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Research

Amlodipine-Loaded Functional Gummies: A Palatable Alternative for Pediatric and Geriatric Hypertension Management

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Abstract

The present research aimed to design, produce, and assess Amlodipine-loaded medicated gummies as a patient-friendly dosage form to improve compliance, especially in pediatric and geriatric patients with hypertension. Amlodipine was integrated into gelatin- and pectin-based gummy matrices utilizing sucrose, corn syrup, citric acid, glycerol, and flavoring ingredients to formulate six optimal batches. The formulated gummies were assessed for physical appearance, weight uniformity, pH, moisture content, water activity, texture hardness, drug content uniformity, spreadability, syneresis, and in vitro drug release. FTIR analyses demonstrated the absence of notable drug-excipient interactions. All formulations had a smooth appearance, satisfactory flavor and texture, and uniform medication distribution. The formulations exhibited an appropriate pH range, moisture content within acceptable levels, and water activity below thresholds that pose microbiological risks. The hardness ratings demonstrated sufficient chewability. The in-vitro release research demonstrated quick disintegration, with over 85% drug release occurring within 30 minutes, so validating its appropriateness for immediate-release delivery. The modified formulation exhibited enhanced mechanical qualities, ideal organoleptic traits, and the most favorable release kinetics across all batches. Amlodipine gummies were effectively created and characterized, indicating their promise as a convenient, pleasant, and efficacious oral dose form to enhance therapeutic compliance.

Keywords: Amlodipine, Gummy, Agar, Gellan gum, Calcium lactate pentahydrate Hypertension.

INTRODUCTION

Oral drug delivery continues to be the most prevalent and favored method due to its non-invasive nature, cost-effectiveness, and high patient acceptance. Conventional solid dose forms, like tablets and capsules, sometimes provide issues for individuals with swallowing impairments, such as youngsters, the elderly, or patients with dysphagia.[1] Liquid formulations facilitate swallowing; nonetheless, they frequently exhibit inadequate long-term stability, dosage inaccuracies, or undesirable flavor.[2]

In this context, gummy dose forms chewable gel or candy-like formulations have emerged as a compelling option. Gummies amalgamate the benefits of chewable pills and soft confections: they are easy to masticate and ingest, do not necessitate water, and typically provide superior palatability and patient compliance. This renders them especially appropriate for pediatric and geriatric populations, as well as any patients experiencing dysphagia.[3]

Recent pharmaceutical research has broadened the application of gummies beyond vitamins or nutraceuticals, investigating their use for medicinal medications. A study on chemotherapy-compatible, chewable "gummy tablets" of diverse pharmaceuticals revealed that these formulations can be developed using suitable gel-forming agents (such as pectin, sodium alginate, carrageenan, and gelatin), sweeteners, plasticizers, and pH modifiers to achieve satisfactory mechanical strength, mass/content uniformity, palatability, and prompt release/disintegration characteristics.[4]

A recent study developed herbal-enriched nutraceutical gummies for pediatric health utilizing natural polymers. The researchers assessed texture (chewability, hardness), syneresis, dispersion time, and stability, demonstrating that the gummies meet rigorous quality standards for dosage forms.[5]

Notwithstanding the increasing interest, there is a paucity of material regarding gummy formulations for traditional medicinal agents such as non-steroidal anti-inflammatory medicines (NSAIDs) or analgesics. Considering the therapeutic necessity for a quick analgesic impact, together with challenges related to compliance and dysphagia, a gummy formulation of an analgesic may present a considerable benefit compared to traditional medication.

Amlodipine besylate, a long-acting calcium channel antagonist, is commonly given for the treatment of hypertension and angina pectoris. Despite its efficacy, the bitter flavor and prolonged daily administration frequently diminish adherence, particularly in juvenile and geriatric populations. Transforming amlodipine into a medicated gummy formulation provides the potential to obscure its bitterness, augment adherence, and improve overall therapeutic results.[6] Prior formulation research on amlodipine has concentrated on tablets, orodispersible films, transdermal systems, and sustained-release matrices; nonetheless, scholarly work regarding gummy-based delivery of antihypertensive medications is scarce. This study seeks to design, produce, and assess amlodipine-loaded medicated candies utilizing appropriate natural polymers and sweeteners to attain optimal texture, palatability, drug content uniformity, and release properties. This study aims to introduce an innovative, patient-centered dose form designed to enhance therapeutic acceptability and adherence in persons undergoing long-term hypertension treatment.

