Design, Development and Characterization of Medicated Jellies by Using Different Gums

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Abstract: The present research describes the design and evaluation of a novel oral medicated jelly incorporating Cephalexin and Flurbiprofen, aimed at improving patient acceptability while ensuring rapid and reliable drug delivery. Comprehensive preformulation studies established the identity, purity, and compatibility of both active pharmaceutical ingredients with selected excipients. Cephalexin exhibited adequate solubility in commonly used solvents, whereas the poor solubility of Flurbiprofen necessitated formulation-level optimization to achieve uniform dispersion and release. Drug–excipient compatibility and thermal stability were confirmed through FTIR and DSC analyses, which showed no evidence of significant interactions.

A total of thirteen jelly formulations were prepared by varying gelling agent concentrations and pH modifiers to optimize physicochemical and release characteristics. Among them, formulation F5 emerged as the optimized composition, demonstrating an elegant appearance, acceptable pH (6.0), optimal viscosity (6140 cP), and excellent drug content uniformity (~99%). In-vitro dissolution studies indicated rapid and efficient drug release, with approximately 98% cumulative release achieved within 60 minutes. Stability studies conducted for 60 days revealed no significant changes in physical properties or drug content, confirming formulation robustness. Overall, the developed medicated jelly represents a novel, stable, and patient-friendly dosage form with potential clinical advantages for combined antibiotic and anti-inflammatory therapy.

Keywords: Medicated jelly, Cephalexin, Oral drug delivery, In-vitro release, Stability studies.

I.INTRODUCTION

The advancement of patient-centric and innovative drug delivery systems has become a key focus in contemporary pharmaceutical research, particularly for pediatric, geriatric, and dysphagic populations who experience difficulty swallowing conventional solid dosage forms. In this context, medicated jellies have gained increasing attention as a promising oral delivery platform due to their palatable nature, ease of administration, and non-invasive characteristics. These semi-solid formulations rapidly disintegrate or dissolve in the oral cavity, eliminating the need for water and significantly improving patient compliance. Their soft texture, pleasant mouthfeel, and flexibility in accommodating diverse active pharmaceutical ingredients (APIs) make medicated jellies well suited for personalized and on-demand therapeutic applications. The incorporation of natural and synthetic gums plays a critical role in defining the rheological behavior, drug release characteristics, and stability of jelly formulations. Gelling agents such as xanthan gum, guar gum, and carrageenan are particularly advantageous owing to their biocompatibility, mucoadhesive properties, and ability to form stable gels under mild processing conditions.

Cephalexin, a first-generation cephalosporin antibiotic, exhibits broad-spectrum antibacterial activity primarily against Gram-positive organisms and selected Gram-negative bacteria by inhibiting bacterial cell wall synthesis. It is widely prescribed for respiratory tract, skin, soft tissue, urinary tract, and ear infections, and is known for its favorable safety profile and high oral bioavailability. Despite its therapeutic efficacy, administration of Cephalexin in conventional tablet or capsule form can be challenging for patients with swallowing difficulties, often leading to poor compliance. Incorporation of Cephalexin into a medicated jelly matrix offers a patient-friendly alternative that may enhance dosing accuracy, improve drug stability, and effectively mask the unpleasant taste associated with cephalosporin antibiotics, thereby increasing acceptance among pediatric and elderly patients.

Flurbiprofen is a potent non-steroidal anti-inflammatory drug (NSAID) belonging to the

propionic acid derivative class, widely used for its analgesic, anti-inflammatory, and antipyretic effects. It exerts its pharmacological action through inhibition of cyclooxygenase enzymes, resulting in reduced prostaglandin synthesis responsible for pain and inflammation. Although effective, conventional oral administration of Flurbiprofen is often associated with gastrointestinal irritation and patient discomfort, particularly during prolonged therapy. Delivery through a medicated jelly system may facilitate rapid drug release, enhance mucosal absorption, and potentially minimize gastrointestinal adverse effects. Moreover, the jelly dosage form improves ease of administration and patient comfort, making it especially beneficial for individuals requiring frequent analgesic therapy.

