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Research Article

Design, Formulation, Physicochemical Characterization and *In Vitro* Evaluation of Alfuzosin HCL -Loaded Microspheres Using 3d Printing Technology

Himansu Bhusan Samal[1], Itishree Jogamaya Das[2], Sumit kumar Das[1], Rasmita Jena[1], Amulyaratna Behera[3], Suddhasattya Dey[4], Smita Das[4]*

[1]*Centurion University of Technology and Management, Bhubaneswar, Odisha*

[2]*Medical Science and Research, Sai NathUniversity, Ranchi, Jharkhand, India*

[3]*School of Pharmacy, DRIEMS University, Cuttack, Odisha, India*

[4]*Department of Pharmaceutical Sciences, IQ City Institute of Pharmaceutical Sciences, Durgapur, India*

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Abbreviations:

AF: Alfuzosin Formulation
BPH: Benign Prostatic Hyperplasia
CDR: Cumulative Drug Release
HCl: Hydrochloride
HPMC: Hydroxypropyl Methylcellulose
IR: Immediate Release
PEO: Polyethylene Oxide
RH: Relative Humidity
RPM: Revolutions per minute
SD: Standard Deviation
SR: Sustained Release
USP: United States Pharmacopeia
µm: Micrometer

ABSTRACT

Introduction

Alfuzosin hydrochloride, is an α_1-adrenergic antagonist, is widely used for the treatment of moderate to severe benign prostatic hyperplasia (BPH). While effective, its immediate-release (IR) formulations require multiple daily doses, affecting patient compliance. To overcome this, a sustained-release formulation was developed using 3D printing technology for prolonged drug action and reduced side effects.

Objective

To develop a formulation of Alfuzosin hydrochloride microsphere by using different ratio of sodium alginate act as a biodegradable polymer with 3Dprinting technique.

Materials and Methods

Microspheres containing Alfuzosin hydrochloride were formulated using sodium alginate as the polymer via 3D printing. The prepared microspheres were evaluated for flow properties, entrapment efficiency, particle size, percent yield, *in-vitro* buoyancy, surface morphology, and drug release behaviour in 0.1N HCl to simulate gastric conditions.

Results

Micrometrics studies of optimised formulation indicated good flow properties, with a maximum entrapment efficiency of 86.49%. The average particle size was 984.72µm. Buoyancy studies showed that the microspheres had an *in-vitro* buoyancy of 95.34,with a floating time of more than 10 hours, suggesting suitability for gastric retention. *In-vitro* drug release was conducted in 0.1N HCl solution, mimicking gastric conditions. The release profile demonstrated a sustained drug release over an extended period.

Conclusion

The study successfully developed 3D printed microspheres of Alfuzosin hydrochloride with sustained release and gastroretentive properties. This formulation holds promise for improving therapeutic efficacy, reducing dosing frequency, and enhancing patient compliance in the

* Corresponding author *E-mail address:* dassmita707@gmail.com (Smita Das).

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Introduction

Microspheres are small, spherical drug carriers introduced in the 1960s, typically ranging from 1 to 1000 µm, and are extensively used in modern drug delivery due to their controlled release capabilities and biodegradability[1]. These systems improve solubility, ensure targeted and sustained drug release, reduce side effects, bypass first-pass metabolism, and enhance gastrointestinal tolerability, while also offering patient-friendly features like taste masking and reduced dosing frequency [2]. But some limitation also marked such as Controlled release formulations have higher drug loads, and any disruption can cause toxicity. Temperature, pH, solvent addition and evaporation may influence the stability of core particle to be encapsulated. Food, gut transit, and dose variability affect release rate. These forms must not be chewed or crushed [3]. Some controlled release formulations and microsphere of different drugs are discuss bellow.

In the class of α1-adrenoceptor blocker there are many drugs but their activity differs in different aspects. The drug Doxazosin is an α1-adrenoceptor blocker used to treat BPH, high blood pressure and sometimes erectile dysfunction and its impact on blood vessels and other areas in the body [4]. Condition investigated that Prazosin hydrochloride, a short half-life drug generally used in treatment of hypertension, BPH and post-traumatic stress disorder with low gastric bioavailability, was formulated into gastroretentive floating microspheres using solvent evaporation having 24 hours of floating time in gastric fluid with 99.87% drug release, demonstrating excellent buoyancy and sustained drug release over 24 hours [5].

