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Research

Formulation and Evaluation of Nebivolol Oral Jellies Using Natural Polymers for Patient-Centric Antihypertensive Therapy

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Abstract

This study aimed to formulate and evaluate nebivolol oral jellies using natural polymers as a patient-friendly antihypertensive dosage form suited for pediatric, geriatric, and dysphagic populations. Six formulations (F1–F6) were prepared employing sodium alginate (F1–F3) and a xanthan gum–locust bean gum blend (F4–F6) at varying concentrations to assess their influence on gel strength, drug release, and stability. A validated UV–Visible spectrophotometric method (2–10 µg/mL, R^2 = 0.999) ensured accurate drug quantification. FTIR spectra confirmed the absence of drug–polymer interactions. All formulations met quality parameters, displaying uniform weight, acceptable pH (4.02–4.20), appropriate moisture content (21–23%), controlled water activity (0.57–0.62), and consistent drug content (97–99%). Texture analysis showed increased firmness with polymer concentration, while in-vitro dissolution demonstrated >80% drug release within 60 minutes for all batches. Among them, F4 exhibited the most desirable balance of firmness, spreadability, stability, and rapid drug release (91.28% at 60 minutes). Accelerated stability testing (40°C/75% RH, 60 days) revealed no significant physicochemical changes. The findings support F4 as a robust, palatable, and stable natural-polymer-based nebivolol jelly with strong potential for patient-centric antihypertensive therapy.

Keywords: Nebivolol, Xanthan gum, Locust bean gum, Oral Jellies, Natural Polymers, Antihypertensive.

INTRODUCTION

Oral administration is the predominant method for medication delivery owing to its ease, non-invasiveness, and high patient compliance. Conventional solid oral dosage forms (tablets/capsules) may pose adherence challenges in specific populations, including pediatrics, geriatrics, and individuals with dysphagia. Additionally, these forms may experience delayed onset or variable bioavailability due to swallowing difficulties and first-pass metabolism effects. Patient-centric dosage forms that enhance palatability, facilitate administration, and ensure timely medication availability represent a significant domain of pharmaceutical innovation.[1] Nebivolol is a third-generation, cardioselective β_1-blocker that possesses a nitric oxide-mediated vasodilatory effect, an advantageous hemodynamic and metabolic profile, and proven effectiveness in the therapy of hypertension and heart failure. The pharmacological profile endorses its application in scenarios requiring enhanced vascular function and tolerability; nonetheless, akin to other oral antihypertensives, therapeutic efficacy is contingent upon adherence and prompt beginning of action. Administering nebivolol in a more patient-friendly format may increase acceptability and potentially boost therapeutic results in individuals that have difficulty with traditional dosing forms.[2]

Oral medicated jellies (OMJs) are soft, palatable, non-flowing semisolid dosage forms formulated with natural or semi-synthetic gelling agents (such as pectin, alginate, agar, or gelatin). They merge the benefits of liquids and solids, facilitating easy swallowing without water, providing a pleasant mouthfeel, masking taste, and allowing for either rapid or modulated release based on the gel matrix. Recent evaluations and experimental investigations have demonstrated that OMJs are promising for medications necessitating rapid onset (e.g., analgesics) or enhanced adherence (pediatrics/geriatrics), and they have been effectively created for various APIs utilizing natural polymers to modulate texture and release.[3] Natural polymers including sodium alginate, pectin, and agar serve as appealing gelling agents due to their biocompatibility, abundant availability, and the ease of regulating rheology and drug release via polymer concentration, cross-linking, and plasticizer content. Multiple studies on oral jellies and analogous chewable/gel dosage forms indicate that modifying the type and concentration of polymers facilitates precise regulation of texture (hardness, chewability), water activity (microbial safety), and dissolution kinetics crucial characteristics for an antihypertensive jelly that requires both patient acceptability and consistent systemic absorption.[4] Despite the investigation of oral jellies for various cardiovascular agents and the proof-of-concept report of an edible gel containing nebivolol, the systematic development of nebivolol oral jellies utilizing natural polymer systems and contemporary characterization techniques is still constrained. This study aims to formulate and assess nebivolol oral jellies utilizing natural polymers, optimize the formulation for taste and mechanical stability, and characterize drug release and stability, with the objective of creating a patient-centered antihypertensive dosage form for individuals with dysphagia or low adherence.[5]

MATERIALS AND METHODS

Chemicals

Nebivolol HCl was obtained as a gift sample from UniChem laboratories Ltd., Mumbai. Sodium algenate and xanthan gum were purchased from Global Exports Private Ltd., Mumbai, India. Locust bean gum and Sodium benzoate from Merck Life Science, Mumbai. Sucrose and Citric acid were purchased from S.D. Fine- Chemical Ltd, Mumbai. Strawberry flavor from Givaudan India Pvt. Ltd.

