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Formulation and Evaluation of Amlodipine-Loaded Natural Polymer-Based Chewable Gummies for Enhanced Patient Compliance and Controlled Release

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Abstract: This study aimed to formulate and evaluate amlodipine-loaded natural polymer-based chewable gummies with controlled drug-release characteristics. Six formulations (F1–F6) containing Amlodipine equivalent to 5 mg amlodipine were prepared by the heating and congealing method using gelatin and sodium alginate. The gummies were evaluated for appearance, weight variation, surface pH, hardness, moisture content, drug content, swelling, syneresis, disintegration, in vitro drug release, release kinetics, and accelerated stability. Increasing polymer concentration increased hardness, swelling, and disintegration time while reducing syneresis and drug-release rate. Drug content ranged from 98.42 ± 5.12% to 100.24 ± 5.38%. F5 showed acceptable texture, hardness of 7.86 ± 0.58 N, drug content of 100.24 ± 5.38%, swelling index of 108.27 ± 8.46%, and 91.28% drug release at 8 h. Its release followed the Korsmeyer–Peppas model (R^2 = 0.9987; n = 0.7024). F5 remained physically and chemically acceptable during three months of accelerated storage. The gelatin–sodium alginate matrix therefore provided a feasible chewable platform for controlled amlodipine release.

Keywords: Amlodipine; chewable gummies; gelatin; sodium alginate; natural polymers; controlled release.

INTRODUCTION

Oral administration remains the most widely accepted route for long-term pharmacotherapy because it is convenient, economical, non-invasive, and suitable for self-administration. However, conventional tablets and capsules may be difficult to use in paediatric, geriatric, dysphagic, and uncooperative patients. Difficulty in swallowing, unpleasant taste, fear of choking, pill burden, and the need for prolonged treatment can reduce medication acceptance. Medicated gummies offer a soft and chewable alternative that combines active pharmaceutical ingredients with gelling polymers, sweeteners, flavours, plasticisers, and stabilising agents [1].

Pharmaceutical gummies have developed beyond conventional vitamin and nutritional supplements. Three-dimensional printing has been used to prepare gummies with controlled geometry and personalised drug doses [2]. Metformin-loaded gummies have demonstrated the suitability of this platform for paediatric drug administration [3], while semisolid extrusion has enabled the preparation of personalised dual-drug gummies [4]. These studies indicate that gummy matrices can accommodate pharmaceutical ingredients while retaining acceptable shape, texture, and dose distribution.

Palatability is an important quality attribute of chewable dosage forms. Taste-masking studies involving epinastine hydrochloride gummies showed that suitable sweeteners, flavours, and gel-forming materials can reduce unpleasant drug taste and improve organoleptic acceptance [5]. More complex systems, including risperidone-containing pellets incorporated into gummy matrices, have also been developed, demonstrating that gummies can serve as carriers for modified-release drug components [6]. Nevertheless, pharmaceutical gummies require careful control of unit weight, drug distribution, moisture, microbial stability, mechanical strength, and release behaviour.

Controlled-release formulations are designed to regulate drug liberation over a predetermined period and may reduce rapid changes in drug concentration [7]. In hydrophilic matrices, release commonly occurs through penetration of dissolution medium, polymer hydration, swelling, drug diffusion, and gradual matrix erosion. Polymer type, concentration, viscosity, matrix density, and drug solubility determine the overall release pattern [8].

Amlodipine is a dihydropyridine calcium-channel blocker used for the treatment of hypertension and angina. It inhibits calcium influx into vascular smooth-muscle cells, produces peripheral vasodilatation, decreases vascular resistance, and lowers blood pressure. Amlodipine has a gradual onset and prolonged elimination half-life of approximately 30–50 h, supporting once-daily administration [9]. Its established antihypertensive activity and widespread use make it relevant to long-term oral therapy [10]. However, some patients may experience difficulty swallowing conventional tablets or may prefer an alternative chewable formulation.

Gelatin is a natural protein obtained by partial hydrolysis of collagen. It forms thermoreversible gels that liquefy on heating and solidify during cooling. In gummy formulations, gelatin provides elasticity, chewability, mechanical strength, and structural integrity. Increasing gelatin concentration generally produces firmer gummies but may also prolong erosion and drug release.

