistent with reported melting point range of Flurbiprofen (117-120°C), the results confirm the nature and purity of the drug which is assessed by the capillary tube method.

Calibration plot of Flurbiprofen:

The solution of Flurbiprofen was prepared in the specified concentration range of 1-8 µg/mL, and the calibration curve of Flurbiprofen was obtained in UV-wavelength of 247 nm. Good linearity with a regression coefficient of 0.9991 was observed as indicated in figure 1. The tested concentration range also obeyed Beer-Lambert's law.

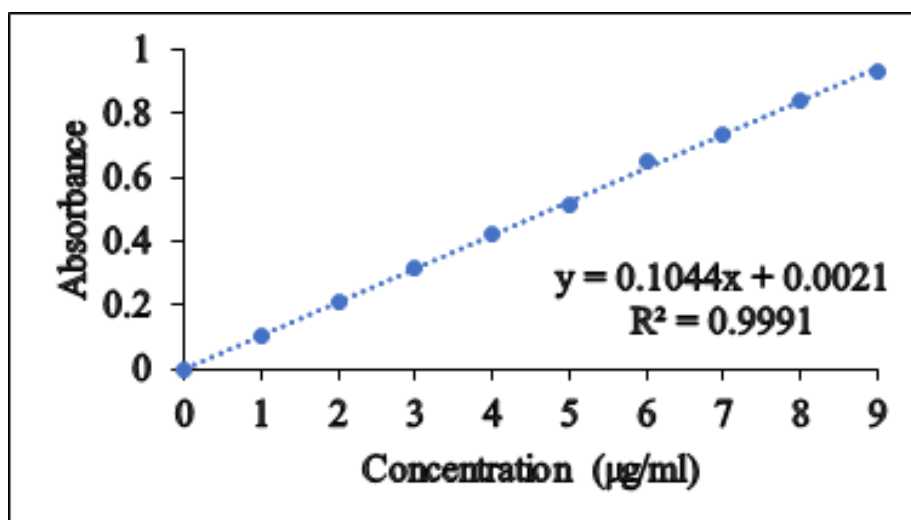


Figure 1: Calibration plot of Flurbiprofen

Compatibility study:

The FTIR spectrum (figure 2 - 4) of pure Flurbiprofen displayed the distinctive absorption peaks at 3621.56 cm⁻¹ (O-H stretching), 1691.85 cm⁻¹ (C=O stretching of the carboxylic acid group), 1562.42 cm⁻¹ (aromatic C=C stretching), 1445.93 cm⁻¹ (C-H bending), and 1214.07 cm⁻¹ (C-O stretching), validates the identity of the drug. The FTIR spectrum of the physical mixture indicates characteristic absorption bands at 3366.71 cm⁻¹ (O-H stretching), 2973.65 cm⁻¹ and 2888.90 cm⁻¹ (C-H stretching), 1725.42 cm⁻¹ (C=O stretching), 1614.12 cm⁻¹, 1505.11 cm⁻¹, and 1043.80 cm⁻¹. These peaks represent the functional groups of Flurbiprofen, and polymers indicating that the drug retains its characteristic functional groups in appearance of the polymers. The FTIR analysis of the selected floating microballons formulation

displayed the characteristic absorption bands 3406.25 cm⁻¹ (O-H stretching), 3061.64 cm⁻¹ and 2975.12 cm⁻¹ (C-H stretching), 1721.99 cm⁻¹ (C=O stretching), 1596.37 cm⁻¹, 1504.71 cm⁻¹, 1330.63 cm⁻¹, and 1065.92 cm⁻¹. The distinctive peaks of Flurbiprofen were remained with only slight shifts in peak positions and changes in intensity, potentially due to hydrogen bonding and physical entrapment of the drug in the EC-HPMC K4M polymer matrix. There are no new peaks appeared and no characteristic peaks of Flurbiprofen disappeared, it indicated the absence of chemical interaction between Flurbiprofen and the polymers. These results depict that the polymers are compatible with Flurbiprofen, and the drug stays chemically stable during the formation of the microballons.

