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FORMULATION AND EVALUATION OF NASAL DECONGESTANT GUMMIES

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ABSTRACT

This study aimed to develop and characterize a formulation of vegan gummies containing nasal decongestants optimized for pediatric use. The objectives included prioritizing palatability, ease of administration, and safety. Methods encompassed formulation development, physical characterization, dissolution studies, FTIR analysis, rheological studies, and stability evaluation. Results indicated successful formulation with suitable physical properties, optimized drug release kinetics, and chemical compatibility. The formulated gummies offer promise for improving patient compliance and treatment outcomes. In conclusion, this study presents a valuable addition to pediatric nasal decongestant therapy.

Keywords: Vegan gummies, Nasal decongestants**,** Pediatric use**,** Pectin, Texture Analysis**,** Patient compliance

1. INTRODUCTION

Nasal congestion, a common symptom of rhinologic conditions like allergic rhinitis, rhinosinusitis, and nasal polyposis, poses a significant burden on individuals worldwide. Allergic rhinitis affects 10% to 20% of the global population, with similar prevalence rates in the United States. Rhinosinusitis impacts approximately 1 in 6 adults in the U.S., while nasal polyposis contributes to nasal obstruction in 2% to 4% of individuals [1]. Meanwhile, gummies, beloved for their taste and texture, have garnered popularity but raise concerns due to their high sugar content. This has led to exploration of natural ingredients and multivitamin formulations to address health concerns. In our study, we investigate the potential of natural ingredient-based gummies as a novel drug delivery system for managing nasal congestion [2]. Through formulation refinement and rigorous trials, we aim to develop effective and palatable treatments to alleviate nasal congestion symptoms, thereby improving patient outcomes and promoting public health.

2. MATERIALS & METHODS

2.1. Materials

API and all other ingredients were obtained as a gift sample from Panacea Biotech Pharma Limited, Ambala-Chandigarh Highway, Lalru, Punjab.

2.2. Formulation of Nasal Decongestant Gummies

The Gummies were prepared by using Gelation method. The production process begins with the formulation of a dry mix containing the gelling agent and half the quantity of sucrose, followed by the addition of distilled water to this mixture. The solution is heated until it reaches boiling point. Meanwhile, another mixture is prepared by combining sucrose, glucose syrup, and distilled water, which is also heated to boiling.

Subsequently, the two solutions are mixed and heated together until reaching a consistent boiling state, maintaining a temperature of 115°C. At this stage, active Pharmaceutical Ingredients (API) are added to the solution. Once the temperature reaches 115°C, drops of flavor and color are carefully introduced. As the temperature gradually drops to between 80°C and 90°C, citric acid is added to the mixture [3]. Finally, the prepared mixture is poured into molds and left to set at room temperature until it achieves the desired consistency, completing the production process.

Table 1. Formulation table

Ingredients	Formulations (mg)									
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
API	5	5	5	5	5	5	5	5	5	5
Pectin HSC-105	50	–	–	–	–	–	–	–	–	–
Pectin Slow Set	–	50	–	–	–	–	–	–	–	–
Agar 800 GS	–	–	30	–	–	–	–	–	–	–
Xanthan Gum	–	–	–	20	–	–	–	–	–	–
Carrageenan Gum	–	–	–	–	50	–	–	–	–	–
Pectin Vit	–	–	–	–	–	30	30	85.5	17.8	50
Sucrose	630	630	630	630	630	850	410	642	642	642
Glucose Syrup	700	700	700	700	700	540	960	731	731	731
Citric Acid	10	10	10	10	10	10	10	10	10	10
Ginger Extract	20	20	20	20	20	20	20	20	20	20
Honeycomb Flavour	20	20	20	20	20	20	20	20	20	20
Colour Yellow Supra	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Purified Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

3. Evaluation of the Nasal Decongestants Gummies

3.1. Physical parameters: The assessment of medicated gummies encompassed an evaluation of clarity, texture, and consistency. Specifically, the texture of the gummies, with a focus on stickiness, was appraised through visual examination of the product.