Sodium alginate is a hydrophilic anionic polysaccharide capable of forming viscous dispersions and swollen polymeric matrices. Natural-polymer hydrogels can control drug release through water uptake, chain relaxation, diffusion, and erosion [11]. Natural polymers are extensively investigated as drug-delivery carriers because they are capable of forming gels and can be combined to modify mechanical and release characteristics [12]. Sodium alginate has also been used with other natural polymers in chewable gummy tablets, confirming its suitability as a carrier and matrix-forming excipient [13].

The mechanical and hydration properties of gummies depend on the ratio of gelling agents and plasticisers. Optimisation studies involving gelatin-based gummies have demonstrated that variation in polymer concentration affects hardness, springiness, cohesiveness, moisture retention, and sensory acceptability [14]. Excessively low polymer concentrations may produce soft and sticky gummies, whereas high polymer concentrations may result in hard or rubbery products.

Several alternative amlodipine formulations have previously been investigated. Fast-dissolving tablets containing co-processed superdisintegrants were developed to reduce disintegration time [15]. Amlodipine oral thin films were formulated to provide flexible and rapidly dispersing dosage forms [16]. Rapidly disintegrating films of Amlodipine were also evaluated for physical properties, drug content, disintegration, and dissolution [17]. A review of amlodipine formulations reported the use of different delivery approaches and emphasised the importance of formulation composition and storage conditions for maintaining drug stability [18].

Although amlodipine has been investigated in rapidly disintegrating tablets and oral films, limited information is available on controlled-release chewable gummies prepared with a gelatin–sodium alginate matrix. Such a formulation requires an appropriate balance between chewability, gel strength, moisture retention, drug-content uniformity, swelling, syneresis, erosion, and release control. Therefore, the present study was undertaken to formulate and evaluate amlodipine-loaded natural polymer-based chewable

gummies and to determine the effect of gelatin and sodium alginate concentrations on their physicochemical properties, in vitro release, release kinetics, and accelerated stability.

MATERIALS AND METHODS

Chemicals

Amlodipine (AML) was obtained as a gift sample from UniChem Laboratories Ltd., Mumbai, India. Gelatin and sodium alginate were procured from Global Exports Private Ltd., Mumbai, India. Glycerin and sodium benzoate were obtained from Merck Life Science, India. Sorbitol was procured from S.D. Fine-Chemical Ltd., Mumbai, India, and orange flavour was obtained from Givaudan India Pvt. Ltd. Purified water was used throughout the formulation process.

Calibration of amlodipine

Standard amlodipine solutions of 5–25 µg/mL were prepared in phosphate buffer at pH 6.8. Absorbance was measured at 238 nm against the corresponding buffer blank, and the calibration curve was obtained by plotting absorbance against concentration.

FTIR compatibility study

FTIR spectra of amlodipine, gelatin, sodium alginate, and the optimised formulation were recorded over 4000–400 cm^{-1}. The spectra were compared for retention, shifting, broadening, appearance, or disappearance of characteristic peaks.

Formulation design

Six formulations containing Amlodipine equivalent to 5 mg amlodipine per gummy were prepared. Gelatin and sodium alginate concentrations were varied, while glycerin, sorbitol, sodium benzoate, flavour, and total gummy weight were maintained as shown in Table 1.

Table 1: Composition of amlodipine chewable gummies

Ingredients (mg/gummy)	F1	F2	F3	F4	F5	F6
AML besylate (equv to 5mg)	6.94	6.94	6.94	6.94	6.94	6.94
Gelatin	250	300	350	250	300	350
Sodium alginate	50	50	50	100	100	100
Glycerin	150	150	150	150	150	150
Sorbitol	600	600	600	600	600	600
Fruit flavour	30	30	30	30	30	30
Sodium benzoate	20	20	20	20	20	20
Purified water	1893.06	1843.06	1793.06	1843.06	1793.06	1743.06
Total weight	3000	3000	3000	3000	3000	3000

Preparation of gummies

Gelatin and sodium alginate were separately hydrated in purified water. The gelatin dispersion was heated at 60–70°C, followed by gradual addition of the sodium alginate dispersion. Sorbitol, glycerin, and sodium benzoate were mixed into the polymeric base. After cooling to 45–50°C, Amlodipine and fruit flavour were incorporated. The homogeneous mass was transferred into silicone moulds, allowed to set, removed, cured, and stored in airtight containers.

Evaluation

The gummies were evaluated for appearance, colour, odour, chewability, stickiness, weight variation, surface pH, hardness, moisture content, and drug-content uniformity.