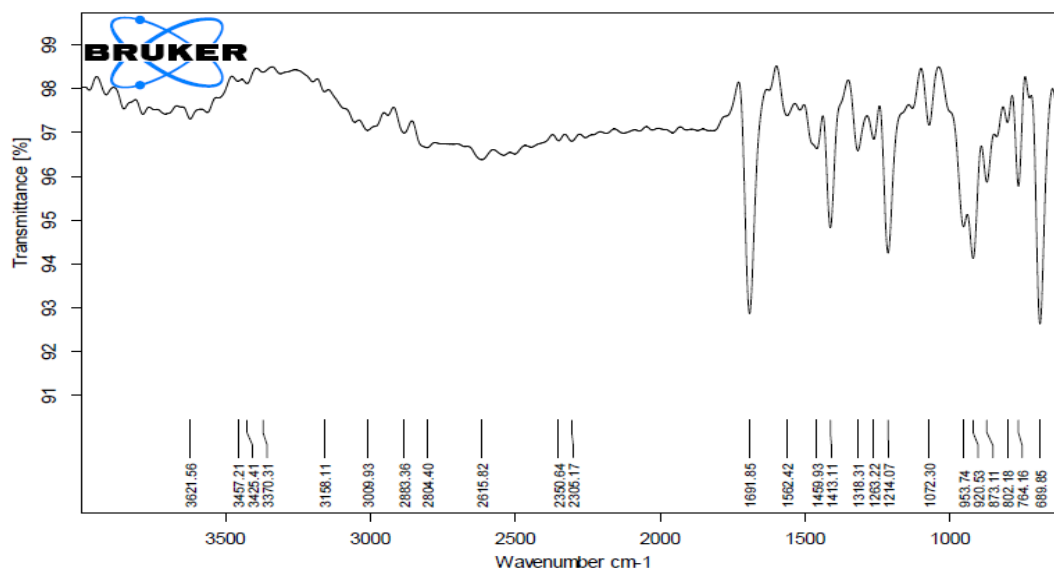


Figure 2: FTIR spectra of pure drug Flurbiprofen

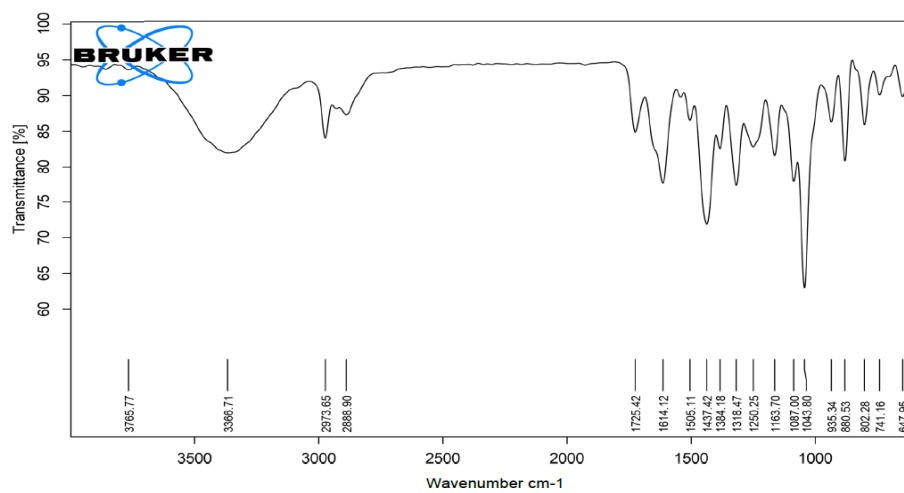


Figure 3: FTIR spectra of Physical mixture of drug + EC + HPMC K4M

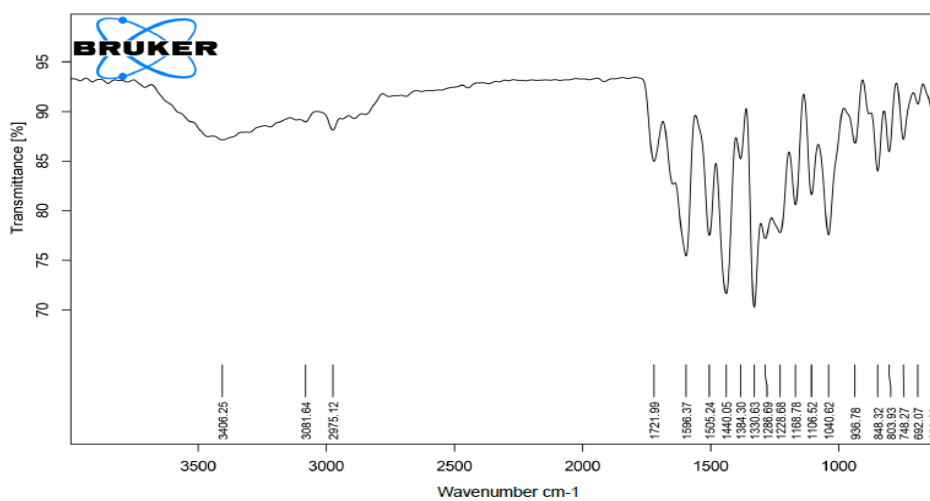


Figure 4: FTIR spectra of formulation F8

Physicochemical characterization of floating microballons:

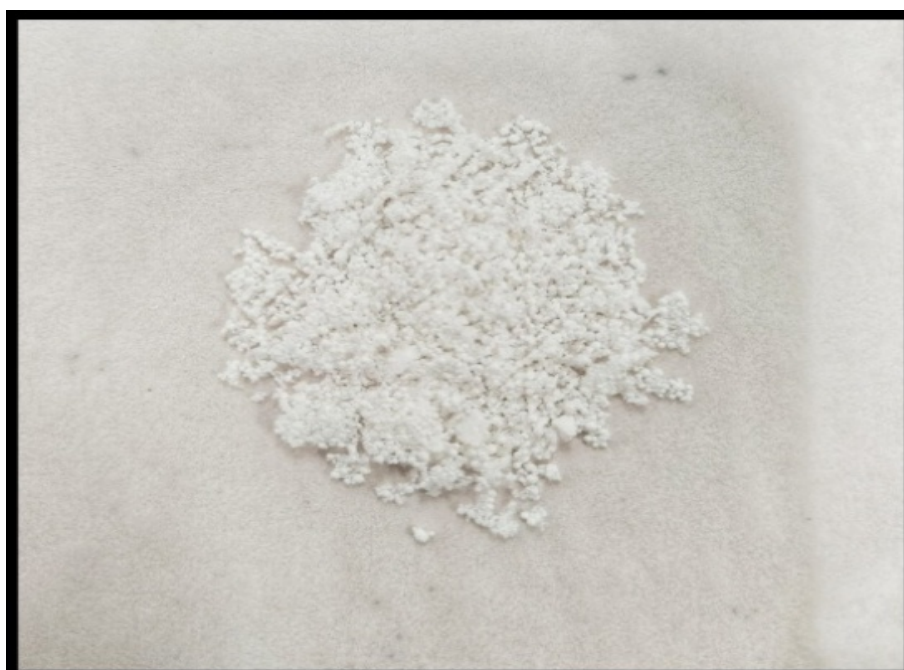


Figure 5: Flurbiprofen floating microballons

Percentage yield

Percentage yield of prepared floating microballons formulations ranged between 71.2 to 90.54 %. The results indicated good yield obtained by the process.

Drug content

Drug content of all the formulations ranges between 35.83 ± 0.19 mg to 44.84 ± 0.14 mg. The drug content of developed formulations is within the satisfactory range which indicated that the formulations retain the drug.

Entrapment efficiency

Entrapment efficiency of all the formulations ranges between 72.25 ± 0.17 to 92.25 ± 0.06 %.

Particle diameter determination

The prepared microballons were nearly spherical in shape and diameter of the produced floating microballons ranged between 49.82 ± 1.74 to $106.17 \pm 0.15 \mu\text{m}$.