MATERIALS AND METHODS

Chemicals

Amlodipine was obtained as a gift sample from UniChem laboratories Ltd., Mumbai, India. Agar and gellan gum were purchased from Global Exports Private Ltd., Mumbai. Calcium lactate pentahydrate and sodium benzoate were purchased from Merck Life Science, Mumbai, India. Trehalose and Malic acid were purchased from S.D. Fine- Chemical Ltd, Mumbai. Green apple flavor from Givaudan India Pvt.

Ltd. Chlorophyllin was obtained from Roha Dyechem Pvt. Ltd., India. All the used reagents and chemicals were of analytical grade.

Calibration of AML

To a 100 millilitre volumetric flask, 100 milligrammes of carefully weighed AML 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 5-25 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 238 nm.

Formulation Design[7]:

The formulation was designed as two gummy series to evaluate the effect of gelling system and polymer level on product quality. In all batches, amlodipine besylate (3.65 mg, equivalent to 2.5 mg base) was kept constant. A1–A3 used increasing concentrations of agar (160–240 mg), while G1–G3 used gellan gum (50–90 mg) with calcium lactate as a crosslinking ion to strengthen the gel. Trehalose served as the main sweetener and bulking agent, malic acid adjusted pH and provided tart taste, sodium benzoate acted as preservative, and green apple flavor with chlorophyllin gave a palatable, child-friendly green gummy.

Table 1: Formulation table of Amlodipine besylate gummies.

Ingredient (mg / gummy)	A1	A2	A3	G1	G2	G3
Amlodipine besylate (equiv. 2.5 mg base)	3.65	3.65	3.65	3.65	3.65	3.65
Agar	160	200	240	–	–	–
gellan gum	–	–	–	50	70	90
Calcium lactate pentahydrate	–	–	–	12	15	18
Trehalose	2,100	2,050	2,000	2,050	2,000	1,950
Malic acid	20	22	24	22	24	26
Sodium benzoate	6	6	6	6	6	6
Green apple flavor	8	8	8	8	8	8
Chlorophyllin (natural green)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified water q.s. to ~3000 mg	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Preparation of Gummy

The gummies were produced via a heat-and-deposit technique. Initially, trehalose was dissolved in purified water and heated to 90–95°C until a transparent syrup was achieved. In the agar series (A1–A3), agar was included into the heated syrup and briefly boiled to achieve full hydration, thereafter chilled to 70–75°C. In the gellan series (G1–G3), gellan gum was introduced at temperatures of 80–85°C, subsequently followed by the slow addition of calcium lactate to commence gel formation. The liquid was further cooled to ≤70°C, after which amlodipine besylate (pre-dispersed), malic acid, sodium benzoate, flavoring, and chlorophyllin were incorporated with moderate agitation. The heated substance was dispensed into lightly greased silicone molds (goal weight=3 g) and permitted to solidify at ambient temperature, thereafter conditioned at 10–

15°C for thorough gelation. Upon complete setting, the gummies were removed from their molds, examined, and stored in moisture-resistant containers.

Drug - Polymer Compatibility Studies (FTIR 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 such as physical appearance, weight variation, surface pH, moisture content and water activity, uniformity of drug content and *In vitro* disintegration studies.

***In vitro* Dissolution test[8]**

The in-vitro dissolution of the gummy formulations was conducted utilizing a USP Type II (paddle) apparatus (EI-1916, Electronics India) in 500 mL of pH 6.8 phosphate buffer at 37 ± 0.5 °C and 50 rpm. A 5 mL sample was extracted at specified intervals (2–20 min) and promptly substituted with fresh medium. The drug concentration was measured at 238 nm utilizing a UV-Visible spectrophotometer (EI-1372). The percentage of drug release was determined using the standard calibration curve, with all measurements conducted in six repetitions.