For swelling studies, preweighed gummies were immersed in 50 mL phosphate buffer at pH 6.8 and 37 ± 0.5°C. Swelling was calculated using:

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

Syneresis was determined from the weight loss caused by liquid separation:

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

Disintegration or erosion time was determined in 50 mL simulated saliva at pH 6.8 and 37 ± 0.5°C.

In vitro dissolution

Drug-release studies were performed using a USP type II paddle apparatus containing 900 mL phosphate buffer at pH 6.8, maintained at 37 ± 0.5°C and 50 rpm. Samples were collected at predetermined intervals up to 8 h and analysed at 238 nm. The study was conducted in six replicates.

Release kinetics

Dissolution data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. The model showing the highest R^2 was considered the best fit. The release exponent, n, was used to interpret the release mechanism [19].

Stability study

The optimised formulation was packed appropriately and stored at 40 ± 2°C and 75 ± 5% relative humidity for three months. Samples were examined for appearance, pH, hardness, moisture content, drug content, syneresis, disintegration time, and drug release [20].

RESULTS AND DISCUSSION

Calibration of amlodipine

The calibration curve showed a linear increase in absorbance over 5-25 µg/mL. The regression equation was y = 0.0366x - 0.0035, with R^2 = 0.9994, confirming suitability of the method for estimating amlodipine in formulation and dissolution samples.

Drug-excipient compatibility: FTIR

Pure amlodipine showed characteristic bands at 3406, 2980, 2924, 1692, 1647, 1610, 1546, 1518, 1298, 1244, 1171, and 1110 cm^{-1}. The principal drug and polymer bands were retained in the optimised formulation with only minor shifts and broadening. The absence of additional major peaks suggested no major chemical interaction between amlodipine, gelatin, and sodium alginate.

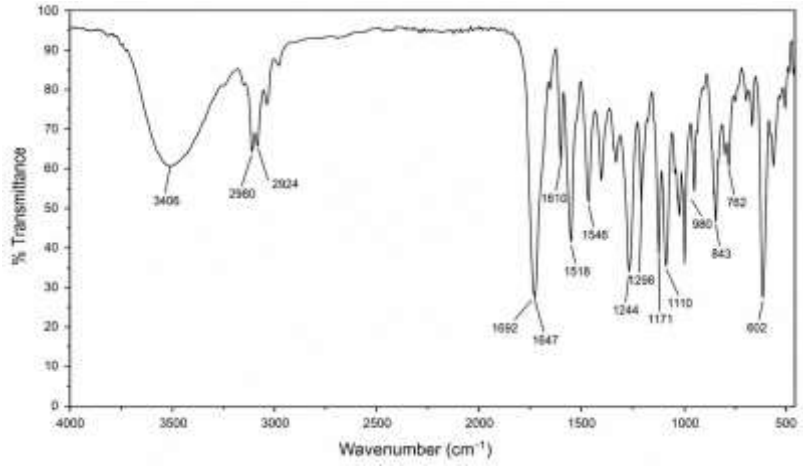

Fig 1: FTIR spectrum of pure amlodipine.

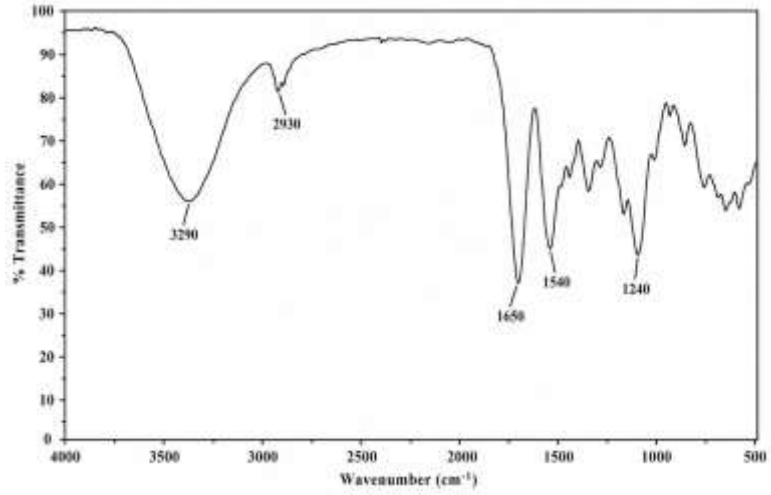

Fig 2: FTIR spectrum of gelatin.