The present study is directed toward the formulation, development, and characterization of medicated jellies using different gelling agents to assess their influence on physicochemical properties, drug release behavior, and formulation stability. The combined incorporation of Cephalexin and Flurbiprofen represents a novel dual-therapeutic strategy aimed at simultaneous management of bacterial infection and associated inflammation. This approach is expected to enhance therapeutic efficacy while improving patient compliance and convenience. Systematic evaluation through physicochemical characterization, in-vitro drug release studies, and stability testing provides critical insight into the potential of medicated jellies as an advanced and patient-friendly oral drug delivery system.[1-25]

II.MATERIALS AND METHODS

MATERIALS:

The present study employed a range of pharmaceutical-grade materials and excipients to formulate and evaluate medicated jellies. Cephalexin, a first-generation cephalosporin antibiotic, was procured from Sigma-Aldrich, while Flurbiprofen, a non-steroidal anti-inflammatory drug, was obtained from Yarrow Chem Products. These active pharmaceutical ingredients (APIs) were selected for their broad therapeutic applications and compatibility with oral jelly formulations.

METHODS:[25-52]

Pre-formulation Studies

Pre-formulation studies were conducted to evaluate the physicochemical properties of Cephalexin and Flurbiprofen before formulation development. These studies help in understanding the drug's behavior and compatibility with excipients, and in designing an effective dosage form.

Physical Characteristics and Melting Point

Cephalexin and Flurbiprofen were visually examined for physical attributes. Both appeared as white to off-white crystalline powders. Their melting points were determined using the capillary method to assess purity and stability.

Solubility Studies

Solubility of both drugs was evaluated in various solvents including water, ethanol, methanol, phosphate buffer (pH 6.8), and 0.1 N HCl. Drug solutions were shaken for 24 hours, filtered, and analyzed via UV spectrophotometry to determine solubility profiles essential for formulation.

UV-Visible Spectroscopy and λmax Determination

UV-Vis spectroscopy was used to identify the λmax of each drug by scanning in the 200–400 nm range. These values were used for further drug quantification in formulations.

Calibration Curve Preparation

Standard and working solutions of Cephalexin and Flurbiprofen were prepared in phosphate buffer (pH 6.8). A calibration curve was plotted over a range of concentrations (5–30 µg/mL for Cephalexin and 1–11 µg/mL for Flurbiprofen), and absorbance was measured to establish linearity.

Formulation and Development of Medicated Jelly

Cephalexin and Flurbiprofen-loaded medicated jellies were formulated using the heating and congealing technique. A sucrose syrup was prepared by dissolving sucrose in water and heating to 80°C with constant stirring. Gelatin was dissolved separately in warmed water and added to the sucrose solution under continuous agitation. Cephalexin (100 mg) and Flurbiprofen (200 mg) were then incorporated, followed by excipients such as citric acid, dextrose, methyl paraben, and orange oil. The mixture was poured into single-use molds, allowed to cool, and jellify. After setting, jellies were wrapped in butter paper and stored for further evaluation.

Table 1: Formulation table of Cephalexin and Flurbiprofen loaded medicated jelly (10 mg)

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Cephalexin	100	150	200	100	100	150	200	100	150	200	100	150	200
Flurbiprofen	200	300	400	200	200	300	400	200	300	400	200	300	400
Guar Gum	200	300	400	–	–	–	–	–	–	–	–	–	–
Xanthan Gum	–	–	–	200	–	–	–	–	–	–	–	–	–
Gelatin	–	–	–	–	300	400	200	–	–	–	–	–	–
Sodium Alginate	–	–	–	–	–	–	–	300	400	200	–	–	–
Pectin	–	–	–	–	–	–	–	–	–	–	300	400	200
Citric Acid	5	5	5	5	5	5	5	5	5	5	5	5	5
Dextrose	10	10	10	10	10	10	10	10	10	10	10	10	10
Methyl Paraben	10	10	10	10	10	10	10	10	10	10	10	10	10
Orange Oil	10	10	10	10	10	10	10	10	10	10	10	10	10
Sucrose	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000
Purified Water	Q.S.	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Preformulation Studies

Preformulation studies were conducted to assess the flow and physical properties of the powdered excipients used in jelly formulation. Bulk density and tapped density were measured by weighing a 10 g sample in a graduated cylinder before and after tapping. Hausner's ratio was calculated to evaluate flowability. The angle of repose was determined by allowing the powder to form a cone through a funnel, and measuring the angle formed by the heap to infer powder flow characteristics.

