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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  $97.84 \pm 1.26\%$  to  $99.64 \pm 0.96\%$ . F5 showed acceptable texture, hardness of  $14.16 \pm 1.08$  N, swelling index of  $72.48 \pm 5.64\%$ , syneresis of  $4.12 \pm 0.33\%$ , and 76.92% drug release at 120 min. Release predominantly followed first-order kinetics. F5 remained stable during three months at  $40 \pm 2^\circ\text{C}/75 \pm 5\%$  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<sup>-1</sup>. 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  $40 \pm 2^\circ\text{C}/75 \pm 5\%$  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

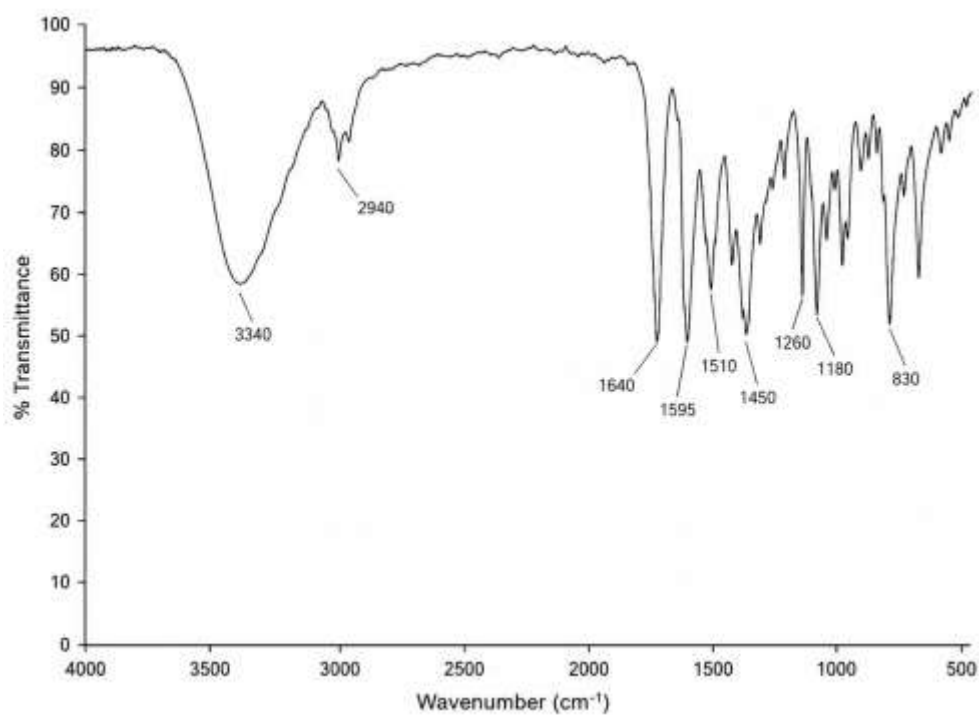
Absorbance increased linearly over the concentration range of 2–10  $\mu\text{g/mL}$ . The regression equation was  $y = 0.0616x + 0.0702$  with  $R^2 = 0.9986$ , confirming adequate linearity for quantitative analysis.