Tamsulosin Hcl a drug belonging to this class but used for different disease. Its sustained-release pellets were developed using ethyl cellulose and Eudragit L100-55 as an enteric coating agent applied through solution using coating technology. The optimized formulation (TC8) showed zero-order drug release and high similarity (f2 = 88.3) to the innovator product. Stability studies were also performed having consistent drug release with no changes after one month at 40°C/75% RH [6].

Microspheres containing ciprofloxacin were developed using floating techniques, achieving up to 89.90% drug entrapment and sustained release of 90.70% over 10 hours [7]. Floating microspheres of Ranitidine Hydrochloride were formulated using HPMC K100, Xanthan gum, and Eudragit S-100 in ratios of 1:1, 1:2, and 1:3 to enhance gastric retention and bioavailability. During the evaluations of different formulations using three polymer showed improved floatability, sustained drug release, and better absorption.

Among the standard polymers it has been noticed HPMC showed superior performance [8] . Floating microspheres of Drotaverine hydrochloride, optimized using a 32 full factorial design and Expert® version 13, showed excellent flow, high entrapment (84.83%), and buoyancy (69.23%–84.72%), delivering 67.23% drug release in 0.1N HCl, thereby enhancing bioavailability and reducing dosing frequency. [9]

Alfuzosin hydrochloride is a selective α1-adrenergic receptor antagonist used to treat benign prostatic hyperplasia (BPH). It relaxes smooth muscles in the prostate and bladder neck, improving urine flow. Due to its short half-life, it often requires sustained-release formulations to enhance efficacy and patient compliance [10]. Some different sustained release formulations are as follows.

The literature review suggests controlled-release alfuzosin tablets using low-viscosity HPMC K-100 and HPMC15cps by direct compression method. All formulations showed consistent drug content do not vary more than 1% and 12-hour of drug release. The drug release followed zero-order and Higuchi kinetics. Among them zero-order being more suitable, confirming effective sustained release using these polymers [11].

A formulation study was develop and extended for 20-hour extended-release alfuzosin tablets using HPMC K100M and cross-linked xyloglucan prepared with sodium trimetaphosphate. It was formulated by direct compression and optimized via simplex centroid design, the tablets showed acceptable properties and sustained drug release following zero-order kinetics with anomalous diffusion, offering potential for once-daily dosing in BPH treatment, it also suitable of sustained release drug delivery system [12]. In a study it has been found a floating-mucoadhesive beads of alfuzosin hydrochloride using calcium silicate, calcium alginate, and HPMC via internal-external gelation and a 3^2 factorial design having an yield (57–78%) and entrapment (50–83%) [13]. A gastro-retentive composite matrix for Alfuzosin HCl was also developed using polyethylene oxide (PEO), hydroxyl propyl methylcellulose, sodium bicarbonate, citric acid and polyvinyl pyrrolidone indicating comparable performance to the marketed product and potential for enhanced bioavailability [14].

3D printing in medicine helps create accurate and personalized drug forms with specific release patterns for each patient. It is useful in both early and final stages of drug development, though using it on a large scale still has some difficulties [15] .

Based on literature review study we found that most studies are focused on floating tablets, beads, or sponges, not true microspheres.

* Corresponding author *E-mail address:* dassmita707@gmail.com (Smita Das).

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This study focuses on formulating Alfuzosin hydrochloride microspheres using sodium alginate, a natural and biocompatible polymer widely applied in pharmaceuticals for its gel-forming capacity and sustained drug release potential. [16].An innovative technique (3D printing technique), which enable the method is less time consuming, having uniformity in size, minimizing error and cost effective. Basically the research focuses on developing a sustained-release oral dosage form that can improve therapeutic efficacy, reducing dose frequency and enhance patient compliance. Furthermore stability study was also conducted which demonstrated the enhance stability and performance of final formulations.

