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Formulation, Optimization and In Vitro Evaluation of Loratadine Oral Medicated Jelly Using Natural Polymers for Superior Allergy Relief

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Abstract: Difficulty in swallowing conventional solid dosage forms is a common problem in paediatric, geriatric and dysphagic patients and frequently compromises adherence. Oral medicated jellies have emerged as a palatable, easy-to-swallow alternative that disintegrates rapidly in the mouth and may improve patient compliance. The present study was concerned with the formulation, optimization and in vitro evaluation of an oral medicated jelly of loratadine, a second-generation antihistamine used for the symptomatic relief of allergic rhinitis and urticaria. Jellies were prepared by the heating-and-congealing method using gelatin and guar gum as natural gelling and film-forming polymers, sucrose as a sweetener, citric acid as a cross-linking and pH-adjusting agent, and methyl and propyl paraben as preservatives. Five formulations (F1–F5) were designed with the aid of a design-of-experiments (DoE) approach in which the polymer concentrations were varied systematically. The prepared jellies were evaluated for drug–excipient compatibility (FT-IR), physical appearance, pH, viscosity, spreadability, drug content and in vitro dissolution. FT-IR confirmed the absence of any interaction between loratadine and the excipients. All formulations were smooth, palatable and uniform, with near-neutral pH (6.5–6.9) and acceptable drug content (94.6–96.6%). Formulation F1 exhibited the most favourable in vitro release, with about 89% of the drug released within 60 min. The results indicate that a loratadine oral jelly based on gelatin and guar gum offers a promising, patient-friendly dosage form for improved allergy relief.

Keywords: *Loratadine; Oral Medicated Jelly; Guar Gum; Gelatin; Design of Experiments; Allergy; Patient Compliance.*

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I. INTRODUCTION

The oral route remains the most widely accepted means of drug administration owing to its convenience, safety and patient acceptability. Conventional solid dosage forms such as tablets and capsules can, however, be difficult to swallow for paediatric, geriatric and dysphagic patients, and this difficulty often leads to poor adherence and sub-optimal therapy.[4,5] To overcome this limitation, a variety of patient-friendly dosage forms have been developed, among which oral medicated jellies have attracted considerable attention.[1,5]

Oral medicated jellies are semi-solid preparations that combine the palatability of a confectionery product with the precision of a pharmaceutical dosage form. They disintegrate rapidly in the oral cavity, are easy to administer without water, and can mask the unpleasant taste of many active substances, making them especially suitable for children and the elderly.[5,14] Rapid disintegration in saliva and absorption across the oral mucosa can also allow a portion of the dose to bypass hepatic first-pass metabolism, which may improve bioavailability for drugs that are extensively metabolised.[2,5] Natural polymers such as gelatin, guar gum, pectin and xanthan gum are commonly used as gelling agents because they are biocompatible, non-toxic and capable of forming jellies of suitable consistency and drug-release behaviour.[4,13]

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Loratadine is a long-acting, second-generation tricyclic antihistamine that selectively antagonises peripheral histamine H_1 receptors with little affinity for central receptors, and is therefore widely prescribed for allergic rhinitis and chronic urticaria with minimal sedation (Figure 1). Its therapeutic usefulness by the conventional oral route is nevertheless limited by poor aqueous solubility and extensive hepatic first-pass metabolism, both of which reduce and render variable its oral bioavailability.[2,3,10] These limitations, together with the swallowing difficulties associated with tablets, provide a clear rationale for formulating loratadine as an oral medicated jelly.

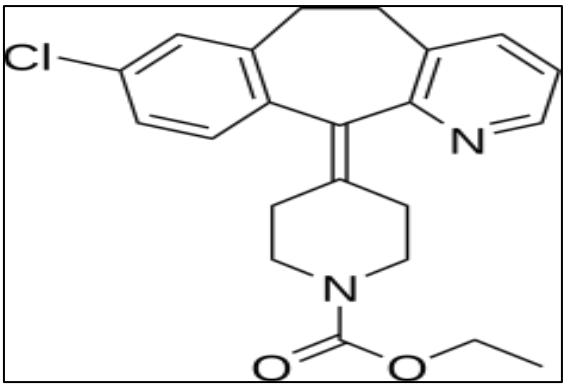

Fig 1 Chemical Structure of Loratadine.

Accordingly, the aim of the present work was to design, optimise and evaluate an oral medicated jelly of loratadine using gelatin and guar gum as natural polymers. A design-of-experiments (DoE) approach was employed to study the influence of the polymer concentrations on the formulation responses and to identify a suitable composition, with the broader objective of improving the disintegration, dissolution and overall patient acceptability of the drug.[9]

II. MATERIALS AND METHODS

➢ *Materials*

Loratadine, methyl paraben and citric acid were obtained from commercial suppliers (loratadine and methyl paraben from Yarrow Chemicals; citric acid from Carbanio). Gelatin, guar gum, sucrose and propyl paraben were procured from Loba Chemie. All reagents used were of analytical grade. The materials and their suppliers are listed in Table 1.

Table 1 Materials Used and Their Suppliers.