### Drug–Excipient Compatibility

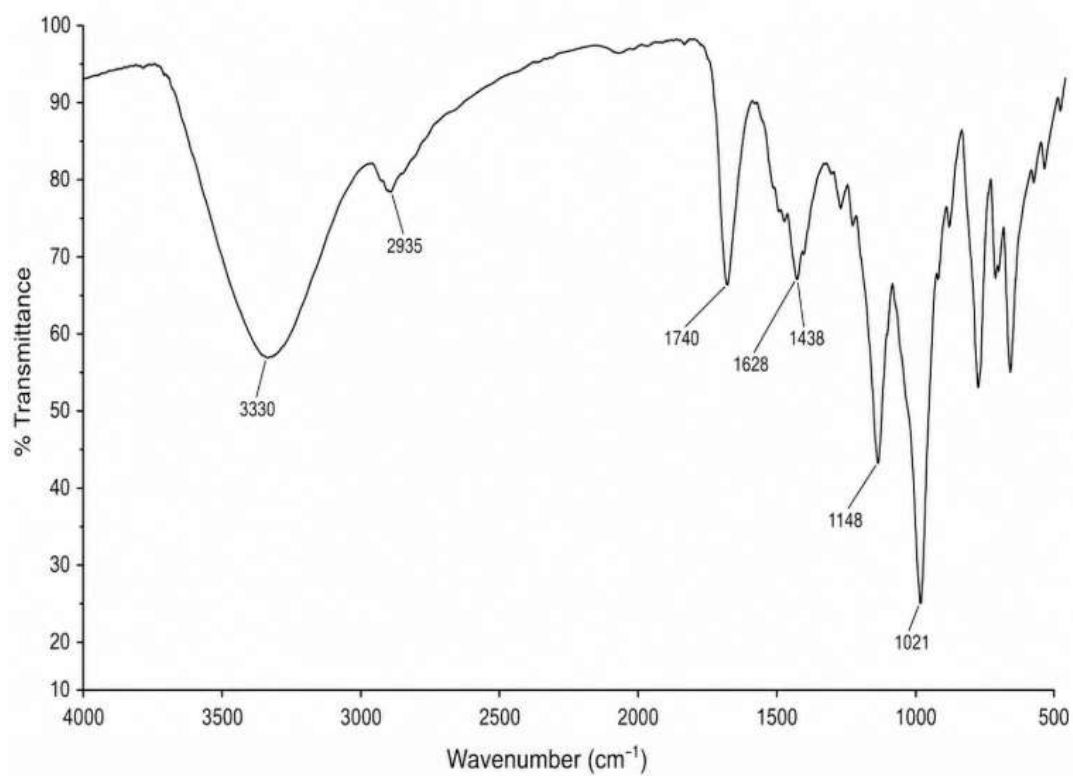
The characteristic peaks of alfuzosin were retained in the optimized formulation with only minor shifts and broadening. No additional major peaks or complete disappearance of characteristic bands was observed, suggesting absence of a major chemical interaction between alfuzosin, pectin, and kappa-carrageenan.