Materials and methods

Materials

Alfuzosin hydrochloride (Alfuzosin HCL), the model drug used in the study, was obtained as a gift sample from Hetero Drugs Ltd., Baddi. Sodium alginate, used as the polymer matrix for microsphere formulation, was procured from Yarrow Chem Products, Mumbai. Calcium chloride, employed as the cross-linking agent, was obtained from Mahalakshmi Chemicals, Bangalore. Acetic acid and n-hexane were supplied by S D Fine Chem Limited, Mumbai.

Preparation of microspheres of Alfuzosin hydrochloride using 3D Printing Technology

All the required materials, Alfuzosin hydrochloride, sodium alginate, and calcium chloride were accurately weighed. The required amount of sodium alginate is blended with distilled water to form a mucilage and heated for 5-10 minutes in a hot plate. Then make 100mL solution which consist 1% (W/V) calcium chloride solution that included 10% (v/v) acetic acid .After preparation of the aqueous mucilage of sodium alginate is stirred using a magnetic stirrer at a suitable speed (rpm) for 30 minutes. The drug is subsequently dispersed in the aqueous mucilage of sodium alginate and stirred at a suitable speed using a magnetic stirrer.After dispersion of the drug the solution was loaded in 3D printer [17]. The microparticles are formed using a glass syringe fitted with a 23-gauge needle, loaded with bubble-free dispersion, and dropped into the gently agitated calcium chloride solution [18]. The microparticles are filtered & thoroughly washed with distilled water after remaining in the solution for 30minute.The pellets were then oven dried for 2-4 hrs at about 50º C. The microparticles are dried in room temperature for some hour and utilized for further evaluation [19] .

Micromeritics Characterization

Particle size and morphology, bulk Characteristics

Particle size was determined by optical microscopy using a calibrated micrometre. Around 100 microspheres were measured, and the average size was reported as mean ± standard deviation [20].These all the bulk characteristics of microspheres were evaluated by following the procedure mention in The Theory and Practice of Industrial Pharmacy book [21].

Percentage Entrapment Efficiency

Accurately weighed **100 mg of dried microspheres** were **pulverized using a mortar and pestle** and dispersed in **ethanol**. To ensure complete extraction of **Alfuzosin hydrochloride**, the dispersion was subjected to **sonication for several hours**. The resulting solution was filtered through a 0.45 µm membrane filter to remove any particulate matter. The **absorbance of the filtrate** was measured at **254 nm** using a **UV-visible spectrophotometer** with **ethanol as the blank** [22]**.**

Percentage yield

The **percentage yield** of microspheres was calculated by comparing the practical mass of dried beads obtained to the total initial weight of non-volatile components (drug and excipients) used in the formulation. The yield was calculated and recorded in table 5 using the formula:

% yield=(Actual yield/Theoretical yield)×100%

Swelling Index

Weigh 10 mg of dried microspheres accurately (W_1).Immerse in 100 mL of suitable swelling medium 0.1 N HCl. Incubate at 37°C for a fixed time (commonly 24 hours) to reach equilibrium swelling. Remove microspheres, blot gently to remove surface moisture. Weigh the swollen microspheres (W_2).

Swelling index (%)= $(W_2 – W_1/W_1)\times100$

%Drug Loading

Took a known weight of drug-loaded microspheres. **Dissolve** in 0.1NHCL to extract the drug. **Centrifuged** to remove polymer particles. **Analysed the drug concentration** using a UV-Visible spectrophotometer.

Drug loading (%)=(Weight of drug in microsphere/Total weight of microsphere)×100

In vitro drug release studies

A fixed amount of microspheres is placed in the medium. Observe and record the floating lag time and duration of floating .An in-vitro dissolution study was carried out by using USP XXII apparatus on alfuzosin HCl microspheres in 900 mL of pH 1.2 or 0.1N HCL buffer at 37 ± 1°C and 50 rpm. Samples (1 ml) were withdrawn at intervals and analysed spectrophotometrically at 430 nm after appropriate dilution. After study *of In-vitro* drug release kinetics of drug release

* Corresponding author *E-mail address:* dassmita707@gmail.com (Smita Das).

