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Formulation and In-Vitro Assessment of Alfuzosin Medicated Gummies as a Patient-Friendly Oral Dosage Form

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Abstract: The study aimed to formulate and evaluate alfuzosin medicated gummies as a patient-friendly oral dosage form for long-term therapy of benign prostatic hyperplasia. Six formulations (F1–F6) containing 10 mg alfuzosin hydrochloride per gummy were prepared by the heating and congealing method using pectin and kappa-carrageenan as natural gelling polymers. The formulations were evaluated for appearance, weight variation, pH, hardness, moisture content, drug-content uniformity, swelling, syneresis, disintegration, in vitro drug release, release kinetics, and accelerated stability. Increasing polymer concentration increased hardness and disintegration time while reducing syneresis and drug-release rate. Drug content ranged from 97.84 ± 1.26% to 99.64 ± 0.96%. F5 showed acceptable texture, hardness of 14.16 ± 1.08 N, swelling index of 72.48 ± 5.64%, syneresis of 4.12 ± 0.33%, and 76.92% drug release at 120 min. Release predominantly followed first-order kinetics. F5 remained stable during three months at 40 ± 2°C/75 ± 5% RH. The pectin–kappa-carrageenan matrix therefore provided a suitable platform for alfuzosin medicated gummies.

Keywords: Alfuzosin hydrochloride; medicated gummies; pectin; kappa-carrageenan; benign prostatic hyperplasia; patient-friendly dosage form.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a non-malignant enlargement of the prostate associated with proliferation of stromal and epithelial cells, particularly within the transition and periurethral zones. The prevalence of clinically relevant BPH increases with age and may lead to lower urinary tract symptoms (LUTS), including weak urinary flow, urinary hesitancy, incomplete bladder emptying, increased frequency, urgency, and nocturia [1,2]. Although BPH is not malignant, persistent LUTS can adversely affect sleep, daily activities, sexual function, and overall quality of life [3,4].

Pharmacological treatment remains an important approach for patients with moderate to severe LUTS. Alpha-1 adrenergic receptor antagonists reduce smooth-muscle tone in the prostate, bladder neck, and prostatic urethra and thereby decrease dynamic bladder-outlet resistance. Alfuzosin hydrochloride is an alpha-1 adrenergic antagonist used for symptomatic treatment of BPH. It improves urinary flow without directly reducing prostate volume [5]. The marketed extended-release formulation is commonly administered as a 10 mg tablet once daily after food and should be swallowed intact rather than crushed, chewed, or divided [5,6].

Long-term oral treatment may be difficult for some older patients, particularly those experiencing dysphagia or reduced acceptance of conventional tablets. Patient-friendly dosage forms are therefore receiving increased attention because dosage-form texture, palatability, ease of administration, and treatment convenience may influence medication use. Medicated gummies represent soft, chewable oral matrices incorporating active pharmaceutical ingredients with suitable gelling polymers, sweeteners, plasticizers, flavouring agents, and stabilizers [7].

Recent advances have extended gummy formulations beyond conventional vitamin and nutraceutical preparations. Three-dimensional printing has demonstrated the feasibility of manufacturing gummies with individualized drug doses and controlled geometries [8]. Metformin-loaded printed gummies have been developed for paediatric administration [9], while semisolid-extrusion technology has enabled the manufacture of personalized dual-drug gummy systems [10]. These approaches demonstrate that gummy matrices may provide sufficient flexibility for pharmaceutical drug incorporation while maintaining acceptable physical characteristics.

Palatability remains particularly important for chewable pharmaceutical preparations. Tanaka et al. demonstrated that organoleptic taste-masking strategies could improve the palatability of epinastine-containing gummy preparations [11]. More complex drug-delivery approaches have incorporated risperidone-containing pellets within gummy matrices, demonstrating that pharmaceutical gummies may accommodate drug-containing systems while preserving acceptable dosage-form characteristics [12]. Child-friendly anti-infective gummies have also been evaluated for physicochemical, micromechanical, and taste properties [13].

The properties of medicated gummies are strongly influenced by the polymer matrix. Natural hydrocolloids can modify viscosity, gel formation, swelling, moisture retention, mechanical strength, and drug-release behaviour. Horison and Surini showed that combinations of polysaccharide gelling agents could influence gel strength, hydration, and physical stability of jelly-type formulations [14]. Similarly, optimization of functional gummies demonstrated that the proportion of gelling polymers significantly affected hardness, springiness, cohesiveness, and product acceptability [15]. Herbal-enriched gummies have also shown that variation in polymer concentration can alter texture, dispersion, and structural integrity [16].

Pectin is a plant-derived polysaccharide widely used as a gelling, thickening, stabilizing, and matrix-forming material. Its gel-forming properties depend on the degree of esterification, pH, ionic environment, and concentration [17]. Kappa-carrageenan is a sulfated polysaccharide derived from red seaweed with strong gel-forming and viscosity-modifying properties. It can form firm gels in the presence of suitable ions and may improve structural strength, elasticity, water retention, and matrix stability [18]. A combination of pectin and kappa-carrageenan may therefore provide a suitable polymer network for chewable gummies.