**Table 2:** Comparative FTIR Peaks

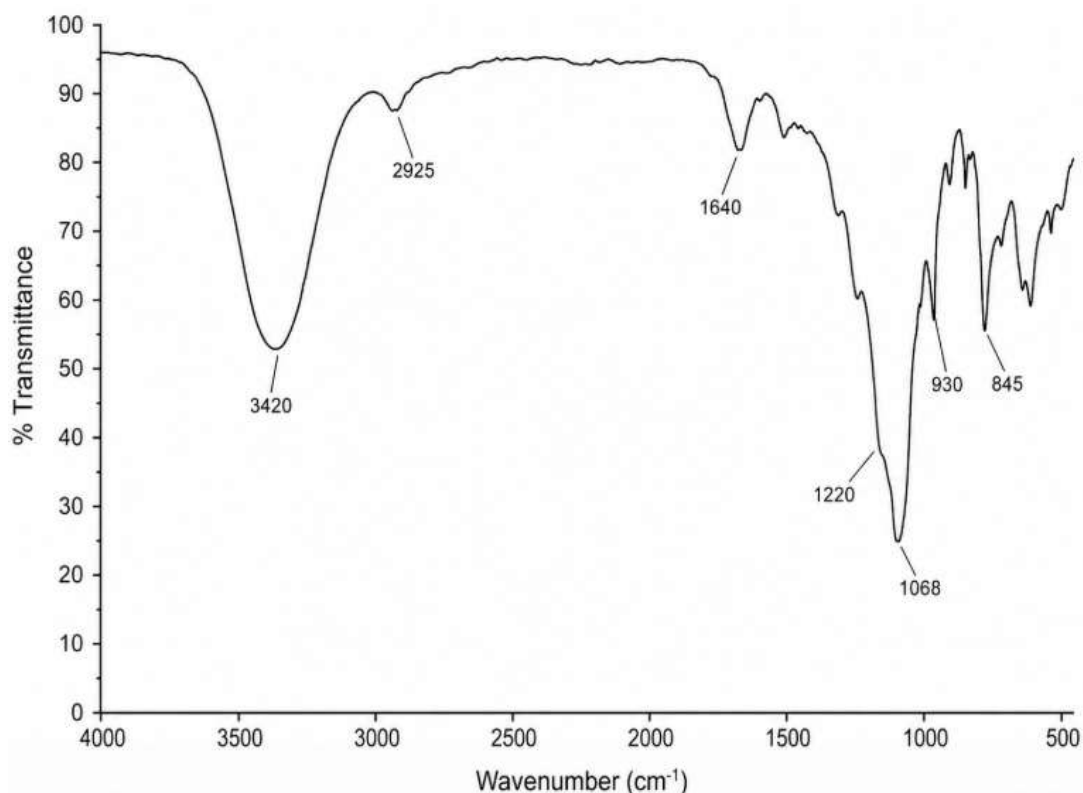
| Functional group                | Alfuzosin ( $\text{cm}^{-1}$ ) | Pectin ( $\text{cm}^{-1}$ ) | Kappa-carrageenan ( $\text{cm}^{-1}$ ) | Optimized formulation ( $\text{cm}^{-1}$ ) |
|---------------------------------|--------------------