ISSN: 2231-3656

International Journal of Pharmacy and Industrial Research (IJPIR)

IJPIR |Vol.16 | Issue 1 | Jan - Mar-2026

www.ijpir.com

DOI : https://doi.org/10.61096/ijpir.v16.iss1.2026.193-201

# Formulation and In-Vitro Evaluation of Alfuzosin-Loaded Sodium Alginate Microspheres for Controlled Release in Benign Prostatic Hyperplasia

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Published by: 24.02.2026



**Abstract** This study sought to develop and assess sodium alginate-based microspheres of alfuzosin for the controlled release of medication in the treatment of benign prostatic hyperplasia (BPH). Alfuzosin, noted for its brief biological half-life and frequent dosing necessities, is an ideal candidate for sustained-release delivery methods. Microspheres were synthesised via the ionotropic gelation method, utilising sodium alginate as the principal polymer and calcium chloride as the cross-linking agent. Five formulations (F1–F5) were created by altering alginate concentration while keeping the medication load constant. Preformulation experiments demonstrated exceptional linearity of alfuzosin within the range of 5–25 µg/mL ($R^2$ = 0.999), hence verifying UV spectrophotometric analysis. The synthesised microspheres displayed a smooth, spherical morphology, with particle size escalating from 142.6 ± 4.8 µm to 238.9 ± 8.1 µm as polymer concentration augmented. Entrapment efficiency markedly increased from 61.4 ± 2.3% to 87.4 ± 3.6%, although drug content remained consistent (94.8–99.3%). In vitro dissolution tests revealed polymer-dependent drug release, with the optimised formulation F5 attaining sustained release for up to 12 hours. Release kinetics demonstrated a transition from Higuchi diffusion to near zero-order release at elevated polymer concentrations, with the Korsmeyer–Peppas model indicating anomalous transport behaviour. The stability investigations validated the resilience of the optimised formulation. Sodium alginate microspheres constitute a promising controlled-release mechanism for once-daily alfuzosin treatment in benign prostatic hyperplasia (BPH).

**Keywords:** Alfuzosin; Sodium alginate; Microspheres; Controlled release; Ionotropic gelation; Benign prostatic hyperplasia.

## INTRODUCTION

Microspheres are classified as solid, almost spherical particles with sizes ranging from 1 to 1000 µm. They consist of polymeric, waxy, or other protective compounds, including biodegradable synthetic polymers and modified natural substances such as starches, gums, proteins, lipids, and waxes. Natural polymers encompass albumin and gelatin, while manufactured polymers comprise polylactic acid and polyglycolic acid. Microspheres are diminutive and possess a high surface-to-volume ratio. At the smaller end of their size spectrum, they exhibit colloidal characteristics. The interfacial characteristics of microspheres are critically

significant, frequently determining their functionality.[1]

Sodium alginate is a naturally occurring, linear, unbranched polymer predominantly sourced from brown seaweeds, including species of Laminaria, Macrocystis, and Ascophyllum. It is structurally comprised of 1,4-linked β-D-mannuronic acid (M) and α-L-guluronic acid (G) residues organized into homopolymeric blocks of M (M-blocks), G (G-blocks), and alternating MG-blocks.[2] Alginate has been widely utilized as a matrix polymer in microsphere and bead preparations for regulated medication delivery.

Benign Prostatic Hyperplasia (BPH) is a non-cancerous expansion of epithelial and stromal cells in the transition zone and peripheral periurethral area of the prostate, resulting in increased prostate volume (benign prostate enlargement, BPE) and possible lower urinary tract blockage. The term "BPH" has been inconsistently utilized; nonetheless, the clinically pertinent definition typically pertains to males exhibiting lower urinary tract symptoms (LUTS) due to prostate enlargement and urine outflow obstruction, frequently accompanied by bladder dysfunction. Histologically, benign prostatic hyperplasia (BPH) is prevalent with increasing age; however, clinical manifestations are not as widespread.[3, 4] Lower urinary tract symptoms related to benign prostatic hyperplasia (BPH) encompass voiding symptoms (hesitancy, weak stream, straining, prolonged voiding), storage symptoms (frequency, urgency, nocturia), and post-micturition symptoms (dribbling, incomplete emptying). These symptoms generally intensify with age and may vary, advancing in numerous guys throughout time.[5]