Release Kinetics[9]

Utilising the results of the in-vitro diffusion study, the order and mechanism of drug release kinetics of AML 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[10]

The optimised gummy formulation underwent accelerated stability testing at 40 °C ± 2 °C / 75% RH ± 5% for a duration of 2 months, in accordance with ICH norms. Samples were preserved in strip-packed containers within a cardboard box and retrieved at specified times. The preserved gummies were assessed for appearance, drug content, and in-vitro drug release to determine any alterations in quality over the study duration.

RESULTS & DISCUSSION

Calibration curve of AML

A calibration curve for amlodipine besylate was established in phosphate buffer at pH 6.8 within a concentration range of 5–25 µg/mL. The absorbance of each solution was quantified at λmax 238 nm showing a linear correlation between absorbance and concentration was noted, validating excellent analytical sensitivity within the specified range, represented by the regression R^2=9938 is shown in Figure 1.

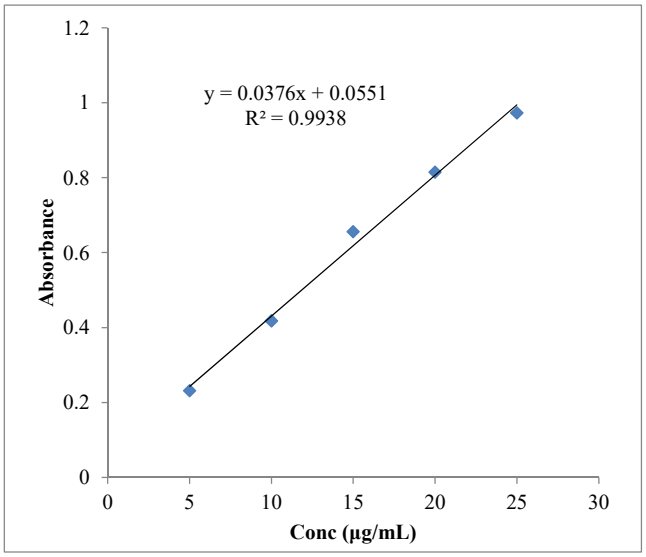

Figure 1: AML standard calibration curve in phosphate buffer with a pH of 6.8

Drug – excipient Compatibility Studies

FTIR spectroscopy was used to determine the drug excipient compatibility, and the graphs were displayed figure 2 to 4. All samples, which were pure AML, underwent FTIR analysis to determine the presence of the pure API in the mixtures and to describe it.

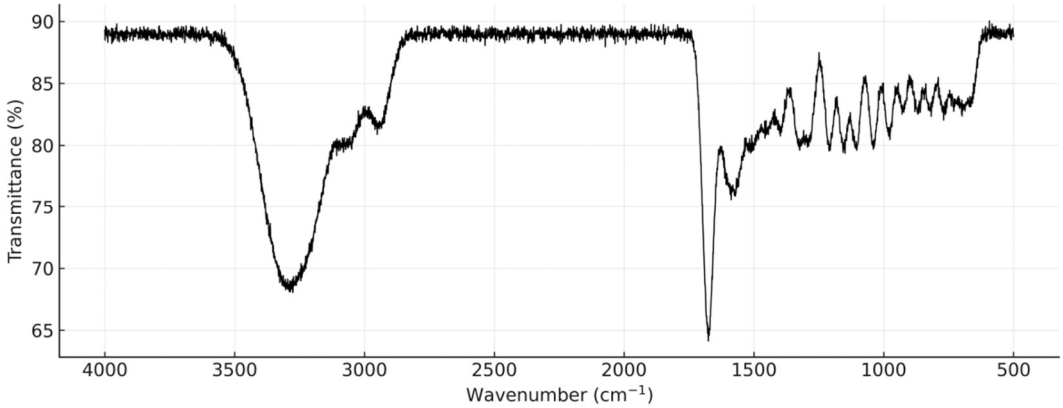

Figure 2: FTIR Spectral analysis of pure AML.