Risk Assessment of Jelly Formulation

A risk estimation matrix (REM) was used to identify and evaluate critical process parameters (CPPs) such as gelling agent concentration, pH adjuster, stirring speed, and heating temperature that could affect critical quality attributes (CQAs) including drug release, viscosity, and pH. Each parameter was rated as low, medium, or high risk based on its impact.

Formulation Optimization Using QbD and Box-Behnken Design

Formulation optimization was achieved using the Quality by Design (QbD) approach via Box-Behnken Design (BBD) with Design Expert software (v13.0). Three independent variables (amounts of drug, gelling agent, and pH adjuster) were analyzed at three levels (−1, 0, +1) across 13 experimental runs. The impact of these variables on viscosity, pH, and drug release was assessed using a second-order quadratic polynomial model, helping identify optimal formulation parameters.

Evaluation of Medicated Jelly

1. Physical Appearance:

Jellies were evaluated visually for clarity, color, smoothness, transparency, and absence of grittiness or air bubbles.

2. pH Determination:

A 1 g jelly sample was dispersed in 10 mL of distilled water and the pH was measured using a digital pH meter, targeting a range suitable for oral administration (4.0–7.0).

3. Weight Variation:

Ten jellies from each batch were weighed individually to assess consistency. Average weight and standard deviation were calculated.

4. Content Uniformity:

Drug content was analyzed by dissolving individual jellies in phosphate buffer, filtering, and measuring absorbance using UV spectroscopy at respective λmax values.

5. Viscosity Measurement:

Viscosity was determined with a Brookfield Viscometer using an appropriate spindle at room temperature (25 ± 1°C). Measurements were taken in triplicate and reported in cP.

6. Gel Strength:

Gel strength was evaluated by measuring the time required for a 50 g weight to penetrate 5 cm into the jelly, indicating mechanical firmness.

7. Syneresis Study:

Jellies were stored at room and refrigerated temperatures, and observed at 24, 48, and 72 hours for any liquid separation, indicating stability.

III.RESULT AND DISCUSSION

Pre-formulation Studies of Cephalexin and Flurbiprofen

The pre-formulation evaluation of Cephalexin and Flurbiprofen included analysis of physical characteristics, melting point, and solubility profile. Both drugs were found to be white crystalline powders with a free-flowing nature, suitable for oral jelly formulation. Cephalexin was odorless, while Flurbiprofen exhibited a slight characteristic odor. Melting point determination using the capillary tube method confirmed the identity and purity of both drugs, with observed values aligning with standard references—indicating their thermal stability under mild heating. Solubility studies revealed that Cephalexin is freely soluble in ethanol, methanol, and 0.1 N HCl, with moderate solubility in phosphate buffer (pH 6.8), making it suitable for both gastric and intestinal absorption. In contrast, Flurbiprofen showed poor aqueous solubility and slight solubility in buffer and acidic media, though it was soluble in ethanol and methanol. These findings highlight the need for solubilizers or formulation strategies to enhance Flurbiprofen's dispersion in jelly formulations.