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kinetics of drug release is calculated and plotted in graphically of different kinetic models at.

Stability studies

The selected formulations were subjected to stability studies for a duration of 60 days. During this period, they were evaluated for changes in physical appearance, drug entrapment efficiency, and *in-vitro* drug release behaviour to ensure formulation consistency and performance over time.

Result and discussion

Preparation of Microspheres

The formulation was prepared by using of drug Alfuzosine HCL, sodium alginate as a polymer and calcium chloride as a crosslinking agent for gel formation to follow the ionic cross linking method (Figure 1(a)) .The polymer ratio gradually increase from formulation AF1–AF5. All the procedure carried out by 3D printer technology (Table 1) (Figure 1(b)).

Table 1: Formulation of Alfazosine HCL Microspheres

Drug/Excipient	AF1 (mg)	AF2 (mg)	AF3 (mg)	AF4 (mg)	AF5 (mg)
Alfazosine HCL	10	10	10	10	10
Sodium alginate	20	25	30	35	40
Calcium chloride	10	10	10	10	10

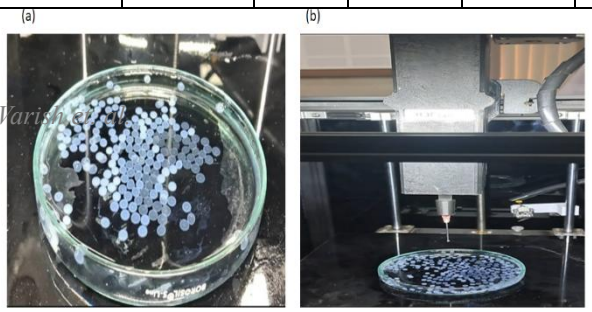

Figure 1 (a) Alfazosin hydrochloride microspheres & 1 (b) 3d Printer technique

Bulk Properties

After Alfuzosin HCl sodium alginate microspheres were synthesized, they were tested for micrometrics in a number of different ways. Variable characteristics such as bulk density, tapped density, % Compressibility index, Hausner's ratio, and angle of repose were used to analyse each of the five Alfuzosin HCl microsphere formulations AF1–AF5 according to standard pharmacopeia methods as described by Martin (1993).All of the formulations from AF1 to AF5 had a satisfactory flow property which provide insight in to the flowability and packing behaviour of microspheres, essential for their handling and formulation performance (Table 2).

Particle size and morphology

The all formulations were analyzed by optical microsphere and observed particle size ranges from 326-984 µm. All formulations were observed spherical and smooth surface. Among all we optimized the formulation AF4 shows larger particle size which allow slower diffusion of drug ideal for sustained release formulation. Bigger particles often encapsulated more drug due to more polymer content. Larger particle also shows more chemically and physically stable under storage (Table 3).

Table 3; Particle size of microspheres

Formulations	Particle size µm ±SD
AF1	365.92±3.62
AF2	495.68±5.94
AF3	526.31±10.24
AF4	984.72±15.62
AF5	326.51±11.74

Evaluations

Among all formulations, AF4 showed superior performance with the highest entrapment efficiency (86.49%), drug loading (48.35%), swelling index (4.95), and buoyancy (95.34%), making it the most promising formulation, but it has slightly lower %yield. AF3 had the highest yield (92.58%) but lower buoyancy. AF1 showed the lowest drug loading. Overall, results indicate that formulation composition significantly impacts microsphere characteristics, and AF4 observed optimal formulation of gastroretentive drug delivery (Table 4)

Table 2: Bulk properties of Microspheres

Formulations	Bulk density(g/cm3)	Tapped density(g/cm^3)	Angle of repose (θ)	Car's index(%)	Hausner's Ratio

* Corresponding author *E-mail address:* dassmita707@gmail.com (Smita Das).