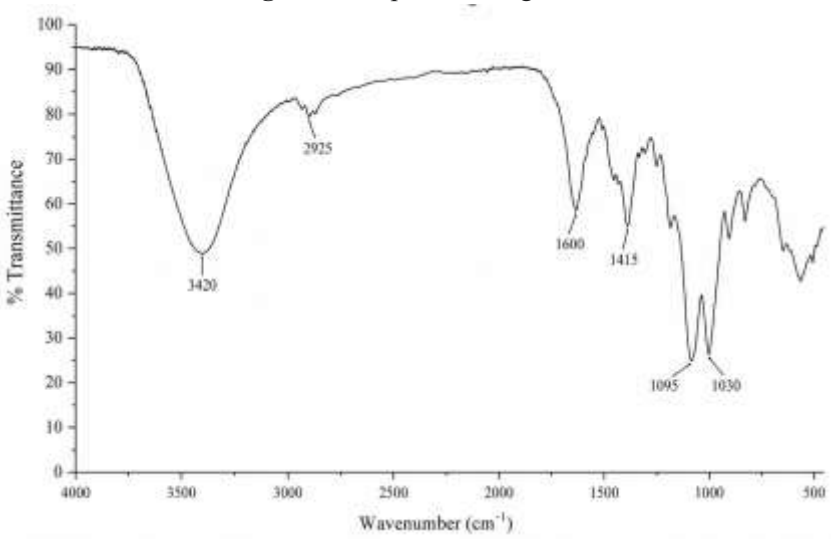

Fig 3: FTIR spectrum of sodium alginate

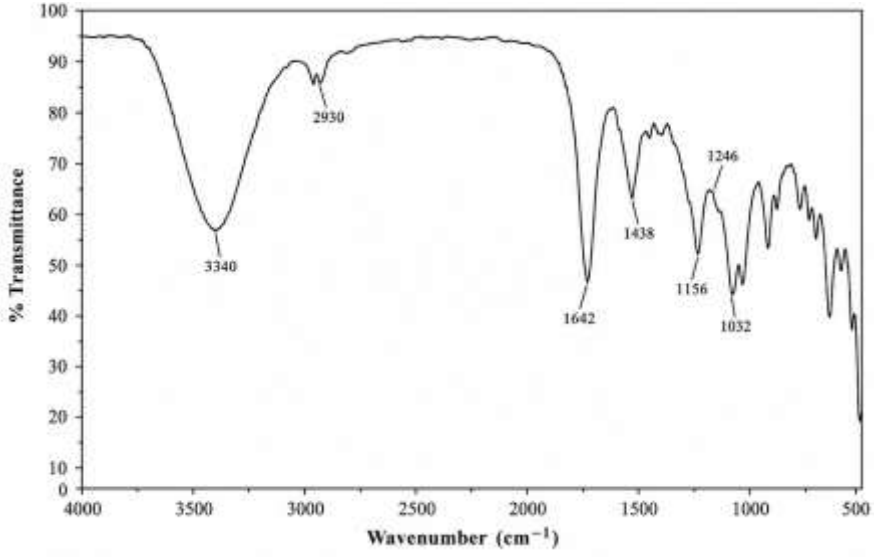

Fig 4: FTIR spectrum of the optimised amlodipine gummy formulation.

Appearance and organoleptic properties

All formulations were smooth, uniform, light-orange to orange gummies with a pleasant fruity odour. Increasing polymer concentration reduced stickiness and improved firmness. F5 showed the most acceptable combination of smooth surface, glossiness, elasticity, chewability, and minimal stickiness. F6 was comparatively harder and less easily chewable.

Table 2: Physical and organoleptic characteristics of amlodipine chewable gummies

Formulation	Colour	Odour	Surface appearance	Chewability	Stickiness	Overall observation
F1	Light orange	Pleasant fruity	Smooth and uniform	Easily chewable	Slightly sticky	Acceptable
F2	Light orange	Pleasant fruity	Smooth and uniform	Good	Minimal	Good
F3	Orange	Pleasant fruity	Smooth and glossy	Good	Minimal	Good
F4	Light orange	Pleasant fruity	Smooth and uniform	Good	Slightly sticky	Good
F5	Orange	Pleasant fruity	Smooth, glossy, and uniform	Very good	Minimal	Best acceptable
F6	Orange	Pleasant fruity	Smooth and firm	Moderate	Very minimal	Acceptable but slightly hard

Physicochemical evaluation

Average gummy weight ranged from 2996.42 ± 41.36 to 3006.18 ± 44.96 mg, indicating consistent mould filling. Surface pH ranged from 5.98 ± 0.37 to 6.22 ± 0.39 and was considered suitable for oral administration.