S. No	Material	Supplier
1	Loratadine	Yarrow Chemicals
2	Gelatin	Loba Chemie
3	Guar gum	Loba Chemie
4	Sucrose	Loba Chemie
5	Citric acid	Carbanio
6	Methyl paraben	Yarrow Chemicals
7	Propyl paraben	Loba Chemie

➢ *Drug–Excipient Compatibility Studies*

Compatibility between loratadine and the selected excipients was assessed by Fourier-transform infrared (FT-IR) spectroscopy using a Shimadzu infrared spectrophotometer. Samples were mixed with potassium bromide in an approximate 1:10 ratio, compressed into pellets on a KBr press, and scanned over the range 4000–400 cm^{-1}. The spectra of the pure drug, the individual excipients and the final formulation were compared for any shift in the position or intensity of the characteristic peaks.

➢ *Optimization by Design of Experiments (DoE)*

A design-of-experiments approach was used to examine, in a systematic manner, the relationship between the formulation variables and the measured responses. DoE allows controllable input factors to be varied deliberately so that their individual and combined effects on the output can be quantified, while reducing the number of experimental runs required.[9] In this study the concentrations of the gelling polymers (gelatin and guar gum) were treated as the principal independent variables, while the measured responses included viscosity, spreadability and in vitro drug release. Contour and three-dimensional response-surface plots were generated to visualise the effects of the factors and to identify an optimal region, and a desirability function was used to derive the final solution.

➢ *Preparation of the Oral Medicated Jelly*

The jellies were prepared by the heating-and-congealing method. Accurately weighed quantities of gelatin, guar gum and sucrose were used. Gelatin was dissolved in 5 mL of purified water, and guar gum was dispersed slowly into 10 mL of water on a magnetic stirrer fitted with a heater. The gelatin solution was then added to the gum dispersion, sucrose was incorporated and the mixture was stirred until uniform. Citric acid was added as a cross-linking and pH-adjusting agent, followed by methyl paraben and propyl paraben as preservatives. Loratadine was incorporated into the blend with continuous stirring to ensure even distribution. The resulting mass was poured into jelly moulds and allowed to set in a refrigerator for about 1.5 h, after which the jellies were removed from the moulds and stored in suitable containers. The composition of the five formulations (F1–F5) is given in Table 2.

Table 2 Composition of the Loratadine Oral Jelly Formulations.

Formulation	Loratadine (mg)	Gelatin (g)	Guar gum (g)	Sucrose (g)	Citric acid (g)	Water (mL)
F1	10	0.180	0.118	1.044	0.3	10
F2	10	0.160	0.130	1.000	0.3	10
F3	10	0.170	0.110	1.100	0.3	10
F4	10	0.190	0.110	1.050	0.3	10
F5	10	0.195	0.095	1.030	0.3	10

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➢ *Calibration Curve of Loratadine*

A standard stock solution was prepared by dissolving loratadine in 0.1 N HCl to obtain a concentration of 100 µg/mL. Serial dilutions were prepared and their absorbance measured against a blank by UV–visible spectrophotometry at λmax 247 nm. A calibration curve of absorbance against concentration was constructed and used for subsequent quantification of the drug.

➢ *Evaluation of the Oral Medicated Jelly*

- *Physical Appearance and pH*

All prepared jellies were examined visually for colour, transparency, homogeneity and consistency; grittiness and stickiness were assessed by gentle rubbing between the fingers. For pH determination, 1 g of jelly was dispersed in 100 mL of distilled water and the pH measured with a calibrated pH meter.

- *Drug Content (Assay)*

A weighed quantity of jelly was dissolved in phosphate buffer (pH 7.2), stirred, filtered and suitably diluted, and the drug content determined spectrophotometrically and expressed as a percentage of the labelled amount.

- *Viscosity*

Viscosity was measured with a Brookfield (LV) viscometer using spindle no. 63, the system being non-Newtonian, for a fixed time of 2 min at 30 rpm and room temperature (25 ± 5 °C).

- *Spreadability*

Spreadability was determined by the parallel-plate method, in which a fixed mass of jelly was pressed between two plates and the resulting spread recorded.

