ISSN: 2320-2831

International Journal of Pharmacy and Analytical Research (IJPAR)

IJPAR | Vol.15 | Issue 1 | Jan - Mar -2026

www.ijpar.com

DOI: https://doi.org/10.61096/ijpar.v15.iss1.2026.321-331

Formulation and in-Vitro Assessment of Doxazosin Mesylate Medicated Gummies as A Patient-Compliant Antihypertensive Dosage Form

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Published by: 24.02.2026

Abstract: This study concentrated on the development and in-vitro assessment of Doxazosin Mesylate-loaded medicated gummies as an innovative, patient-friendly oral dosage form for hypertension treatment. Gummies were formulated with gelatin as the gelling ingredient to enhance palatability, facilitate administration, and increase medicinal efficacy. Five formulations (F1–F5) were developed using the direct cook-and-pour method, each comprising 2 mg of Doxazosin Mesylate with a total gummy weight of 3.0 g, while altering gelatin concentration to examine its effect on physic mechanical and release properties. The quantitative analysis was confirmed by a UV–visible spectrophotometric technique in a pH 6.8 phosphate buffer, exhibiting exceptional linearity ($R^2 > 0.999$). FTIR analyses validated the compatibility between the medication and excipients, demonstrating the retention of distinct functional groups without notable changes. All formulations had a consistent appearance, appropriate surface pH, regulated moisture content, and adequate water activity. Texture study indicated that increased gelatin content resulted in greater firmness, with F5 exhibiting the highest firmness at 4.32 ± 0.20 N. In-vitro dissolution experiments indicated a gradual improvement in drug release correlated with elevated polymer concentration, culminating in a maximum cumulative release of 98.5% within 60 minutes for F5. The release kinetics exhibited first-order behaviour characterised by non-Fickian diffusion according to the Korsmeyer–Peppas model. Stability experiments verified the physical and chemical stability of the optimised formulation for 90 days under accelerated settings. Medicated gummies of Doxazosin Mesylate offer a viable alternative to traditional pills for enhancing patient adherence in hypertension treatment.

Keywords: Doxazosin Mesylate; Medicated gummies; Gelatin; Patient-compliant dosage form; Antihypertensive therapy; In-vitro drug release.

INTRODUCTION

Medicated gummies are a novel and swiftly advancing category of pharmaceutical dosage forms that combine the chewable and enjoyable characteristics of confections with the therapeutic effectiveness of traditional oral drugs. This innovative drug delivery system has arisen to address the difficulties associated with conventional oral dosage forms, particularly for patient demographics such as children, the elderly, and

individuals with dysphagia, who frequently experience poor adherence and medication evasion due to unfavourable taste or formulation.

Historically, oral administration has been the most favoured method for medication delivery because to its simplicity, cost-effectiveness, convenience of use, and patient compliance. Ancient civilizations, such as those in India and China, employed natural gums, herbal extracts, and excipients similar to contemporary gummy bases for therapeutic applications. Conventional solid dose forms, such as tablets and capsules, frequently encounter challenges related to swallowing difficulty, unpleasant taste, and inflexible dosing, particularly in paediatric and geriatric populations. Liquid formulations such as syrups, while more palatable, present issues including dosage accuracy, limited shelf life, and cumbersome handling. To mitigate these constraints, pharmaceutical experts have created medicated gummies as a user-friendly alternative that merges ease of administration with enhanced palatability.[i]

Medicated gummies presently occupy a distinctive place at the convergence of medicines, nutraceuticals, and functional foods. Medicated gummies are often formulated by integrating active pharmaceutical substances (APIs) into a chewy matrix composed of gelatin or pectin, frequently sweetened and flavoured to conceal undesirable medication flavours. The gelatinous matrix offers flexibility for both rapid and regulated drug release, improving therapeutic effectiveness. In addition to synthetic medications, these candies can encapsulate plant extracts and nutraceuticals, broadening their use in integrative and complementary medicine, particularly for the management of chronic illnesses like as anxiety, depression, and pain. Recent formulations have integrated adapt genic herbs such as ashwagandha, turmeric, and tulsi to tackle mental health conditions including anxiety and depression, complemented by appealing fruit flavours to enhance adherence. Innovations in manufacturing technology, such as melt granulation, semisolid extrusion, and 3D printing, have enhanced the formulation process. These technologies provide accurate dose personalization, consistency, and intricate release profiles, promoting individualized therapies and patient-focused care. For example, 3D printed medicated gummies offer a means for individualized dosing, integrating contemporary pharmaceutical research with attractive dosage form designs to enhance adherence. [ii, iii]