------------|-----------------------------|----------------------------------------|--------------------------------------------|
| 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                                        |



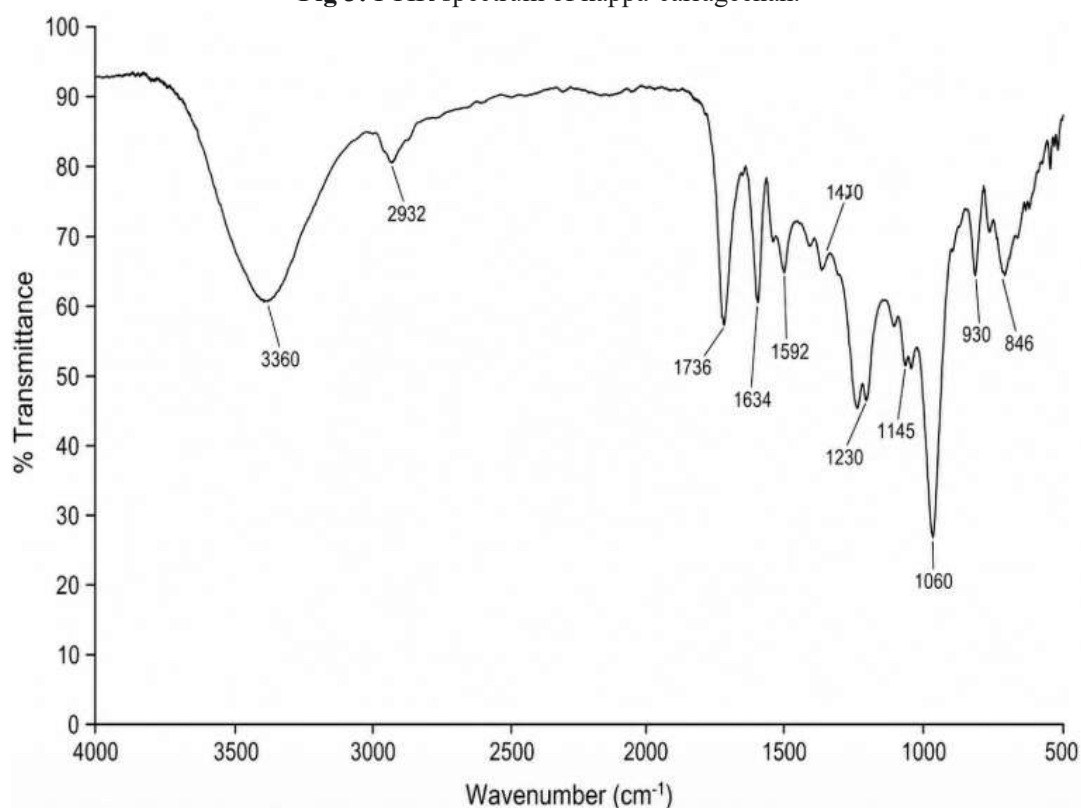
**Fig 1:** FTIR spectrum of alfuzosin.



