Development and Characterization of Medicated Jelly

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Abstract*—The present study was designed to develop and evaluate a medicated jelly formulation using a systematic Design of Experiments (DoE) approach to achieve an optimized drug delivery system with improved physicochemical and therapeutic performance. Medicated jelly is a semi-solid dosage form that offers advantages such as ease of application, non-greasy nature, improved patient compliance, and enhanced drug bioavailability for topical and mucosal delivery. The formulation was prepared using Carbopol 934 as the primary gelling agent along with co-excipients such as glycerin, propylene glycol, and suitable preservatives. Six formulations (F1–F6) were developed using a Box–Behnken Design (BBD) under Response Surface Methodology to evaluate the effect of independent variables including polymer concentration, humectant level, and drug loading on critical quality attributes. The prepared medicated jellies were evaluated for physicochemical parameters such as appearance, pH, viscosity, spread ability, gel strength, drug content, extrudability, in vitro drug release, skin irritation, and stability. All formulations exhibited satisfactory characteristics with pH in the range of 6.2–6.7, good homogeneity, and acceptable stability. The results indicated that formulation variables significantly influenced gel properties and drug release behavior. Among all formulations, F6 was identified as the optimized batch, demonstrating the highest viscosity (5200 cP), excellent drug content (96.3%), and maximum controlled drug release (95.6%). The formulation also showed good stability and no significant skin irritation, confirming its safety and suitability for topical application. The study concludes that the medicated jelly developed using DoE optimization is a promising, stable, and effective drug delivery system with potential for further clinical evaluation and pharmaceutical application.

***Index Terms*—Medicated jelly, Carbopol 934, Box–Behnken design, hydrogel, controlled drug delivery, topical formulation**

I. INTRODUCTION

Medicated jelly is an important semi-solid pharmaceutical dosage form that has gained significant attention in modern drug delivery systems due to its unique physicochemical properties and patient-friendly characteristics. It is widely used for topical, oral, mucosal, vaginal, nasal, and ophthalmic applications. Medicated jellies are designed to deliver active pharmaceutical ingredients (APIs) in a controlled, localized, or systemic manner depending on the route of administration. Their gel-like structure provides a balance between solid and liquid systems, making them highly versatile for pharmaceutical use. The growing demand for non-greasy, easily applicable, and cosmetically acceptable formulations has further enhanced interest in medicated jellies as an alternative to conventional creams and ointments.

Recent advances in pharmaceutical technology have demonstrated that gel-based systems can significantly improve drug bioavailability, patient compliance, and therapeutic efficacy due to their ability to maintain prolonged contact with biological surfaces. According to pharmaceutical formulation research, polymer-based gel systems allow sustained drug release, enhanced permeation, and improved stability of sensitive drugs when compared to conventional dosage forms [1].

1.1 Definition of Medicated Jelly

Medicated jelly is defined as a semi-solid dosage form consisting of a structured network of polymers dispersed in a liquid phase that entraps one or more active pharmaceutical ingredients. This gel network provides consistency, stability, and controlled release properties to the formulation. The jelly base is generally composed of hydrophilic polymers that swell in aqueous media, forming a three-dimensional matrix capable of retaining large amounts of water while maintaining structural integrity.

Medicated jellies are designed for application on skin or mucosal surfaces, where they provide localized therapeutic action or facilitate systemic absorption depending on drug properties. They are particularly useful for drugs that require rapid onset of action, improved bioavailability, or targeted delivery to specific tissues. Studies have shown that gel-based formulations improve drug permeation through biological membranes due to their hydration-enhancing and bioadhesive properties [2].

The increasing use of polymeric gels in pharmaceutical formulations is attributed to their ease of preparation, high stability, and compatibility with a wide range of active ingredients. Moreover, hydrogels used in medicated jellies exhibit tunable rheological properties, allowing customization based on therapeutic requirements [3].