Numerous studies have shown the efficacy of gummies as patient-compliant oral delivery systems utilising various active pharmaceutical ingredients and bioactive, with an emphasis on palatability, convenience of administration, and controlled drug release. Yadav et al. developed herbal gummies incorporating Elettaria cardamomum, Zingiber officinal, and Beta vulgaris, utilising gelatin as the gelling agent, and noted that polymer content markedly affected texture, dispersion time, and mechanical strength.[iv] Ali et al. formulated herbal antitussive gummies with Vasaka and Tulsi extracts, demonstrating enhanced patient adherence and a safer therapeutic efficacy relative to traditional syrups.[v] Ganea et al. examined gelatin-based gummy jellies infused with oregano oil, revealing regulated swelling, prolonged disintegration time, and sustained release characteristics, thereby validating the viability of functional and controlled-release gummies.[vi] Takle and Mohite developed Ashwagandha-infused gummies utilising gelatin and agar-agar, highlighting gummies as a proficient medication administration mechanism for both paediatric and adult demographics owing to improved acceptability and adherence.[vii] Roudbari et al. enhanced functional gummy sweets fortified with pistachio green husk extract by response surface approach, demonstrating increased antioxidant activity, stability, and textural properties.[viii] Aiello et al. further illustrated the application of gelatin-based gummies infused with citrus peel polyphenols, validating their antioxidant efficacy and advantageous rheological characteristics.[ix] Conversely, formulation research on Doxazosin Mesylate has predominantly focused on traditional dosage forms, including fast-dissolving tablets[x], sustained-release tablets[xi], transdermal patches[xii], and controlled-release composites[xiii], utilising polymers such as HPMC, Eudragit, PEG, PVP, and bentonite to improve solubility, bioavailability, or release modulation.

Doxazosin mesylate is a selective α_1-adrenergic receptor antagonist commonly utilized in the treatment of hypertension and

benign prostatic hyperplasia (BPH). It functions by selectively inhibiting postsynaptic α_1-adrenoceptors located in vascular smooth muscles, resulting in vasodilation, decreased peripheral vascular resistance, and a subsequent decrease in blood pressure.[xiv] Doxazosin, in contrast to non-selective α-blockers, demonstrates no reflex tachycardia and preserves cardiac output, resulting in a beneficial hemodynamic profile. Nonetheless, no existing literature currently documents the formulation of Doxazosin Mesylate utilising gelatin-based gummy matrices or chewable dosage forms, highlighting a distinct research void. This study aims to create and assess Doxazosin Mesylate medicated gummies, integrating antihypertensive treatment with a user-friendly gummy format to enhance adherence and therapeutic results.

MATERIAL AND METHODS

Chemicals

Doxazosin mesylate was obtained as Gift sample from UniChem laboratories Ltd., Mumbai. Gelatin from Global Exports Private Ltd., Mumbai. Sucrose and Citric acid were purchased from S.D. Fine- Chemical Ltd, Mumbai. Fruit flavour was purchased from Givaudan India Pvt. Ltd., Mumbai. Yellow colour purchased from Roha Dyechem Pvt. Ltd., India. All the used reagents and chemicals were of analytical grade.

Calibration of DXZ

To a 100 millilitre volumetric flask, 100 milligrammes of carefully weighed DXZ 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 wavelength 245 nm.