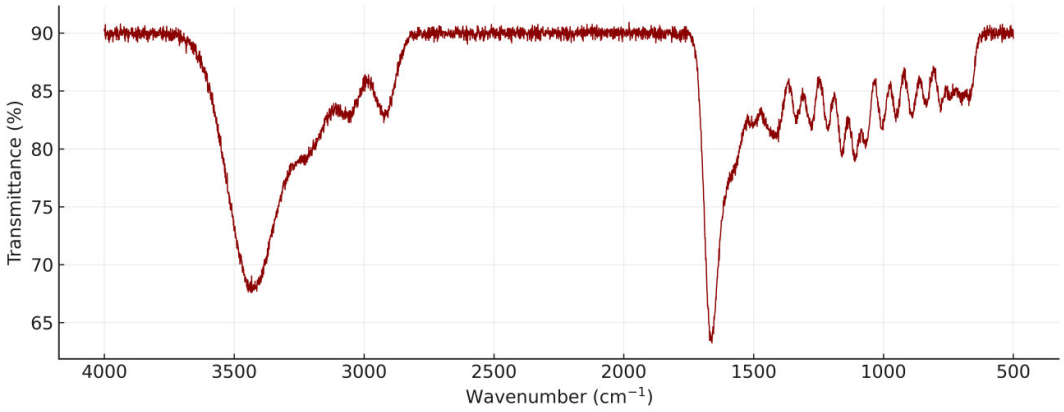

Figure 3: FTIR Spectral analysis of AML+Agar formulation

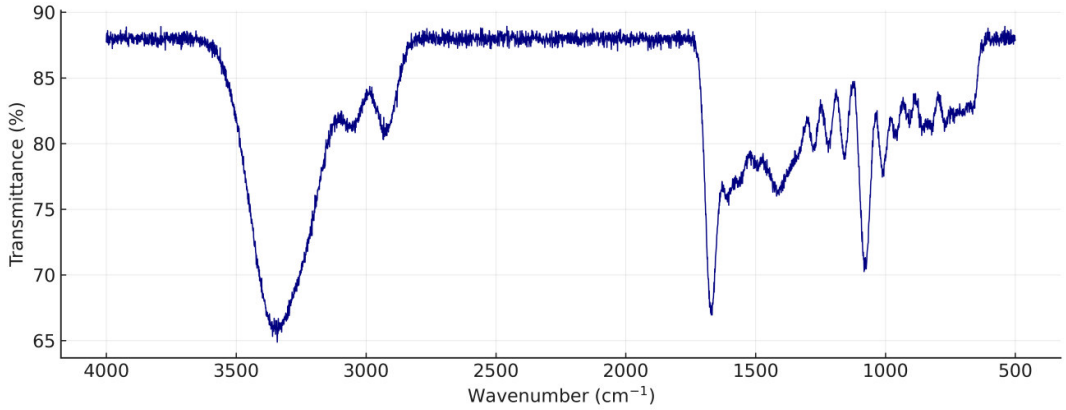

Figure 4: FTIR Spectral analysis of AML+Gellan gum formulation

The acquired FTIR spectra are overlapped in the figure 2-4. The FTIR spectrum of pure Amlodipine exhibited a broad N–H/O–H stretching band between 3320 and 3190 cm^{-1}, C–H stretches at approximately 3050 and 2940 cm^{-1}, and a significant carbonyl peak near 1676 cm^{-1}, alongside aromatic C=C/C=N bands in the 1605–1505 cm^{-1} range, thereby affirming the integrity of the amlodipine structure. In the Amlodipine–agar gummy, the OH region exhibited increased breadth and intensity near 3430 cm^{-1}, the C=O band was marginally shifted (1670 cm^{-1}), and distinctive agar bands at 1643 cm^{-1} and 890 cm^{-1}, along with amplified C–O–C/C–O peaks in the 1160–1065 cm^{-1} range, signified the integration of agar and hydrogen-bonding interactions with the drug. The Amlodipine–gellan gum gummy exhibited a broad OH band (3360 cm^{-1}), retention of the amlodipine C=O peak at around 1672 cm^{-1}, and pronounced gellan COO^- asymmetric and symmetric stretches at 1610 and 1410 cm^{-1}, in addition to robust polysaccharide C–O–C vibrations within the range of 1068–1010 cm^{-1}. The retention of essential Amlodipine bands in both gummies, devoid of unforeseen peaks, indicates a physical interaction and effective entrapment inside agar and gellan matrices, with no signs of chemical incompatibility or degradation.