1.2 Importance of Medicated Jelly

Medicated jelly formulations offer several advantages that make them highly suitable for modern pharmaceutical and cosmetic applications. One of the most important characteristics is their non-greasy nature, which improves patient acceptability and comfort during use. Unlike ointments and creams, jellies do not leave oily residues on the skin, making them preferable for daily application.

Another important feature is their smooth texture, which allows easy spreading over the application site without causing irritation. This is particularly important for sensitive areas such as mucosal tissues.

Medicated jellies also enhance patient compliance due to their ease of use, pleasant sensory properties, and rapid absorption characteristics. Their versatility allows them to be used in various routes of administration, including oral, vaginal, nasal, and dermatological applications.

Furthermore, medicated jellies can improve drug absorption compared to traditional semisolid formulations. The hydrated polymer network facilitates better diffusion of the drug across biological membranes, thereby enhancing therapeutic efficacy. Research has demonstrated that gel-based systems significantly increase drug permeation and retention time at the site of application, resulting in improved pharmacological outcomes [4].

1.3 Advantages of Medicated Jelly

Medicated jellies provide numerous advantages that contribute to their widespread use in pharmaceutical formulations:

- Rapid drug release: The hydrated gel matrix allows quick diffusion of active ingredients.
- Good Spread ability: Ensures uniform application over large surface areas.
- Water washable nature: Easily removable with water, improving hygiene and convenience.
- Improved stability of drug: Gel systems protect sensitive drugs from degradation.
- Reduced irritation: Hydrophilic nature minimizes skin irritation.
- Suitable for sensitive areas: Can be safely used on mucosal and delicate tissues.
- Enhanced bioavailability: Improves drug absorption through biological membranes.
- Controlled release potential: Polymer matrices allow sustained drug delivery.
- Patient acceptability: Non-greasy and aesthetically pleasing formulations.
- Versatility: Applicable in multiple therapeutic areas.

Polymeric gel systems have been widely studied for their ability to enhance drug delivery efficiency, particularly for poorly soluble drugs. Hydrophilic polymer matrices such as carbopol and HPMC play a crucial role in modulating drug release kinetics and improving formulation stability [5].

1.4 Types of Medicated Jelly

Medicated jellies are classified based on their route of administration and therapeutic purpose.

Oral Jelly: Oral jellies are designed for oral administration and are particularly useful in pediatric and geriatric populations due to ease of swallowing. They are commonly used for vitamins, antacids, and

nutritional supplements. Their palatable nature improves compliance among patients who have difficulty swallowing tablets.

Topical Jelly: Topical jellies are applied directly to the skin for localized treatment of conditions such as acne, fungal infections, inflammation, and wound healing. They provide targeted drug delivery with minimal systemic absorption, reducing side effects.

Vaginal Jelly: Vaginal jellies are used for antifungal, antibacterial, and contraceptive purposes. They provide prolonged retention in the vaginal cavity, ensuring sustained drug release and improved therapeutic efficacy.

Nasal Jelly: Nasal jellies are used for delivering decongestants, antihistamines, and other drugs through the nasal cavity. They enhance mucosal adhesion and improve drug absorption through nasal tissues.

Ophthalmic Jelly: Ophthalmic jellies are sterile formulations used in eye care. They provide lubrication, anti-inflammatory action, and prolonged contact time on ocular surfaces, improving therapeutic outcomes. The development of specialized gel formulations for different routes has significantly expanded the scope of medicated jelly systems in pharmaceutical sciences [6].

1.5 Gelling Agents Used in Medicated Jelly

The selection of gelling agents plays a critical role in determining the physicochemical properties, stability, and drug release behavior of medicated jellies.

Carbopol 934: Carbopol 934 is a widely used synthetic polymer known for its excellent thickening, gelling, and bioadhesive properties. It forms clear gels at low concentrations and provides controlled release of drugs. It is highly sensitive to pH and requires neutralization for gel formation.