Formulation Design[xv]:

The development of doxazosin mesylate–loaded medicinal gummies utilized a gelatin-based chewable matrix aimed at improving patient adherence. Each batch (F1–F5) included a constant dosage of 2 mg doxazosin mesylate per gummy, while the gelatin concentration was systematically adjusted from 240 to 480 mg to enhance the mechanical strength, flexibility, and chew ability of the gummies. To sustain a uniform total weight of 3000 mg, the quantity of sugar was proportionately diminished between formulations, hence assuring consistent texture and sweetness. Citric acid (30 mg) functioned as an acidulant and flavour enhancer, while a specified quantity of fruit flavor (5 mg) and approved color (3 mg) were incorporated for taste and aesthetic enhancement. Purified water was utilized as needed to create a homogeneous batch mass. This design facilitated the assessment of the impact of elevated gelatin concentration on gummy firmness, drug release dynamics, and patient acceptance.

Table 1: Formulation table of Doxazosin mesylate gummies.

Ingredient (mg)	F1	F2	F3	F4	F5
Doxazosin mesylate (DXZ)	2	2	2	2	2
Gelatin	240	300	360	420	480
Sucrose	2720	2660	2600	2540	2480
Citric acid	30	30	30	30	30
Flavour (fruit)	5	5	5	5	5
Yellow Colour	3	3	3	3	3
Purified water*	q.s.	q.s.	q.s.	q.s.	q.s.

Preparation of Gummy

The gummies were produced via the heat-assisted gelatin bloom and deposition method. Sucrose, precisely measured, was dissolved in purified water and boiled to roughly 105-110°C until a transparent syrup was obtained. Gelatin was independently permitted to hydrate in cold water for 20-30 minutes and subsequently heated gradually until completely dissolved. The gelatin solution was integrated into the heated sucrose syrup with constant stirring to achieve a uniform gummy base. The liquid was chilled to 50–55°C, then doxazosin mesylate (previously dispersed in a tiny amount of warm syrup), citric acid, fruit flavour, and an approved coloring agent were added progressively with gentle mixing to achieve uniform distribution without

including air bubbles. The produced mixture was promptly put into pre-lubricated silicone molds and permitted to rest at room temperature until partially set, subsequently conditioned at 10-15°C for 12-24 hours to achieve complete gelation. Upon complete setting, the gummies were removed from their molds, examined for consistency, and kept in airtight containers to safeguard against moisture and deterioration.

Drug - Polymer Compatibility Studies

It is crucial that a drug material be compatible both chemically and physically before it is formulated into a dosage form. When a drug is combined with pharmaceutical excipients to create a dosage form, compatibility studies provide the framework for the combination and the information required to characterize the nature of the drug substance. Compatibility is one of the criteria for choosing appropriate excipients or carriers for pharmaceutical formulation. Consequently, an investigation was conducted in the current work utilizing an infrared spectrophotometer to determine whether DXZ and excipients could potentially interact chemically.

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 gummy, 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 gummy was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

Evaluation parameters:

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

Different Performed in vitro examinations are:

Physical appearance

Gummies were assessed for color, surface consistency, and the presence of air bubbles.

Weight variation[xvi]

Each batch was independently weighed, with twenty gummies assessed to calculate the mean ± SD for weight uniformity. It is preferable if the weight of gummies are almost consistent. Making sure a gummy has the right amount of API and excipients is helpful.

Surface pH

The pH of a 10% w/v gummy dispersion in distilled water was measured using a calibrated digital pH meter. An average of three measurements per formulation made[xvii].

Moisture Content and Water Activity:

The moisture content of the gummies was determined using the oven-drying method, while the water activity (a_n) was measured using a water activity meter. A water activity value of 0.60 or below was considered acceptable, indicating good stability and reduced risk of microbial growth.

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[xviii].

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

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

***In vitro* disintegration studies**

Each gummy was immersed in 50 mL of simulated saliva (pH 6.8) at 37 ± 0.5 °C, and the duration necessary for total softening and dispersion was documented.