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AF1	0.432±0.002	0.516±0.012	29.36±0.25	16.27±1.24	1.194±0.01
AF2	0.441±0.005	0.602±0.035	30.42±0.36	26.74±1.35	1.365±0.03
AF3	0.439±0.012	0.553±0.025	34.29±0.25	20.61±1.05	1.259±0.15
AF4	0.451±0.009	0.579±0.014	36.84±0.16	22.10±0.98	1.283±0.08
AF5	0.447±0.014	0.594±0.036	27.95±0.42	24.74±0.68	1.328±0.09

Table 4: Different evaluation of microspheres

Formulations	%Yield	Entrapment Efficiency	Swelling Index	% Drug loading	Buoyancy
AF12	86.35±0.69	72.15±0.36	4.62±0.01	23.51±0.26	76.35±0.24
AF2	79.68±1.24	69.53±0.95	4.31±0.11	36.52±0.59	80.39±1.35
AF3	92.58±3.25	76.35±1.25	4.52±0.05	26.59±1.05	69.25±1.68
AF4	73.21±2.01	86.49±0.43	4.95±0.02	48.35±1.24	95.34±1.04
AF5	80.95±2.16	69.31±0.57	4.36±0.04	33.51±1.38	69.87±1.11

In-vitro drug release

From this drug release study we find out that AF4 showed the highest cumulative release (~60% at 12 h), closely followed by AF1 and AF2. AF5 exhibited moderate release (~44%), while AF3 showed the slowest (~29%). These variations indicate different release mechanisms, formulation composition and matrix characteristics. The graphical presentation plot in below showing formulation AF4 steady drug release as compared formulation AF1.Based on drug release profile we optimise the formulation AF4 and selected for kinetic studies (Table 5) (Figure2).

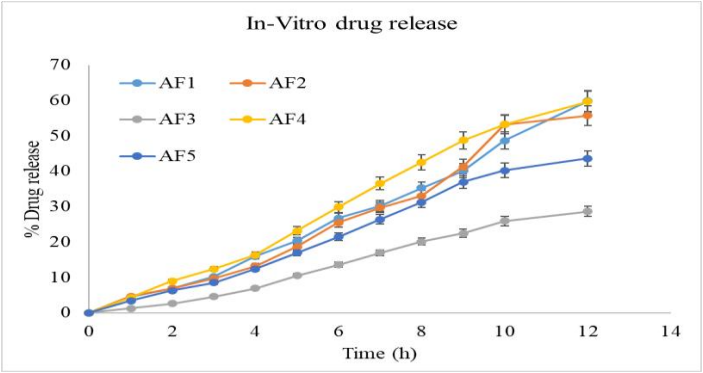

Figure 2 In-vitro drug release

Table 5: In-vitro drug release of formulation F1-F5

Time (h)	**% Drug release**				
	AF1	**AF2**	**AF3**	**AF4**	**AF5**
0	0	0	0	0	0
1	4.53±0.02	4.65±0.01	1.24±0.01	4.36±0.21	3.45±0.21
2	6.85±0.23	6.95±0.21	2.65±0.03	8.95±0.51	6.25±0.15
3	10.24±0.41	9.73±0.31	4.58±0.05	12.43±0.34	8.51±0.14
4	15.96±0.52	13.24±0.15	6.95±0.14	16.35±0.16	12.43±0.36
5	20.35±0.26	18.69±0.36	10.48±0.13	23.15±0.51	16.95±0.25
6	26.79±0.14	25.46±0.11	13.57±1.02	29.87±0.24	21.45±0.61
7	30.24±0.26	29.75±0.21	16.94±0.69	36.54±0.68	26.39±0.24
8	35.26±0.31	33.02±0.12	20.15±0.52	42.51±0.14	31.25±0.35

* Corresponding author *E-mail address:* dassmita707@gmail.com (Smita Das).