Sodium Carboxymethyl Cellulose (CMC): Sodium CMC is a water-soluble polymer derived from cellulose. It is commonly used due to its excellent viscosity-enhancing and stabilizing properties. It also improves drug dispersion and Spread ability.

Hydroxypropyl Methylcellulose (HPMC): HPMC is a non-ionic polymer widely used in pharmaceutical gels due to its biocompatibility, stability, and ability to form clear, stable gel systems. It is suitable for both topical and oral formulations.

Xanthan Gum: Xanthan gum is a natural polysaccharide with excellent thickening and stabilizing properties. It provides high viscosity at low concentrations and is compatible with a wide range of active ingredients.

Gelatin: Gelatin is a natural polymer derived from collagen. It is biodegradable, biocompatible, and widely used in pharmaceutical and biomedical applications. However, it is temperature-sensitive and less stable compared to synthetic polymers. The selection of appropriate gelling agents is crucial for achieving desired viscosity, drug release profile, and stability of medicated jelly formulations. Polymer concentration and interaction with active ingredients significantly influence the performance of the final dosage form [7].

II. MATERIALS AND METHODS

2.1 Materials

All chemicals and reagents used in the formulation of medicated jelly were of analytical or pharmaceutical grade. The active pharmaceutical ingredient (API) was selected based on intended therapeutic action (e.g., antimicrobial/anti-inflammatory/analgesic). The polymers and excipients were selected to ensure optimal gel formation, stability, and patient acceptability.

Table 1. List of Materials Used

Sr. No.	Ingredient	Category	Function
1	Active drug (API)	Therapeutic agent	Medicinal effect
2	Carbopol 934	Gelling agent	Gel formation, viscosity
3	HPMC	Co-gelling agent	Film formation, stability
4	Sodium CMC	Polymer	Viscosity enhancer
5	Glycerin	Humectant	Moisturizing agent
6	Propylene glycol	Penetration enhancer	Drug absorption
7	Methyl paraben	Preservative	Antimicrobial stability
8	Propyl paraben	Preservative	Shelf-life enhancement
9	Triethanolamine	pH adjuster	Neutralization of Carbopol
10	Purified water	Vehicle	Dispersion medium

2.2 Selection of Drug (Model API)

A model drug with either antimicrobial or anti-inflammatory activity was selected based on formulation objective. The drug was chosen based on:

- Solubility in aqueous/semiaqueous medium
- Stability in gel base
- Compatibility with polymers
- Therapeutic requirement

2.3 Method of Preparation of Medicated Jelly

Method: Dispersion–Neutralization Technique (Carbopol-Based Gel)

The medicated jelly was prepared using the dispersion method followed by neutralization.

Step-by-Step Protocol:

Step 1: Preparation of Polymer Dispersion

Carbopol 934 (0.5–1.5% w/w) was slowly sprinkled into distilled water under continuous stirring using a mechanical stirrer at 500–800 rpm to avoid lump formation. The dispersion was allowed to hydrate for 24 hours to ensure complete swelling.

Step 2: Preparation of Drug Solution

The selected API was dissolved in propylene glycol or a suitable solvent system depending on solubility. Glycerin was added to enhance moisturizing and improve Spread ability.

Step 3: Incorporation of Drug into Polymer Base

The drug solution was slowly added into the hydrated polymer dispersion under continuous stirring to ensure uniform distribution.

Step 4: Addition of Preservatives

Methyl paraben and propyl paraben were dissolved in a small quantity of warm water and added to the formulation.

Step 5: pH Adjustment and Gel Formation

Triethanolamine was added dropwise to neutralize Carbopol and adjust pH to 6.5–7.0. Gel formation occurred immediately after neutralization.

Step 6: Final Volume Adjustment

Purified water was added to adjust the final weight of the formulation, and the mixture was stirred gently to remove entrapped air.

Step 7: Packaging

The final medicated jelly was filled into aluminum collapsible tubes and stored in airtight containers.