FTIR Spectra of Cephalexin

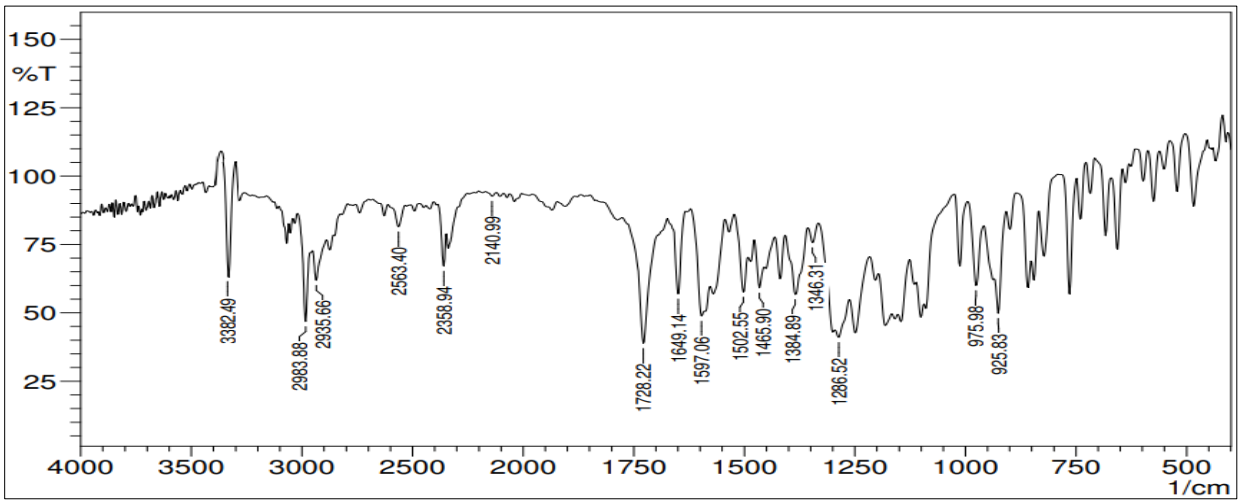

Figure 1: FTIR Spectra of Cephalexin

FTIR Spectra of Flurbiprofen

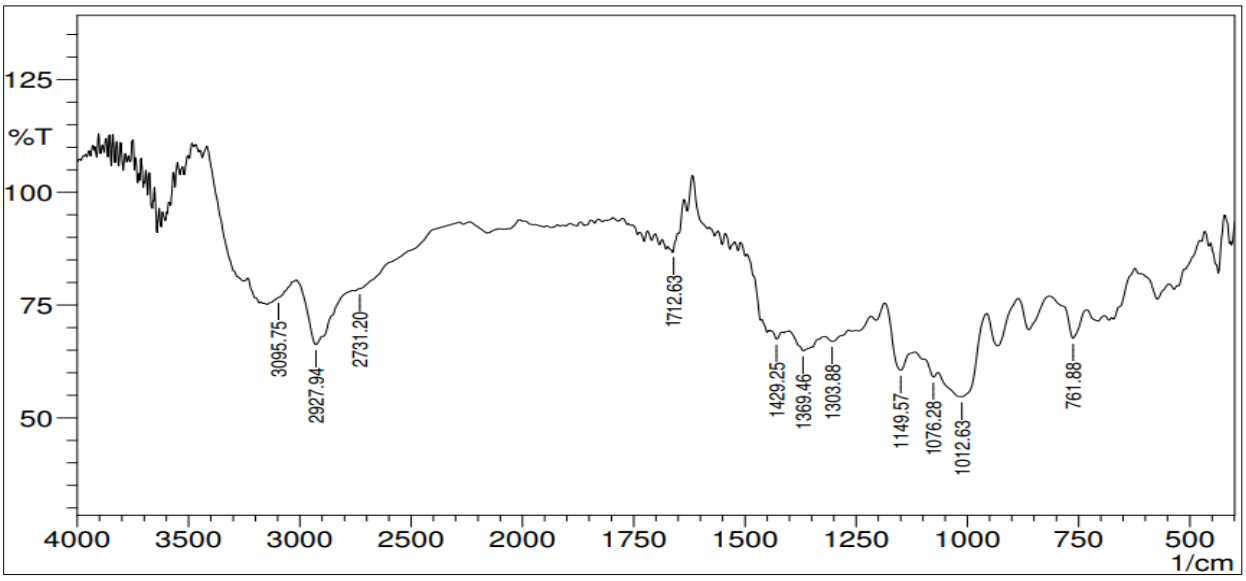

Figure 2: FTIR Spectra of Flurbiprofen

FTIR Spectra of Cephalexin and Flurbiprofen with excipients mixture

The FTIR spectrum of the mixture containing Cephalexin, Flurbiprofen, Gelatin, Citric Acid, and Dextrose displays characteristic peaks confirming the presence of multiple functional groups. A broad, intense band around 3300–3400 cm^{-1} corresponds to overlapping O–H and N–H stretching vibrations, indicating the presence of hydroxyl groups (from citric acid and dextrose), carboxylic acids, and peptide bonds (gelatin and cephalexin). A strong peak near 1700–1725 cm^{-1} represents C=O stretching of carboxylic acids and amide groups, confirming contributions from flurbiprofen, citric acid, and cephalexin. Amide I and II bands appear around 1650 cm^{-1} and 1540 cm^{-1}, typical of peptide bonds in gelatin and cephalexin. The aromatic C=C stretching from flurbiprofen and cephalexin is observed around 1500–1600 cm^{-1}, and a unique C–F stretch around 1150 cm^{-1} confirms the