Previous formulation studies of alfuzosin have mainly focused on modified-release solid dosage forms. Pagariya and Patil developed a multiparticulate gastroretentive alfuzosin system using drug, effervescent, and gas-retaining layers to modify gastric residence and drug release [19]. These studies indicate that polymer composition can effectively regulate alfuzosin release. However, limited information is available regarding alfuzosin incorporated into a soft pectin–kappa-carrageenan gummy matrix.

The development of an alfuzosin gummy therefore requires an appropriate balance between gel strength, chewability, moisture retention, swelling, syneresis, drug-content uniformity, disintegration, and drug release. Accordingly, the present study was undertaken to formulate and evaluate alfuzosin medicated gummies using different concentrations of pectin and kappa-carrageenan and to assess their physicochemical characteristics, in vitro drug release, release kinetics, and accelerated stability.

MATERIALS AND METHODS

Chemicals

Alfuzosin hydrochloride was obtained as a gift sample from UniChem Laboratories Ltd., Mumbai. Pectin and kappa-carrageenan were procured from Global Exports Private Ltd., Mumbai. Glycerin and sodium

benzoate were obtained from Merck Life Science, India. Xylitol and potassium chloride were procured from S.D. Fine-Chemical Ltd., Mumbai, and orange flavour was obtained from Givaudan India Pvt. Ltd.

Calibration of Alfuzosin

A 1 mg/mL stock solution of alfuzosin was prepared in phosphate buffer pH 6.8. Suitable dilutions corresponding to 2–10 µg/mL were prepared and analysed at 245 nm using phosphate buffer pH 6.8 as blank.

Formulation Design

Six formulations (F1–F6) containing 10 mg alfuzosin per gummy were prepared. Pectin was varied from 120–200 mg and kappa-carrageenan from 80–120 mg. Glycerin, xylitol, potassium chloride, fruit flavour, sodium benzoate, and total gummy weight were maintained as specified in Table 1.

Table 1: Composition of Alfuzosin Medicated Gummies

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Alfuzosin	10	10	10	10	10	10
Pectin	120	160	200	120	160	200
Kappa-carrageenan	80	80	80	120	120	120
Glycerin	200	200	200	200	200	200
Xylitol	550	550	550	550	550	550
Potassium chloride	10	10	10	10	10	10
Fruit flavour	25	25	25	25	25	25
Sodium benzoate	15	15	15	15	15	15
Purified water	1990	1950	1910	1950	1910	1870
Total weight	3000	3000	3000	3000	3000	3000

Preparation of Alfuzosin Gummies

Pectin and kappa-carrageenan were dispersed in purified water, hydrated, and heated at approximately 70–80°C with continuous stirring. Xylitol, glycerin, potassium chloride, and sodium benzoate were incorporated into the polymeric base. After cooling to 45–50°C, alfuzosin was added and mixed uniformly, followed by fruit flavour. The gummy mass was transferred into silicone moulds, allowed to set at room temperature, removed from the moulds, cured, and stored in airtight containers.

FTIR Compatibility Study

FTIR spectra of alfuzosin, pectin, kappa-carrageenan, and the optimized formulation were recorded over 4000–400 cm^{-1}. Characteristic absorption peaks were compared to identify major changes or possible drug–excipient interactions.

Evaluation of Gummies

The gummies were evaluated for appearance, colour, taste, texture, chewability, stickiness, weight variation, surface pH, hardness, moisture content, and drug-content uniformity. Swelling was determined by immersing preweighed gummies in 50 mL phosphate buffer pH 6.8 at 37 ± 0.5°C. Syneresis was calculated from liquid loss from the gel matrix. Disintegration or erosion time was determined in 50 mL simulated saliva fluid pH 6.8 at 37 ± 0.5°C.

$$\text{Swelling index (\%)} = [(W_t - W_0) / W_0] \times 100$$

$$\text{Syneresis (\%)} = [(W_1 - W_2) / W_1] \times 100$$

In Vitro Drug Release

Dissolution studies were performed using USP type II paddle apparatus with 900 mL phosphate buffer pH 6.8 at 37 ± 0.5°C and 50 rpm. Samples of 5 mL were withdrawn at predetermined intervals and analysed at 245 nm. Drug release was expressed as cumulative percentage released.

Release Kinetics

Dissolution data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. Regression coefficients and the release exponent n were used to identify the predominant release pattern.

Stability Study

The optimized formulation was stored under accelerated conditions of 40 ± 2°C/75 ± 5% RH for three months. Samples were evaluated for appearance, pH, hardness, moisture content, drug content, disintegration time, and drug release in accordance with the stability approach described [20].

RESULTS AND DISCUSSION

Calibration of Alfuzosin

Absorbance increased linearly over the concentration range of 2–10 µg/mL. The regression equation was $y = 0.0616x + 0.0702$ with $R^2 = 0.9986$, confirming adequate linearity for quantitative analysis.

Drug–Excipient Compatibility

The characteristic peaks of alfuzosin were retained in the optimized formulation with only minor shifts and broadening. No additional major peaks or complete disappearance of characteristic bands was observed, suggesting absence of a major chemical interaction between alfuzosin, pectin, and kappa-carrageenan.