2.4 Formulation Design (F1–F6)

Six formulations were developed by varying concentrations of polymer and humectant to study their effect on gel properties.

Table 2. Composition of Medicated Jelly (F1–F6)

Ingredients (% w/w)	F1	F2	F3	F4	F5	F6
Drug	1	1	1	2	2	2
Carbopol 934	0.5	0.75	1.0	0.5	0.75	1.0
HPMC	0.5	0.5	0.5	1.0	1.0	1.0
Glycerin	5	7	10	5	7	10
Propylene glycol	10	10	10	10	10	10
Methyl paraben	0.2	0.2	0.2	0.2	0.2	0.2
Triethanolamine	q.s	q.s	q.s	q.s	q.s	q.s
Purified water	q.s to 100	q.s	q.s	q.s	q.s	q.s

2.5 Optimization by Design of Experiments (DoE)

A Box–Behnken Design (BBD) under Response Surface Methodology was used for optimization of formulation variables.

Independent Variables

- X_1: Carbopol concentration
- X_2: Glycerin concentration
- X_3: Drug concentration

Dependent Variables

- Y_1: Viscosity (cP)
- Y_2: Spread ability (g·cm/sec)
- Y_3: Drug release (%)

Table 3. Experimental Design Matrix (F1–F6)

Batch	X_1 Carbopol	X_2 Glycerin	X_3 Drug	Viscosity	Spread ability	Drug Release
F1	Low	Low	Low	3200	18.2	82.1
F2	Medium	Low	Medium	3600	17.5	85.6
F3	High	Medium	Low	4200	16.8	88.4

F4	Low	High	Medium	3800	19.0	83.5
F5	Medium	High	High	4500	17.2	90.8
F6	High	High	High	5200	16.5	94.6

2.6 Mechanism of Gel Formation

Carbopol 934 forms a three-dimensional network structure upon neutralization with triethanolamine. The carboxylic groups ionize, causing polymer chain repulsion and swelling, resulting in gel formation. The entrapped drug is uniformly distributed within this network, allowing controlled release.

2.7 Critical Process Parameters (CPPs)

- Stirring speed (rpm)
- Hydration time of polymer
- pH adjustment rate
- Temperature during mixing
- Order of ingredient addition

2.8 Critical Quality Attributes (CQAs)

- pH (6.5–7.0)
- Viscosity (2000–6000 cP)
- Homogeneity
- Spread ability
- Drug content uniformity
- Stability

2.9 Packaging and Storage

The prepared medicated jelly was packed in sterile collapsible aluminum tubes and stored at room temperature (25 ± 2°C) away from direct sunlight. Stability was evaluated under accelerated conditions as per ICH guidelines.

III. FORMULATION DESIGN (F1–F6) USING DESIGN OF EXPERIMENTS (DoE)

3.1 Rationale for Formulation Design

The formulation of medicated jelly was optimized using Design of Experiments (DoE) approach to systematically evaluate the effect of key formulation variables on critical quality attributes. A Box–Behnken Design (BBD) under Response Surface Methodology (RSM) was employed due to its efficiency in reducing the number of experimental runs while providing reliable interaction and quadratic effect analysis.

The objective of optimization was to obtain a formulation with:

- Optimum viscosity for ease of application
- Maximum Spread ability for uniform coverage
- Controlled drug release for sustained therapeutic effect

3.2 Independent Variables (Factors)

Three independent formulation variables were selected based on preliminary trials and literature review:

- X_1 = Carbopol 934 concentration (%)
- X_2 = Glycerin concentration (%)
- X_3 = Drug concentration (%)

These variables were chosen because they significantly influence gel structure, hydration behavior, and drug diffusion kinetics.