3.2. Drug Content Uniformity Study: Content uniformity was assessed by measuring the weight equivalent to one gummy and dissolving its powder content in a 100 ml volumetric flask containing 50 ml of 6.8 phosphate buffer, allowing it to stand for 30 minutes. The mixture was then adjusted to volume with buffer pH 6.8. The absorption of the diluted samples was recorded at 273 nm. Three replications of each test were analyzed for mean and standard deviation. For gummy formulations containing larger dose drugs, the permitted official potency range typically falls between not less than 90% and not more than 110% of the labeled amount.

3.3. Weight Variation Test: Ten gummies from each batch were weighed individually in grams using an analytical balance. The average weight and standard deviations were then calculated. Subsequently, the individual weight of each gummy was determined using the same method and compared with the average weight [4]. Any weight variation observed was assessed to ensure it fell within the prescribed limits, which typically include 10% for gummies weighing 130 mg or less, 7.5% for those weighing between 130 mg to 324 mg, and 5% for gummies weighing more than 324 mg.

3.4. pH Study: A pH study of gummies involves measuring their acidity or alkalinity levels to understand how pH affects taste, texture, and shelf life [5]. By testing different formulations, pH data helps optimize taste profiles, texture, and shelf stability. This study ensures product safety and consistency in the confectionery industry.

3.5. Moisture Content: By Gravimetric method, one gram sample is weighed and placed in a

desiccator at for 24hrs [6]. Final weight is subtracted from initial and the difference in moisture content is calculated:

% Moisture content = Initial weight – Final weight /Initial weight × 100

***3.6. In-vitro* Drug Release Study:** An in-vitro drug release studies of the prepared nine formulations of Nasal Decongestant Gummies were conducted for a period of 40 mins using an eight station USP type 2 apparatus (paddle type). The agitation speed was 50 rpm. Gummies were added to 900 ml of 6.8ph Phosphate Buffer at 37 ± 0.5°C. 5 ml aliquots were withdrawn at time intervals of 5, 10, 15, 20, 25, 30, 35, 40 min. and filtered through Whatman No. 41 filter paper. An equal volume of fresh dissolution medium was replaced to maintain the volume of dissolution medium [7]. The filtered samples were analysed spectrophotometrically at 273 nm. Cumulative percentage of labelled amount of drug released was calculated.

3.7. Chemical interaction study of Optimized formulation: An interaction study was conducted using a Fourier Transform Infrared Spectrophotometer (FTIR) with the Potassium Bromide pellet technique. The spectra of the pure drug and the optimized formulation were meticulously examined and compared to detect any interactions between the components.

3.8. Evaluation of in-vitro release kinetics of optimized formulation: The data obtained from the dissolution study were subjected for analysis to know the release pattern of the drug from the dosage form [8]. To analyse the mechanism of release and release rate kinetics of the dosage form, the data obtained were fitted into Zero order, First order and Korsmeyer-Peppas model. Based on the r-value, the best-fit model was selected.

i. Zero order kinetics:

Drug dissolution from pharmaceutical dosage forms that do not disaggregate and release the drug slowly, assuming that the area does not change and no equilibrium conditions are obtained can be represented by the following equation,

$Q_t = Q_o + K_o t$

Where Q t = amount of drug dissolved in time t.
Q o = initial amount of the drug in the solution
K o = zero order release constant.

ii. First order kinetics:

To study the first order release rate kinetics, the release rate data were fitted to the following equation,

$\text{Log } Q_t = \log Q_o + K_1 t/2.303$

Where Q t is the amount of drug released in time t, Q o is the initial amount of drug
in the solution and K1 is the first order release constant.

iii. Higuchi model:

To analyze the Higuchi release kinetics, researchers utilized the following equation:

$F = K.t_{1/2}$

Here, 'F' represents the amount of drug release, 'K' denotes the release rate constant, and 't' signifies the release time. Upon plotting the data as cumulative drug released against the square root of time, a linear relationship emerges, suggesting that drug release occurred via a diffusion mechanism. The slope of this line corresponds to 'K'.

iv. Korsmeyer – Peppas release model:

The release rate data were fitted to the following equation,

$M_t / M_\infty = K.t^n$

Where, M t / M ∞ is the fraction of drug release, ‘K’ is the release constant, ‘t’ is the release time and ‘n’ is the diffusion exponent for the drug release that is dependent on the shape of the matrix dosage form. When the data is plotted as Log fraction of drug released versus Log time, yields a straight line with a slope equal to ‘n’ and the ‘K’ can be obtained from Y-intercept. (*Table 2*) summarizes the relationship between the release exponent (n), drug transport mechanisms, and the drug release rate over time in polymeric systems. For Fickian diffusion (n = 0.55), the release rate follows ($t^{-0.5}$). Non-Fickian diffusion ($0.45 < n \leq 0.89$) involves both diffusion and polymer relaxation, with a release rate of (t^{n-1}). Case II transport (n = 0.89) has a zero-order release, indicating a constant rate. Super case II transport (n > 0.89) involves significant polymer relaxation, with the release rate also following (t^{n}-1). Understanding these mechanisms aids in designing effective drug delivery systems.