Table 2: Comparative FTIR Peaks

Functional group	Alfuzosin (cm^{-1})	Pectin (cm^{-1})	Kappa-carrageenan (cm^{-1})	Optimized formulation (cm^{-1})
O–H and N–H stretching	3340	3330	3420	3360
Aliphatic C–H stretching	2940	2935	2925	2932
Ester carbonyl stretching	–	1740	–	1736
Carbonyl and bound-water region	1640	1628	1640	1634
Aromatic/ring-associated region	1595, 1510, 1450	1438	–	1592, 1410
Sulfate ester region	–	–	1220	1230
C–O/C–N fingerprint region	1260, 1180	1148, 1021	1068	1145, 1060
3,6-Anhydrogalactose region	–	–	930	930
Sulfated galactose region	830	–	845	846

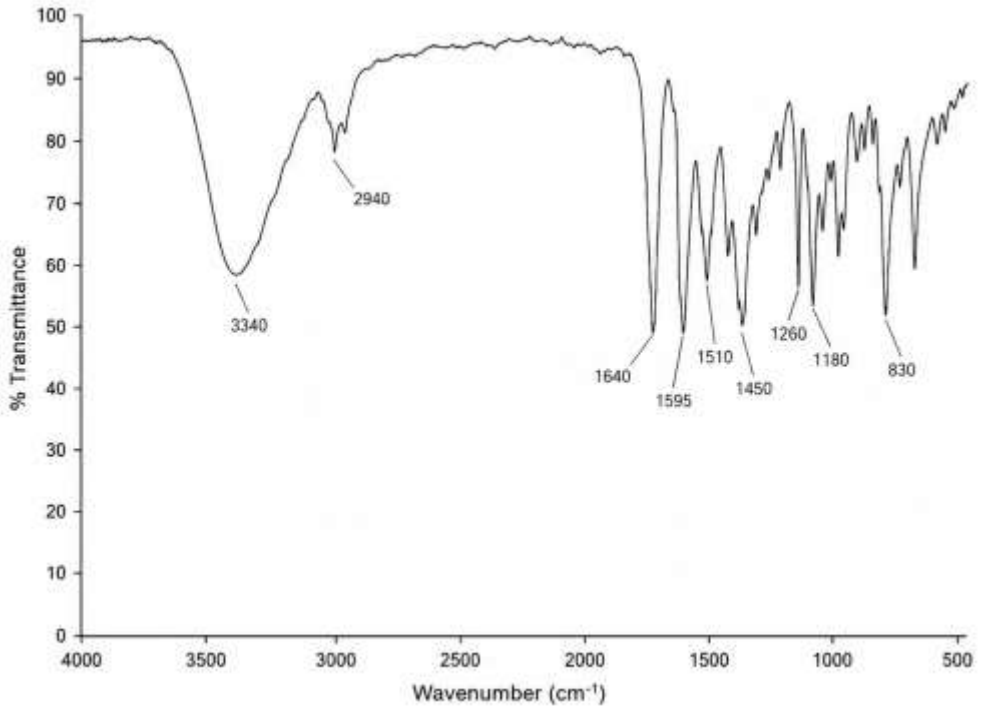

Fig 1: FTIR spectrum of alfuzosin.

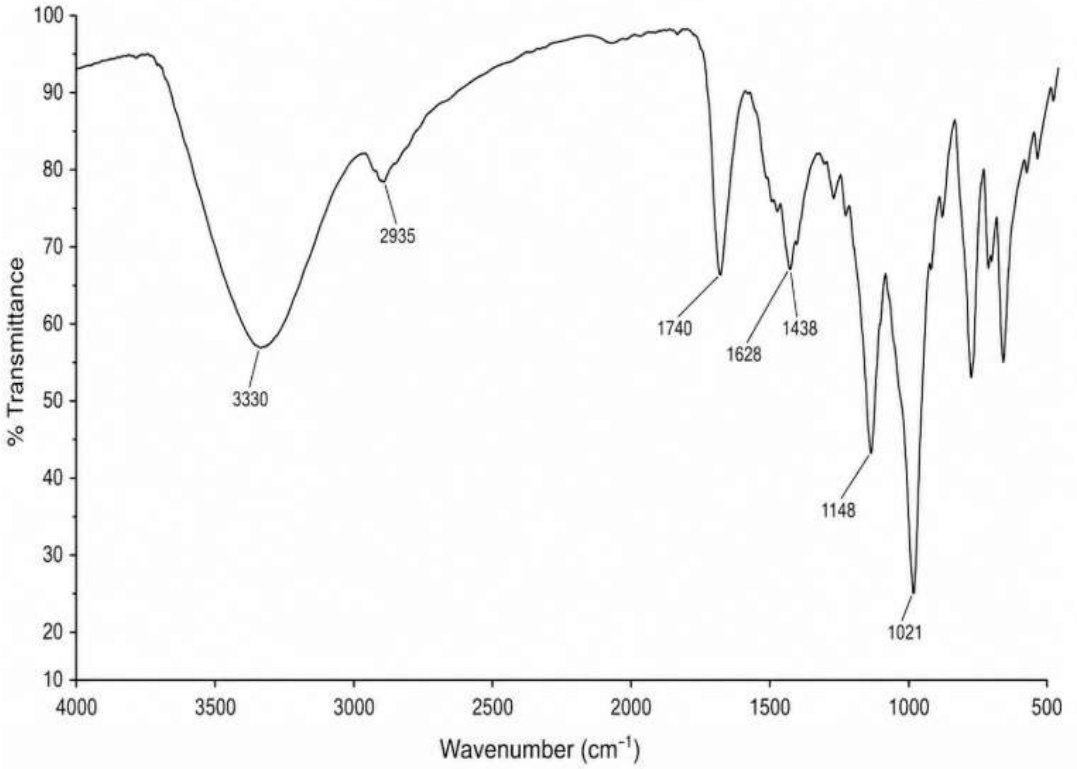

Fig 2: FTIR spectrum of pectin.