presence of fluorine in flurbiprofen. The C–O stretching vibrations between 1050–1250 cm^{-1} further support the presence of alcohol and acid functionalit`ies from citric acid, dextrose, and cephalexin. The spectrum thus confirms the coexistence of all key functional groups from the components in the mixture.

Calibration curve for Cephalexin

The regression equation was found to be y=0.0407x+0.0227 with regression coefficient 0.9995 which is closer to 1 states the concentration is in linear proportion. The concentration range for the calibration was found to be 5-30 µg/ml at λ_{max} 236nm. Maximum wavelength was found to be 236nm.

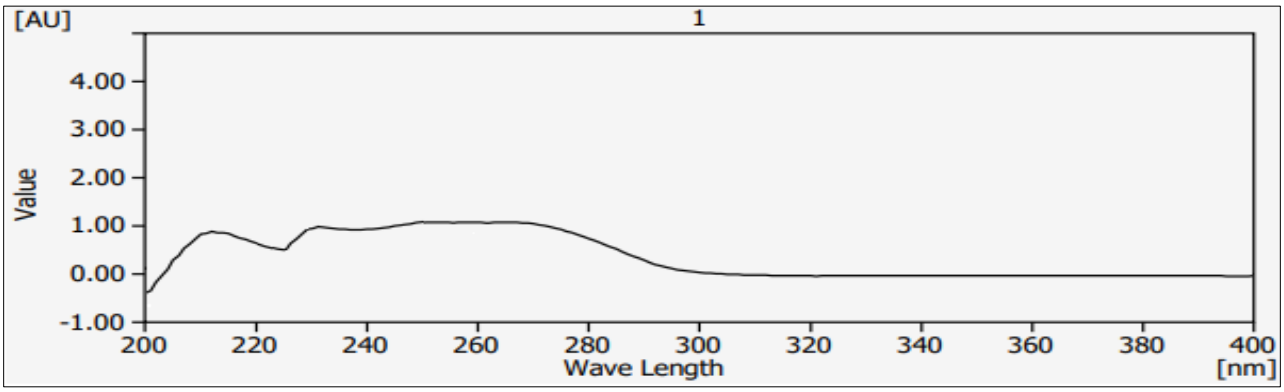

Figure 3: Calibration curve for Cephalexin (Maximum wavelength)

Calibration curve for Flurbiprofen

The regression equation was found to be y=0.0936x+0.0944 with regression coefficient 0.9993 which is closer to 1 states the concentration is in linear proportion. The concentration range for the calibration was found to be 1-11 µg/ml at 247nm. Maximum wavelength was found to be 247 nm.

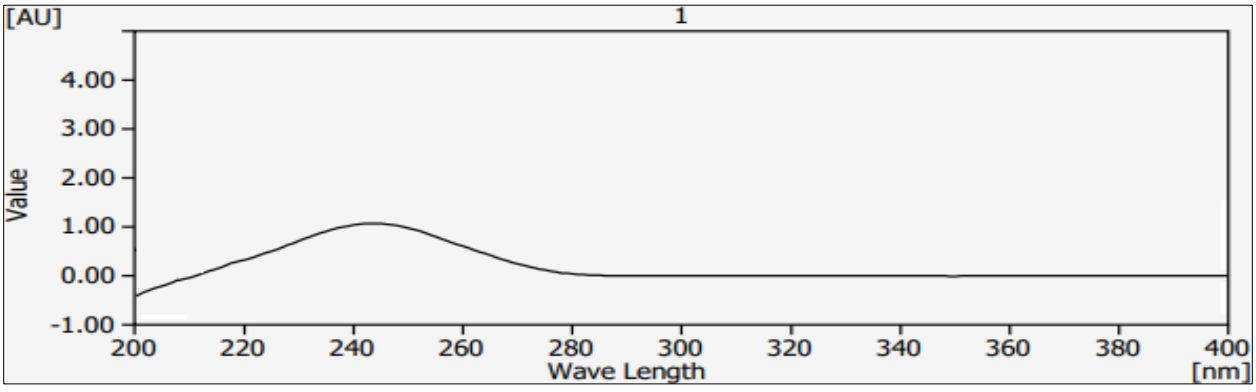

Figure 4: Calibration curve for Flurbiprofen (Maximum wavelength)