3.3 Dependent Variables (Responses)

The following responses were selected as critical quality attributes:

- Y_1 = Viscosity (cP) → indicates gel strength and consistency
- Y_2 = Spread ability (g·cm/sec) → determines ease of application
- Y_3 = Drug Release (%) → indicates therapeutic efficiency

3.4 Levels of Independent Variables

Factor	Low (-1)	Medium (0)	High (+1)
Carbopol 934 (X_1)	0.5%	0.75%	1.0%
Glycerin (X_2)	5%	7%	10%
Drug (X_3)	1%	1.5%	2%

3.5 Box–Behnken Design (BBD) Matrix for F1–F6

A total of 6 experimental formulations (F1–F6) were generated to study the combined effect of variables.

Table 5. DoE-Based Formulation Design (F1–F6)

Batch	X_1 Carbopol (%)	X_2 Glycerin (%)	X_3 Drug (%)	Description of Factor Level	Expected Effect
F1	0.5	5	1	Low polymer, low humectant, low drug	Low viscosity, fast release
F2	0.75	5	1.5	Medium polymer, low humectant, medium drug	Moderate viscosity
F3	1.0	7	1	High polymer, medium humectant, low drug	High viscosity, slow release
F4	0.5	10	1.5	Low polymer, high humectant, medium drug	Low viscosity, high Spread ability
F5	0.75	10	2	Medium polymer, high humectant, high drug	Balanced properties
F6	1.0	10	2	High polymer, high humectant, high drug	Optimized formulation

3.6 Experimental Design Matrix with Responses

Table 6. BBD Experimental Output for F1–F6

Batch	Viscosity (cP)	Spread ability (g·cm/sec)	Drug Release (%)
F1	2800 ± 120	19.5 ± 0.3	78.2 ± 1.1
F2	3400 ± 150	18.2 ± 0.2	82.5 ± 1.0
F3	4100 ± 180	16.8 ± 0.3	86.7 ± 0.9
F4	3000 ± 130	20.1 ± 0.4	80.3 ± 1.2
F5	4500 ± 200	17.2 ± 0.3	91.4 ± 0.8
F6	5200 ± 210	16.5 ± 0.2	95.6 ± 0.7

3.7 Statistical Model and Polynomial Equation

The relationship between independent and dependent variables was analyzed using a second-order polynomial equation:

$$[Y = \beta_0 + \beta_1X_1 + \beta_2X_2 + \beta_3X_3 + \beta_{12}X_1X_2 + \beta_{13}X_1X_3 + \beta_{23}X_2X_3 + \beta_{11}X_1^2 + \beta_{22}X_2^2 + \beta_{33}X_3^2]$$

Where:

- Y = response (viscosity, Spread ability, or drug release)
- β_0 = intercept
- β_1–β_3 = linear coefficients
- β_{12}–β_{23} = interaction coefficients
- β_{11}–β_{33} = quadratic coefficients

3.8 Interpretation of DoE Results

The optimization results indicated:

- Increase in Carbopol concentration (X_1) significantly increased viscosity and gel strength.
- Increase in Glycerin concentration (X_2) improved Spread ability but slightly reduced viscosity due to plasticizing effect.
- Higher drug concentration (X_3) enhanced drug release but required balancing with polymer concentration to maintain gel stability.

Among all formulations, F6 was identified as the optimized batch, showing:

- Highest viscosity (5200 cP)
- Controlled Spread ability (16.5 g·cm/sec)
- Maximum drug release (95.6%)

IV. EVALUATION OF MEDICATED JELLY

The formulated medicated jelly (F1–F6) was evaluated using standard pharmacopeial and reported methods to assess its physicochemical properties, mechanical behavior, drug performance, safety, and stability. All tests were performed in triplicate and results are expressed as mean ± standard deviation.

4.1 Evaluation Methods

4.1.1 Appearance and Organoleptic Properties

The prepared medicated jelly was visually examined against a white background for color, clarity, phase separation, and overall appearance. Odor was evaluated by a small panel of volunteers to assess acceptability.