Table 2. Diffusion exponent and solute release mechanism

Release exponent (n)	Drug transport mechanism	Rate as a function of time
0.55	Fickian diffusion	$t^{-0.5}$
0.45<n=0.89	Non-fickian diffusion	t^{n-1}
0.89	Case II transport	Zero order release
Higher than 0.89	Super case II transport	t^{n-1}

i. Zero Order Reaction -% Cumulative drug release Vs Time in hrs
ii. First Order Reaction – Log % Cumulative drug remaining Vs Time in hrs
iii. Higuchi kinetics -% Cumulative drug release Vs square root of time
iv. Korsmeyer – Pappas equation -log cumulative % of drug released Vs log time

3.9. Rheological study:

Texture analysis of gummies involves evaluating several parameters such as hardness, chewiness, elasticity, and stickiness. This assessment is typically conducted using a texture analyzer equipped with a probe or set of jaws that applies controlled force to the gummy sample while recording its deformation [6]. Here's a breakdown of the general procedure:

1. Sample Preparation: Gummies are prepared uniformly by cutting them into standardized shapes or sizes to ensure consistency during testing.

2. Testing Procedure: The prepared gummy sample is positioned on the platform of the texture analyzer. A probe or set of jaws is then lowered onto the gummy with controlled force, and the resulting deformation is recorded.

3. Force vs. Time Curve: Throughout the test, the texture analyzer measures the force exerted on the gummy at each moment, generating a force vs. time curve.

4. Analysis: Various parameters are derived from the force vs. time curve to characterize the texture of the gummy. These parameters include:

a. Hardness: The peak force required to deform the gummy.

b. Chewiness: The energy needed to masticate the gummy to a certain point, often calculated as the area under the force vs. time curve.

c. Elasticity: The gummy's ability to regain its original shape after deformation, typically assessed by examining the slope of the force vs. time curve during the relaxation phase.

d. Stickiness: The force necessary to detach the probe or jaws from the gummy after deformation.

5. Data Interpretation: Texture analysis parameters provide essential insights into gummy texture, aiding quality control, product development, and comparative analysis. For manufacturers, texture analysis ensures product consistency, consumer satisfaction, and regulatory compliance, enhancing product quality and competitiveness.

3.10. Stability Studies:

The optimized formulation was wrapped in aluminum foil and stored in an oven at 45 ±2°C and 75±5% RH for one month. Weight variation, pH, Moisture Content, Disintegration Time, drug content uniformity and Drug release were analysed [9]. Stability studies were conducted following ICH Q1A guidelines to assess the product's resilience under normal temperature and humidity conditions.

4. RESULTS AND DISCUSSION

4.1. Formulation of Nasal Decongestant Gummies

The study aimed to formulate and assess nasal decongestant gummies using the gelation method. Equal Quantity of Drug used in all formulations. Ten distinct formulations (F1 to F10) were developed employing various gelling agents, including Pectin, Agar, Xanthan Gum, and Carrageenan Gum, to achieve the desired gummy texture.

In formulations F1 to F6, different types of pectin and additional gelling agents such as Pectin HSC 105, Pectin Slow Set, Agar 800GS, Xanthan Gum, Carrageenan Gum, and Pectin Vit were utilized. Among these, formulation F6 exhibited superior gummy texture compared to formulations F1 to F5,

indicating that Pectin Vit is the most suitable option for further formulations.