**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  $2986.42 \pm 98.36$  to  $3010.28 \pm 116.76$  mg, indicating reproducible mould filling. Surface pH remained within  $5.29 \pm 0.26$  to  $5.47 \pm 0.34$ . Hardness increased from  $8.64 \pm 0.72$  N in F1 to  $16.38 \pm 1.31$  N in F6 as the polymer content increased. Moisture content decreased from  $22.48 \pm 1.86\%$  to  $17.28 \pm 1.22\%$ . Drug content ranged from  $97.84 \pm 1.26\%$  to  $99.64 \pm 0.96\%$ , 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     | $2986.42 \pm 98.36$   | $5.42 \pm 0.31$ | $8.64 \pm 0.72$  | $22.48 \pm 1.86$     | $97.84 \pm 1.26$ |
| F2     | $2994.76 \pm 104.52$  | $5.38 \pm 0.28$ | $10.26 \pm 0.84$ | $21.36 \pm 1.74$     | $98.62 \pm 1.18$ |
| F3     | $3002.18 \pm 112.64$  | $5.31 \pm 0.27$ | $12.48 \pm 0.96$ | $20.24 \pm 1.62$     | $99.18 \pm 1.04$ |
| F4     | $2991.54 \pm 96.85$   | $5.47 \pm 0.34$ | $11.32 \pm 0.91$ | $19.86 \pm 1.48$     | $98.76 \pm 1.12$ |
| F5     | $3005.62 \pm 108.43$  | $5.35 \pm 0.29$ | $14.16 \pm 1.08$ | $18.42 \pm 1.36$     | $99.64 \pm 0.96$ |
| F6     | $3010.28 \pm 116.76$  | $5.29 \pm 0.26$ | $16.38 \pm 1.31$ | $17.28 \pm 1.22$     | $99.26 \pm 1.08$ |

### Swelling, Syneresis, and Disintegration

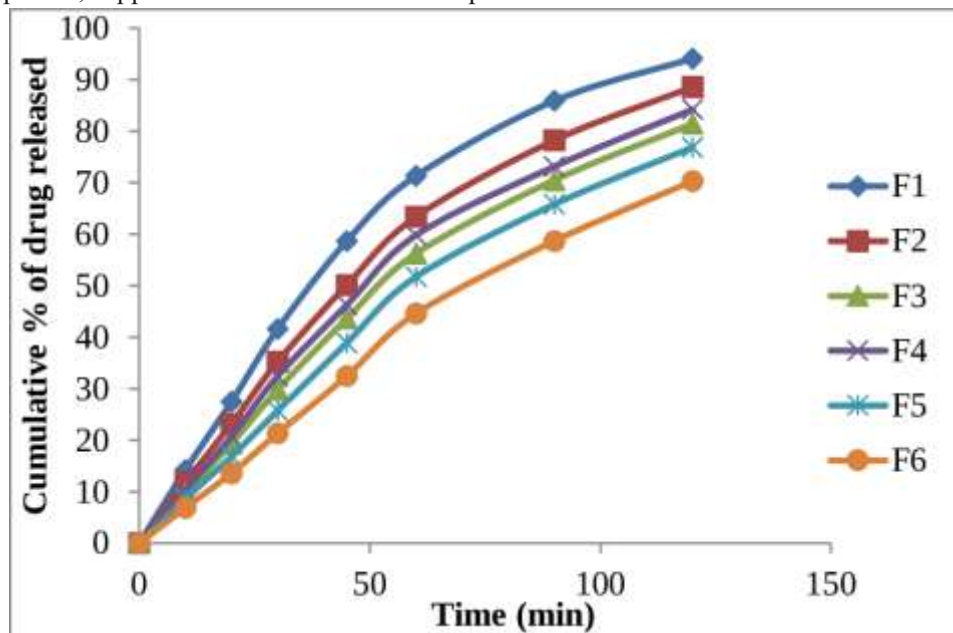
Swelling increased with polymer hydration and ranged from  $48.64 \pm 3.72\%$  in F1 to a maximum of  $72.48 \pm 5.64\%$  in F5. Syneresis decreased from  $8.74 \pm 0.66\%$  in F1 to  $3.56 \pm 0.27\%$  in F6, demonstrating improved water retention at higher polymer concentrations. Disintegration or erosion time increased from  $16.78 \pm 1.24$  min to  $48.56 \pm 3.92$  min. F5 showed an intermediate value of  $39.72 \pm 3.08$  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.