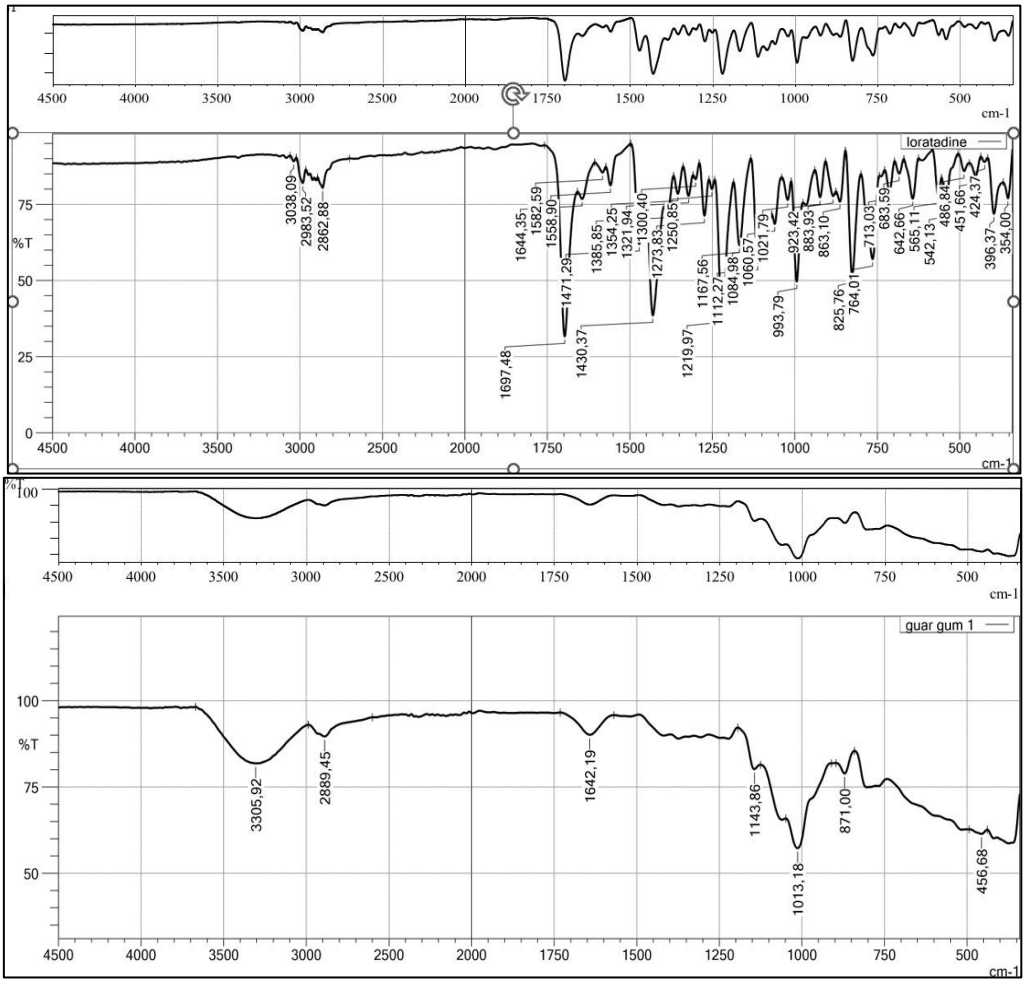
- *In Vitro Dissolution*

Drug release was studied using a USP paddle apparatus (apparatus II) at 50 rpm and 37 °C in phosphate buffer (pH 7.2). Aliquots were withdrawn at 5, 10, 15, 20, 25, 30, 40, 50 and 60 min, filtered, diluted and analysed spectrophotometrically at λmax 247 nm, and the cumulative percentage of drug released was calculated.[6,7]

III. RESULTS AND DISCUSSION

➢ *Drug–Excipient Compatibility (FT-IR)*

The FT-IR spectra of pure loratadine, the individual excipients (guar gum, citric acid and gelatin) and the final formulation are shown in Figure 2. The characteristic absorption bands of loratadine were retained in the formulation spectrum without any appreciable shift in position or intensity, indicating that the drug remained compatible with the selected excipients and that no chemical interaction had occurred.



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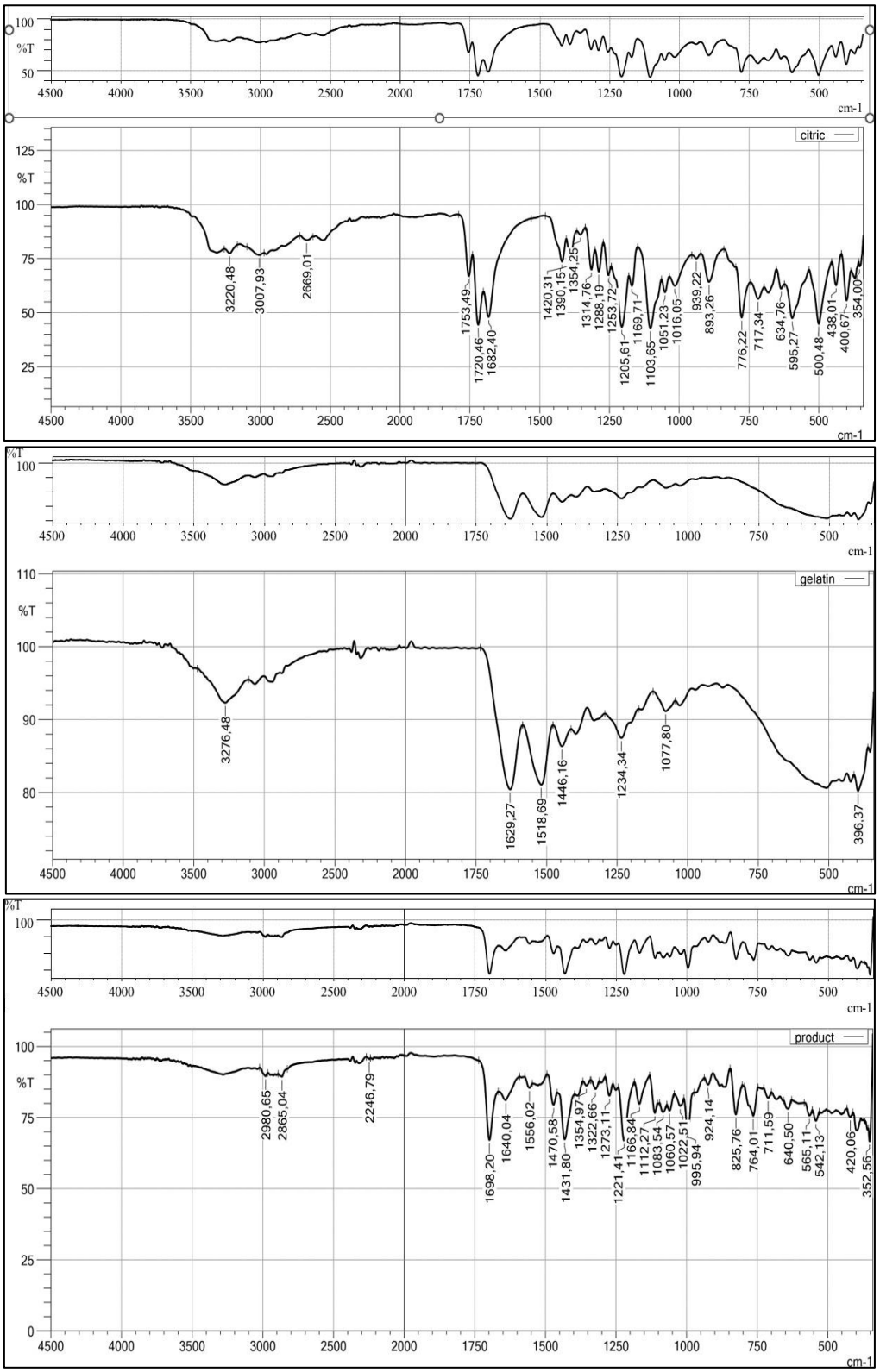