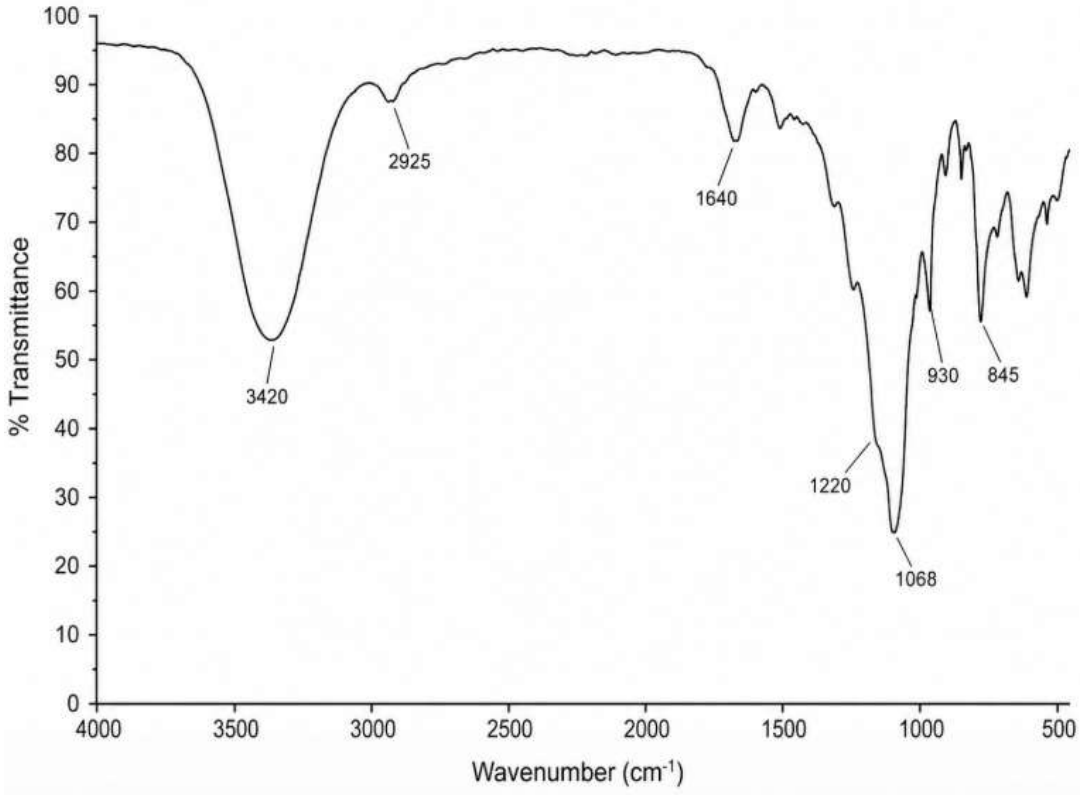

Fig 3: FTIR spectrum of kappa-carrageenan.