Hardness increased from 4.82 ± 0.32 N in F1 to 9.14 ± 0.72 N in F6 because higher gelatin and sodium alginate concentrations formed a stronger matrix. Moisture content decreased from 18.46 ± 1.34% to 15.72 ± 1.05% with increasing polymer concentration. Drug content ranged from 98.42 ± 5.12% to 100.24 ± 5.38%, indicating acceptable drug distribution among the formulations.

Table 3: Weight, pH, hardness, moisture content, and drug content of amlodipine gummies

Formulation	Weight, mg	pH	Hardness, N	Moisture content, %	Drug content, %
F1	2996.42 ± 41.36	6.22 ± 0.39	4.82 ± 0.32	18.46 ± 1.34	98.42 ± 5.12
F2	3003.78 ± 38.94	6.18 ± 0.42	5.64 ± 0.41	17.88 ± 1.26	99.16 ± 4.98
F3	3001.24 ± 45.28	6.13 ± 0.36	6.78 ± 0.49	16.92 ± 1.18	99.58 ± 5.46
F4	2998.86 ± 42.74	6.08 ± 0.40	6.12 ± 0.44	17.34 ± 1.23	98.86 ± 4.76
F5	3002.56 ± 36.82	6.04 ± 0.34	7.86 ± 0.58	16.26 ± 1.10	100.24 ± 5.38
F6	3006.18 ± 44.96	5.98 ± 0.37	9.14 ± 0.72	15.72 ± 1.05	99.74 ± 4.92

Swelling, syneresis, and erosion

Swelling increased from 62.48 ± 4.36% in F1 to 124.58 ± 9.74% in F6 due to greater hydration of the higher-polymer matrices. Syneresis decreased from 8.64 ± 0.61% to 3.88 ± 0.31%, demonstrating improved water retention with increasing gel strength.

Disintegration or erosion time increased from 18.36 ± 1.42 min in F1 to 44.18 ± 3.56 min in F6. The higher polymer concentration produced a denser hydrated matrix and delayed erosion. F5 showed adequate swelling, low syneresis, and an intermediate erosion time of 36.25 ± 2.91 min.

Table 4: Swelling index, syneresis, and in vitro disintegration or erosion time

Formulation	Swelling index at 60 min, %	Syneresis, %	Disintegration or erosion time, min
F1	62.48 ± 4.36	8.64 ± 0.61	18.36 ± 1.42
F2	75.36 ± 5.28	7.18 ± 0.54	24.72 ± 1.86
F3	88.92 ± 7.14	6.43 ± 0.49	31.48 ± 2.37
F4	93.64 ± 6.82	5.96 ± 0.43	28.64 ± 2.18
F5	108.27 ± 8.46	4.72 ± 0.35	36.25 ± 2.91
F6	124.58 ± 9.74	3.88 ± 0.31	44.18 ± 3.56

In vitro drug release

Drug release decreased as gelatin and sodium alginate concentrations increased. F1 showed the fastest release, reaching 98.72% at 8 h, whereas F6 released 82.64%. The slower release from the higher-polymer formulations was attributed to formation of a thicker hydrated barrier that restricted drug diffusion. F5 released 12.46% at 0.5 h, 53.82% at 4 h, and 91.28% at 8 h. This formulation provided better release control than F1–F4 while releasing more drug than the comparatively harder F6 formulation.