Evaluation parameters of formulated floating microballons of Flurbiprofen:

The percentage yield of the received microballons ranged from 71.2% to 90.54%, with formulation F9 establishes

the highest yield. The elevated in percentage yield due to increase in polymer concentration, it led to improved entrapment efficiency and reduced material loss during the formulation. Drug content of the formulated microballons ranged from 35.83 ± 0.19 to 44.84 ± 0.14 mg. The encapsulation efficiency of the formulated microballons ranged from 72.25 ± 0.17 to 92.25 ± 0.06 %, respectively. It was showed that a gradual increase in drug content and encapsulation efficiency happened due to an increasing polymer concentration, it shows that the improved in drug incorporation into the polymeric matrix. The particle size of formulated microballons ranged from 49.82 ± 1.74 to $106.17 \pm 0.15 \mu\text{m}$, with formulation F1 showing the smallest value and formulation F9 showed the largest particle size. A steady increase in particle size was mainly because of increase in polymer concentration, which offers in high viscous polymeric solution and increased emulsion droplet size during solvent evaporation. These larger droplets then solidify into microballons of larger particle size. The small standard deviation values represent a narrow particle size distribution and good reproducibility of the preparation method.

Table 3: Evaluation parameters of prepared floating microballons of Flurbiprofen

Formulation code	Percentage yield (%)	Drug content $\pm$ SD (mg)	% Entrapment efficiency $\pm$ SD	Particle size $\pm$ SD (μm)
F1	71.2	35.83 ± 0.19	72.25 ± 0.17	49.82 ± 1.74
F2	84.66	36.17 ± 0.21	76.30 ± 0.26	63.35 ± 2.06
F3	73.5	37.92 ± 0.18	78.90 ± 0.04	71.78 ± 2.31
F4	81.21	38.23 ± 0.20	79.50 ± 0.20	79.46 ± 2.18
F5	83.33	39.68 ± 0.17	82.10 ± 0.07	76.29 ± 2.45
F6	78	42.71 ± 0.16	88.30 ± 0.04	87.63 ± 2.69
F7	89.16	41.32 ± 0.17	85.6 ± 0.12	82.1 ± 2.84
F8	82.4	44.84 ± 0.14	92.25 ± 0.06	98.74 ± 3.02
F9	90.18	43.71 ± 0.15	90.01 ± 0.09	106.17 ± 0.15

Values are mean $\pm$ SD (n=3) mean $\pm$ SD (n=100)

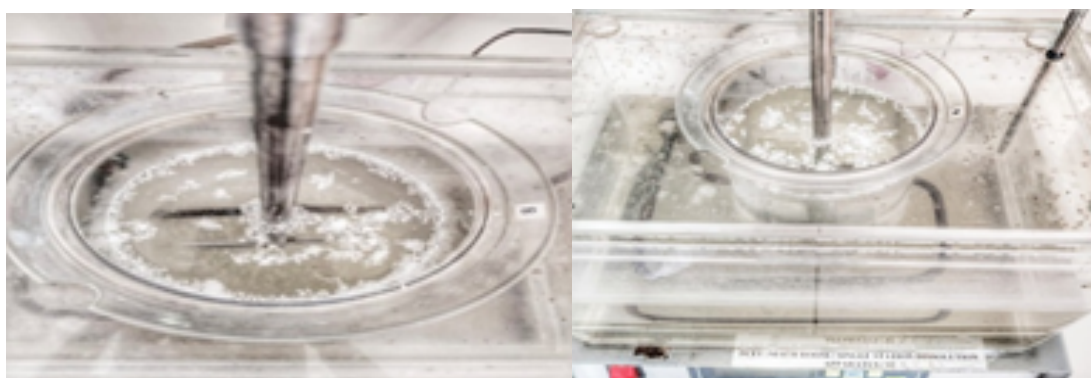
Floating properties of floating microballons of Flurbiprofen:

Figure 6: In-vitro floating behaviour of the formulation F8

All the formulations prepared from F1 to F9 shows immediate floating with zero buoyancy lag time and stays float for more than 12 h, which shows good floating behaviour. The immediate floating may be attributed to the formation of low-density microballons containing entrapped air within the polymeric matrix. The combined use of ethyl cellulose and HPMC K4M may have

facilitated to the formation of a stable and porous polymer matrix, which helped the microballons remain buoyant for an extended period. The sustained floating behaviour shows that the prepared EC and HPMC K4M-based microballons possess good potential for gastro-retentive drug delivery. The percentage buoyancy of the Flurbiprofen microballons that stays float over the

surface of the medium after 12 h ranged from 86.54 ± 5.68 ability.
% to $93.25 \pm 1.21\%$, which shows the sustained floating

Table 4: Floating properties of microballons of Flurbiprofen

Formulation code	Floating lag time (min)	Floating duration (h)	% Buoyancy $\pm$ SD
F1	0	>12	89.56 ± 1.56
F2	0	>12	87.98 ± 2.89
F3	0	>12	90.57 ± 3.36
F4	0	>12	88.66 ± 3.12
F5	0	>12	91.18 ± 1.87
F6	0	>12	89.61 ± 4.69
F7	0	>12	93.25 ± 1.21
F8	0	>12	86.54 ± 5.68
F9	0	>12	92.31 ± 2.82

Scanning Electron Microscopy:

The SEM images of surface and internal structures of the selected formulations are displayed in Figure 7, All floating microballons were in spherical shape with

smooth surface. Internal hallow cavity of the microballons were shown in the image. It is formed due to slow diffusion and evaporation of DCM it contributes for floating of microballons.

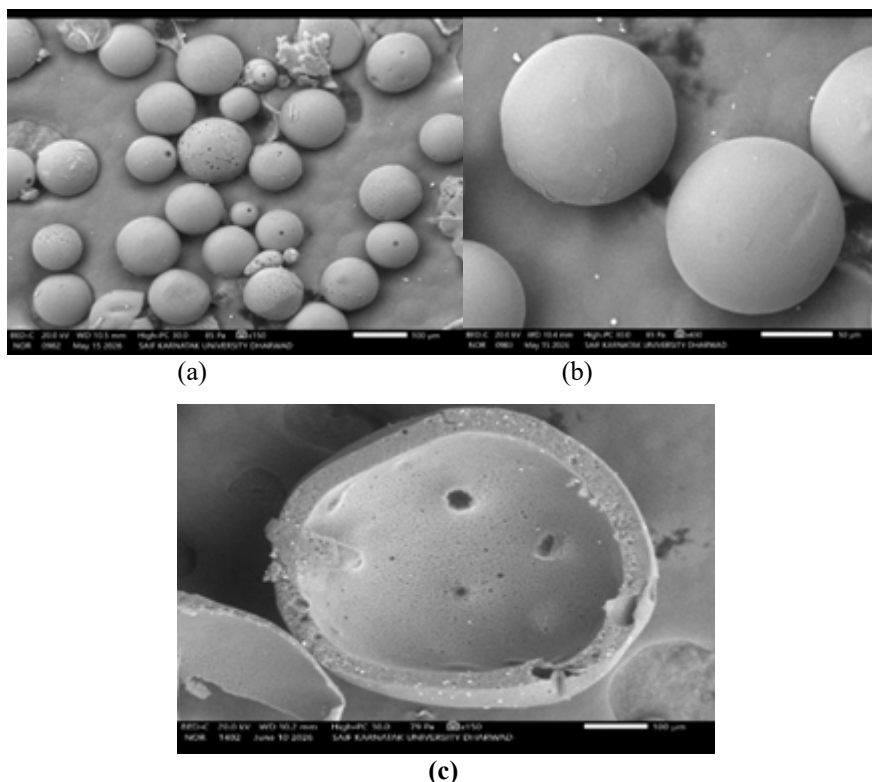


Figure 7: SEM images of outer surface (a) and (b) and internal cavity of floating microballons (c) of Formulation F8

In-vitro drug release studies of prepared floating microballons of Flurbiprofen:

The in-vitro drug release profile of Flurbiprofen-loaded microballons (F1–F9) are displayed in Table 5. The in-vitro drug release was carried out by using 0.1N HCl for 2 hours, then the microballons were transferred to a phosphate buffer solution (pH 6.8) by using type II dissolution apparatus. Among all the prepared formulations, formulation F1 showed the lowest % CDR (47.46 ± 0.37 %) after 9 h; this may be due hydrophobic ethyl cellulose matrix effectively retarded drug diffusion. Formulations F2 and F3 indicated higher drug release

because of the presence of HPMC K4M, which increased matrix hydration and facilitated drug diffusion. With gradual elevation in the concentration of ethyl cellulose in formulations F4–F9 sequentially retarded release of drug by formation of denser hydrophobic polymer matrix. However, formulations containing higher levels of HPMC K4M showed comparatively greater drug release than those with lower HPMC content because of enhanced swelling and pore formation. Among all formulations, formulation F3 showed the highest drug release (89.43 ± 0.23 %) over 9 h, whereas formulation F8 showed the lowest release (63.72 ± 0.58 %) over 9 h, indicating the

strongest sustained-release effect. Overall, the results confirmed that a suitable blend of ethyl cellulose and HPMC K4M efficiently controlled the release of Flurbiprofen from the microballons.

In-vitro drug release studies of prepared floating microballons of Flurbiprofen in 0.1 N HCl and phosphate buffer solution of (pH 6.8)

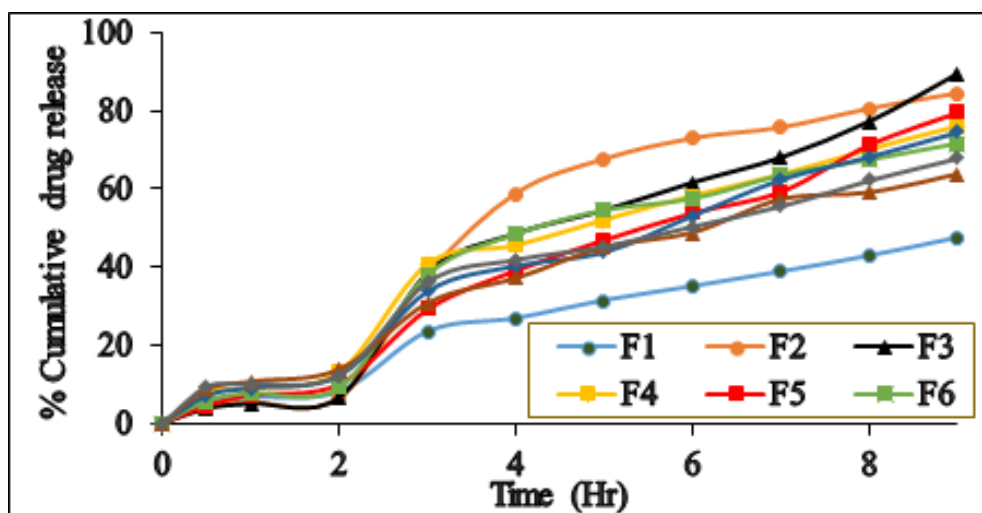


Figure 8: In- vitro drug release profile of Flurbiprofen formulations F1 to F9

Drug release kinetics of floating microballons:

Table 5: Drug release kinetics of floating microballons

Formulation	Drug release kinetics			
	Zero order (R ²)	First order (R ²)	Higuchi model (R ²)	Korsmeyer-Peppas model (n)
F1	0.983	0.766	0.929	1.143
F2	0.889	0.711	0.894	0.782
F3	0.956	0.758	0.909	0.434
F4	0.943	0.682	0.940	1.161
F5	0.988	0.797	0.910	0.928
F6	0.930	0.721	0.919	0.250
F7	0.973	0.714	0.935	1.005
F8	0.965	0.694	0.944	0.891
F9	0.928	0.647	0.939	1.201