Formulations F6 and F7 were prepared with varying concentrations of sucrose and liquid glucose. Notably, formulation F7 demonstrated enhanced hardness compared to other formulations due to the increased quantity of liquid glucose. In formulations F8 and F9, different concentrations of Pectin Vit were employed. However, formulation F8 exhibited a frosty and harder texture, rendering it unsuitable for gummy formulation, likely due to the elevated concentration of Pectin Vit compared to F9. After evaluating all formulation data, formulation F10 was developed using an optimum concentration of Pectin Vit and a balanced ratio of sucrose and glucose syrup to achieve the desired gummy texture. Among the formulations, F10 emerged as the most promising option, characterized by its distinct texture, consistency, hardness, and appearance. Composition is discussed in the Material and Methods section (*Table 1*).

4.2. Evaluation of the Nasal Decongestants Gummies

Evaluation of the Nasal Decongestants Gummies revealed that formulations F5, F6, and F8 exhibited a cloudy or frosty appearance. F5 was soft and slightly sticky, while F6 and F8 were firm and non-sticky. However, the standout formulation was F10, characterized by a translucent appearance, soft texture, and non-stickiness, making it highly suitable for various applications. Moreover, analysis of drug content percentage demonstrated that F10 exhibited the highest drug content uniformity (100.54% ± 1.50%), indicating precise dosage consistency and potentially improved therapeutic outcomes. Additionally, weight variation assessment across formulations showed uniformity in gummy weight, ensuring consistent dosing. pH studies revealed that formulations maintained acidity within the recommended range (3.0 to 4.0), contributing to the preservation of active ingredients and enhancing palatability.

However, moisture content analysis indicated variations among formulations, with F10 falling within the standard limits of 10 to 15%, ensuring optimal manufacturing and packaging conditions.

Therefore, based on comprehensive evaluation, F10 stands out as the most reliable and promising formulation for nasal decongestants gummies, offering optimal physical attributes, drug content uniformity, and suitable moisture content. This formulation holds significant potential for further development and pharmaceutical applications in addressing nasal congestion effectively.

Table 3. Physical Parameters of Nasal Decongestants Gummies

Formulation	Physical parameters		
	Appearance	Texture	Stickiness
F1	Translucent	Soft	Slightly Sticky
F2	Translucent	Gooey	Sticky
F3	Translucent	Chewy	Non-Sticky
F4	Translucent	Soft	Slightly Sticky
F5	Cloudy	Soft	Slightly Sticky
F6	Frosty	Firm	Non-Sticky
F7	Translucent	Gooey	Sticky
F8	Cloudy	Firm	Non-Sticky
F9	Translucent	Soft	Slightly Sticky
F10	Translucent	Chewy	Non-Sticky

Table 4. Evaluation Parameters of Nasal Decongestants Gummies

Formulation	Drug Content %	Weight variation (g)	pH Study	Moisture content
F1	94.13±2.42	2.013±0.039	3.0±0.298	4.53 %
F2	91.43±3.31	2.191±0.032	3.4±0.318	8.35 %
F3	96.94±2.35	2.249±0.040	6.5±0.321	6.42 %
F4	98.24±3.05	2.165±0.038	6.2±0.315	7.16 %
F5	90.28±2.48	2.234±0.059	8.3±2.025	21.21 %
F6	95.15±2.67	2.071±0.041	3.4±0.167	15.04 %
F7	97.29±2.53	2.042±0.030	3.8±0.189	10.39 %
F8	95.29±2.53	2.187±0.023	3.5±0.179	20.55 %
F9	98.12±3.07	2.038±0.036	3.7±0.185	9.65 %
F10	100.54±1.50	2.023±0.029	3.2±0.166	12.33 %

4.3. *In- vitro* Drug Release Study

The cumulative percentage of drug release for formulations F1 and F2, which contain different grades of Pectin (HSC-105 and Slow Set), as gelling agents, showed 99.43% at 25 minutes and 99.84% at 30 minutes, respectively. Formulation F3, containing Agar as a gelling agent, exhibited a drug release of 6.94% at 40 minutes. Formulations F4 and F5, utilizing Xanthan Gum and Carrageenan Gum as gelling agents, respectively, demonstrated an extended release profile. F4 achieved a release rate of 99.88% within 25 minutes, while F5 showed a cumulative drug release of 98.98% at 20 minutes. Increasing the amounts of sucrose and glucose syrup in formulations F6 and F7 led to a delay in drug release. Specifically, F6 achieved a release rate of 99.55% within 30 minutes, whereas F7 exhibited a cumulative drug release of 100.49% at 35 minutes. Formulations F8, F9, and F10 contained 85.5mg, 17.8mg, and 50mg of Pectin Vit, respectively, as a gelling agent. These formulations showed cumulative drug releases of 89.02% in 40 minutes, 98.12% in 35 minutes, and 100.44% in 40 minutes, respectively. Consequently, formulation F10, containing 50mg of Pectin Vit, which achieved a 100.44% drug release at the end of 40 minutes, was considered the optimized formulation. It was selected for further evaluation and stability studies.