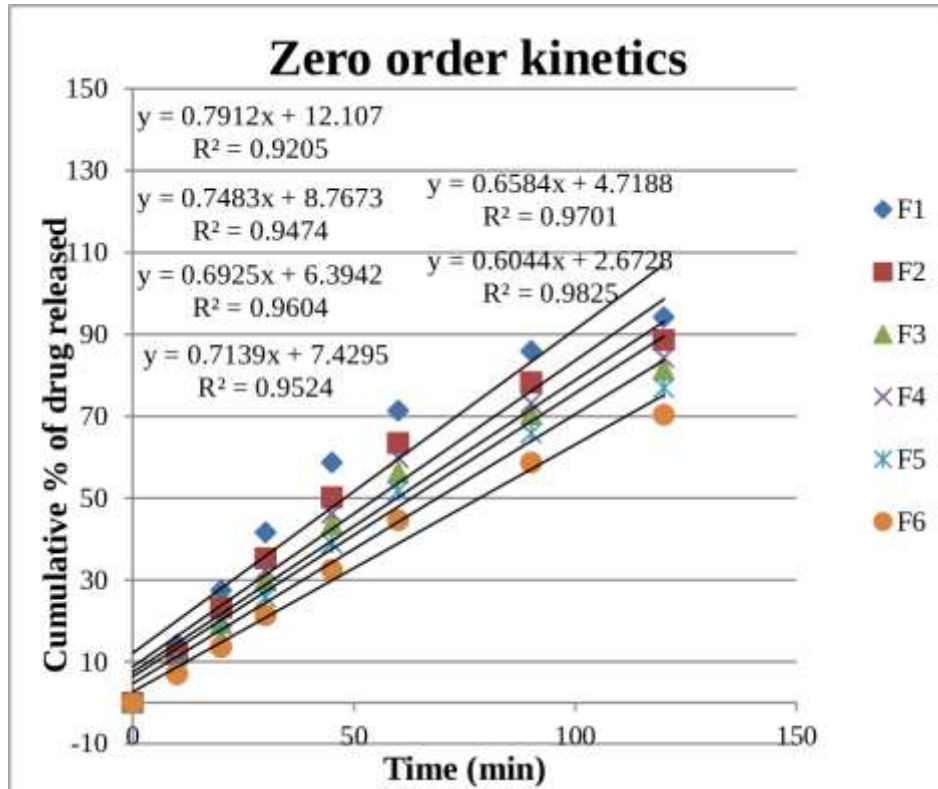


Fig 6: Zero-order kinetics plot of alfuzosin formulations

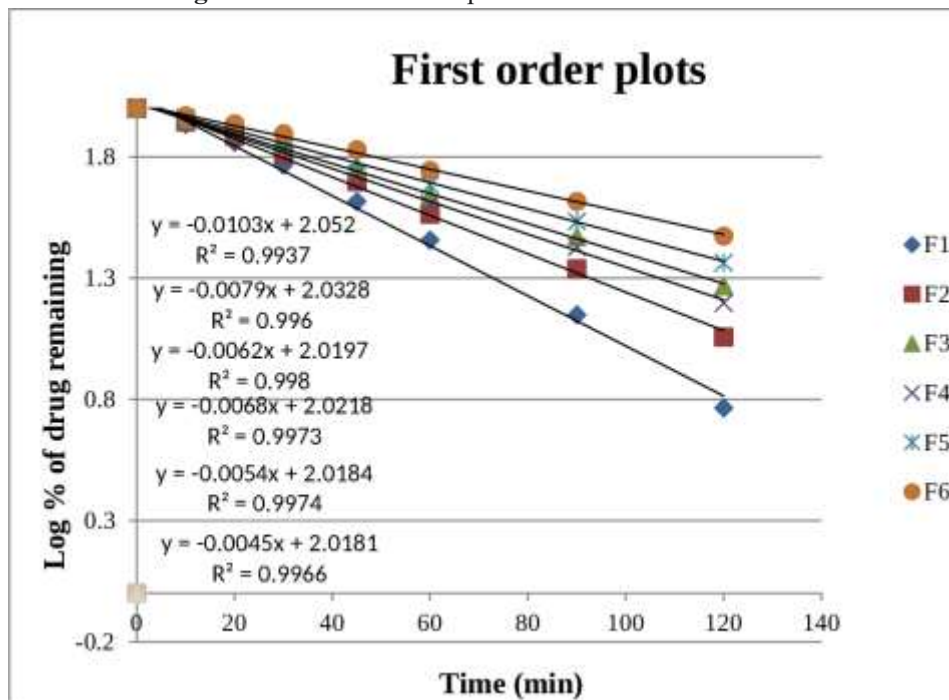


Fig 7: First-order kinetics plot of alfuzosin formulations.