Ponceau 4R (red color) was purchased from Roha Dyechem Pvt. Ltd., India. All the used reagents and chemicals were of analytical grade.

Calibration of NBV

To a 100 millilitre volumetric flask, 100 milligrammes of carefully weighed NBV 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 wavelenth 281 nm.

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

Formulation Design[6]:

Nebivolol oral jellies were formulated in six batches (F1–F6) utilizing natural hydrophilic polymers to create palatable, easy-to-swallow dosage forms for patient-centered hypertension treatment. Batches F1–F3 incorporated sodium alginate at escalating concentrations (150, 200, 250 mg/5 mL) to examine the influence of alginate gel strength on consistency and drug release. Batches F4–F6 employed a xanthan gum–locust bean gum (1:1) mixture at increasing concentrations (60/60, 80/80, 100/100 mg/5 mL) to produce elastic, mucoadhesive jellies. In all formulations, nebivolol HCl (5 mg/5 mL) remained constant, sucrose functioned as a sweetener and base, citric acid modulated pH and flavor, sodium benzoate served as a preservative, and strawberry flavor with Ponceau 4R contributed to sensory qualities and visual appeal.

Table 1: Formulation table of Nebivolol jellies.

Ingredient (mg / 5 mL jelly)	F1	F2	F3	F4	F5	F6
Nebivolol HCl	5	5	5	5	5	5
Sodium alginate	150	200	250	–	–	–
Xanthan gum	–	–	–	60	80	100
Locust bean gum	–	–	–	60	80	100
Sucrose	2500	2500	2500	2500	2500	2500
Citric acid	18	20	22	18	20	22
Sodium benzoate	5	5	5	5	5	5
Strawberry flavor	5	5	5	5	5	5

Ponceau 4R (red color)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified water (q.s. to 5000 mg)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Preparation of Jellies

The specified amounts of sugar and citric acid were dissolved in a quantified volume of filtered water and heated to approximately 70–75°C. Sodium alginate was gradually introduced into the heated syrup for F1–F3 while maintaining continuous agitation until a homogeneous dispersion was achieved. For F4–F6, a previously combined xanthan and locust bean gum mixture was similarly disseminated. The mass was cooled to approximately 50–55°C, after which nebivolol HCl (previously dissolved in a minimal volume of warm water), sodium benzoate, strawberry flavor, and Ponceau 4R were incorporated and mixed gently to prevent air entrapment. The heated gelatinous substance was dispensed into calibrated molds or cups (5 mL each unit) and permitted to cool at ambient temperature until solidified, subsequently kept in securely sealed receptacles for further assessment.

Evaluation parameters:

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

Different Performed in vitro examinations are: Physical appearance, Weight variation, Surface pH, Moisture Content, Water Activity, Texture, Spreadability, Investigation of Syneresis, In vitro disintegration studies and Uniformity of drug content.

***In vitro* Dissolution test:**[7]

The in-vitro dissolving characteristics of the prepared nebivolol jellies were assessed utilizing a USP Type II (paddle) apparatus (EI-1916, Electronics India, Pune). Each jelly specimen was immersed in 500 mL of phosphate buffer at pH 6.8, kept at 37 ± 0.5°C, and agitated at 50 rpm. At specified intervals (2–20 minutes), 5 mL aliquots were extracted and promptly substituted with new medium. Samples were analyzed at 281 nm with a UV–Visible spectrophotometer (EI-1372), and drug release was measured utilizing the calibration curve. All tests were conducted in six repetitions, and the mean % drug release data were documented.