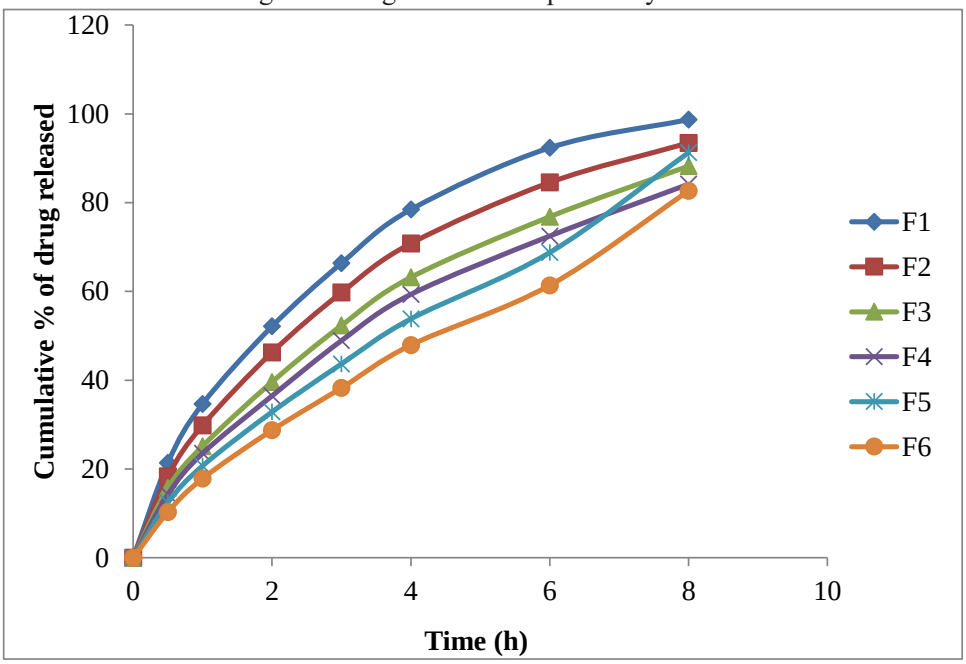

Fig 5: In vitro drug-release profiles of amlodipine gummy formulations F1–F6.

Release kinetics

F1 showed the highest correlation with the Higuchi model, while F2–F4 generally showed better first-order fitting. F5 and F6 showed the highest correlation with the Korsmeyer–Peppas model, with R^2 values of 0.9987 and 0.9984, respectively. The release exponent ranged from 0.5620 to 0.7311, indicating anomalous or non-Fickian transport. Drug release therefore occurred through a combination of diffusion, polymer swelling, relaxation, and erosion.

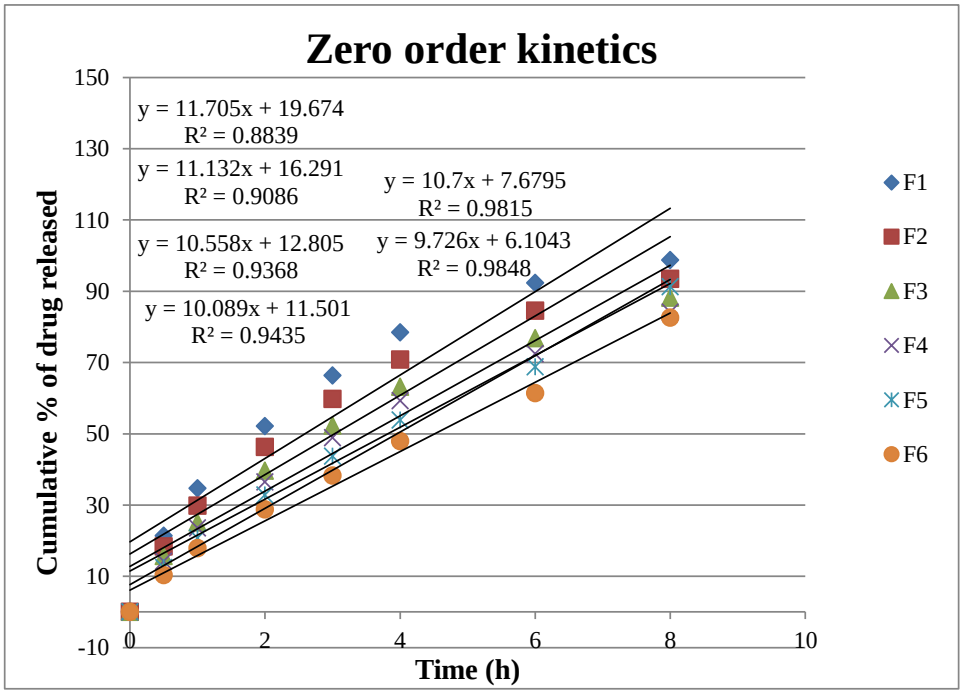

Fig 6: Zero-order release plots of amlodipine gummies.