Several studies have explored polymer-based sustained and gastroretentive drug delivery systems to improve therapeutic efficacy. Pagariya and Patil developed floating pellets of alfuzosin hydrochloride using multilayer-coated Celphere® cores, achieving optimized buoyancy and controlled release.[6] Fahmy reported floating, mucoadhesive gastroretentive beads using calcium silicate and HPMC, demonstrating enhanced entrapment and diffusion-controlled release.[7] Floating and extended-release alfuzosin tablets were successfully formulated by Kakkerle et al.,[8] Nalini and Sai Kishore,[9] and Roni et al.,[10] using HPMC and Eudragit polymers, achieving prolonged gastric retention and non-Fickian release. Additionally, polymeric microsphere systems reported by Ghumman et al.,[11] Harwansh and Deshmukh,[12] Bácskay et al.,[13] Nagpal et al.,[14] Deshmukh et al., [15] and Semalty and Adhikari[16] demonstrated the effectiveness of alginate- and gum-based carriers in achieving sustained drug release and improved bioavailability.

Alfuzosin hydrochloride is a selective α1-adrenergic receptor antagonist from the quinazoline class, primarily utilized in the treatment of benign prostatic hyperplasia (BPH), an age-related condition marked by nonmalignant prostate enlargement resulting in lower urinary tract symptoms (LUTS) such as urinary frequency, nocturia, and weak stream.[17] Alfuzosin functions by inhibiting postsynaptic α1-adrenoceptors in the smooth muscle of the prostate, bladder neck, and urethra, leading to muscular relaxation, decreased urethral resistance, and enhanced urine flow, while without influencing detrusor contractility.[18]

Despite extensive research on alfuzosin sustained-release tablets and gastroretentive systems, no reported work has focused on sodium alginate–based microspheres for controlled alfuzosin delivery, highlighting a clear research gap in particulate polymeric systems for BPH therapy. The aim of this study was to develop and evaluate alfuzosin-loaded sodium alginate microspheres capable of providing controlled, once-daily drug release to improve therapeutic efficacy and patient compliance in benign prostatic hyperplasia.

## MATERIALS AND METHODS

### Chemicals

Alfuzosin was obtained as Gift sample from Cipla Ltd., Mumbai, India. Sodium algenate purchased from HI media Lab Pvt Ltd., Mumbai. Calcium chloride purchased from Merck Life Sciences, Mumbai, India. Tween 80 from S.D. Fine- Chemical Ltd, Mumbai .All the used reagents and chemicals were of analytical grade.

### Calibration of ALF

To a 100 millilitre volumetric flask, 100 milligrammes of carefully weighed ALF are introduced. The volume was raised to 100 ml using a stock solution of 1 mg/ml of 6.8 pH

phosphate buffer. The stock solution was diluted to obtain solutions with concentrations of 2-10 µg/ml using 6.8 pH phosphate buffer. A UV-VIS spectrophotometer (EI 1372, Electronics India, Pune, India) phosphate buffer blank 6.8 pH was used to quantify these solution's absorbance using a standard graph at wavelenth 245 nm.

**Formulation Design[19]:**

Alfuzosin microspheres were developed utilising sodium alginate as a natural, biocompatible polymer matrix to facilitate regulated release for the treatment of benign prostatic hyperplasia. Five formulations (F1–F5) were created by altering the concentration of sodium alginate (100–300 mg) while maintaining a constant Alfuzosin dosage (50 mg) to investigate the influence of polymer concentration on particle size, entrapment efficiency, and drug release characteristics. Cross-linking was accomplished with a 2% w/v calcium chloride solution, which facilitates ionic gelation of alginate chains. A minimal quantity of Tween 80 (0.1% v/v) was integrated into the gelling medium to enhance droplet dispersion and inhibit aggregation, facilitating the creation of distinct, spherical microspheres appropriate for oral controlled-release delivery.

Different formulation's formulas:

**Table 1:** Formulation table of Alfuzosin microsphere.

| Ingredient | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|
| Alfuzosin (mg) | 50 | 50 | 50 | 50 | 50 |
| Sodium alginate (mg) | 100 | 150 | 200 | 250 | 300 |
| Calcium chloride ($CaCl_2$) (%) | 2.0% | 2.0% | 2.0% | 2.0% | 2.0% |
| Tween 80 (% v/v) | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Purified water (mL) | q.s. | q.s. | q.s. | q.s. | q.s. |

*In the above formulation water = q.s. to prepare polymer–drug dispersion (e.g., 50 mL).