Formulation and development of medicated jelly formulation

Preformulation Study:

The bulk and tapped densities across the formulations are within acceptable ranges, with slight variations indicating uniform granule packing. Hausner ratios

ranged between 1.20–1.22, suggesting good to fair flow properties. The angle of repose values mostly fall between 29.5° to 33.5°, confirming fair to good flow characteristics of the powder blends. These parameters ensure that the formulations have favorable flow properties, crucial for consistent dosing and processing in jelly preparation.

Table 2: Preformulation Evaluation Parameters for Jelly Formulations

Formulation	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Hausner Ratio	Angle of Repose (°)
F1	0.51	0.62	1.21	30.2
F2	0.50	0.60	1.20	29.8
F3	0.55	0.66	1.20	33.5
F4	0.53	0.64	1.21	31.6
F5	0.50	0.61	1.22	29.9
F6	0.52	0.63	1.21	30.8
F7	0.51	0.62	1.22	31.4
F8	0.54	0.65	1.20	32.5
F9	0.53	0.64	1.21	31.7
F10	0.55	0.66	1.20	32.8
F11	0.49	0.59	1.20	29.5
F12	0.52	0.63	1.21	30.7
F13	0.50	0.60	1.20	30.0

Formulation Development and Optimization of medicated jelly

Heating and congealing technique generated thirteen Cephalexin and Flurbiprofen medicated jelly formulations which were then improved using the QbD-enabled DOE approach. Nonetheless, optimization has aided in determining how formulation parameters, such as Viscosity (Y1), drug release (Y2), and pH (Y3), impact the responses. The estimated quality target product profile (QTTP) and the main goal for creating improved medicated jelly. They used 100-300: 200-600 mg drugs (Cephalexin and Flurbiprofen, respectively), 200-400 mg of gelling agent, and 0.5-1.5% of pH adjuster to develop medicated jelly. Additionally, the actual values closely matched the predicted ones for every response. The statistical impacts of the all formulation factors interaction on Y1. For the quadratic model, specific component concentrations were significant, yielding p-values of 0.0082, 0.0413, and 0.0416 for Y1, Y2, and Y3, respectively. Consequently, Y1-Y3 are significantly impacted (*$p < 0.05$) by the interplay of variables A and B (alterations in the quantity of drug and gelling agent). At the same time, factor C had little impact on the responses instead of Y3. Thus, the quadratic model is used to analyze the design space. Accordingly, the most significant coefficient values of factor A for Y1 (+6128.00 cP), Y2 (+77.00%), and Y3 (+6.10) in the generated polynomial equations on the interaction of aspects on answers like Y1, Y2, and Y3 confirmed the considerable effect of factors A and B on all responses. Drug and gelling agent conc., ultimately lead to an increase in viscosity and drug release as well as no impact on pH, as seen by the significant effects of factors A and B on viscosity and drug release. On the other hand, higher viscosity can retard drug release, leading to sustained drug release at the site of action. The % error, which was less than 5%, showed that the projected and experimental values were very close. The percentage inaccuracy assisted in forecasting the precision of the program's equations. A 100:200 mg medication combination of Cephalexin and Flurbiprofen, 300 mg of gelling agent, 0.5% of pH adjuster, was used to manufacture an optimal batch of F5 medicated jelly. At the same time, the final optimized medicated jelly composition. The target values for viscosity (6140 cP), optimal drug release (92%), and ideal pH (6.0) were met by this mixture. This formulation was chosen for additional examination as every result accurately correlated with the F5 medicated jelly formulation.