Table 5. Drug Release data of Nasal Decongestant Gummies (F1 to F10)

Time (min)	Cumulative % Drug Released									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
0	0	0	0	0	0	0	0	0	0	0
5	24.31	33.84	2.90	36.74	15.88	25.69	36.74	12.51	28.45	16.71
10	46.41	50.60	3.61	58.49	34.07	34.95	56.83	20.80	43.80	37.52
15	66.69	62.48	3.63	72.35	65.06	46.74	66.82	28.78	57.72	48.78
20	84.32	70.29	4.48	86.42	98.98	56.12	79.48	37.36	69.64	65.62
25	99.43	81.58	4.50	99.88	-	81.70	84.33	48.75	78.17	74.27
30	-	99.84	5.91	-	-	99.55	93.77	63.80	84.81	80.20
35	-	-	5.94	-	-	-	100.49	78.79	98.12	86.16
40	-	-	6.94	-	-	-	-	89.02	-	100.44

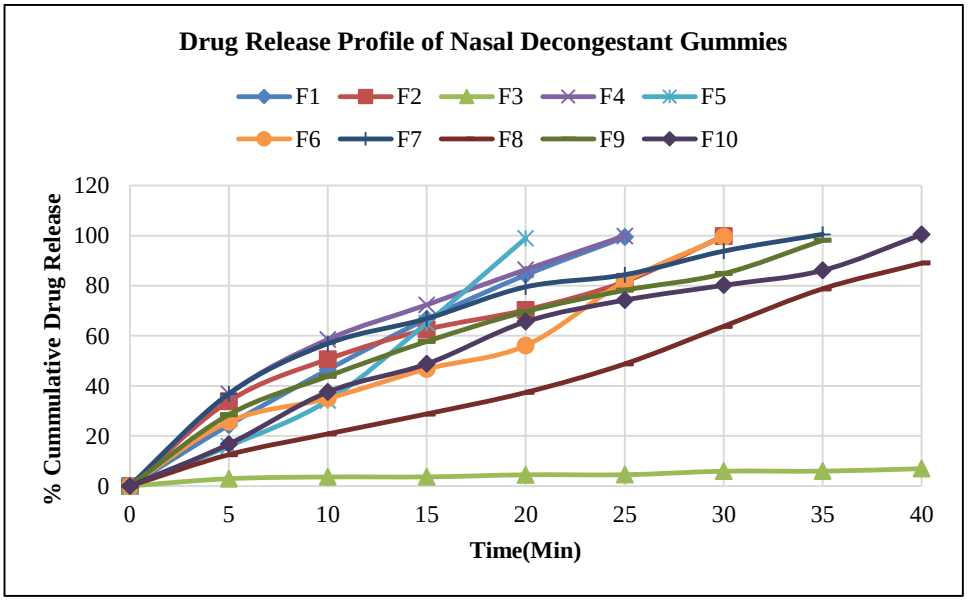


Figure C. Drug Release Profile of Ten prepared formulations (F1 to F10)

4.4. Chemical interaction study of Optimized formulation

The FTIR spectra of the Pure Drug (Figure A) were compared with the FTIR spectra of the Optimized Formulation (Figure B). There was no

disappearance of characteristic peaks of the drug in the FTIR spectra, indicating no interaction between the Pure drug and Optimized Formulation.