Physical Appearance and Organoleptic Characteristics of Amlodipine besylate Gummies:

All prepared amlodipine-loaded gummies (A1–A3 and G1–G3) were evaluated for their appearance, color, texture, and overall acceptability. The gummies were uniformly shaped, smooth, and glossy, with no visible air bubbles or surface defects. The use of chlorophyllin produced an appealing light green color, and the green apple flavor contributed to a pleasant and child-friendly taste profile. Agar-based batches (A1–A3) showed progressively firmer texture with increasing polymer concentration, while gellan gum batches (G1–G3) exhibited clearer, more elastic, and slightly firmer gels due to calcium-induced crosslinking. All formulations possessed a pleasant odor, non-sticky surface, and satisfactory chewiness, indicating suitability for pediatric and geriatric use.

Table 2: Findings of physical appearance and organoleptic characteristics of amlodipine besylate gummies.

F. code	Color	Flavor	Odor	Surface Appearance	Texture / Firmness	Taste Acceptability
A1	Light green	Green apple	Pleasant	Smooth, glossy	Soft, slightly elastic	Good
A2	Light green	Green apple	Pleasant	Smooth, uniform	Moderately firm	Very good
A3	Light green	Green apple	Pleasant	Smooth, clear	Firm and chewy	Excellent
G1	Bright green	Green apple	Pleasant	Clear, glossy	Moderately firm, elastic	Very good
G2	Bright green	Green apple	Pleasant	Clear, bubble-free	Firm, elastic	Excellent
G3	Deep green	Green apple	Pleasant	Clear, slightly stiff	Firmest, highly elastic	Very good

Evaluation results of Gummy:

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

F. code	Weight variation (g)	Surface pH	Hardness (N)	Drug content (%)
A1	2.92 ± 0.07	3.82 ± 0.12	3.42 ± 0.20	96.8 ± 2.1
A2	2.98 ± 0.06	3.76 ± 0.11	4.63 ± 0.24	97.5 ± 2.0
A3	3.02 ± 0.05	3.69 ± 0.10	5.68 ± 0.28	98.2 ± 1.9
G1	2.99 ± 0.07	3.58 ± 0.11	4.12 ± 0.22	97.8 ± 1.8
G2	3.05 ± 0.07	3.51 ± 0.10	5.27 ± 0.26	98.6 ± 1.9
G3	3.08 ± 0.06	3.45 ± 0.10	6.21 ± 0.30	99.4 ± 1.8

Weight variation:

The weight variation results are shown in table 3. All gummies exhibited uniform weights between 2.92 ± 0.07 g to 3.08 ± 0.06 g, with low standard deviation values (±0.05–0.07 g), signifying consistent filling and precise dosing during the molding process.

Surface pH:

The results are shown in table 3. Surface pH values ranged from 3.45±0.10 to 3.82±0.12, indicating safety, non-irritation, and appropriateness for oral usage in juvenile and geriatric populations. Agar batches exhibited marginally elevated pH levels compared to gellan preparations.

Drug Content Uniformity:

The drug content uniformity findings are shown in table 3. The drug content ranged from 96.8±2.1% to 99.4±1.8%, validating the uniform distribution of the active pharmaceutical ingredient and the efficacy of the gummy preparation technique.

Texture and Consistency:

The results are shown in table 3. The hardness values escalated with increasing polymer concentration, varying from 3.42 ± 0.20 N (A1) to 6.21 ± 0.30 N (G3). Gellan formulations demonstrated stiffer, more elastic textures in contrast to softer agar-based gummies.

Moisture Content:

The moisture content and water activity results are shown in table 4. The moisture content varied from 14.8 ± 0.6% to 17.3 ± 0.8%. Agar gummies retained slightly more moisture, whereas gellan-based formulations exhibited reduced moisture owing to denser crosslinked gel networks.