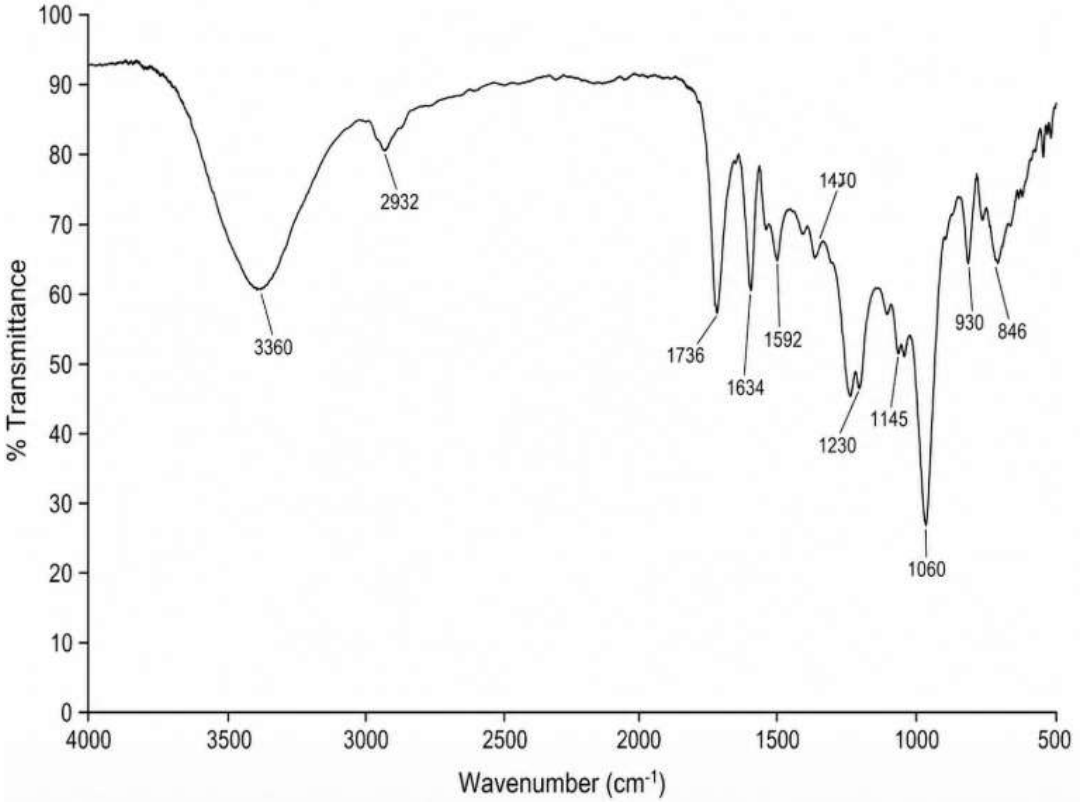

Fig 4: FTIR spectrum of optimized formulation.

Physical and Organoleptic Characteristics

All formulations produced light-yellow to pale-yellow gummies with a pleasant fruity odour and acceptable taste. Increasing polymer concentration improved firmness and reduced stickiness. F1 was

relatively soft and slightly sticky, whereas F6 was comparatively firm and tough. F5 showed the best balance of smooth appearance, elasticity, chewability, and non-sticky texture.

Table 3: Organoleptic Characteristics of Alfuzosin Medicated Gummies

F code	Colour	Appearance	Odour	Taste	Texture	Stickiness	Overall observation
F1	Light yellow	Smooth and translucent	Pleasant fruity	Sweet, mild aftertaste	Soft and slightly weak	Slightly sticky	Acceptable but less firm
F2	Light yellow	Smooth and uniform	Pleasant fruity	Sweet, acceptable	Soft and elastic	Minimal	Good
F3	Pale yellow	Smooth and slightly opaque	Pleasant fruity	Sweet, acceptable	Firm and chewable	Non-sticky	Good
F4	Light yellow	Smooth and translucent	Pleasant fruity	Sweet, mild aftertaste	Elastic and slightly firm	Minimal	Good
F5	Pale yellow	Smooth, uniform and glossy	Pleasant fruity	Sweet and acceptable	Soft, elastic and chewable	Non-sticky	Best acceptable batch
F6	Pale yellow	Smooth but slightly firm	Pleasant fruity	Sweet, acceptable	Firm and slightly tough	Non-sticky	Acceptable but less soft

Evaluation

Average gummy weight ranged from 2986.42 ± 98.36 to 3010.28 ± 116.76 mg, indicating reproducible mould filling. Surface pH remained within 5.29 ± 0.26 to 5.47 ± 0.34. Hardness increased from 8.64 ± 0.72 N in F1 to 16.38 ± 1.31 N in F6 as the polymer content increased. Moisture content decreased from 22.48 ± 1.86% to 17.28 ± 1.22%. Drug content ranged from 97.84 ± 1.26% to 99.64 ± 0.96%, indicating uniform incorporation of alfuzosin.

Table 4: Physicochemical Properties of Alfuzosin Gummies

F code	Weight variation (mg)	pH	Hardness (N)	Moisture content (%)	Drug content (%)
F1	2986.42 ± 98.36	5.42 ± 0.31	8.64 ± 0.72	22.48 ± 1.86	97.84 ± 1.26
F2	2994.76 ± 104.52	5.38 ± 0.28	10.26 ± 0.84	21.36 ± 1.74	98.62 ± 1.18
F3	3002.18 ± 112.64	5.31 ± 0.27	12.48 ± 0.96	20.24 ± 1.62	99.18 ± 1.04
F4	2991.54 ± 96.85	5.47 ± 0.34	11.32 ± 0.91	19.86 ± 1.48	98.76 ± 1.12
F5	3005.62 ± 108.43	5.35 ± 0.29	14.16 ± 1.08	18.42 ± 1.36	99.64 ± 0.96
F6	3010.28 ± 116.76	5.29 ± 0.26	16.38 ± 1.31	17.28 ± 1.22	99.26 ± 1.08

Swelling, Syneresis, and Disintegration

Swelling increased with polymer hydration and ranged from 48.64 ± 3.72% in F1 to a maximum of 72.48 ± 5.64% in F5. Syneresis decreased from 8.74 ± 0.66% in F1 to 3.56 ± 0.27% in F6, demonstrating improved water retention at higher polymer concentrations. Disintegration or erosion time increased from 16.78 ± 1.24 min to 48.56 ± 3.92 min. F5 showed an intermediate value of 39.72 ± 3.08 min, indicating adequate matrix integrity without the excessive firmness observed for F6.