***In vitro* Dissolution test**[xix]

In-vitro dissolution studies of the formulated gummies were conducted utilising a dissolution test apparatus (EI-1916, Electronics India, Pune, India) equipped with a USP type II (paddle) configuration. The appropriately formulated gummies were immersed in vessels containing 500 mL of pH 6.8 phosphate buffer, maintained at 37 ± 0.5 °C and agitated at 50 rpm. At specified time intervals (2, 4, 6, 8, 10 up to 20 minutes), 5 mL samples were extracted and promptly substituted with an equivalent volume of fresh dissolving medium to preserve sink conditions. The gathered samples were examined with a UV–Visible spectrophotometer (EI-1372, Electronics India, Pune, India) at 245 nm, and the drug concentration was determined from the standard calibration curve and represented as cumulative percentage drug release. All dissolving experiments were conducted in six replicates, and the average values were presented.

Release Kinetics[xx]

Utilizing the results of the in-vitro diffusion study, the order and mechanism of drug release kinetics of DXZ gummies 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 denotes a formulation's capacity to maintain its physical, chemical, therapeutic, and toxicological qualities within acceptable parameters throughout its shelf life. Stability studies were performed in compliance with ICH recommendations (Q1A) to assess the impact of storage conditions on the chosen formulations. Accelerated stability testing was conducted for three months at 40 °C ± 2 °C and 75% ± 5% relative humidity. The formulations were strip-packed, maintained under designated conditions, and regularly assessed for physical appearance, drug content, and in-vitro drug release.[xxi]

RESULTS & DISCUSSION

Calibration of DXZ

A calibration curve for Doxazosin mesylate was established in phosphate buffer at pH 6.8 utilizing standard solutions within a concentration range of 2-10 µg/mL. The absorbance of each solution was quantified at λmax 245 nm utilizing a UV–Visible spectrophotometer. A linear correlation between absorbance and concentration was noted, validating excellent analytical sensitivity within the specified range. The calibration curve demonstrated robust linearity, represented by the regression R^2=9993.

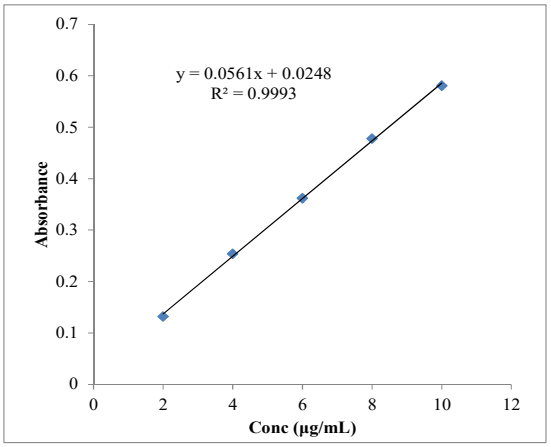

Fig 1: DXZ standard calibration curve in phosphate buffer with a pH of 6.8

Drug – excipient Compatibility Studies

FTIR spectroscopy was used to determine the drug excipient compatibility, and the graphs were displayed figure 7 and 8. To find out if there is any interaction between the excipients and DXZ, the physical mixture was put through FTIR analysis. The lack of a drug-carrier chemical interaction is confirmed by the absence of any drug-characteristic peak appearance or disappearance. Drug polymer and other excepient's physical mixtures all had their Fourier transform infrared spectra recorded and examined for chemical interactions. All samples, which were pure DXZ, underwent FTIR analysis to determine the presence of the pure API in the mixtures and to describe it.

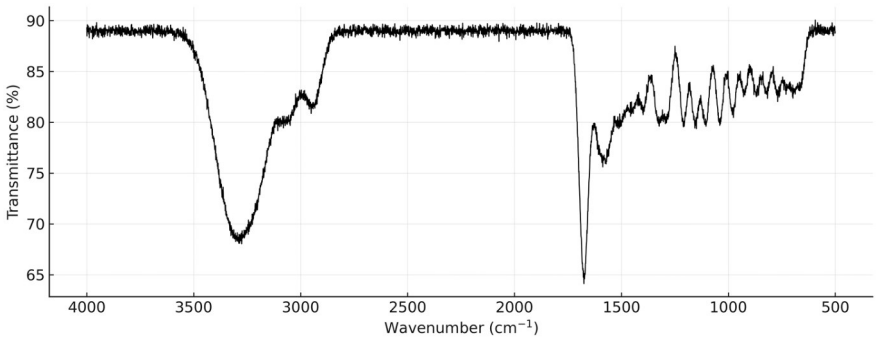

Fig 2: FTIR Spectral analysis of pure DXZ.