Release Kinetics:[8]

Utilising the results of the in-vitro diffusion study, the order and mechanism of drug release kinetics of NBV jellies 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

The optimized Nebivolol jelly formulation underwent accelerated stability testing in accordance with ICH Q1A(R2) criteria. Jellies were enclosed in sealed aluminum-laminated pouches and preserved in a stability chamber regulated at 40 °C ± 2 °C / 75% RH ± 5% for a duration of 60 days. Samples were extracted at specified intervals (0, 30, and 60 days) and analyzed for appearance, pH, moisture content, water activity, stiffness, drug content, and in-vitro dissolution to evaluate any physical or chemical alterations. All analyses were conducted in triplicate, and average values were documented.[9]

RESULTS & DISCUSSION

Calibration of NBV

A calibration curve for Nebivolol 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 281 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=9999.

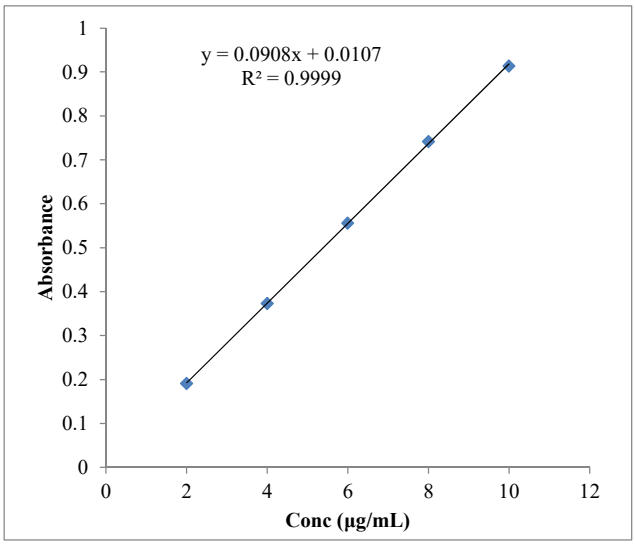

Figure 1: NBV standard calibration curve in phosphate buffer with a pH of 6.8

Drug – excipient Compatibility Studies

FTIR spectroscopy was used to determine the drug excipient compatibility, and the graphs were displayed figure 2-4. To find out if there is any interaction between the excipients and NBV, 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 NBV, underwent FTIR analysis to determine the presence of the pure API in the mixtures and to describe it.

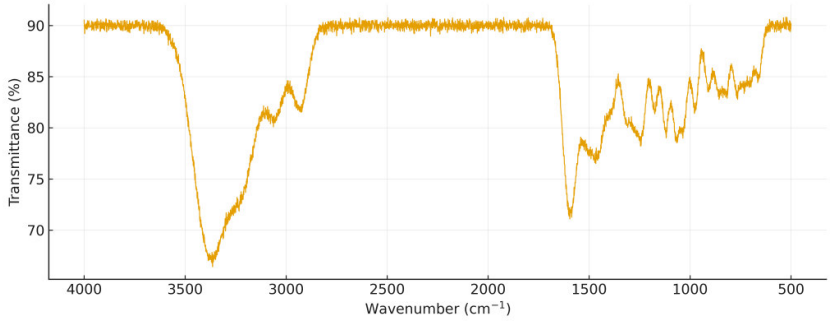

Figure 2: FTIR Spectral analysis of pure NBV.