Fig 2 FT-IR Spectra of (a) Pure Loratadine, (b) Guar Gum, (c) Citric Acid, (d) Gelatin and (e) the Final Formulation.

➢ *DoE Optimization*

The design table and the fit summary generated by the experimental design are presented in Figure 3, and the corresponding ANOVA and lack-of-fit analyses in Figure 4. The relationship between the polymer concentrations and the measured responses was visualised by means of contour plots (Figure 5) and a three-dimensional response-surface plot (Figure 6). The optimal formulation region was then identified from the desirability analysis, together with the associated constraints and solutions (Figure 7).

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Std	Run	Factor 1 A:Gelatin gm	Factor 2 B:Guar Gum gm	Factor 3 C:Sucrose gm	Response 1 ASSAY %	Response 2 DISSO %
9	1	0.175	0.08	0.7	70	70
10	2	0.175	0.15	0.7	73	73
1	3	0.1	0.08	0.95	82	82
13	4	0.175	0.115	0.95	85	85
7	5	0.1	0.115	1.2	100	100
11	6	0.175	0.08	1.2	103	103
5	7	0.1	0.115	0.7	76	76
12	8	0.175	0.15	1.2	106	106
2	9	0.25	0.08	0.95	88	88
3	10	0.1	0.15	0.95	91	91
14	11	0.175	0.115	0.95	94	94
8	12	0.25	0.115	1.2	109	109
6	13	0.25	0.115	0.7	79	79
4	14	0.25	0.15	0.95	97	97

Build Information

File Version	13.0.5.0		
Study Type	Response Surface	Subtype	Randomized
Design Type	Box-Behnken	Runs	14.00
Design Model	Quadratic	Blocks	No Blocks
Build Time (ms)	1.0000		

Fig 3 DoE Design Table and Fit Summary.

ANOVA for Linear model

Response 1: ASSAY

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	1944.00	3	648.00	62.61	< 0.0001	significant
A-Gelatin	72.00	1	72.00	6.96	0.0248	
B-Guar Gum	72.00	1	72.00	6.96	0.0248	
C-Sucrose	1800.00	1	1800.00	173.91	< 0.0001	
Residual	103.50	10	10.35			
Lack of Fit	63.00	9	7.00	0.1728	0.9605	not significant
Pure Error	40.50	1	40.50			
Cor Total	2047.50	13				

Factor coding is **Coded**.
Sum of squares is **Type III - Partial**

The **Model F-value** of 62.61 implies the model is significant. There is only a 0.01% chance that an F-value this large could occur due to noise.

P-values less than 0.0500 indicate model terms are significant. In this case A, B, C are significant model terms. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

The **Lack of Fit F-value** of 0.17 implies the Lack of Fit is not significant relative to the pure error. There is a 96.05% chance that a Lack of Fit F-value this large could occur due to noise. Non-significant lack of fit is good -- we want the model to fit.

Fit Statistics

Std. Dev.	3.22	**R²**	0.9495
Mean	89.50	**Adjusted R²**	0.9343
C.V. %	3.59	**Predicted R²**	0.9102
		Adeq Precision	20.9347

The **Predicted R²** of 0.9102 is in reasonable agreement with the **Adjusted R²** of 0.9343; i.e. the difference is less than 0.2.