Table 5: Swelling, Syneresis, and Disintegration of Alfuzosin Gummies

F code	Swelling index at 120 min (%)	Syneresis after 72 h (%)	Disintegration time (min)
F1	48.64 ± 3.72	8.74 ± 0.66	16.78 ± 1.24
F2	57.28 ± 4.36	7.18 ± 0.54	24.93 ± 1.86
F3	65.76 ± 5.18	6.42 ± 0.48	33.46 ± 2.71
F4	62.35 ± 4.72	5.38 ± 0.41	28.15 ± 2.13
F5	72.48 ± 5.64	4.12 ± 0.33	39.72 ± 3.08
F6	68.16 ± 5.21	3.56 ± 0.27	48.56 ± 3.92

In Vitro Drug Release

Drug release was dependent on the polymer concentration. F1 showed the fastest release, reaching 94.18% at 120 min, whereas F6 showed the slowest release of 70.35%. Increasing pectin and kappa-carrageenan produced a stronger hydrated matrix and progressively reduced drug release. F5 released 8.64% at 10 min, 51.76% at 60 min, and 76.92% at 120 min. This release profile, together with its acceptable texture and matrix properties, supported selection of F5 as the optimized formulation.

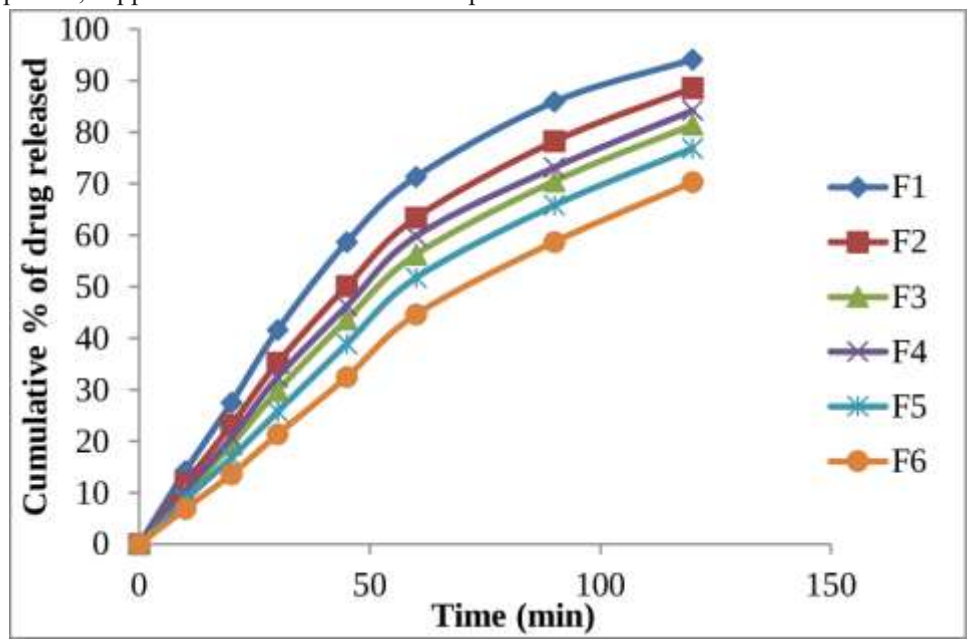

Fig 5: In vitro dissolution profile of alfuzosin gummies.

Release Kinetics

The formulations predominantly followed first-order kinetics, with R^2 values ranging from 0.9937 to 0.9980, indicating concentration-dependent drug release. Korsmeyer–Peppas analysis also showed good model fitting. The release exponent increased from 0.7749 in F1 to 0.9581 in F6. The values indicated anomalous to super Case-II transport, suggesting that diffusion, polymer swelling, relaxation, and erosion collectively contributed to drug release.