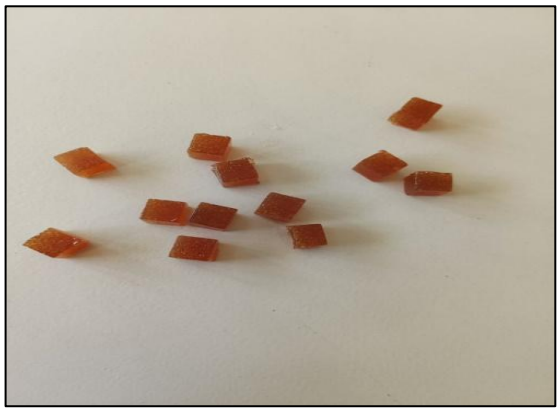

Figure 5: Prepared Medicated Jelies

Table 3: Optimization of Cephalexin and Flurbiprofen Medicated Jelly Formulation

Formulation	Formulation factors			Responses		
	A: Drug ratio (1:2) (Cephalexin: Flurbiprofen) (mg)	B: Gelling agent Conc. (mg)	C: pH Adjuster (%)	Y_1: Viscosity (cP)	Y_2: Drug release (%)	Y_3: pH
F1	-1	-1	0	4259	87	6.2
F2	0	-1	-1	4590	93	5.4
F3	1	1	0	7450	64	5.9
F4	1	0	1	6287	83	6.5
F5	*-1*	*0*	*-1*	*6140*	*92*	*6.0*
F6	0	1	-1	6980	72	5.3
F7	-1	0	1	5872	75	6.5
F8	1	0	-1	6327	79	5.5
F9	0	1	1	6627	74	6.3
F10	-1	1	0	6480	78	5.8
F11	0	-1	1	4129	96	6.4
F12	0	0	0	6128	77	6.1
F13	1	-1	0	4832	98	6

Table 4: the statistical impacts of the all formulation factors interaction

Independent Variables	Level used, actual coded		
	Low (-1)	Medium (0)	High (+1)
A= Drug ratio (Cephalexin: Flurbiprofen) (mg)	100:200	200:400	300:600
B= Gelling agent Conc. (mg)	200	300	400
C= pH Adjuster (%)	0.5	1.0	1.5

Evaluation of Medicated Jelly Formulations

The prepared medicated jellies were evaluated for physical appearance, pH, weight variation, content uniformity, viscosity, gel strength, and syneresis. Batch F5 consistently outperformed others across all parameters. It exhibited a clear, smooth, glossy appearance without stickiness or grittiness. The pH of F5 was 6.0, falling within the ideal oral range (4.0–7.0), ensuring both stability and patient comfort. Weight variation in F5 was minimal (1.9%), indicating uniformity in dosage. Content uniformity analysis revealed 99.0% drug content, confirming consistent distribution of active ingredients. The viscosity of 6140 cP was optimal for easy administration and stability, while gel strength testing showed excellent mechanical stability with strong structure. Moreover, F5 showed no syneresis under storage conditions, indicating high formulation stability. Overall, Batch F5 was identified as the most suitable jelly formulation for further development and clinical application.

Table 5: Evaluation Parameters of medicated jelly batches

Evaluation Parameter	Batch F1	Batch F2	Batch F3	Batch F4	Batch F5	Batch F6	Batch F7	Batch F8	Batch F9	Batch F10	Batch F11	Batch F12	Batch F13
pH	6.2	5.4	5.9	6.5	6.0	5.3	6.5	5.5	6.3	6.4	6.1	6.0	6.0
Weight Variation (%)	3.2	2.8	4.5	4.2	1.9	3.5	3.1	3.3	4.0	3.7	3.0	3.2	3.4
Content Uniformity (%)	97.8	95.6	98.0	96.7	99.0	94.5	96.2	97.2	95.8	96.4	94.7	95.9	96.5
Viscosity	4259	4590	7450	6287	6140	6980	5872	6327	6627	6480	4129	6128	4832

(cP)													
Gel Strength (seconds)	40	38	50	42	55	48	44	46	49	43	41	47	40
Syneresis	No	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes

In-Vitro Drug Release Study

The in-vitro drug release study was conducted using USP Type II paddle apparatus to assess the release characteristics of different jelly batches. Among the thirteen formulations (F1–F13), Batch F5 demonstrated a superior release profile with a cumulative drug release of 98% within 60 minutes, outperforming all other batches. This suggests an efficient and sustained release pattern, potentially due to the optimal interaction of the drug with the gum used in F5. The consistent and higher release rate supports its candidacy as the optimized batch for further development.