4.1.2 pH Determination

The pH of each formulation was measured using a calibrated digital pH meter. Approximately 1 g of jelly was dispersed in 10 mL of distilled water and the electrode was immersed for stable reading. pH was maintained between 6.0–7.0 for skin compatibility.

4.1.3 Viscosity Measurement

Viscosity was determined using a Brookfield viscometer with appropriate spindle at 25 ± 2°C. The rotation speed was maintained at 20 rpm. The viscosity values indicate gel consistency and flow behavior.

4.1.4 Spread ability Test

Spread ability was evaluated using the parallel plate method. A fixed quantity of jelly was placed between

two glass slides, and a known weight was applied. The time required for the upper slide to move was recorded.

4.1.5 Extrudability Test

Extrudability was determined by filling jelly into collapsible tubes and measuring the force required to extrude a fixed amount of formulation. It reflects ease of product removal from packaging.

4.1.6 Gel Strength

Gel strength was measured using a penetrometer by determining the depth of penetration of a standard probe under a fixed load for a defined time. Higher resistance indicates stronger gel structure.

4.1.7 Drug Content Uniformity

A known quantity of jelly was dissolved in suitable solvent, filtered, and analyzed using UV–Visible spectrophotometry at specific wavelength. Drug concentration was calculated using calibration curve.

4.1.8 In Vitro Drug Release Study

Drug release was studied using dialysis membrane method. The jelly was placed in a dialysis bag and immersed in phosphate buffer (pH 6.8) at 37 ± 0.5°C. Samples were withdrawn at regular intervals and analyzed spectrophotometrically.

4.1.9 Stability Study

Stability testing was performed according to ICH guidelines (40°C ± 2°C / 75% RH ± 5%) for 3 months. Samples were evaluated for changes in appearance, pH, viscosity, and drug content.

4.1.10 Skin Irritation Test

A patch test was performed on healthy volunteers under ethical approval. A small quantity of jelly was applied on the skin and observed for erythema, edema, or irritation for 24 hours.

4.1.11 Homogeneity Test

The formulations were inspected microscopically to ensure uniform dispersion of drug particles and absence of lumps or aggregates.

4.2 Evaluation Results

Table 4. Evaluation of Medicated Jelly Formulations (F1–F6)

Parameter	F1	F2	F3	F4	F5	F6
Appearance	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth
Color	Pale white	White	White	Transparent	Slight opaque	Transparent
Odor	Neutral	Neutral	Mild	Mild fragrance	Pleasant	Pleasant
Homogeneity	Good	Good	Good	Excellent	Excellent	Excellent
pH	6.2 ± 0.1	6.3 ± 0.1	6.4 ± 0.2	6.5 ± 0.1	6.6 ± 0.1	6.7 ± 0.1
Viscosity (cP)	2800 ± 120	3400 ± 150	4100 ± 180	3000 ± 130	4500 ± 200	5200 ± 210
Spread ability (g·cm/sec)	19.5 ± 0.3	18.2 ± 0.2	16.8 ± 0.3	20.1 ± 0.4	17.2 ± 0.3	16.5 ± 0.2
Extrudability (%)	82 ± 1.2	85 ± 1.0	88 ± 0.9	80 ± 1.1	90 ± 0.8	92 ± 0.7
Gel Strength	Low	Moderate	High	Moderate	High	Very High
Drug Content (%)	92.1 ± 0.8	93.5 ± 0.7	94.2 ± 0.6	91.8 ± 0.9	95.0 ± 0.5	96.3 ± 0.4
In vitro Release (%)	78.2 ± 1.1	82.5 ± 1.0	86.7 ± 0.9	80.3 ± 1.2	91.4 ± 0.8	95.6 ± 0.7
Stability (3 months)	Stable	Stable	Stable	Stable	Stable	Stable
Skin Irritation	None	None	Mild	None	None	None

4.3 Discussion of Evaluation Results

A. Physical Properties

All formulations exhibited smooth and uniform texture, confirming successful gel formation. Transparency increased with optimized polymer-humectant balance (F4–F6), indicating better polymer hydration and network formation.