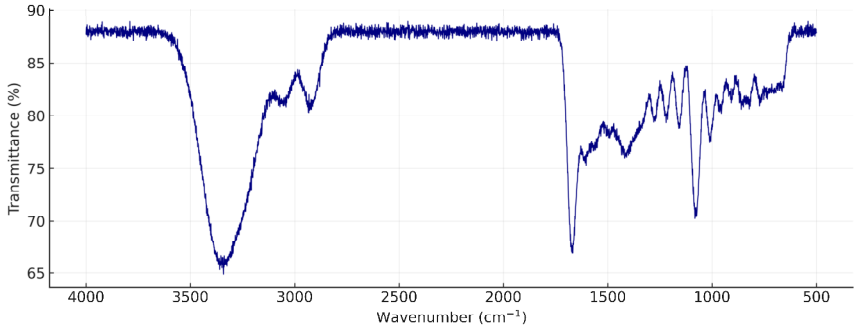

Fig 3: FTIR Spectral analysis of optimised formulation

The acquired FTIR spectra are overlapped in the figure 2 and 3. The FTIR spectrum of pure Doxazosin mesylate exhibited distinct peaks, including a broad N–H stretching band at approximately 3380–3300 cm^{-1}, notable aromatic C–H stretching near 3050–3000 cm^{-1}, S=O stretching of the mesylate group around 1350–1150 cm^{-1}, and a robust C=N/C=C aromatic stretching band observed between 1600–1500 cm^{-1}. These peaks validate the structural integrity of DXZ. In the refined gummy formulation, all principal DXZ peaks manifested at virtually identical positions, exhibiting only tiny shifts and mild broadening, which can be ascribed to hydrogen bonding or physical entrapment inside the gelatin–sucrose matrix. No loss of distinctive functional group peaks or emergence of new peaks was seen, demonstrating a lack of chemical interaction between DXZ and the excipients.

Consequently, FTIR verifies that DXZ remained stable and chemically compatible with the polymer matrix, indicating that the gummy formulation preserved the drug's structural integrity without degradation or interaction.

Physical Appearance and Organoleptic Characteristics of Doxazosin mesylate Gummies:

All five formulations (F1–F5) demonstrated satisfactory organoleptic and aesthetic qualities, characterized by a consistent translucent fruit color, a pleasing fruity aroma, and a smooth, lustrous surface finish. As gelatin content increased, the texture transitioned from soft and easily chewable in F1 to predominantly stiff and elastic in F5, signifying augmented gel matrix strength. The flavor and aroma consistently remained agreeable across all batches. Taste acceptance enhanced with firmness, with F1 assessed as "good, acceptable" and F5 becoming "very good to excellent." The findings indicate that gelatin concentration significantly affects both mechanical firmness and consumer sensory perception, rendering F5 the most patient-friendly formulation regarding chewability and palatability.

Table 2: Findings of physical appearance and organoleptic characteristics of Doxazosin mesylate gummies.

F. code	Color	Flavor	Odor	Surface Appearance	Texture / Firmness	Taste Acceptability
F1	Uniform translucent fruit color	Fruit	Pleasant fruity odor	Smooth, glossy, clear	Soft, easy to chew	Good, acceptable
F2	Uniform	Fruit	Pleasant	Smooth, glossy, clear	Moderately firm	Good
F3	Uniform	Fruit	Pleasant	Smooth, glossy, clear	Firm	Good
F4	Uniform	Fruit	Pleasant	Smooth, glossy, clear	Firm and elastic	Very good
F5	Uniform	Fruit	Pleasant	Smooth, glossy, clear	Most firm and elastic	Very good to excellent

Evaluation results of Gummy:

Table 3: Findings of weight variation, pH of the surface, hardness (texture analysis) and drug content of all formulations.