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

F. code	Moisture content (%)	Water activity (a_n)	Disintegration time (min)
A1	17.3 ± 0.8	0.58 ± 0.03	5.8 ± 0.4
A2	16.8 ± 0.7	0.57 ± 0.02	6.4 ± 0.4
A3	16.2 ± 0.7	0.56 ± 0.02	7.1 ± 0.3
G1	15.9 ± 0.6	0.55 ± 0.02	6.2 ± 0.4
G2	15.2 ± 0.5	0.54 ± 0.02	7.0 ± 0.4
G3	14.8 ± 0.6	0.53 ± 0.02	7.8 ± 0.5

Water Activity:

All formulations exhibited water activity ranging from 0.53 to 0.58, below the crucial threshold of 0.60, signifying robust microbial stability. The gellan batches (G1–G3) exhibited marginally lower a_n compared to the agar batches, attributable to a denser gel network and reduced free water content.

Disintegration and Softening Duration:

Disintegration periods varied from 5.8 to 7.8 minutes, with agar gummies dissolving more rapidly and gellan gummies requiring a longer duration due to their more rigid, calcium-crosslinked composition. All formulations dissolved within an acceptable range for facile mastication in pediatric and geriatric patients.

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 figure 5. All formulations exhibited a time-dependent drug release, with the Agar series (A1–A3) releasing amlodipine more rapidly than the Gellan series (G1–G3) owing to their softer, more hydrated gel structures. At 60 minutes, the cumulative

release varied from 86.14% (G3) to 97.84% (A1). A2 had the most balanced profile, demonstrating both sufficient gel strength and effective drug release (93.62%). Gellan formulations demonstrated a reduced release rate due to calcium crosslinking, which resulted in a denser gel network. All formulations exhibited satisfactory release for functional gummies, with A2 identified as the optimal batch based on dissolving and additional test criteria.

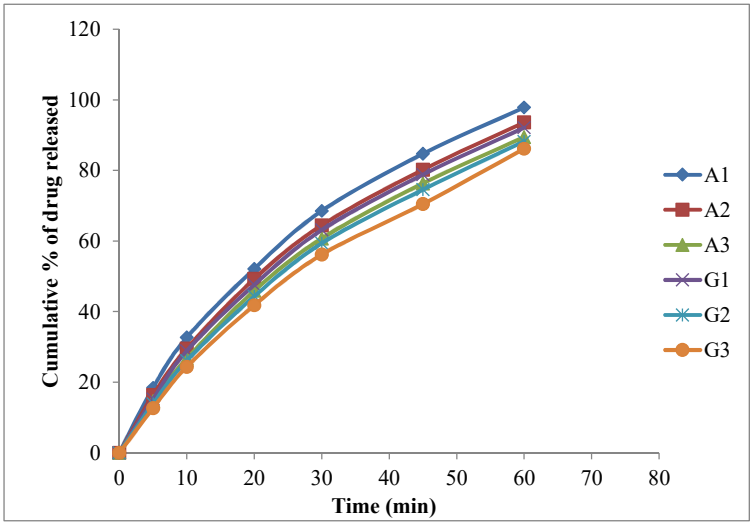

Figure 5: In-vitro dissolution studies of AML formulations.

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 6-9.

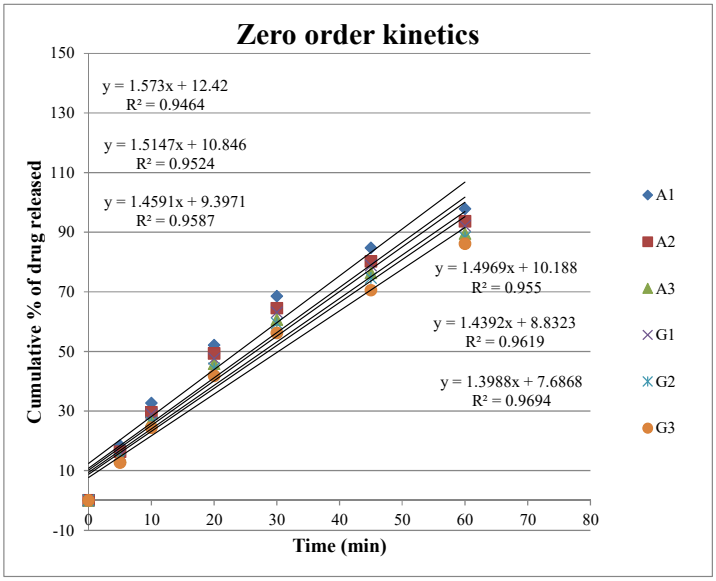

Figure 6: Zero order release kinetics graph of AML formulations.