**Preparation of microsphere:**

Alfuzosin-encapsulated sodium alginate microspheres were synthesised using the ionotropic gelation technique. Sodium alginate (according to F1–F5) was dissolved in purified water to create a uniform polymer solution, into which precisely measured Alfuzosin (50 mg) was incorporated with gentle stirring to achieve a homogeneous drug–polymer mixture. A 2% w/v calcium chloride solution with 0.1% v/v Tween 80 was produced and maintained under moderate agitation. The drug-alginate dispersion was subsequently added dropwise to the calcium chloride solution using a syringe and fine needle, resulting in the immediate creation of gelled microspheres through ionic cross-linking. The microspheres were permitted to cure for approximately 30–60 minutes, subsequently collected via filtration, rinsed with distilled water, and ultimately dried at 40–45°C until a constant weight was achieved, before being stored in airtight containers for further assessment.

**Fourier Transform Infrared (FT-IR) Spectroscopy:**

Using the ATR FTIR spectrometer (Shimadzu FTIR-8400S, Japan) drug's FT-IR spectra were recorded. When using the diffuse reflectance technique, the mid-IR 4000-400 cm-1 spectral region was covered. The sample was placed in sample holder made from Zinc Selenide. The position and relative strength of the absorption maximums in the spectrum produced with the substance under examination match those in the reference spectrum. To create a transparent film, the mixture was taken and compressed in a hydraulic press at a pressure of 10 tons. The particle was scanned in an infrared spectrophotometer between 4000-400 cm-1. Following the light route, the film was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

**Evaluation of oral dissolving films formulations:**

For microsphere formulations, various quality control tests were carried out.

Different Performed in vitro examinations are:

**Yield Percentage:**

The dried microspheres were measured, and the percentage yield was determined using:

$$\text{Percentage Yield (\%)} = \frac{\text{Total weight of dried microspheres}}{\text{Total weight of polymer + drug}} \times 100$$

**Analysis of Particle Size:**

The particle size was ascertained with an optical microscope equipped with a calibrated ocular micrometre. A minimum of 50 microspheres per batch were analysed, and the average particle size was documented.

**Entrapment Efficiency (EE%):**

Fifty milligrammes of microspheres were pulverised and solubilised in 100 millilitres of phosphate buffer at pH 6.8 using sonication. The solution underwent filtration, and absorbance was quantified at the λmax of Alfuzosin.

$$\text{\% Entrapment Efficiency} = \frac{\text{Actual drug content}}{\text{Theoretical drug content}} \times 100$$

**Swelling Index:**

The microspheres were weighed ($W_1$) and immersed in distilled water for a duration of 4 hours. Swollen microspheres were remeasured ($W_2$).

$$\text{Swelling Index (\%)} = \frac{W_2 - W_1}{W_1} \times 100$$

**Uniformity of drug content**

This is determined by any conventional pharmacopoeia API assay technique. Content consistency is determined by examining API content in each strip. 85–115% is the maximum content homogeneity[20].

$$\text{Drug content} = \frac{\text{sample absorbance}}{\text{standard absorbance}} \times \frac{\text{standard dilution}}{\text{sample dilution}} \times \frac{\%\text{purity of drug} \times \text{Avg.wt}}{100}$$

$$\text{\% Drug content} = \frac{\text{Drug content} \times 100}{\text{Label claim}}$$

***In vitro* Dissolution test[21]**

An in-vitro dissolving analysis of the created microsphere formulations was conducted using the EI -1916, Electronics India, Pune, India dissolution test instrument in a USP type II (paddle). Microspheres with the appropriate formulation were taken and put inside the dissolution apparatus's vessels. Samples were taken out of the vessels at various intervals, replaced with an identical volume of the blank solution, and subjected to UV-Vis spectrophotometer analysis using UV-Visible Spectrophotometer, (EI 1372, Electronics India, Pune, India). Drug concentration was determined using the standard graph and reported as a percentage of the drug that was released or dissolved. Six duplicate release studies were carried out, and mean statistics were recorded.