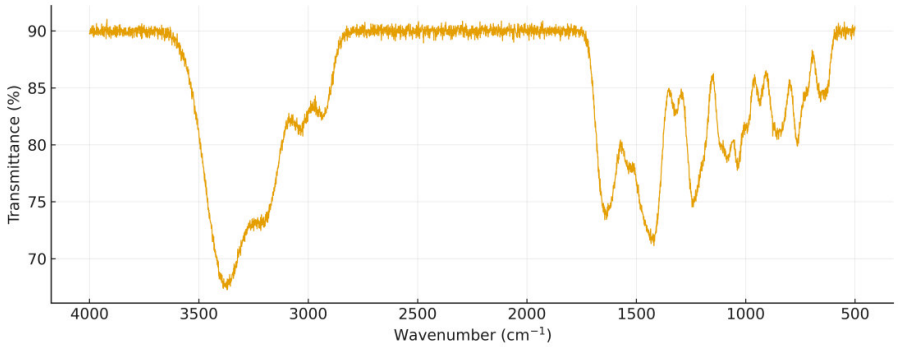

Figure 3: FTIR Spectral analysis of NBV+ Sodium alginate formulation

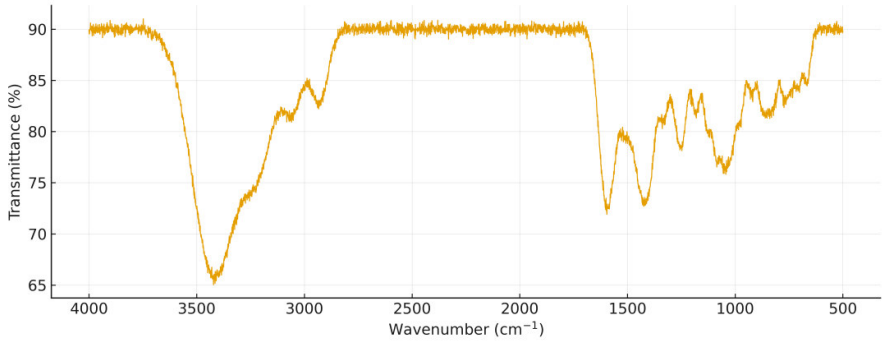

Figure 4: FTIR Spectral analysis of NBV + Xanthan gum + Locust bean gum formulation.

The acquired FTIR spectra are overlapped in the figure 2-4. The FTIR spectrum of pure Nebivolol exhibited a broad O–H/N–H band (about 3380–3210 cm^{-1}), C–H stretches at 3050 and 2930 cm^{-1}, and prominent aromatic C=C peaks within the range of 1610–1500 cm^{-1}, in addition to C–N bands in the 1300–1000 cm^{-1} region, thereby affirming its structural integrity. The Nebivolol–sodium alginate jelly exhibited broadening and a slight shift of the OH band to approximately 3400 cm^{-1}, alongside characteristic alginate COO^- peaks at around 1605 and 1415 cm^{-1}, as well as intensified C–O–C bands in the range of 1080–1035 cm^{-1}, signifying hydrogen bonding and physical interactions between the drug and polymer, while retaining the essential drug peaks. The Nebivolol–xanthan–locust bean gum jelly exhibited further OH broadening (3420 cm^{-1}), polysaccharide COO^- signals (1612 and 1410 cm^{-1}), and pronounced glycosidic C–O–C bands (1088–1015 cm^{-1}), while retaining the aromatic bands of Nebivolol. The spectral alterations indicate effective integration and stable physical entrapment of Nebivolol in all polymeric jellies, with no signs of chemical incompatibility or drug degradation.

Physical Appearance and Organoleptic Characteristics of Nebivolol Jellies:

All six recipes demonstrated consistent coloration, a smooth texture, and an aesthetically pleasing jelly structure. Formulations using sodium alginate (F1–F3) exhibited increased opacity and density, whereas xanthan-based jellies (F4–F6) demonstrated superior clarity and elasticity owing to synergistic gel formation. Elevating polymer concentration in both groups produced firmer and more stable gels, with F3 and F6 exhibiting the greatest firmness and structural integrity. No batch exhibited air bubbles, shrinkage,

syneresis, or stickiness, so affirming excellent physical stability and appropriate gel formation. All formulations had a pleasing strawberry flavor, with F3 and F5 attaining the highest levels of acceptance, rendering them appropriate for juvenile and geriatric patients.

Table 2: Findings of physical appearance and organoleptic characteristics of Nebivolol jellies.

Formulation	Color	Transparency	Surface Appearance	Texture	Flavor Acceptability
F1	Light red	Slightly opaque	Smooth, no bubbles	Soft, flexible	Good
F2	Light red	Slightly opaque	Smooth, uniform	Moderately firm	Very good
F3	Light red	Opaque	Smooth, dense gel	Firm	Excellent
F4	Bright red	Semi-clear	Smooth, glossy	Soft, elastic	Very good
F5	Bright red	Semi-clear	Glossy, uniform	Moderately firm	Excellent
F6	Deep red	Clear	Glossy, well-set	Firmest, elastic	Very good

Evaluation results of Jellies:

All six nebivolol jelly formulations (F1–F6) were assessed for weight uniformity, pH, moisture content, water activity, hardness, and drug concentration. The results exhibited satisfactory performance across all batches.