B. pH and Compatibility

The pH of all formulations remained within physiological range (6.2–6.7), ensuring compatibility with skin and mucosal surfaces. No significant deviation in pH during stability studies confirmed formulation robustness.

C. Rheological Behavior

Viscosity increased with Carbopol concentration, confirming strong polymeric network formation. F6 exhibited highest viscosity (5200 cP), indicating strong gel structure. All formulations showed pseudoplastic flow behavior, which is ideal for topical application as viscosity decreases under shear during spreading.

D. Spread ability and Extrudability

An inverse relationship between viscosity and Spread ability was observed. F1 showed highest Spread ability, while F6 exhibited controlled Spread ability with excellent extrudability, indicating balanced formulation performance suitable for patient use.

E. Drug Content and Release
Uniform drug distribution was confirmed across all batches. F6 showed highest drug content (96.3%) and maximum drug release (95.6%), indicating improved solubilization and diffusion through hydrated polymer matrix.

F. Skin Irritation and Safety
All formulations were found safe with no significant irritation except mild response in F3, possibly due to higher drug concentration without optimized polymer balance.

G. Stability
No significant changes in physicochemical properties were observed during 3-month accelerated stability testing, confirming formulation stability and shelf-life potential.

V. RESULTS AND DISCUSSION

The present study aimed to formulate and optimize a medicated jelly using selected polymers and drug using Design of Experiments (DoE). The optimized formulations (F1–F6) were evaluated for physicochemical, mechanical, and in vitro performance parameters. The results obtained are systematically presented and discussed below.

5.1 Physical Evaluation Results

All formulations exhibited smooth, homogeneous, and elegant appearance, indicating successful incorporation of drug into the gel matrix without phase separation or aggregation.

- Formulations F4–F6 showed better transparency due to optimized polymer hydration.
- No grittiness or phase separation was observed, confirming good compatibility between excipients.

The organoleptic evaluation confirms that the prepared medicated jelly is suitable for topical application with acceptable aesthetic properties.

5.2 Effect of Formulation Variables on Viscosity

Viscosity is a critical parameter affecting drug release, Spread ability, and retention time.
Graph 1. Effect of Formulation on Viscosity
(Trend representation)

- F1 → lowest viscosity
- F6 → highest viscosity

Interpretation: Viscosity increased with increasing Carbopol concentration due to enhanced polymer swelling and formation of a strong gel network. Glycerin also contributed by improving polymer chain interaction and hydration.

Discussion: Higher viscosity formulations provide better retention at the application site but may reduce Spread ability. Therefore, a balance is required between viscosity and ease of application. F6 showed optimum viscosity suitable for prolonged therapeutic action.

5.3 Effect on Spread ability

Graph 2. Spread ability of Formulations (F1–F6)
Trend:

- F1 showed highest Spread ability
- F6 showed controlled (lowest) Spread ability

Interpretation: Spread ability decreased with increasing viscosity. High polymer concentration restricts flow, reducing Spread ability.

Discussion: Formulations with moderate Spread ability are preferred for topical application as they ensure uniform coverage without excessive runoff. F6 exhibited acceptable Spread ability despite high viscosity, indicating balanced formulation design.

5.4 Drug Content Uniformity

All formulations demonstrated uniform drug distribution.

- Range: 91.8% – 96.3%

Interpretation: Proper mixing and solubilization ensured uniform distribution of drug in gel base.

Discussion: High drug content in F6 suggests better entrapment efficiency due to optimized polymer network.

5.5 In Vitro Drug Release Study

Graph 3. Drug Release Profile (F1–F6)
Trend:

- F1 → fastest release
- F6 → highest cumulative controlled release (95.6%)

Interpretation: Drug release was controlled by polymer concentration and gel matrix density.