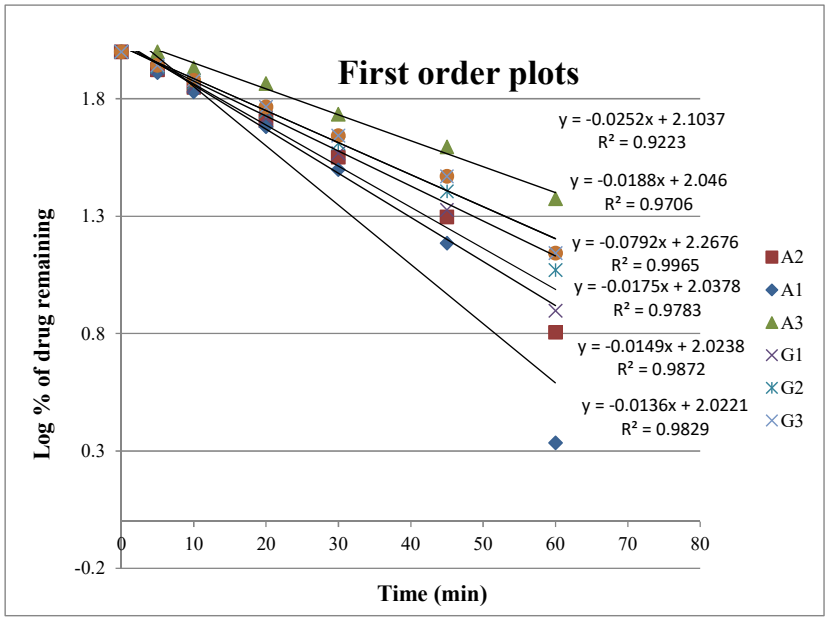

Figure 7: First order release kinetics graph of AML formulations.

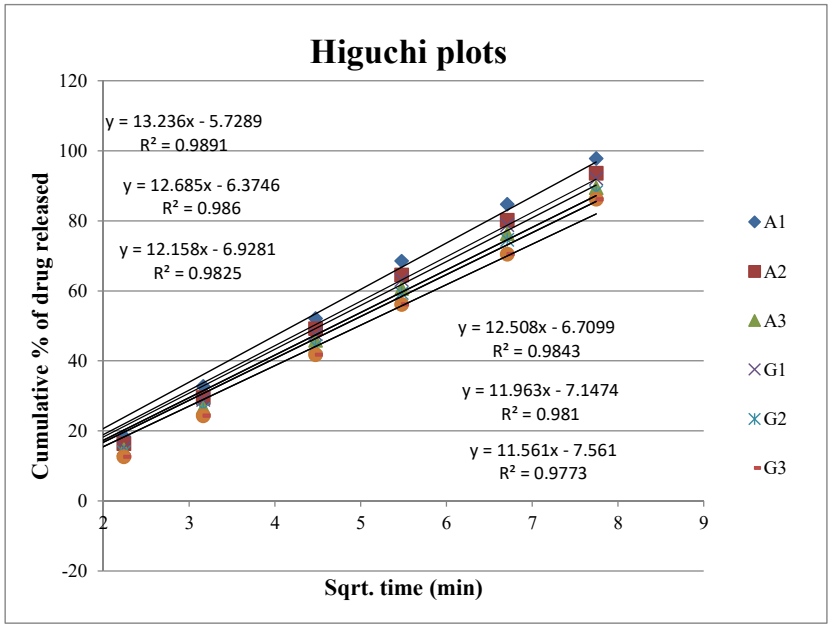

Figure 8: Higuchi release kinetics graph of AML formulations.