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

F code	Weight (g)	Surface pH	Moisture Content (%)	Water Activity (a_n)	Hardness (N)	Drug Content (%)
F1	4.87 ± 0.09	4.12 ± 0.10	22.4 ± 0.9	0.62 ± 0.02	2.38 ± 0.10	97.6 ± 2.0
F2	4.92 ± 0.08	4.08 ± 0.12	21.8 ± 0.8	0.60 ± 0.02	3.12 ± 0.14	98.1 ± 1.8
F3	4.95 ± 0.07	4.02 ± 0.11	21.1 ± 0.9	0.58 ± 0.03	3.98 ± 0.18	99.0 ± 1.7
F4	4.89 ± 0.08	4.20 ± 0.11	23.2 ± 1.0	0.61 ± 0.02	2.89 ± 0.12	97.9 ± 1.9
F5	4.94 ± 0.07	4.14 ± 0.10	22.6 ± 0.9	0.59 ± 0.02	3.65 ± 0.16	98.8 ± 1.6
F6	4.98 ± 0.06	4.10 ± 0.12	21.9 ± 0.8	0.57 ± 0.02	4.32 ± 0.20	99.3 ± 1.5

Weight variation:

The weight variation results are shown in table 3. The jelly weight varied from 4.87 ± 0.09 g (F1) to 4.98 ± 0.06 g (F6), with standard deviation values within acceptable parameters, indicating homogeneous filling and consistent jelly dimensions.

Surface pH:

The results are shown in table 3. Surface pH levels ranged from 4.02 ± 0.11 (F3) to 4.20 ± 0.11 (F4), remaining within the acceptable, non-irritant range for oral administration. Minimal variance among batches signifies uniform acidification by citric acid.

Moisture Content:

Moisture content ranged from 21.1 ± 0.9% (F3) to 23.2 ± 1.0% (F4). All values were suitable for jelly matrices, with marginally increased moisture in the xanthan–LBG mix batches attributable to superior water-binding capacity.

Water Activity (a_n):

Water activity values ranged from 0.57 ± 0.02 (F6) to 0.62 ± 0.02 (F1). All results approached the acceptable threshold (≤0.60), hence assuring adequate microbiological stability. A marginally elevated a_n in alginate batches is anticipated owing to their hydrophilic characteristics.

Hardness (N):

Hardness escalated with polymer content, exhibiting values from 2.38 ± 0.10 N (F1) to 4.32 ± 0.20 N (F6). Xanthan-based gels (F4–F6) showed higher firmness due to stronger gel networks, while alginate batches (F1–F3) formed softer gels.

Drug Content Uniformity:

All formulations exhibited superior drug uniformity, with values ranging from 97.6 ± 2.0% (F1) to 99.3 ± 1.5% (F6), hence affirming consistent drug dispersion and stability throughout the heating process.

Table 4: Spreadability and syneresis data.

Formulation	Spreadability (cm)	Syneresis (%) at 24 h	Syneresis (%) at 48 h
F1	5.8 ± 0.3	0.0	0.0
F2	5.4 ± 0.2	0.0	0.0
F3	5.1 ± 0.2	0.0	0.0
F4	6.2 ± 0.3	0.0	0.0
F5	5.9 ± 0.3	0.0	0.0
F6	5.5 ± 0.2	0.0	0.0

Spreadability:

The spreadability values of the nebivolol jellies varied from 5.1 ± 0.2 cm (F3) to 6.2 ± 0.3 cm (F4). Xanthan-based formulations (F4–F6) demonstrated superior spreadability compared to alginate batches, attributable to their more elastic gel matrix that facilitates deformation under applied weight. The minimal standard deviation values (0.2–0.3 cm) signify uniform and reliable gel behavior among replicates.

Syneresis:

All formulations exhibited 0% syneresis at both 24 and 48 hours, indicating superior water retention and gel stability. The lack of liquid separation indicates

that both polymer systems sodium alginate and xanthan–LBG blend produced robust, stable gels without structural degradation or dehydration during storage. The data demonstrate that all formulations exhibit excellent physical stability and robustness, with F4 displaying the most advantageous spreadability profile.