The drug release kinetics as depicted in the Table 6, the Formulations F1 and F5 showed the highest regression coefficient with the zero-order model ($R^2 = 0.983$ and 0.988 , respectively), indicating a nearly constant drug release rate. The other formulations like F2, F3, F4, F6, and F9 were most suitable to the Higuchi model with R^2 values ranged 0.894 - 0.939 , suggesting that drug release was mainly controlled by diffusion via polymer matrix. The Korsmeyer–Peppas release behavior was identified by using the exponent (n) ranged 0.250 - 1.201 . The formulations F3 and F6 showed Fickian diffusion as the predominant release mechanism. The formulations F2, F5, and F8 exhibits non-Fickian (anomalous) diffusion, while formulations F1, F4, F7, and F9 shows Super Case II transport. The data indicates that drug release from floating microballons was governed mainly by diffusion through the polymer matrix along with polymer relaxation, resulting in sustained drug release.

Stability study:

From the outcomes, it was found that formulation F8 was the best formulation among all the formulations. Hence, formulation F8 was preferred for stability studies. The stability studies of the chosen formulation were performed by storing the formulation at different temperatures that is 5 – 8°C , 27°C , and 42°C , over the duration of 90 days. Formulation F8 was assessed for percentage yield, encapsulation efficiency, drug content, and in vitro drug release at the end of each month up to three months, no major variation was observed in the evaluated parameters before and after the stability studies. The formulation maintained satisfactory physical stability under the selected storage conditions of 5 – 8°C , 27°C , and 42°C for 90 days. The results confirm that formulation F8 containing Flurbiprofen floating microballons remained stable throughout the three-months stability study.

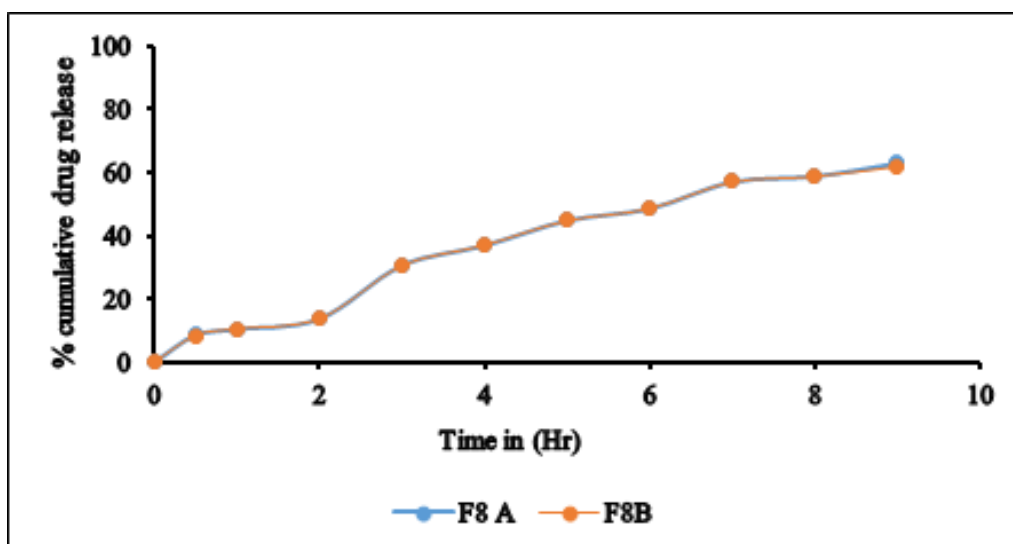


Figure 9: Cumulative % drug release of Formulation before (F8A) and after (F8B) stability studies

CONCLUSIONS

The Flurbiprofen floating microballons were successfully formulated and evaluated using ethyl cellulose and HPMC K4 polymers by solvent evaporation method. All the prepared formulations showed good, drug content, particle size, drug entrapment and buoyancy characteristics, with all formulations showing zero floating lag time and remaining buoyant for more than 12h. Among all the developed formulations, formulation F8 showed the highest entrapment efficiency and drug content while providing sustained release up to 9 h. Overall, the developed floating microballons provide a promising gastro-retentive drug delivery approach for Flurbiprofen and may help improve its therapeutic effectiveness by maintaining the drug in the stomach for an extended period and minimize the frequency of dosing.

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