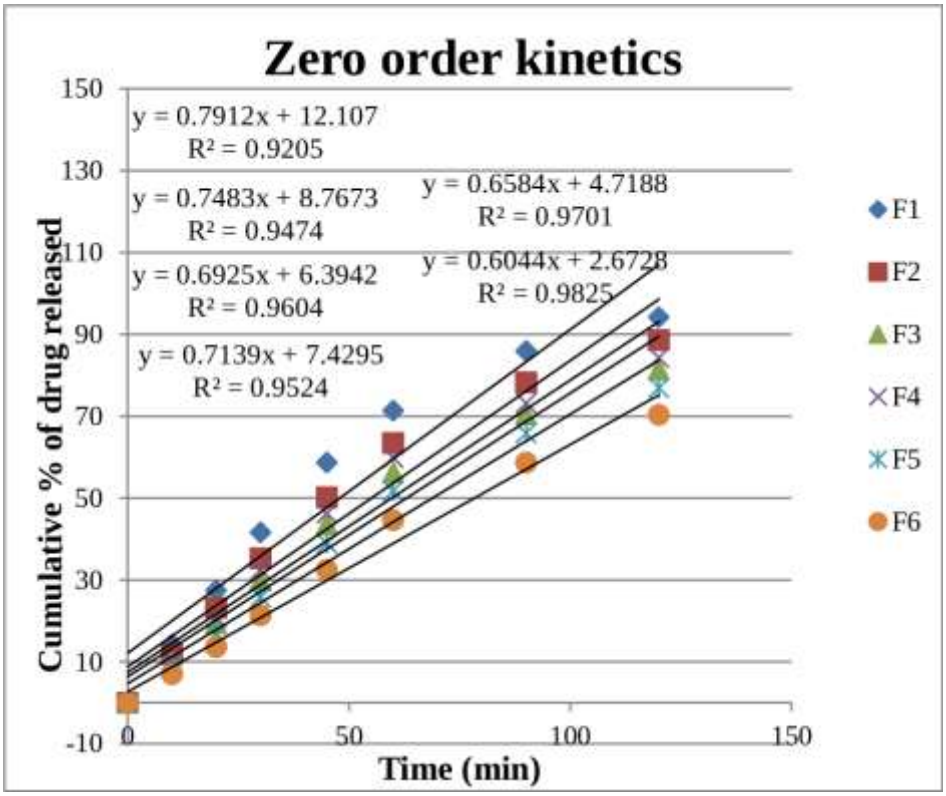

Fig 6: Zero-order kinetics plot of alfuzosin formulations

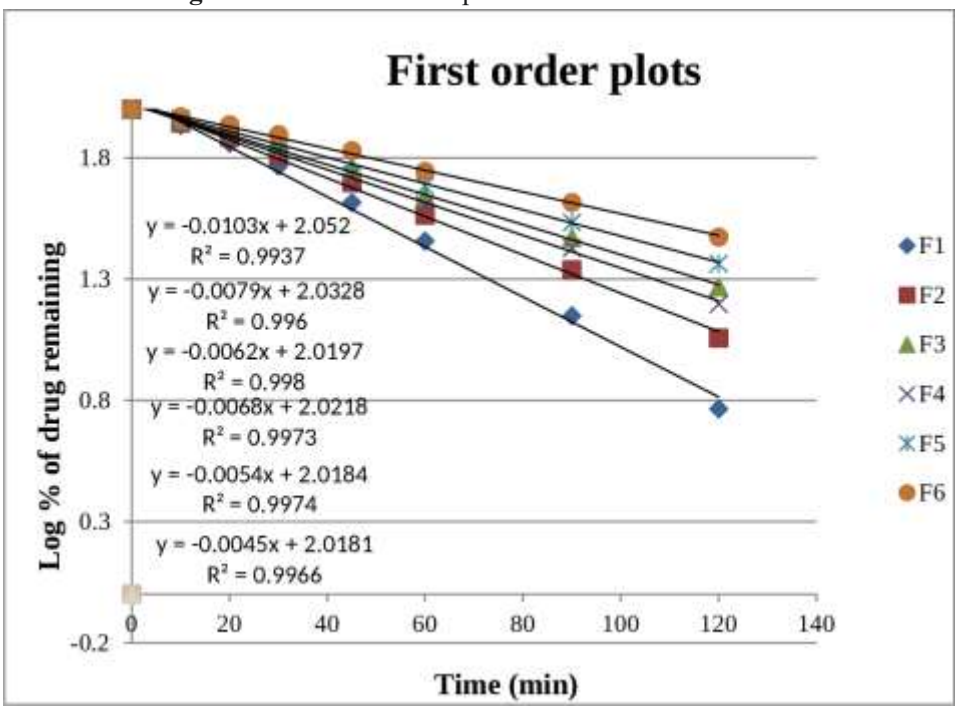

Fig 7: First-order kinetics plot of alfuzosin formulations.