Adeq Precision measures the signal to noise ratio. A ratio greater than 4 is desirable. Your ratio of 20.935 indicates an adequate signal. This model can be used

Coefficients | Coded Equation | Actual Equation

Coefficients in Terms of Coded Factors

Factor	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
Intercept	89.50	1	0.8598	87.58	91.42	
A-Gelatin	3.00	1	1.14	0.4656	5.53	1.0000
B-Guar Gum	3.00	1	1.14	0.4656	5.53	1.0000
C-Sucrose	15.00	1	1.14	12.47	17.53	1.0000

The coefficient estimate represents the expected change in response per unit change in factor value when all remaining factors are held constant. The intercept in an orthogonal design is the overall average response of all the runs. The coefficients are adjustments around that average based on the factor settings. When the factors are orthogonal the VIFs are 1; VIFs

ANOVA for Linear model

Response 2: DISSO

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	1944.00	3	648.00	62.61	< 0.0001	significant
A-Gelatin	72.00	1	72.00	6.96	0.0248	
B-Guar Gum	72.00	1	72.00	6.96	0.0248	
C-Sucrose	1800.00	1	1800.00	173.91	< 0.0001	
Residual	103.50	10	10.35			
Lack of Fit	63.00	9	7.00	0.1728	0.9605	not significant
Pure Error	40.50	1	40.50			
Cor Total	2047.50	13				

Factor coding is **Coded**.
Sum of squares is **Type III - Partial**

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The **Lack of Fit F-value** of 0.17 implies the Lack of Fit is not significant relative to the pure error. There is a 96.05% chance that a Lack of Fit F-value this large could occur due to noise. Non-significant lack of fit is good -- we want the model to fit.

Fit Statistics

Std. Dev.	3.22	**R²**	0.9495
Mean	89.50	**Adjusted R²**	0.9343
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Coefficients | Coded Equation | Actual Equation

Coefficients in Terms of Coded Factors

Factor	Coefficient Estimate	df	Standard Error	95% CI Low	95% CI High	VIF
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The coefficient estimate represents the expected change in response per unit change in factor value when all remaining factors are held constant. The intercept in an orthogonal design is the overall average response of all the runs. The coefficients are adjustments around that average based on the factor settings. When the factors are orthogonal the VIFs are 1; VIFs

Fig 4 ANOVA and Lack-of-Fit Analysis.

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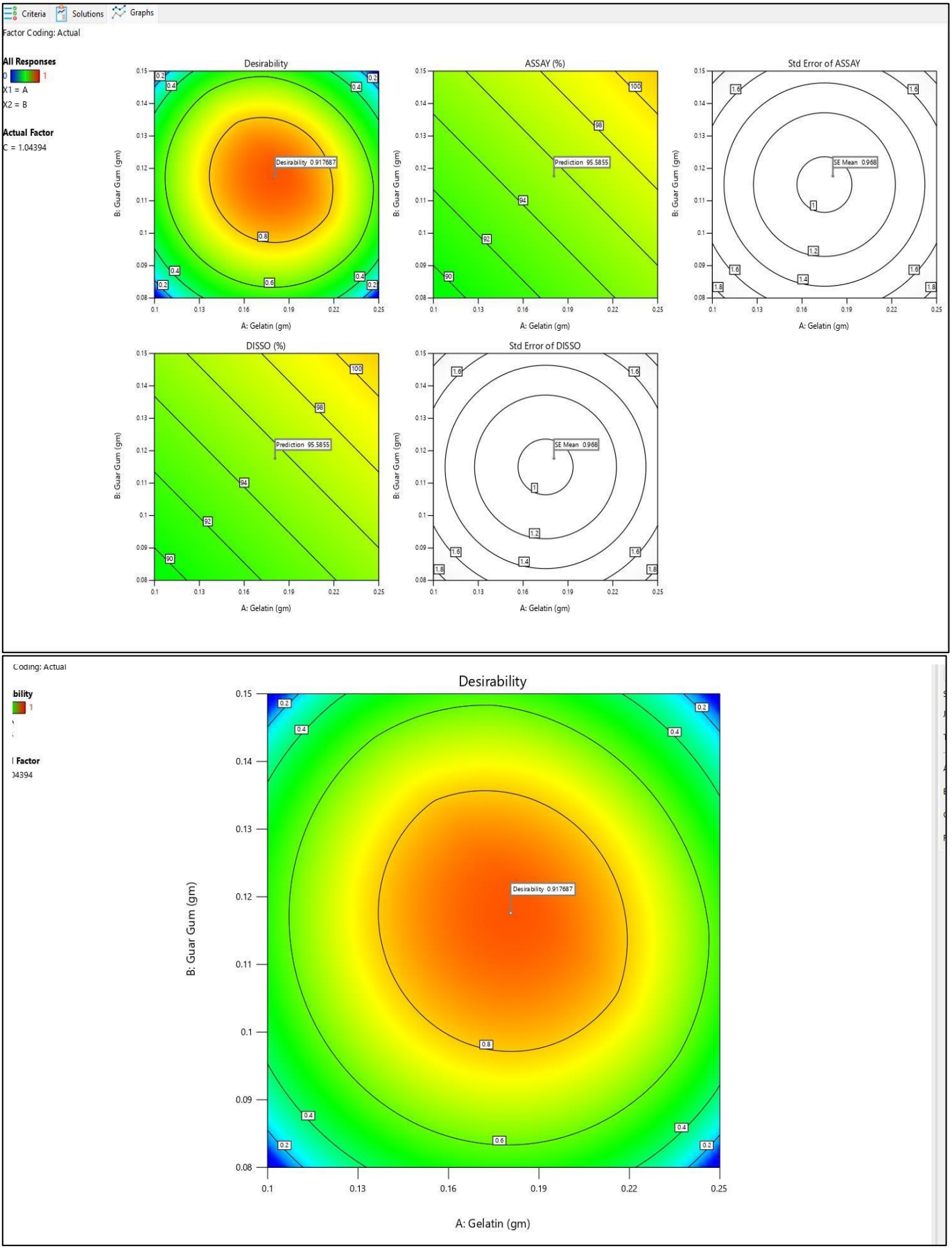