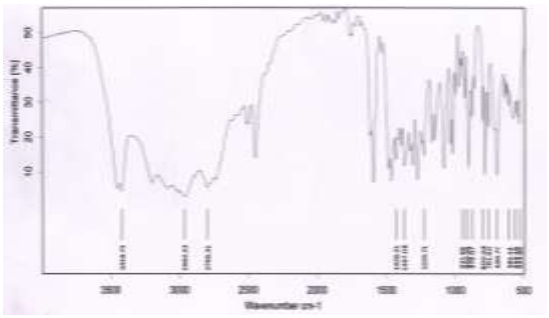


Figure A. The FTIR spectra of the Pure Drug

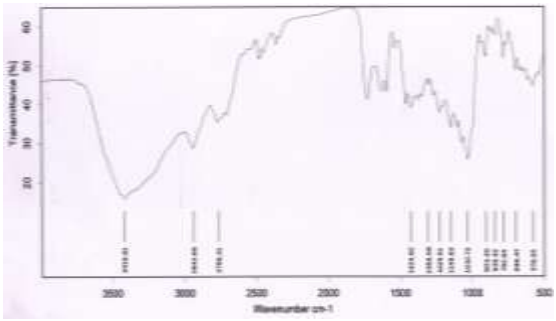


Figure B. The FTIR spectra of the Optimized Formulation

4.5. Evaluation of In-vitro release kinetics of optimized formulation

The summarized data of the in vitro release kinetics suggests several key findings. Both zero-order and first-order kinetics models, with R^2 values of 0.9662 each, indicate that the release process may be independent of concentration or proportional to concentration, respectively. The Higuchi kinetics model, with an R^2 of 0.9619, implies a diffusion-controlled release mechanism. Moreover, the highest correlation coefficient (R^2 = 0.9781) obtained from the Korsemeyer Peppas equation suggests a non-Fickian or anomalous release behavior, likely involving diffusion and polymer relaxation. Overall, these findings highlight a complex interplay of release mechanisms, including diffusion and polymer dynamics.

Table 6. The summarized data of the in vitro release kinetics

Data fitted in	Slope	Intercept	R^2	Linear equation
Zero Order Kinetics	2.4032	8.5718	0.9662	y=2.4032x + 8.5718
First Order Kinetics	-2.4032	91.428	0.9662	y= - 2.4032x+91.428
Higuchi Kinetics	14.585	-4.7549	0.9619	y=14.585x - 4.7549
Korsemeyer Peppas Equation	1.6471	0.7021	0.9781	y=1.6471x + 0.7021

4.6. Rheological studies of optimized formulation

Rheological studies were conducted on the optimized formulation (F10), revealing results for various parameters such as hardness, gumminess, adhesiveness, springiness, and cohesiveness, as shown in Table 5.x. The texture analyzer also generated graphical results depicting Load vs Distance, Distance vs Time, and Load vs Time (Figure D, E, and F). The data from the texture analyzer indicate that the gummies are softer than lozenges but harder than gelatin-based soft candies, allowing them to maintain a chewy texture while still providing prolonged flavor release.

Table 7: Texture analyzer report of optimized formulation

Calculation	Value
Hardness	397.59 g
Gumminess	336.13 gf
Adhesive force	39.72 g
Springiness	1.50 mm
Deformation	1.50 mm
Work done to hardness 1	863.52 gs
Cohesiveness	-
Chewiness	1329.5 gmm
Adhesiveness	-9.31 gs
% Deformation	15.53%
Hardness cycle 2	450.40 g
Work done to hardness 2	4.50 gs