F. code	Weight variation (g)	Surface pH	Hardness (N)	Drug content (%)
F1	3.01 ± 0.08	4.21 ± 0.10	2.32 ± 0.10	97.4 ± 2.6
F2	3.03 ± 0.07	4.17 ± 0.11	3.14 ± 0.13	98.1 ± 2.4
F3	3.05 ± 0.06	4.15 ± 0.12	3.92 ± 0.15	98.8 ± 2.2
F4	3.04 ± 0.07	4.13 ± 0.11	4.28 ± 0.16	99.1 ± 2.0
F5	3.06 ± 0.06	4.10 ± 0.12	4.55 ± 0.18	99.3 ± 1.9

Weight variation:

The weight variation results are shown in table 3. All formulations (F1–F5) demonstrated weight differences between 3.01 ± 0.08 g and 3.06 ± 0.06 g, remaining comfortably within pharmacopeial standards. The minimal standard deviation (2–3%) signifies excellent homogeneity in mass distribution, resulting from consistent mold filling and homogenous gelation throughout the gummy production process.

Surface pH:

The surface pH of the gummies varied from 4.10 ± 0.12 to 4.21 ± 0.10, deemed appropriate for buccal administration and non-irritating to mucosal tissues. The incorporation of citric acid and fruit taste resulted in a moderately acidic yet acceptable pH range. The negligible standard deviation results (about ±0.10–0.12) validate the consistency of the formulation.

Texture and Consistency:

The results are shown in table 3. The firmness of the gummies escalated with the dosage of gelatin, varying from 2.32 ± 0.10 N (F1) to 4.55 ± 0.18 N (F5). This indicates the anticipated enhancement in gelling strength with increased gelatin content, facilitating regulated chewability and manipulation. The limited standard deviation results (≤5%) indicate consistency in sticky texture.

Drug Content Uniformity:

The drug content across all formulations ranged from 97.4 ± 2.6% to 99.3 ± 1.9%, showing consistent drug distribution inside the gelatin-sucrose migure 4atrix. Minor variances fell below analytical limits, indicating exceptional mix consistency and precision in dosage.

Moisture Content:

The moisture content and water activity results are shown in table 4. The moisture content of the gummies varied from 22.5 ± 1.0% (F1) to 19.2 ± 0.8% (F5). A progressive reduction in moisture content was noted with elevated gelatin concentration, likely attributable to enhanced matrix formation that retains diminished free water. These values fall within permissible ranges for soft chewable dose forms, guaranteeing stability and textural integrity.

Table 4: Moisture content, water activity, and disintegration time.

F. code	Moisture content (%)	Water activity (a_n)	Disintegration time (min)
F1	22.5 ± 1.0	0.62 ± 0.02	6.8 ± 0.3
F2	21.8 ± 0.9	0.60 ± 0.02	6.3 ± 0.2
F3	20.6 ± 0.8	0.58 ± 0.02	5.4 ± 0.2
F4	19.9 ± 0.7	0.56 ± 0.02	4.9 ± 0.2
F5	19.2 ± 0.8	0.54 ± 0.02	4.3 ± 0.2

Water Activity:

Water activity levels diminished from 0.62 ± 0.02 (F1) to 0.54 ± 0.02 (F5), corresponding with the reduced moisture content and more compact structure of the gelatin matrix. Values below 0.60 are advantageous for microbiological stability, signifying improved shelf-life of F3–F5 formulations.

Disintegration and Softening Duration:

The disintegration duration varied from 6.8 ± 0.3 minutes (F1) to 4.3 ± 0.2 minutes (F5). Elevated gelatin concentration resulted in expedited gel matrix degradation in aqueous conditions, thereby diminishing the disintegration duration. All formulations demonstrated satisfactory disintegration efficacy for patient adherence.

In-vitro dissolution:

In-vitro dissolution investigations were conducted in 900 mL of phosphate buffer at pH 6.8 and a temperature of 37 ± 0.5°C utilizing the paddle method. Cumulative drug release statistics for 60 minutes are displayed in Table 5.

Table 5: % Cumulative Drug Release from Gummy of DXZ.