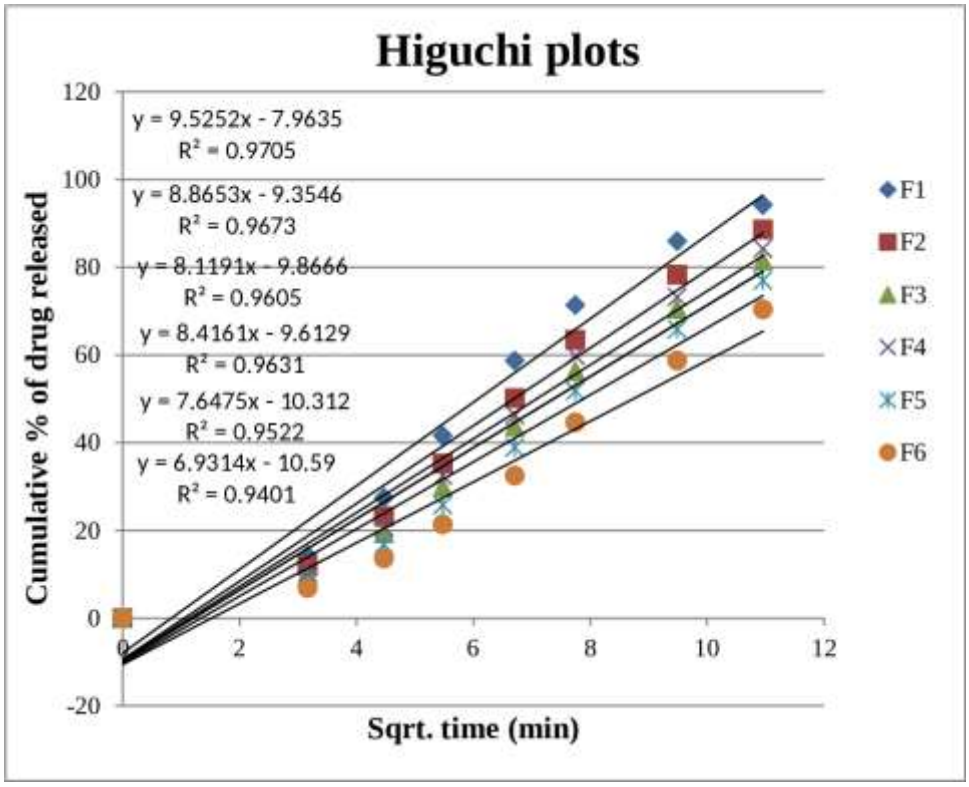

Fig 8: Higuchi diffusion model of alfuzosin formulations.

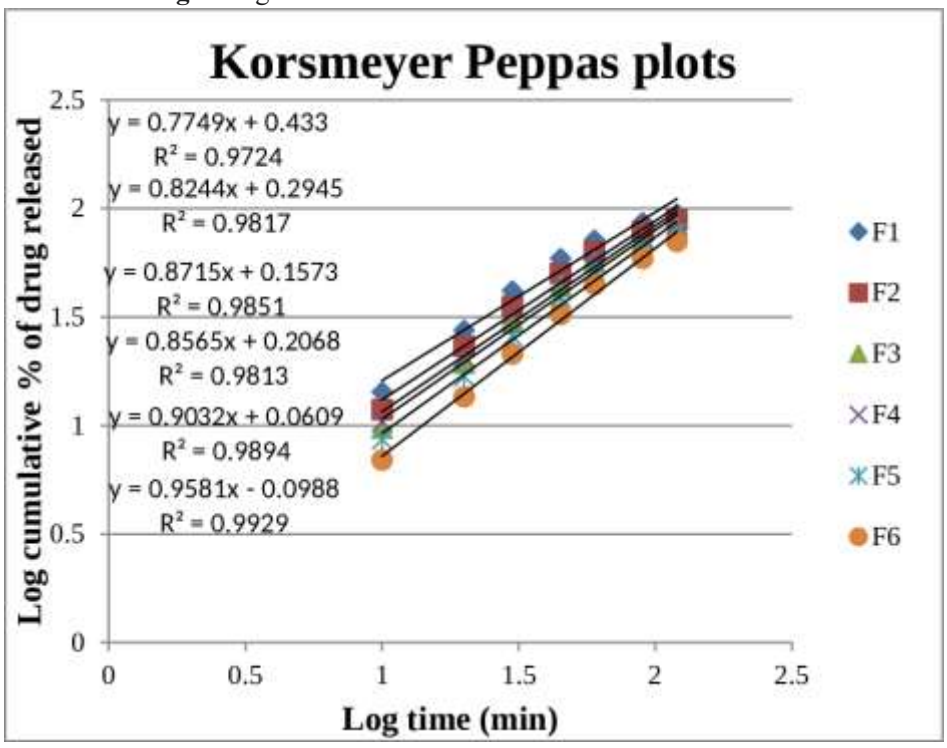

Fig 9: Korsmeyer–Peppas model plot of alfuzosin formulations.

Selection of Optimized Formulation

F5 was selected as the optimized formulation because it provided the most appropriate balance between texture, chewability, hardness, swelling, matrix stability, and drug release. It showed a weight of 3005.62 ± 108.43 mg, pH of 5.35 ± 0.29, hardness of 14.16 ± 1.08 N, moisture content of 18.42 ± 1.36%, and drug

content of 99.64 ± 0.96%. The formulation also exhibited a swelling index of 72.48 ± 5.64%, syneresis of 4.12 ± 0.33%, disintegration time of 39.72 ± 3.08 min, and drug release of 76.92% at 120 min. Although F6 provided slower release, its greater hardness and tougher texture reduced its suitability as the optimized gummy.

Stability Study

F5 remained physically acceptable during three months of accelerated storage. Hardness increased slightly from 14.16 ± 1.08 N to 15.86 ± 1.26 N, while moisture content decreased from 18.42 ± 1.36% to 16.84 ± 1.16%. Drug content decreased only from 99.64 ± 0.96% to 98.26 ± 0.82%, while drug release at 120 min decreased from 76.92% to 73.52%. These limited changes indicated acceptable stability under the tested conditions.

CONCLUSION

Alfuzosin medicated gummies were successfully formulated using a pectin–kappa-carrageenan natural polymer matrix. Variation in polymer concentration affected hardness, moisture content, swelling, syneresis, disintegration, and drug-release behaviour. F5 was selected as the optimized formulation because it provided the best overall balance of chewability, structural integrity, drug-content uniformity, hydration behaviour, and controlled drug release. The formulation released 76.92% alfuzosin at 120 min and predominantly followed first-order release kinetics. During three months of accelerated storage, only minor changes in hardness, moisture content, drug content, and drug release were observed. The study therefore demonstrated the formulation feasibility of pectin–kappa-carrageenan medicated gummies containing alfuzosin. Further work should evaluate sensory acceptability, pharmacokinetics, clinical performance, and scale-up before considering therapeutic or commercial application.

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