Fig 5 Contour Plots of the Measured Responses.

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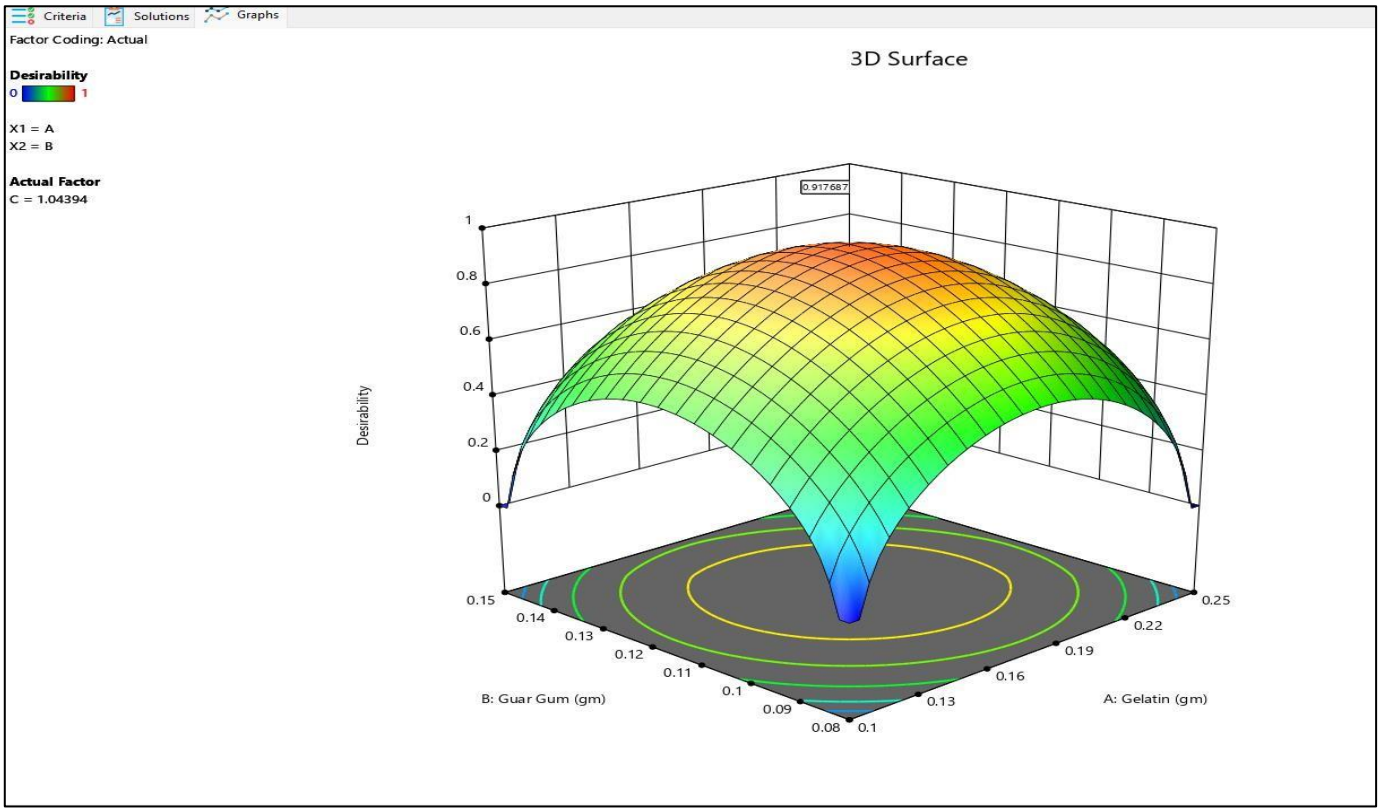

Fig 6 Three-Dimensional Response-Surface Plot.