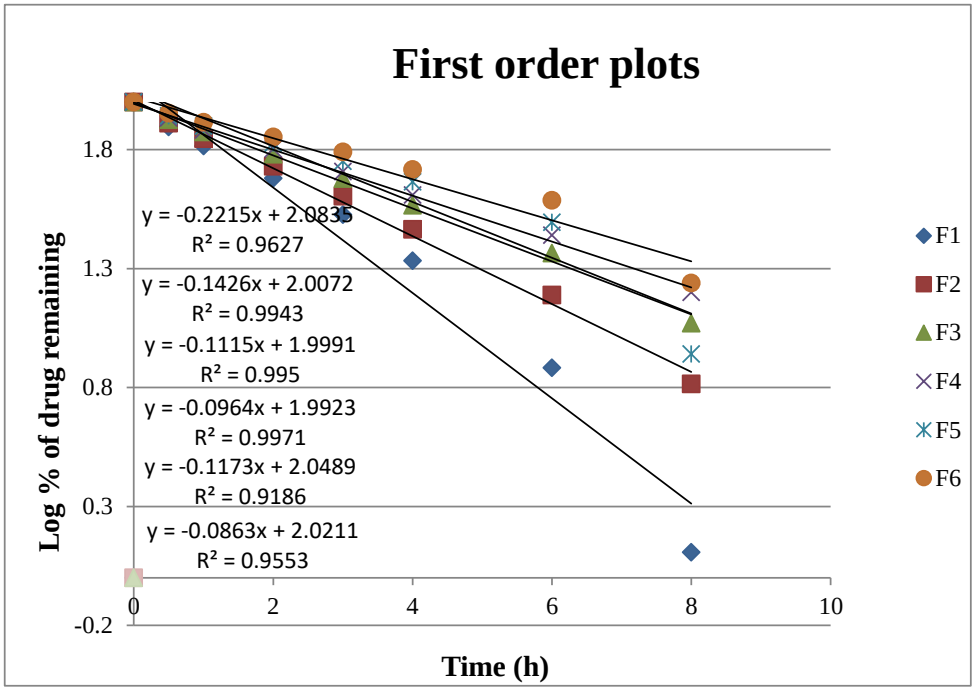

Fig 7: First-order release plots of amlodipine gummies.

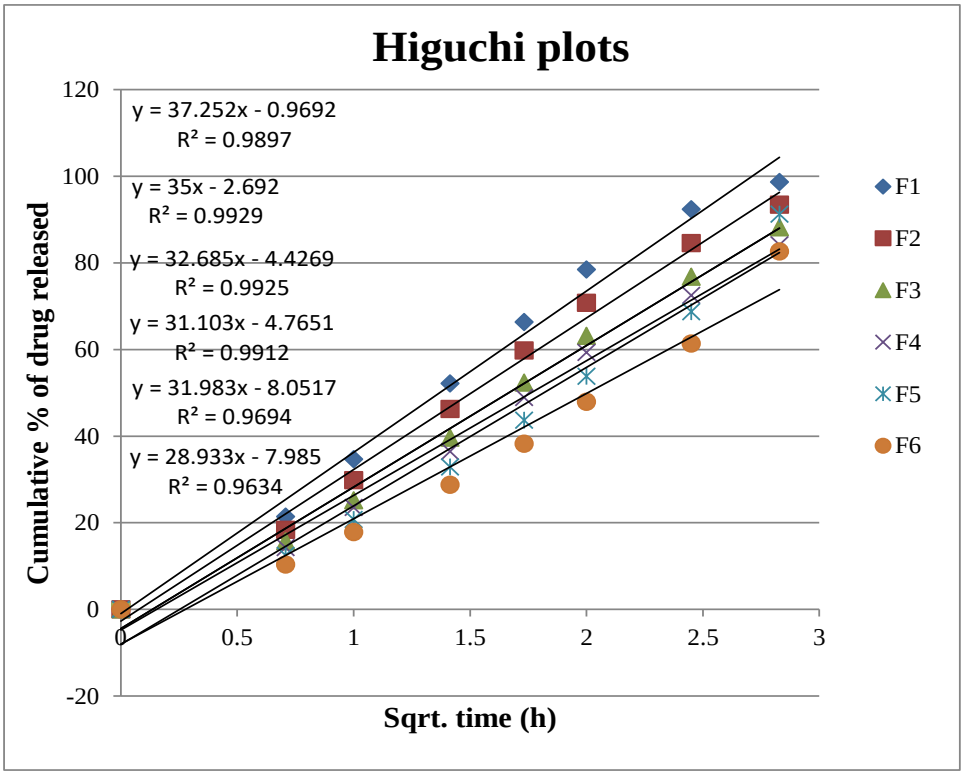

Fig 8: Higuchi release plots of amlodipine gummies.