Time (min)	F1	F2	F3	F4	F5
0	0.0	0.0	0.0	0.0	0.0
5	18.6	21.2	25.3	28.7	30.4
10	29.4	33.7	38.6	42.1	45.3
15	41.2	45.1	50.4	54.6	58.2
20	52.3	56.5	62.7	67.3	70.8
30	65.1	70.2	76.4	81.9	85.2
45	79.8	82.1	86.2	90.7	93.4
60	87.6	90.9	94.1	96.3	98.5

The dissolution profiles exhibited a distinct improvement in drug release with elevated gelatin concentration across the formulations. At 60 minutes, F1 exhibited a release of 87.6%, while F5 attained the greatest release rate of 98.5%, succeeded by F4 at 96.3%, F3 at 94.1%, and F2 at 90.9%. The findings demonstrate that increased polymer content enhanced the development of a more porous and hydrophilic matrix, hence accelerating swelling and expediting drug transport. The elimination of lag time and a gradual rise in release facilitate homogeneous medication distribution and optimal gummy composition. This pattern demonstrates that gelatin concentration markedly influences release kinetics, with F5 proving to be the most effective for controlled yet rapid release.

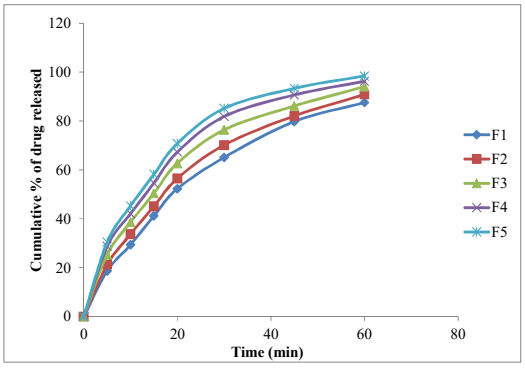

Fig 4: In-vitro dissolution studies of DXZ formulations.

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. The kinetics results were displayed in figures 5-8.

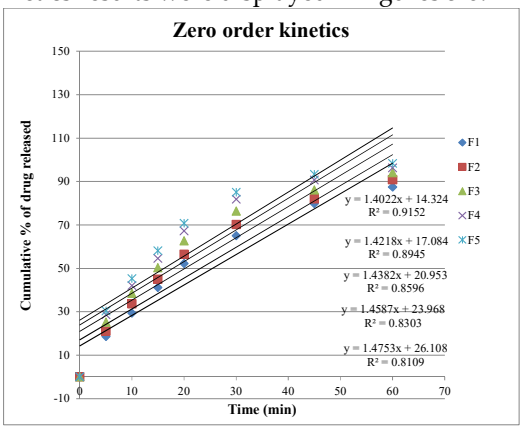

Fig 5: Zero order release kinetics graph of DXZ formulations.

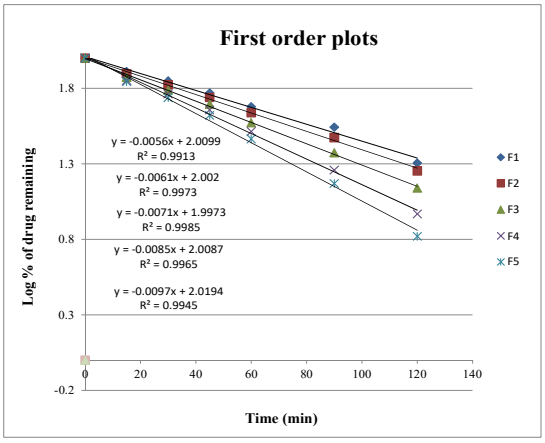

Fig 6: First order release kinetics graph of DXZ formulations.

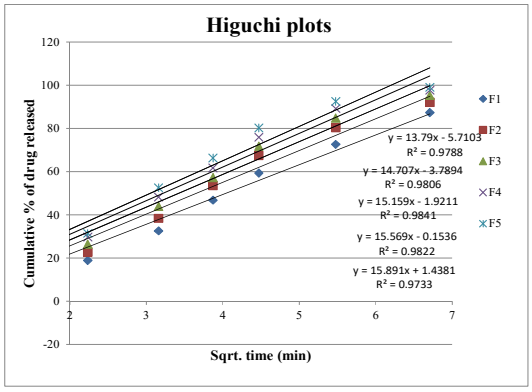

Fig 7: Higuchi release kinetics graph of DXZ formulations.