Constraints

	Name	Goal	Lower Limit	Upper Limit	Lower Weight	Upper Weight	Importance
	A:Gelatin	is in range	0.2	1	1	1	3
	B:Guar Gum	is in range	0.2	0.8	1	1	3
	C:Sucrose	is in range	2	3	1	1	3
	ASSAY	is target = 96	70	109	1	1	3
	StdErr(ASSAY)	minimize	0.859817	1.82395	1	1	3
	DISSO	is target = 96	70	109	1	1	3
	StdErr(DISSO)	minimize	0.859817	1.82395	1	1	3

Solutions Starting Points

Solutions

1 Solutions found

Number	Gelatin	Guar Gum	Sucrose	ASSAY	StdErr(ASSAY)	DISSO	StdErr(DISSO)	Desirability	
1	**0.630**	**0.523**	**2.688**	**95.591**	**0.968**	**95.591**	**0.968**	**0.935**	**Selected**

Fig 7 Desirability Analysis: Solutions and Constraints.

➢ *Calibration Curve*

Loratadine obeyed the Beer–Lambert law over the concentration range studied at λmax 247 nm. The calibration data are given in Table 3 and the resulting plot in Figure 8; the curve was linear with a regression equation of y = 0.0245x and a correlation coefficient (R^2) of 0.9995, confirming its suitability for quantification of the drug.

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Table 3 Calibration-Curve Data for Loratadine (λmax 247 nm).

S. No	Concentration (µg/mL)	Absorbance
1	0	0
2	2	0.052
3	4	0.094
4	6	0.140
5	8	0.197
6	10	0.245
7	12	0.299

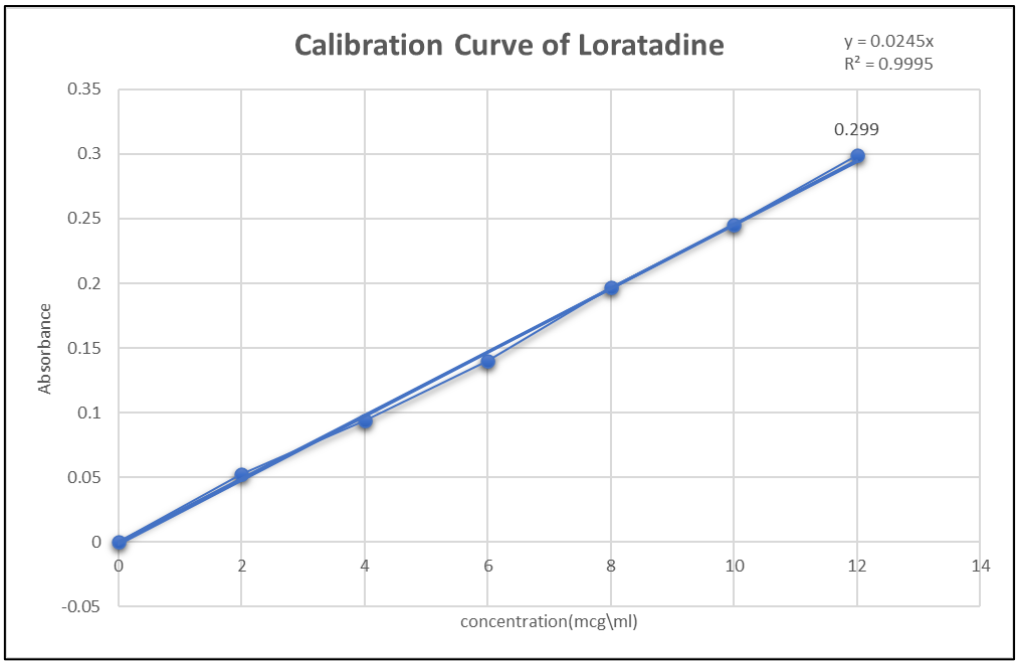

Fig 8 Calibration Curve of Loratadine.

➢ *Micromeritic Flow Properties*

The flow characteristics of loratadine were assessed prior to formulation and are summarised in Table 4. The bulk density, angle of repose (38°), Carr's compressibility index (22%) and Hausner's ratio together indicated that the drug exhibited passable flow, which was adequate for the wet-processing method employed in jelly preparation.

Table 4 Micromeritic Flow Properties of Loratadine.

Parameter	Value	Inference
Bulk density (g/mL)	0.360	—
Angle of repose (°)	38	Passable
Carr's compressibility index (%)	22	Passable
Hausner's ratio	1.28	Passable

➢ *Physicochemical Evaluation*

The physicochemical parameters of the five formulations are presented in Table 5. The surface pH of all formulations lay close to neutrality (6.5–6.9), indicating a low likelihood of oral irritation. The jellies were sufficiently viscous (12 650–14 300 cP) and showed acceptable spreadability, while the drug content ranged from 94.6 to 96.6% of the labelled amount, confirming uniform drug distribution across the batches.[5,8]

Table 5 Physicochemical Evaluation of the Loratadine Jelly Formulations.

Formulation	pH	Viscosity (cP)	Spreadability	Drug content (%)
F1	6.9	14300	7.65	96.6
F2	6.6	14205	6.90	94.6
F3	6.5	12650	6.80	95.4
F4	6.8	14253	6.90	96.2
F5	6.6	14265	7.10	96.1

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➢ *In Vitro Dissolution*

The comparative in vitro release profiles of the five formulations are given in Table 6 and illustrated in Figure 9. Drug release increased progressively over the 60-min study period for every formulation. Formulation F1 displayed the highest cumulative release, reaching approximately 89% at 60 min, followed by F3 (≈82%) and F2 (≈71%); F4 and F5 released the least (≈65% and 63%, respectively). The superior release from F1 can be attributed to the particular gelatin–guar gum ratio used, which produced a jelly that hydrated and eroded readily while retaining adequate consistency.[4,6]

Table 6 Comparative in Vitro Dissolution Profiles (% Drug Released).