**Release Kinetics[22]**

Utilising the results of the in-vitro diffusion study, the order and mechanism of drug release kinetics of ALF films were examined. Plotting of the kinetic models included the zero order, first order, and Higuchi equations; the release was calculated using the Korsmeyer-Peppas equations.

**Stability Studies**

Drug stability refers to the ability of a formulation to retain its physical, chemical, and therapeutic properties within specified limits throughout its shelf life. Stability studies were conducted in accordance with ICH Q1A guidelines to ensure product quality and performance. Accelerated stability testing of the optimized formulations was carried out at 40 ± 2 °C / 75 ± 5% RH for three months**.** The samples were packed in aluminum foil strips and stored

under controlled conditions. At predetermined intervals, formulations were evaluated for appearance, drug content, and in-vitro drug release, confirming their stability over the study period.[23]

## RESULTS & DISCUSSION

### Calibration of ALF

Combine 50 mg of ALF in 100 ml of water to get the stock solution. To make 100 millilitres, 10 millilitres of the stock solution were removed and diluted with water. Using several concentrations (5-25 µg/ml) and the appropriate stock solution dilution, a calibration curve was produced. The absorbance was obtained at 245 nm. The curve that results from calibrating ALF in a pH 6.8 phosphate buffer is showing the linearity at $R^2$= 0.9908 shown in Figure 1.

### Drug – excipient Compatibility Studies

FTIR spectroscopy was used to determine the drug excipient compatibility, and the graphs from the figure were displayed. To find out if there is any interaction between the excipients and ALF, the physical mixture was put through FTIR analysis. All samples, which were pure ALF, underwent FTIR analysis to determine the presence of the pure API in the mixtures and to describe it.