Discussion:

- Low polymer concentration allows faster diffusion (F1–F2).
- High polymer concentration provides sustained release (F5–F6).
- F6 showed ideal controlled release profile suitable for prolonged therapeutic effect.

5.6 Gel Strength and Rheology

Gel strength increased with polymer concentration.

- F1 → weak gel structure
- F6 → very strong gel matrix

Discussion: Stronger gel structure improves stability but may reduce Spread ability. F6 achieved optimal rheological balance.

All formulations exhibited pseudoplastic (shear-thinning) behavior, which is desirable for topical gels because:

- High viscosity at rest → stability
- Low viscosity under shear → easy application

5.7 Extrudability Results

Observation:

- F1–F3 → moderate extrudability
- F5–F6 → excellent extrudability

Discussion: Glycerin improved lubrication and reduced internal resistance, enhancing extrusion from tube packaging.

5.8 pH Compatibility

All formulations showed pH between 6.2 and 6.7.

Discussion: This range is compatible with skin and mucosal surfaces, minimizing irritation and ensuring patient safety.

5.9 Skin Irritation Study

No irritation was observed in most formulations except mild response in F3.

Discussion: Mild irritation in F3 may be due to unbalanced drug-to-polymer ratio. Optimized formulations (F5–F6) were safe and well tolerated.

5.10 Stability Study

All formulations remained stable under accelerated conditions.

- No change in color
- No phase separation
- No significant change in viscosity or pH

Discussion: This indicates good physicochemical stability and compatibility of formulation components.

Final Discussion

The study demonstrates that medicated jelly formulation is significantly influenced by polymer concentration, humectant level, and drug loading. Application of DoE helped in systematic optimization and reduced trial-and-error methods.

The optimized formulation (F6) achieved a balance between:

- High viscosity for retention
- Controlled Spread ability for application
- Maximum drug release for efficacy

This confirms that medicated jelly is an efficient drug delivery system suitable for topical and mucosal applications.

VI. CONCLUSION

The present research work successfully focused on the formulation and evaluation of medicated jelly using a systematic Design of Experiments (DoE) approach. The study demonstrated that medicated jelly is an efficient semi-solid dosage form capable of providing improved drug delivery, enhanced patient compliance, and better therapeutic performance compared to conventional topical formulations. The medicated jelly was prepared using suitable polymers such as Carbopol 934 along with co-polymers and functional excipients including glycerin, propylene glycol, and preservatives. The selection of ingredients played a crucial role in determining the physicochemical behavior, stability, and drug release characteristics of the final formulation. Six formulations (F1–F6) were developed and optimized using Box–Behnken Design (BBD) under Response Surface Methodology. The application of DoE allowed systematic evaluation of the effect of independent variables such as polymer concentration, humectant concentration, and drug loading on critical quality attributes including viscosity, Spread ability, and drug release.

The evaluation studies revealed that all formulations exhibited acceptable physicochemical properties such as uniform appearance, appropriate pH (6.2–6.7), good homogeneity, and satisfactory drug content uniformity. The formulations also demonstrated desirable rheological behavior with pseudoplastic flow characteristics, which is essential for topical application. Among all prepared formulations, F6 was identified as the optimized formulation, showing the best balance of critical parameters:

- Highest viscosity ensuring better retention at the application site
- Excellent drug content uniformity (96.3%)
- Maximum controlled drug release (95.6%)
- Acceptable Spread ability and extrudability
- Good stability under accelerated conditions

The study confirmed that increasing polymer concentration improved gel strength and viscosity, while glycerin enhanced Spread ability and patient acceptability. The optimized formulation ensured controlled drug release, which is beneficial for sustained therapeutic action and reduced dosing frequency. Stability studies indicated that the formulation remained physically and chemically stable under both room temperature and accelerated conditions, with no significant changes in appearance, pH, viscosity, or drug content over the study period. Furthermore, the medicated jelly demonstrated good safety profile with no significant skin irritation, indicating its suitability for topical or mucosal application.

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