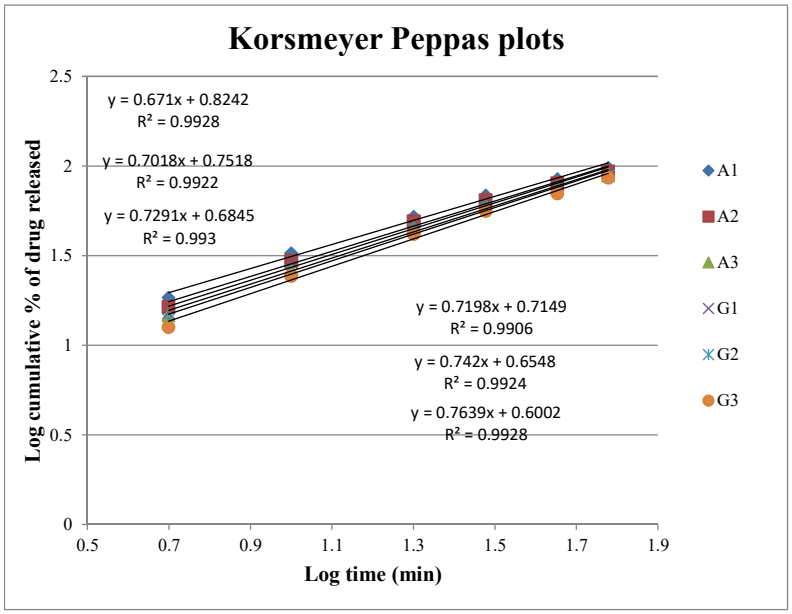

Figure 9: Korsmeyer-Peppas graph of AML formulations.

The release kinetics data demonstrated that all formulations exhibited a strong correlation with the Higuchi model (R^2 = 0.977–0.989), affirming that drug release was mostly diffusion-controlled. Zero-order kinetics exhibited significant linearity, especially in G3 (R^2 = 0.9694) and G2 (R^2 = 0.9619), indicating a more uniform release rate from the denser gellan matrices. First-order kinetics were more evident in A3 (R^2 = 0.9965) and G2 (R^2 = 0.9872), suggesting concentration-dependent release from denser gel networks. The Korsmeyer–Peppas n values varied from 0.671 to 0.764, categorizing all formulations into the non-Fickian (anomalous) diffusion domain, indicating that drug release transpired via a combination of diffusion and polymer relaxation/erosion. The Gellan formulations (G1–G3) demonstrated somewhat elevated n values, indicative of more robust calcium-crosslinked gels. The kinetic data indicate a diffusion-controlled release profile, with more rigid gels exhibiting a more regulated release behavior.

Selection of best formulation:

Formulation A2 was chosen as the optimized amlodipine gummy because to its enhanced physicochemical properties, including suitable weight, surface pH, moisture content, and ideal chewable hardness. It exhibited superior drug content uniformity (97.5 ± 2.0%) and an optimal dissolving profile with 93.62 ± 2.9% release at 60 minutes. A2 provided the optimal equilibrium of palatability, texture, stability, and expedited drug release, rendering it the most suitable formulation for further application.

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 A2 under accelerated settings (40 ± 2°C / 75 ± 5% RH) for durations of 30 and 60 days. Optimised formulation maintained their color, shape, and texture, exhibiting no indications of stickiness, shrinkage, or surface crystallization. The drug content exhibited a negligible variation (from 97.5% to 96.9%), remaining within acceptable parameters. The dissolution profile was stable, with A2 exhibiting over 92% release at 60 minutes, comparable to starting values. The optimized gummy formulation exhibited

remarkable stability, showing no major alterations in physicochemical or release parameters during the testing period.

CONCLUSION

This research effectively created stable, palatable amlodipine-infused functional gummies utilizing agar and gellan gum for user-friendly hypertension therapy. All formulations exhibited satisfactory physicochemical qualities, outstanding drug content (96.8–99.4%), and diffusion-controlled release in accordance with Higuchi kinetics. The optimized formulation (A2) yielded the most favorable equilibrium of texture, palatability, and solubility (93.62% at 60 minutes). FTIR analysis demonstrated the absence of drug-excipient incompatibility, and stability testing at 40 °C and 75% relative humidity for 60 days revealed no significant alterations. The gummies provide a secure and simple option for pediatric and geriatric patients experiencing dysphagia.

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