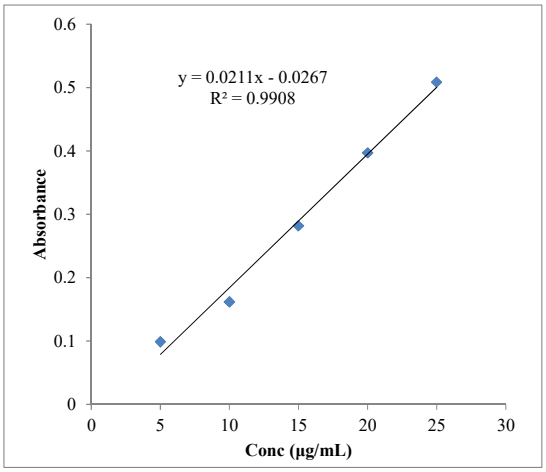


**Fig 1:** ALF standard calibration curve in phosphate buffer with a pH of 6.8

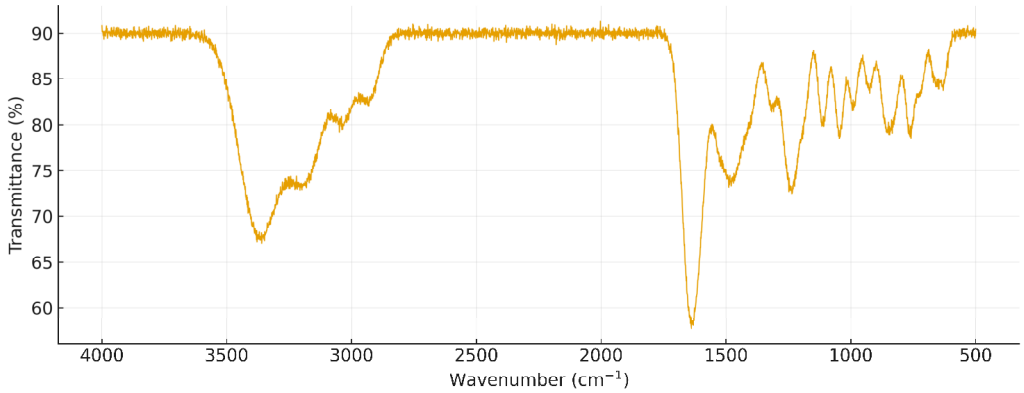


**Fig 2:** FTIR Spectral analysis of pure ALF.

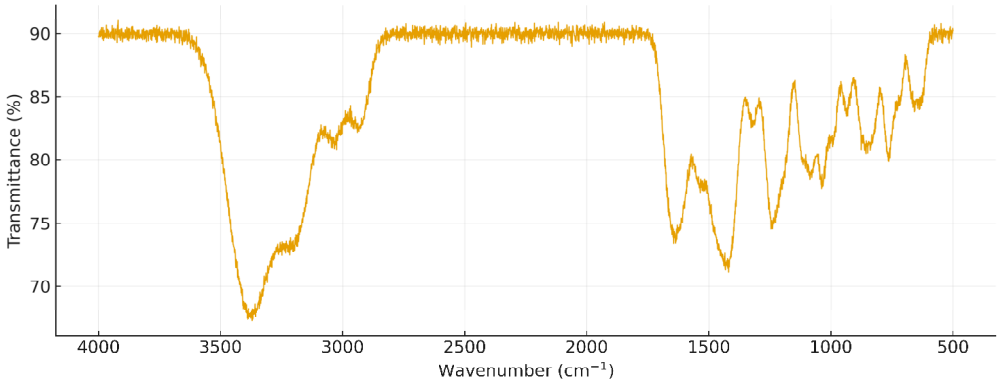


**Fig 3:** FTIR Spectral analysis of optimized formulation (F4).

The FTIR spectra of Alfuzosin–sodium alginate microspheres exhibited distinct drug peaks at the amide (1658 $cm^{-1}$) and aromatic regions (1605–1490 $cm^{-1}$), hence confirming the chemical stability of the medication. The significant expansion of the O–H stretching band near 3380 $cm^{-1}$ and the emergence of unique alginate $COO^-$ symmetric and asymmetric stretches at approximately 1605 $cm^{-1}$ and 1415 $cm^{-1}$ signified ionic and hydrogen-bonding interactions between the drug and the polymer. Further increases in the polysaccharide C–O–C region (1080–1035 $cm^{-1}$) corroborated effective encapsulation. No new peaks or the elimination of significant drug bands were found, indicating physical entrapment without chemical incompatibility.

**Evaluation of microsphere:**

**Table 2:** Finding the particle size, entrapment efficiency, swelling index and drug content of all formulations.

| Formulation | Particle Size (μm) | Entrapment Efficiency (%) | Swelling Index (%) | Drug Content (%) |
|---|---|---|---|---|
| F1 | 142.6 ± 4.8 | 61.4 ± 2.3 | 118.5 ± 4.2 | 94.8 ± 2.5 |
| F2 | 168.3 ± 5.6 | 68.9 ± 2.6 | 135.2 ± 4.8 | 96.2 ± 2.7 |
| F3 | 191.7 ± 6.4 | 74.6 ± 3.0 | 148.6 ± 5.1 | 97.5 ± 2.9 |
| F4 | 216.5 ± 7.2 | 81.8 ± 3.3 | 162.3 ± 5.4 | 98.9 ± 3.1 |
| F5 | 238.9 ± 8.1 | 87.4 ± 3.6 | 175.7 ± 5.8 | 99.3 ± 3.2 |

**Particle size analysis:**

The particle size of the microspheres escalated from 142.6 ± 4.8 μm (F1) to 238.9 ± 8.1 μm (F5) with the augmentation of sodium alginate concentration. Increased polymer concentrations resulted in bigger microspheres due to better viscosity and improved droplet stability during ionotropic gelation.

**Efficiency of entrapment:**

Entrapment efficiency increased with polymer content, ascending from 61.4 ± 2.3% (F1) to 87.4 ± 3.6% (F5). This phenomenon is ascribed to enhanced cross-linked matrices at elevated alginate concentrations, which diminish drug diffusion into the $CaCl_2$ bath during the curing process.

**Swelling index:**

The swelling index exhibited a same trend, varying from 118.5 ± 4.2% (F1) to 175.7 ± 5.8% (F5). Increased alginate content correlates with heightened swelling, indicating enhanced water absorption and gel formation capability.

**Drug Content Uniformity:**

Table 2 shows the results of calculating the percentage of ALF content for different formulations. The drug concentration was consistently high across all formulations (94.8 ± 2.5% to 99.3 ± 3.2%), accompanied by low standard deviation values (2–3%), signifying exceptional batch homogeneity and negligible drug loss during processing.