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 nebivolol jelly formulations exhibited a time-dependent escalation in drug release over a duration of 60 minutes. Sodium alginate-based formulations (F1–F3) had a relatively rapid release, with F1 exhibiting the highest release rate at 89.73%, attributable to its reduced polymer concentration, which facilitates accelerated matrix degradation and drug diffusion. As the concentration of alginate increased (F2, F3), the gel's density augmented, resulting in a marginal deceleration of release. Jellies based on xanthan gum (F4–F6) exhibited accelerated initial wetting and diffusion, with F4 attaining the greatest cumulative release of 91.28% at 60 minutes. Elevated xanthan concentrations (F5, F6) yielded more robust gels, marginally diminishing release owing to enhanced viscosity and diffusion resistance. All batches released over 80% of the medication within 60 minutes, demonstrating its appropriateness for immediate-release oral jelly delivery. Formulations F1 and F4 exhibited the most optimal release profiles, harmonizing gel structure with swift drug diffusion.

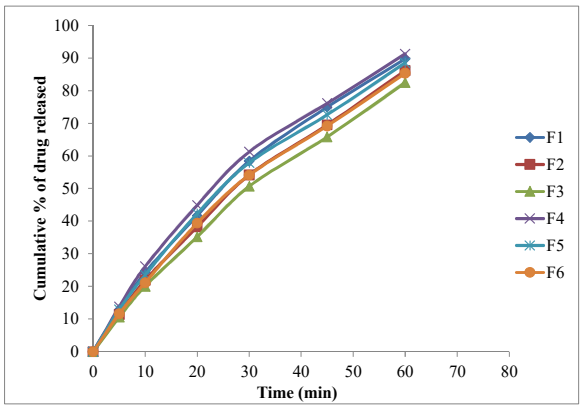

Figure 5: In-vitro dissolution studies of NBV formulations.

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.

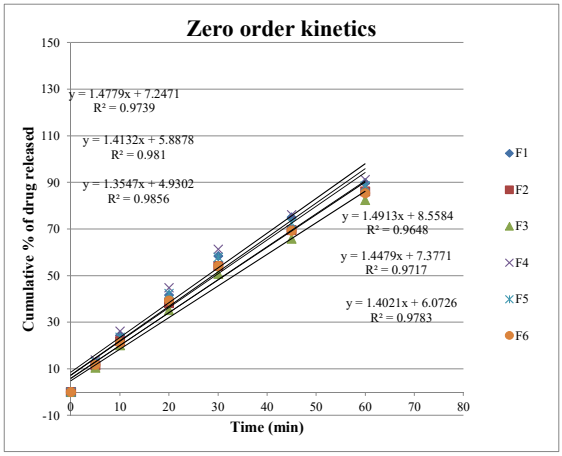

Figure 6: Zero order release kinetics graph of NBV formulations.

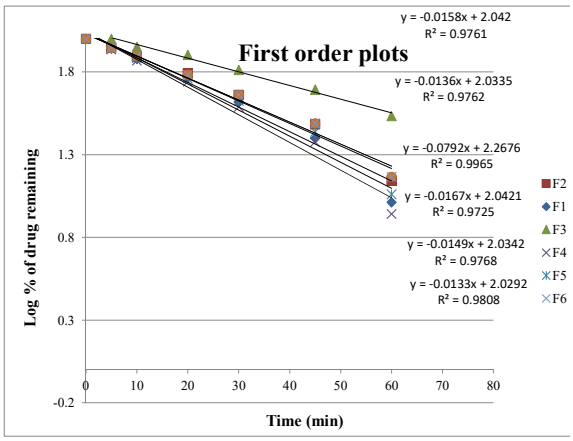

Figure 7: First order release kinetics graph of NBV formulations.

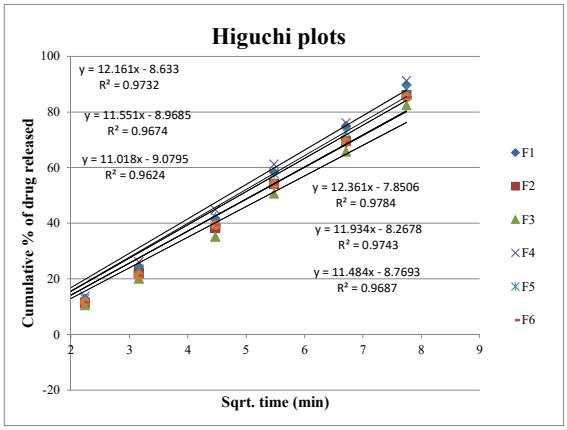

Figure 8: Higuchi release kinetics graph of NBV formulations.