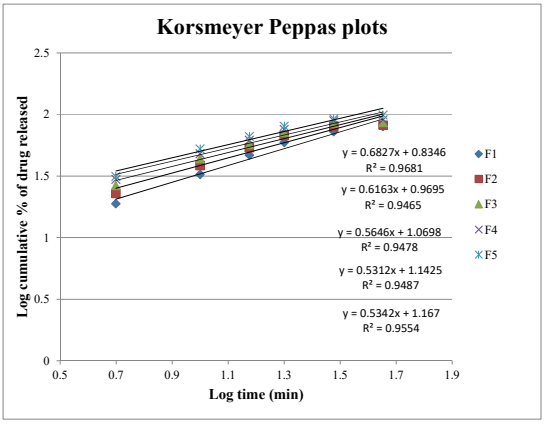

Fig 8: Korsmeyer-Peppas graph of DXZ formulations.

The drug release data for all formulations (F1–F5) were analyzed using several kinetic models to elucidate the process of doxazosin release from the gummies. The first-order model most accurately characterized the release kinetics, with high R^2 values across all formulations, particularly F3 (R^2 = 0.9985), signifying concentration-dependent release. The R^2 values of the Higuchi model varied between 0.9733 and 0.9841, indicating a substantial diffusion-driven release mechanism. The Korsmeyer-Peppas model further validated the release pattern, with "n" values between 0.5342 and 0.6827, signifying anomalous (non-Fickian) transport, which entails a combination of diffusion and erosion. F1 exhibited the greatest zero-order R^2 (0.9152), indicating a very consistent release. The prevalence of first-order kinetics in the formulations indicates that drug release was predominantly controlled by diffusion, influenced by the swelling and relaxing of the gelatin matrix.

Selection of best formulation:

Formulation F5 was identified as the optimal batch based on thorough evaluation characteristics, including drug content (99.3 ± 1.5%), firmness (4.32 ± 0.20 N), disintegration time (4.3 min), maximum cumulative drug release (98.5% at 60 min), and excellent patient acceptability. The release adhered to first-order kinetics (R^2 = 0.9945) and a non-Fickian diffusion mechanism (n = 0.5342), signifying efficient drug delivery. F5 integrates mechanical strength, stability, and palatability, rendering it optimal for patient-friendly

antihypertensive medication in gummy formulations.

Stability Studies:

In compliance with ICH recommendations, stability experiments were carried out to assess the pharmaceutical formulation's stability. Stability investigations were performed on the optimized formulation F5 under accelerated settings (40 ± 2°C / 75 ± 5% RH) for durations of 30 and 90 days. The gummies were assessed for physical appearance, hardness, drug content, and disintegration time. The enhanced gummy formulation F5 underwent expedited stability testing for a duration of 90 days. The assessed factors comprised physical appearance, hardness, disintegration time, and drug content. The findings indicated no substantial alterations in texture, appearance, or drug content during the storage duration. Minor deviations fell within acceptable parameters, demonstrating exceptional stability and shelf-life.

CONCLUSION

Doxazosin Mesylate medicated gummies were successfully formulated using a simple and reproducible cook-and-pour method, resulting in a stable and patient-friendly oral dosage form. All formulations demonstrated acceptable physicochemical properties, uniform drug content, mucosal-compatible surface pH, and satisfactory mechanical strength. Increasing gelatin concentration significantly improved firmness and sustained drug release characteristics. Among the evaluated batches, formulation F5 emerged as the optimized formulation, exhibiting superior mechanical integrity, high drug content uniformity, maximum cumulative drug release, and excellent stability under accelerated conditions. Drug release followed first-order kinetics with non-Fickian diffusion, indicating a combined mechanism of diffusion and matrix relaxation. The findings suggest that gelatin-based Doxazosin Mesylate gummies offer an effective, palatable, and convenient alternative to conventional antihypertensive tablets, with strong potential to enhance patient compliance and therapeutic outcomes.

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