Table 6: *In-Vitro* Drug Release Studies of all Formulations (% release)

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
5	12	15	10	14	16	11	13	12	13	14	11	13	15
10	25	28	22	26	30	24	25	27	25	26	23	26	29
15	40	43	38	41	48	39	40	42	41	44	38	41	45
30	60	63	58	61	70	59	60	62	60	64	57	61	68
45	75	78	72	76	85	74	75	77	76	79	73	76	82
60	89	90	88	91	98	89	88	89	90	91	87	89	96

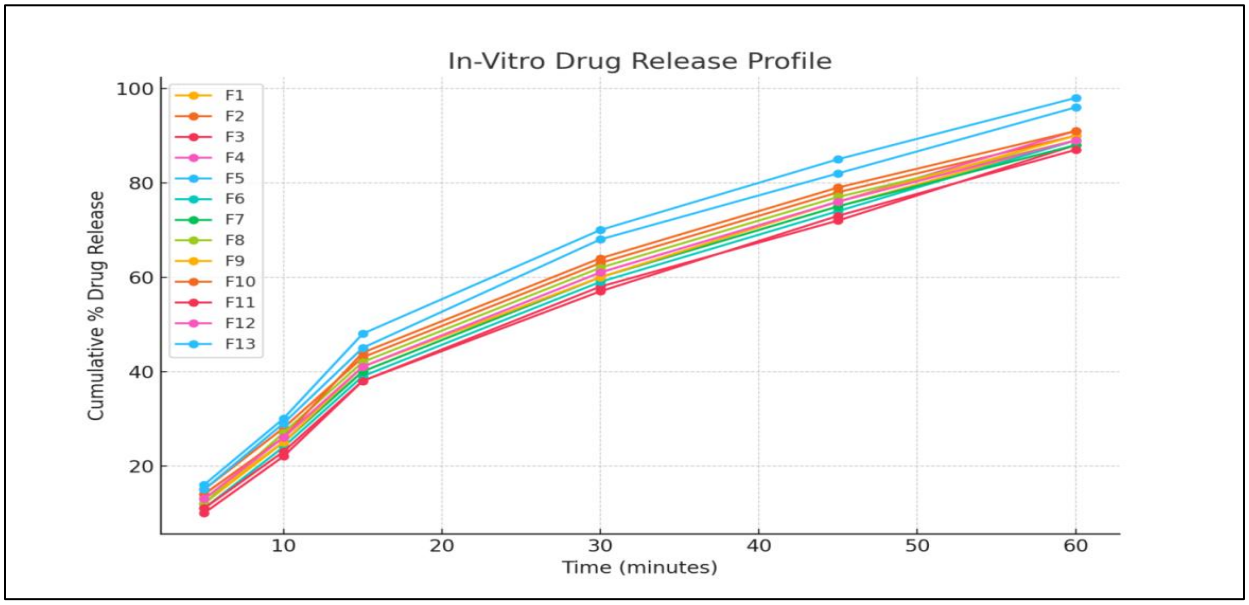

Figure 6: *In-vitro* Drug Release Profile

CONCLUSION

The present study successfully demonstrated the formulation and optimization of a novel medicated jelly containing Cephalexin and Flurbiprofen, designed to enhance patient compliance and ensure reliable drug delivery. Comprehensive preformulation and formulation studies led to the identification of batch F5 as the optimized formulation, which exhibited an elegant appearance, acceptable pH, minimal weight variation, excellent content uniformity (~99%), optimal viscosity, adequate gel strength, and absence of syneresis under stability conditions. In-vitro release studies confirmed rapid and efficient drug release, achieving approximately 98% release within 60 minutes, while stability evaluation over 60 days indicated negligible degradation and consistent physicochemical properties. Collectively, these

findings highlight the potential of the developed medicated jelly as a stable, patient-friendly oral dosage form for combined antibiotic and anti-inflammatory therapy, meriting further in-vivo evaluation and clinical validation for future pharmaceutical development.

CONFLICTS OF INTERESTS:
None.

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