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9	40.15±0.01	41.27±0.14	22.47±0.41	48.76±0.51	36.95±0.18
12	59.86±0.24	55.75±0.14	28.67±0.15	59.67±0.51	43.62±0.15

Study of drug release kinetics

Based on the kinetic drug release data of AF4 best fitted to the korsmeyer peppas model with highest correlation coefficient (R^2value) 0.9936, these values are near to 1. So the drug is released through the combination of diffusion and polymer relaxation mechanisms. This confirms a non-Fickian release pattern, supporting the sustained and controlled drug release behaviour of the formulation (Figure 3(d)).

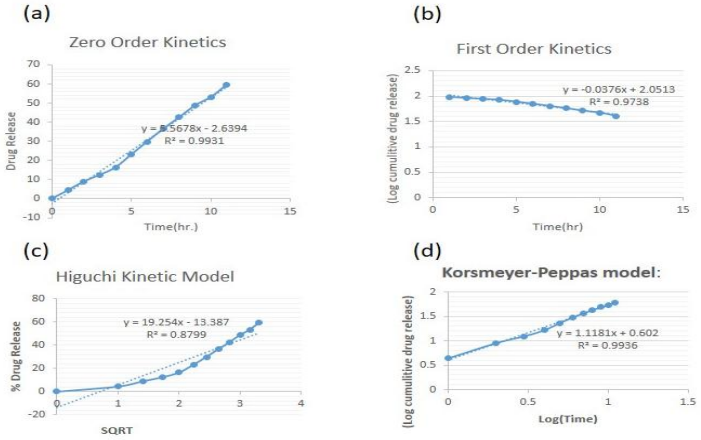

Figure 3(a) Zero order kinetic model, 3(b) First order kinetic model, 3(c) Higuchi kinetic model & 3(d) Korsmeyer –Peppas model

Stability studies

The optimized formulation was subjected to stability studies as per ICH guidelines under accelerated conditions (40 ± 2°C / 75 ± 5% RH) for a period of 3 months. The stability of microspheres were evaluated at intervals of 15,30,45 and 60 days There were no significant changes observed in physical appearance, drug content, or in-vitro drug release profile, indicating that the formulation is stable and retains its therapeutic efficacy over time (Table 6).

Conclusion

Alfuzosin hydrochloride, an α_1-adrenergic antagonist used for BPH, requires multiple daily doses in its IR form. To improve patient compliance, reduce cardiovascular negative effects and improve the symptoms of urine voiding and raise the levels of urine stream, we aimed to develop a single-dose sustained release formulation with stable drug levels. From the present study we concluded that among all the formulations which were carried out by using different ratio of polymer (sodium alginate), formulation AF4 demonstrated more optimised profile, with a sustained release of 59.67±0.51% at 12 hrs closely aligning with pharmacopeia standards for sustained release. It provide good entrapment efficiency of 76.49%, offers an ideal compromise in between retention and release. Additionally AF4 showed the highest swelling index and buoyancy, %yield slightly lower than others but still acceptable for microsphere preparation.AF1 is close to optimised AF4 in release profile but slightly lower in swelling index and drug loading.

Therefore AF4 can be considered the most balanced and optimized formulation by using 3D printing technology which provide a consistent and controlled release formulation. Among all the formulations AF4 offering effective entrapment, sustained release and acceptable physicochemical characteristics. Further in-vivo and bioavailability studies are planned to evaluate the clinical performance and support the sustained release formulation of an Alfuzosin hydrochloride.

Table 6: Stability study of optimized microspheres

Tested after days	% Drug entrapment	% CDR	Buoyancy	Particle size (mm)±SD	% Drug loading
0	86.35±1.25	28.67±0.15	94.25±1.68	526.31±10.24	48.59±1.05
15	85.36±1.29	29.53±0.59	92.36±0.69	523.61±6.59	47.53±0.36
30	84.95±1.35	30.12±0.64	90.46±1.02	530.59±9.56	46.89±0.59
45	83.12±2.04	32.46±0.13	90.13±1.03	531.27±8.34	46.05±0.85
60	80.62±1.37	35.89±0.57	89.25±1.42	536.28±7.25	45.68±0.34

* Corresponding author *E-mail address:* dassmita707@gmail.com (Smita Das).

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* Corresponding author *E-mail address:* dassmita707@gmail.com (Smita Das).

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