Time (min)	F1	F2	F3	F4	F5
0	0	0	0	0	0
5	15	8	9	9	12
10	29	12	16	12	16
15	42	20	35	18	20
20	58	32	42	24	28
25	70	42	48	35	42
30	69	54	58	44	50
40	80	65	66	56	60
50	85	68	76	63	62
60	89	71	82	65	63

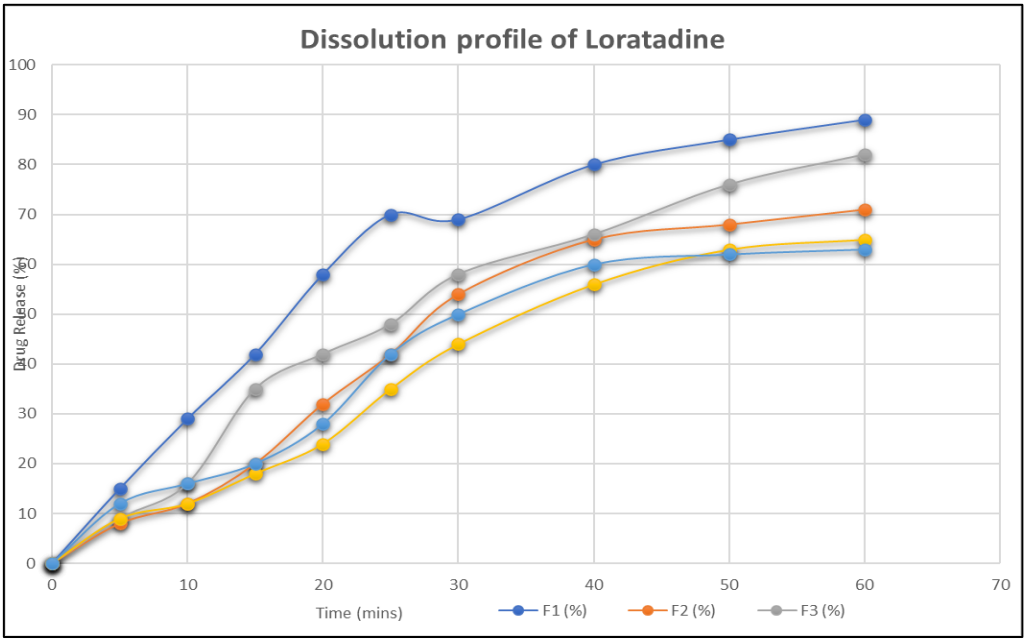

Fig 9 Comparative in Vitro Dissolution Profile of Formulations F1–F5.

➢ *Discussion*

The present study set out to develop and optimise an oral medicated jelly of loratadine using the natural polymers gelatin and guar gum, with citric acid as a cross-linking agent and water as the vehicle. Drug–excipient compatibility was confirmed by FT-IR, which showed no chemical interaction between the pure drug and the excipients.[3,12] Five formulations were prepared by systematically varying the polymer concentrations under the guidance of a DoE framework, and each was evaluated for pH, viscosity, spreadability, drug content and in vitro release.

All formulations were smooth, palatable and homogeneous, with near-neutral pH values that suggest good oral tolerability, and with drug content uniformly above 94%.[5,13] Differences in the gelatin–guar gum ratio were reflected mainly in the viscosity and the rate of drug release: the formulation with the most favourable balance (F1) combined adequate consistency with the fastest and most complete release, achieving about 89% within 60 min. This behaviour is consistent with earlier reports that the type and concentration of gelling polymer strongly influence the texture and dissolution of medicated jellies.[4,8] The DoE-based strategy allowed the effects of the polymers and their interactions to be evaluated efficiently and supported the rational identification of an optimised composition; the approach could readily be extended to refine the polymer levels and processing conditions further.[9]

Taken together, the results indicate that a gelatin–guar gum oral jelly is a viable, patient-friendly platform for delivering loratadine, offering ease of administration, pleasant organoleptic properties and satisfactory in vitro performance, and may be of particular value for paediatric, geriatric and dysphagic patients requiring allergy relief.[1,5]

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IV. CONCLUSION

An oral medicated jelly of loratadine was successfully formulated and optimised using gelatin and guar gum as natural gelling polymers, citric acid as a cross-linking agent and sucrose as a sweetener. FT-IR studies confirmed the absence of drug–excipient incompatibility, and all formulations were palatable, homogeneous and non-irritant, with near-neutral pH and uniform drug content. The optimised formulation (F1) released approximately 89% of the drug within 60 min, demonstrating rapid and near-complete dissolution. The developed jelly offers an easy-to-administer and acceptable dosage form that may improve patient compliance and allergy relief, particularly in paediatric, geriatric and dysphagic populations. Further in vivo, taste-evaluation and stability studies are warranted to confirm its clinical potential.

- *Declaration of Competing Interest*

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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