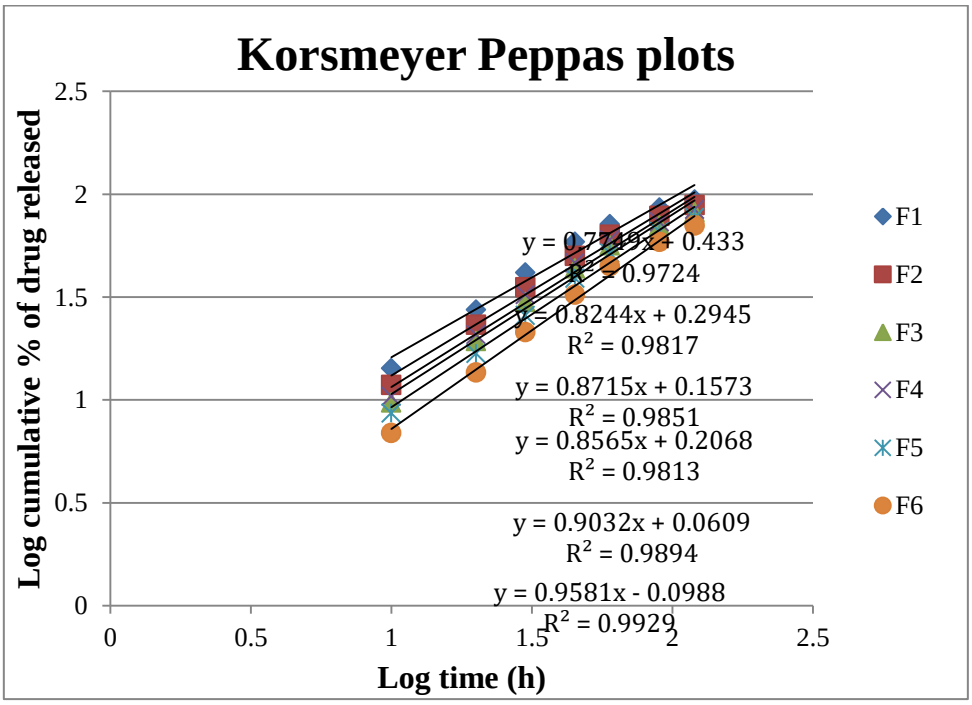

Fig 9: Korsmeyer–Peppas release plots of amlodipine gummies.

Selection of the optimised formulation

F5 was selected as the optimised batch because it showed the best balance between chewability, matrix strength, hydration, syneresis, erosion, and controlled drug release. It had a weight of 3002.56 ± 36.82 mg, pH of 6.04 ± 0.34, hardness of 7.86 ± 0.58 N, moisture content of 16.26 ± 1.10%, and drug content of 100.24 ± 5.38%. F5 showed a swelling index of 108.27 ± 8.46%, syneresis of 4.72 ± 0.35%, disintegration

or erosion time of 36.25 ± 2.91 min, and 91.28% drug release at 8 h. Its release followed the Korsmeyer–Peppas model with $R^2 = 0.9987$ and $n = 0.7024$.

Stability study

F5 remained physically acceptable during three months of accelerated storage. Hardness increased slightly from 7.86 to 8.28 N, while moisture content decreased from 16.26% to 15.18%. Drug content decreased from 100.24% to 98.52%, and drug release at 8 h decreased from 91.28% to 88.96%. These minor changes indicated acceptable stability under the tested conditions.

CONCLUSION

Amlodipine chewable gummies were successfully prepared using gelatin and sodium alginate. Polymer concentration affected hardness, swelling, syneresis, erosion, and drug-release behaviour. F5 was selected as the optimised formulation because it provided acceptable appearance, chewability, drug content, matrix strength, hydration, and controlled release. It released 91.28% amlodipine within 8 h and followed the Korsmeyer–Peppas model, indicating combined diffusion, swelling, and erosion. The formulation also retained acceptable physicochemical characteristics during three months of accelerated storage. These findings confirm the formulation feasibility of a gelatin-sodium alginate gummy matrix for controlled amlodipine delivery. However, patient acceptability, pharmacokinetic behaviour, clinical performance, and scale-up feasibility require further investigation.

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