**In-vitro dissolution**

The in-vitro drug release analysis demonstrated a distinct polymer-dependent sustained-release profile among formulations F1–F5. Lower alginate batches (F1–F2) exhibited quick Alfuzosin release, exceeding 90% after 10 hours, whereas higher-polymer formulations (F4–F5) displayed enhanced matrix integrity and slower diffusion, with F5 indicating the most extended release (80% at 12 hours). The gradual delay in release is ascribed to heightened cross-link density and diminished pore size inside the alginate matrix. The results indicate that increased polymer concentration efficiently regulates and prolongs drug release, establishing F5 as the optimal formulation for controlled-release microspheres.

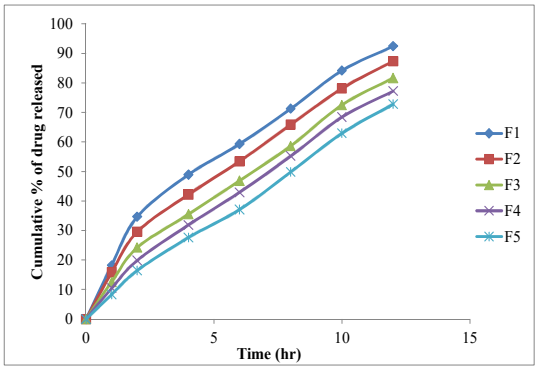


**Fig 4:** In-vitro dissolution studies of formulations (F1-F5)

**Application of Release Rate Kinetics to Dissolution Data:**

The kinetics of drug release were investigated using a range of models. The drug release rate mechanism of the dose form kinetics was examined by fitting a variety of release models, such as first-order, zero-order, higuchi, and Korsmeyer-Peppas, to the collected data.