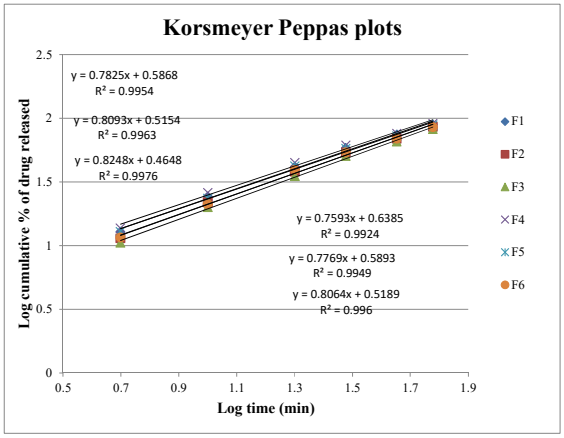

Figure 9: Korsmeyer-Peppas graph of NBV formulations.

The dissolving data of nebivolol jellies conformed most effectively to the Korsmeyer–Peppas model, exhibiting exceptionally high R^2 values (0.9924–0.9976) across all formulations, thereby signifying that this model most precisely characterizes the release profile. The release exponent n (0.76–0.82) indicates non-Fickian (anomalous) transport, signifying that drug release transpires via a combination of diffusion and polymer matrix relaxation/erosion. The zero-order, first-order, and Higuchi models demonstrated strong association (R^2 = 0.96–0.98), indicating a predominantly diffusion-controlled albeit structure-dependent release, with formulations F2, F3, and F6 exhibiting marginally more regulated profiles.

Selection of best formulation:

Following a comprehensive assessment of physicochemical characteristics, mechanical performance, and in-vitro drug release, formulation F4 was identified as the optimal nebivolol oral jelly. F4 exhibited consistent weight (4.89 ± 0.08 g), satisfactory surface pH (4.20 ± 0.11), appropriate moisture content (23.2 ± 1.0%), and water activity (0.61 ± 0.02), signifying robust physical and microbiological stability. The firmness (2.89 ± 0.12 N) yielded a soft, elastic jelly suitable for pediatric and geriatric patients, avoiding excessive brittleness or stickiness. The drug content was within acceptable ranges (97.9 ± 1.9%), guaranteeing dosage homogeneity. In vitro dissolution demonstrated a 91.28% drug release at 60 minutes, ranking among the highest of all batches, characterized by a smooth and progressive release profile. Given its palatability, texture, stability, and advantageous dissolving properties, F4 was selected as the optimal formulation for subsequent characterisation and stability investigations.

Stability Studies:

In compliance with ICH recommendations, stability experiments were carried out to assess the pharmaceutical formulation's stability. The improved jelly (F4) exhibited remarkable stability during 60 days of accelerated testing. The physical look, color, and texture remained constant, signifying no deterioration or syneresis. The surface pH exhibited a negligible reduction, remaining within the permissible non-irritant range. A minor elevation in moisture content (23.2% to 23.9%) and water activity (0.61 to 0.63) was noted, although the values persisted within acceptable thresholds for microbiological stability. The stiffness of the jelly rose slightly, indicating a gradual gel tightening over time, which is characteristic of hydrocolloid-based systems. The drug content exceeded 96%, indicating the chemical stability of nebivolol within the jelly matrix. The dissolution profiles were consistent, with just a slight decrease in 60-minute drug release (91.28% → 89.87%), signifying that the jelly maintained its immediate-release characteristics. F4 exhibited physical, chemical, and functional stability, affirming its appropriateness as a patient-friendly oral jelly formulation for antihypertensive treatment.

CONCLUSION

Nebivolol oral jellies formulated with natural polymers successfully demonstrated excellent physicochemical stability, uniform drug distribution, and rapid dissolution suitable for immediate antihypertensive action. The xanthan–locust bean gum–based formulation F4 emerged as the optimized batch, offering ideal gel strength, acceptable water activity, palatable texture, and >90% drug release within 60 minutes. Stability studies confirmed the robustness of the optimized jelly under accelerated storage. Overall, this work establishes natural-polymer nebivolol jellies as a patient-centric, easy-to-swallow, and effective alternative to conventional solid dosage forms, particularly benefiting geriatric, pediatric, and dysphagic individuals.

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