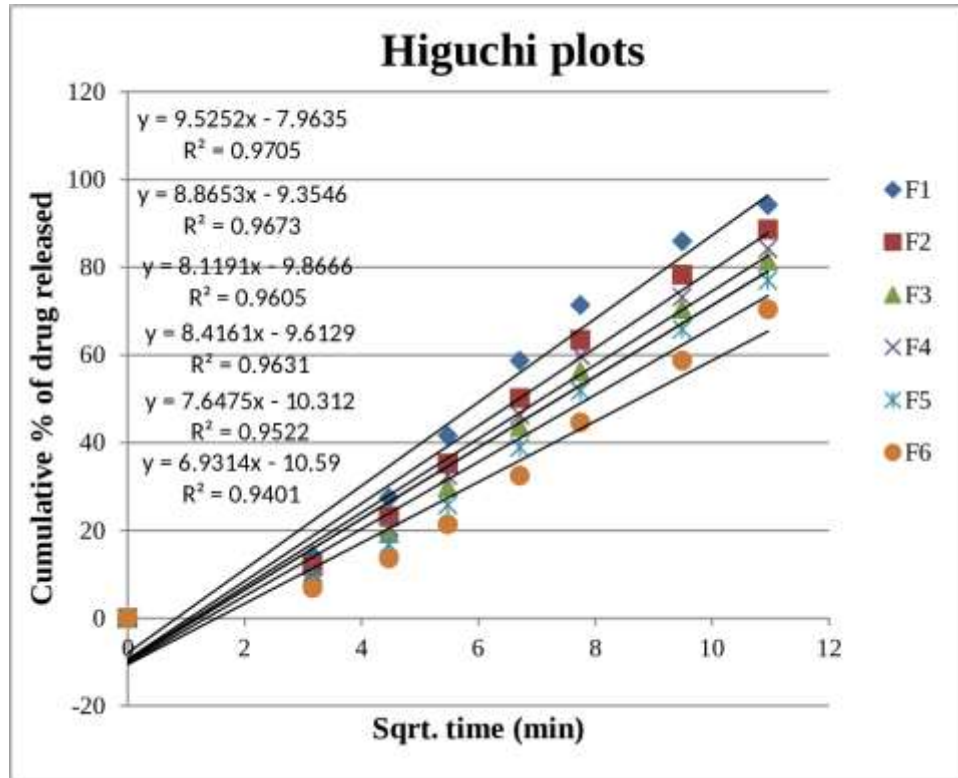


Fig 8: Higuchi diffusion model of alfuzosin formulations.

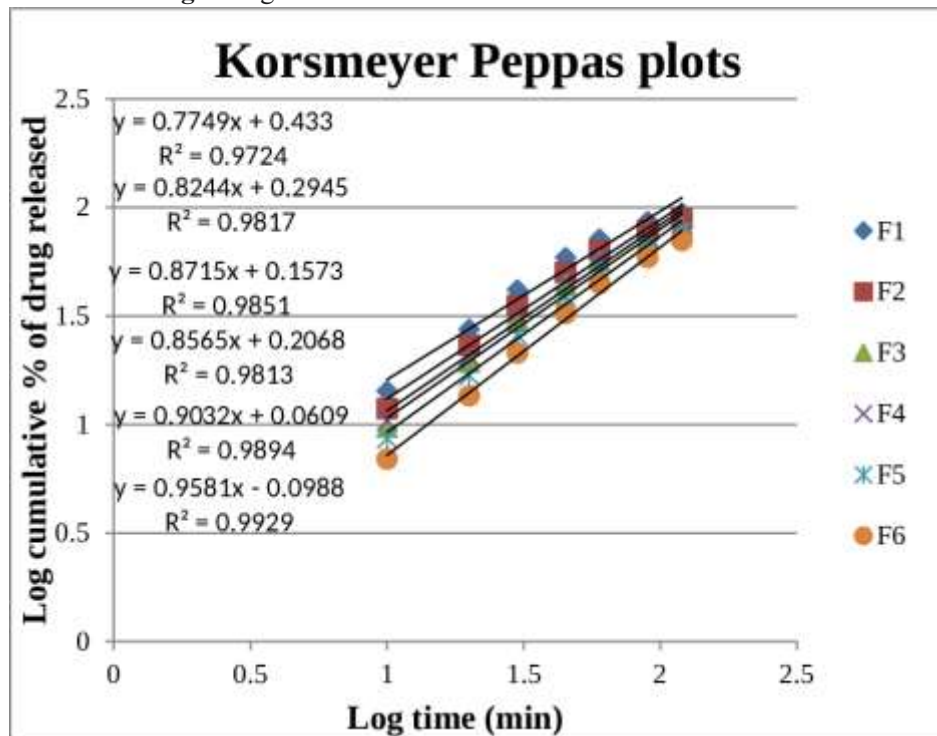


Fig 9: Korsmeyer–Peppas model plot of alfuzosin formulations.

### 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  $3005.62 \pm 108.43$  mg, pH of  $5.35 \pm 0.29$ , hardness of  $14.16 \pm 1.08$  N, moisture content of  $18.42 \pm 1.36\%$ , and drug

content of  $99.64 \pm 0.96\%$ . The formulation also exhibited a swelling index of  $72.48 \pm 5.64\%$ , syneresis of  $4.12 \pm 0.33\%$ , disintegration time of  $39.72 \pm 3.08$  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  $14.16 \pm 1.08$  N to  $15.86 \pm 1.26$  N, while moisture content decreased from  $18.42 \pm 1.36\%$  to  $16.84 \pm 1.16\%$ . Drug content decreased only from  $99.64 \pm 0.96\%$  to  $98.26 \pm 0.82\%$ , 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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