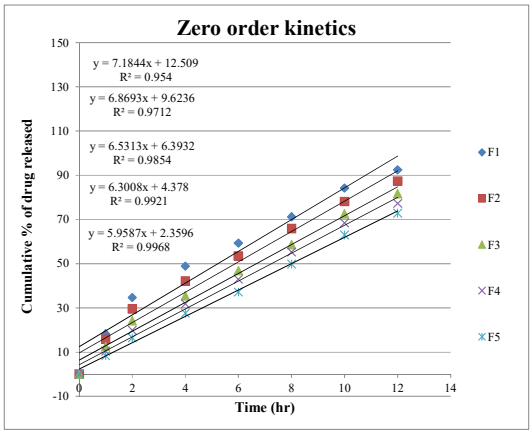


**Fig 5:** Zero order release kinetics graph of ALF formulations (F1-F5)

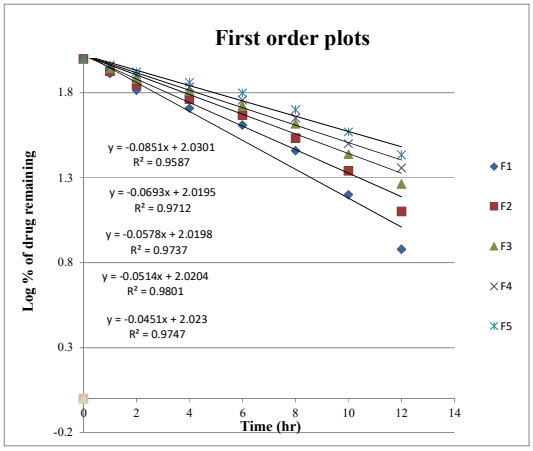


**Fig 6:** First order release kinetics graph of ALF formulations (F1-F5)

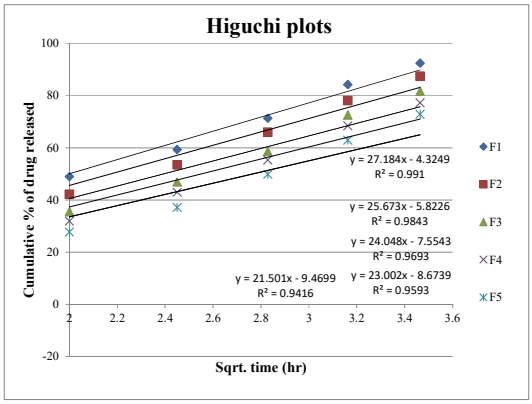


**Fig 7:** Higuchi release kinetics graph of ALF formulations (F1-F5)

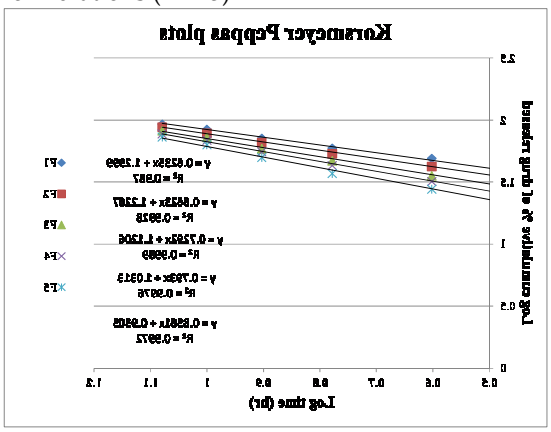

**Fig 8:** Korsmeyer-Peppas graph of ALF formulations (F1-F5)

The drug release kinetics are summarized in Fig. 5 to 8. The release kinetics data for formulations F1–F5 were analysed using Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models. All formulations had elevated regression values, signifying effective model fitting. Formulation F1 demonstrated robust Higuchi kinetics ($R^2$ = 0.991), validating diffusion-controlled release attributed to its reduced polymer content. As the concentration of sodium alginate increased, the release profile transitioned to Zero-order kinetics, evidenced by F3 ($R^2$ = 0.9854) and F4 ($R^2$ = 0.9921), signifying a more consistent and extended drug release. The optimised formulation F5 had the best Zero-order correlation ($R^2$ = 0.9968), indicating a nearly constant release rate during the investigation. The Korsmeyer–Peppas model demonstrated a rising release exponent (n) with elevated polymer concentrations, varying from 0.6235 (F1) to 0.8561 (F5). This process signifies a transition from anomalous (non-Fickian) diffusion to Case-II transport, illustrating the roles of polymer relaxation and erosion in drug release. The elevated $R^2$ values (>0.99) further substantiate the model's dependability. The findings indicate that a higher alginate content improves matrix integrity and reduces drug diffusion, with F5 demonstrating the best regulated and prolonged release characteristics, validating its designation as the optimised formulation.[24]

**Selection of best formulation:**

Among all the formulations (F1–F5), F5 exhibited the most favourable attributes for a

controlled-release microsphere system. It demonstrated the highest entrapment effectiveness (87.4 ± 3.6%), largest particle size (238.9 ± 8.1 μm) favourable for sustained drug release, superior swelling index (175.7 ± 5.8%), and optimal drug content (99.3 ± 3.2%). The in-vitro drug release profile of F5 exhibited the slowest and most regulated release, attaining 81.66% release at 12 hours, which corresponds with the therapeutic objective of sustained alfuzosin release in BPH treatment. Consequently, F5 was chosen as the optimal formulation.

**Stability Studies:**

In compliance with ICH recommendations, stability experiments were carried out to assess the pharmaceutical formulation's stability. Stability investigations for the optimised formulation F5 were conducted under accelerated conditions (40 ± 2°C / 75 ± 5% RH) for durations of 30 and 60 days. The microspheres were assessed for physical characteristics, particle dimensions, entrapment efficacy, and in vitro release. The optimised formulation (F5) exhibited physical stability, showing no signs of aggregation, cracking, or discolouration over the testing period. Minimal alterations were noted in particle size, entrapment effectiveness, and drug content, all remaining within acceptable ICH parameters. The drug release profile exhibited a minor decrease (<2%) after 3 months, signifying that the formulation preserved its controlled-release characteristics. F5 exhibited remarkable stability, affirming its appropriateness for prolonged storage.

## CONCLUSION

Alfuzosin-loaded sodium alginate microspheres were successfully developed using the ionotropic gelation technique and demonstrated favorable physicochemical and release characteristics. Increasing alginate concentration significantly influenced particle size, entrapment efficiency, swelling behavior, and drug release kinetics. Among all formulations, F5 emerged as the optimized batch, exhibiting high entrapment efficiency, uniform drug content, extended drug release up to 12 hours, and excellent stability under accelerated conditions. Release kinetics indicated a transition toward zero-order behavior with combined diffusion and polymer relaxation mechanisms. The findings confirm that sodium alginate–based microspheres provide a biocompatible, stable, and scalable controlled-release platform for alfuzosin, offering a promising alternative to conventional dosage forms for effective management of benign prostatic hyperplasia.

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