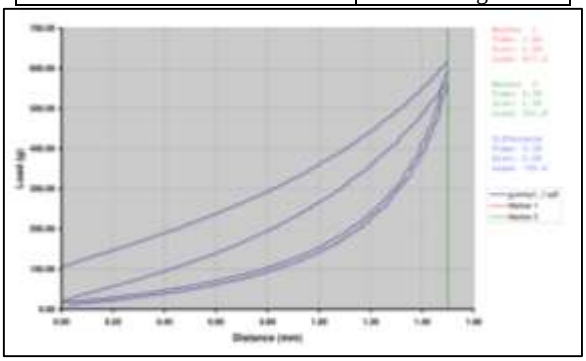


Figure D: Load vs Distance graph

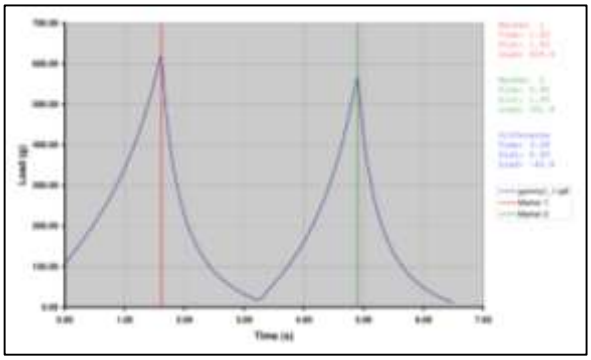


Figure E: Load vs Time graph

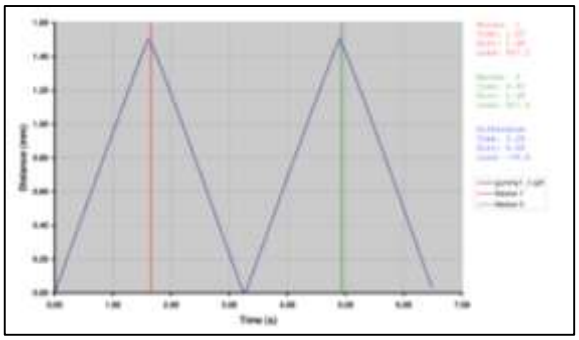


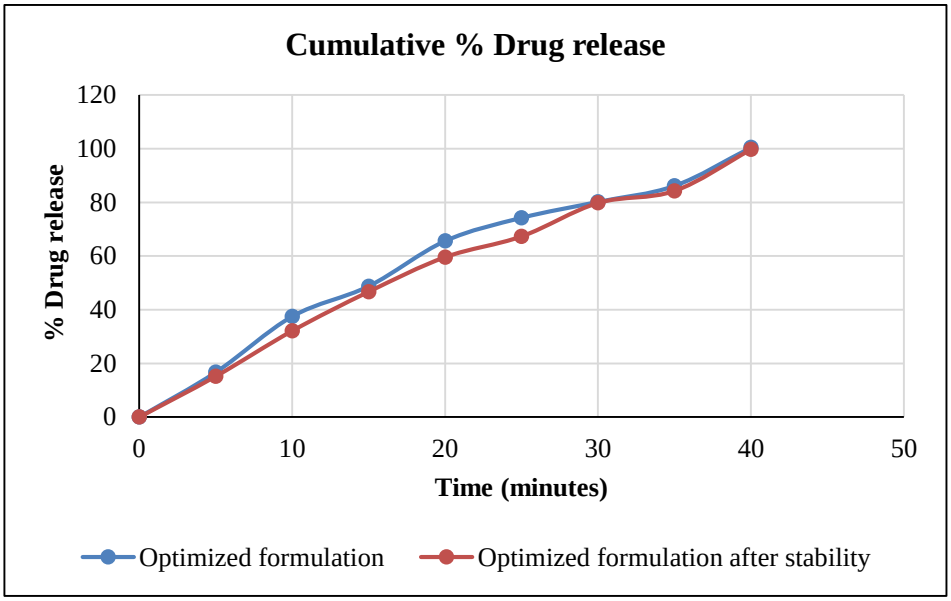
Figure F: Distance vs Time graph

4.7. Stability Studies

Table 8. Evaluation parameters after the stability studies

EVALUATION PARAMETER	OPTIMIZED FORMULATION (F 10)	AFTER STABILITY STUDY OF 1 MONTH
Weight variation	2.023±0.029	2.034±0.036
pH	3.2	3.1
Moisture Content	12.33%	11.21%
Drug Content uniformity	100.54±1.50	100.24±1.42
Drug release	100.44%	99.72%

Figure G. Comparative cumulative % drug release curve for the optimized formulation (F10)



The optimized formulations were subjected to stability studies at temperature i.e. 45ºC /75% RH for a period of one month. There is no change in physicochemical properties after performing stability studies. There is no relative change in the release kinetics of the formulation F10 after stability studies.

5. CONCLUSION

The study successfully developed nasal decongestant-medicated gummies for buccal absorption, ensuring stability and compatibility through FT-IR spectroscopy. Pectin-based formulation F10 stood out, showing superior drug release kinetics, desirable physical properties, and compliance with moisture and drug content standards. These gummies, particularly formulation F10, offer significant advantages for pediatric patients, including ease of administration, pleasant taste, and reduced choking risk. Overall, these medicated gummies present a promising, controlled-release dosage form that enhances patient compliance and effectively manages nasal congestion.

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