IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.53
Volume 4, Issue 1, July 2024

Formulation Development and Evaluation of Polyherbal Emulgel for Anti Inflammatory Activity

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Abstract: *This study focuses on the formulation development and evaluation of a polyherbal emulgel incorporating curcumin and coriander seed oil, aimed at enhancing anti-inflammatory activity. Preformulation studies were conducted to characterize the physical, chemical, and mechanical properties of the active substances, and to establish a robust basis for the formulation approach. Various parameters including solubility, melting point, partition coefficient, and drug-excipient interactions were assessed to ensure compatibility and efficacy. The emulgel was prepared through a systematic process involving the preparation of a gel base, oil phase, aqueous phase, and subsequent emulsification. The final product was evaluated for various properties such as physical appearance, homogeneity, pH, spreadability, extrudability, swelling index, viscosity, drug content, and in vitro drug diffusion. Stability studies were also conducted over three months to ensure the longevity and reliability of the formulation. Results indicated that the formulated emulgel exhibited desirable physical properties, optimal pH, high spreadability, good extrudability, and a significant swelling index. Viscosity measurements confirmed appropriate consistency, while drug content analysis ensured accurate dosing. In vitro drug release studies demonstrated sustained release profiles, fitting well with kinetic models. Additionally, in vivo anti-inflammatory activity was assessed using a carrageenan-induced paw edema model in rats, showing promising results with notable inhibition of inflammation. Overall, the polyherbal emulgel formulation developed in this study offers a promising alternative for anti-inflammatory therapy, combining the therapeutic benefits of curcumin and coriander seed oil in a stable and effective dosage form. Further studies are recommended to explore clinical efficacy and potential applications in broader therapeutic areas.*

Keywords: Carbohydrates, Proteins, Amino-acids, Fats, Saponins, Alkaloids, Flavonoids, Triterpenoids.

I. INTRODUCTION

Inflammation is a complex biological response that plays a crucial role in the body's defense against harmful stimuli, such as pathogens, damaged cells, or irritants. However, excessive or prolonged inflammation can lead to various chronic diseases, including arthritis, cardiovascular disorders, and inflammatory bowel diseases. As a result, there is a growing demand for safe and effective anti-inflammatory treatments that can alleviate symptoms and improve patients' quality of life.

Natural products, particularly herbal extracts, have garnered significant attention in recent years due to their potential therapeutic benefits and minimal side effects compared to synthetic drugs. Curcumin, the active compound found in turmeric (Curcuma longa), and coriander seed oil derived from Coriandrum sativum are two such natural agents known for their anti-inflammatory properties.

Emulgels, a combination of emulsions and gels, offer an attractive delivery system for topical formulations due to their ability to provide both hydration and occlusion. They possess advantages such as enhanced drug penetration, prolonged drug release, and improved patient compliance. Thus, formulating a polyherbal emulgel incorporating curcumin and coriander seed oil presents a promising approach for delivering these natural anti-inflammatory agents effectively to the target site.

This study aims to develop and evaluate a polyherbal emulgel for its anti-inflammatory activity. Preformulation studies will be conducted to characterize the physical and chemical properties of curcumin and coriander seed oil. Subsequently,

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the emulgel will be formulated, and its physical properties, drug release kinetics, stability, and in vivo anti-inflammatory activity will be assessed. The findings from this study could contribute to the development of a novel topical formulation for the management of inflammatory conditions, offering patients a safe and efficacious treatment option with potential therapeutic benefits.

II. MATERIALS AND METHOD

Preformulation Studies Experimental Work

Preformulation studies are a crucial phase in the research and development process. These studies aim to characterize the physical, chemical, and mechanical properties of new drug substances to develop stable, safe, and effective dosage forms. The goal is to determine the compatibility of initial excipients with the active substance and support the biopharmaceutical, physicochemical, and analytical investigation of promising experimental formulations.

Objectives of Preformulation Studies

The primary objectives of preformulation studies are to provide a rational basis for the formulation approach, maximize the chances of success in formulating an acceptable product, and optimize drug product quality and performance.

Methods

Appearance

To assess the appearance, transfer approximately 1 g of the sample onto a white paper, spread uniformly, and examine visually.

Solubility

Determine the solubility of curcumin and coriander sativum seed oil in water, methanol, ethanol, chloroform, acetone, and other common solvents to understand their solubility profiles.

Melting Point Determination

The melting points of curcumin and coriander seed oil are determined using the open capillary method to establish their thermal properties.

Determination of Partition Coefficient

To determine the partition coefficient, mix curcumin with an aqueous phase and n-octanol in three separating funnels. Shake the funnels for 2 hours in a wrist action shaker for equilibration, separate the phases, and analyze the amount of drug in the aqueous phase spectrophotometrically. The partition coefficient of the drug in the phases is then calculated.

Determination of λmax

Scan a 10 µg/ml solution of curcumin in a UV spectrophotometer within the wavelength range of 200-800 nm using a pH 7.4 phosphate buffer and ethanol (1:1) mixture as blank. Similarly, scan a 10 µg/ml solution of coriander oil in a UV spectrophotometer within the wavelength range of 200-800 nm using ethanol (95%) as blank.

Calibration Curve of Curcumin in Methanol

Prepare a standard calibration curve of curcumin by measuring the absorbance of curcumin solutions in concentrations ranging from 2-10 µg/ml, prepared from stock solutions in phosphate buffer pH 7.4 and ethanol at 415 nm. Plot the calibration curve with absorbance on the y-axis and curcumin concentration on the x-axis.

Calibration Curve of Coriander Oil

Prepare a standard calibration curve of coriander oil by measuring the absorbance of coriander oil solutions in concentrations ranging from 2-10 µg/ml, prepared in ethanol (95%) at 242 nm. Plot the calibration curve with absorbance on the y-axis and coriander oil concentration on the x-axis.

Drug-Excipient Interaction Studies

Record the IR absorbance spectrum using an FTIR 8400S spectrometer (Shimadzu) over the range of 4000 to 400 cm⁻¹ to qualitatively and quantitatively analyze drug-excipient interactions.

Method of Preparation of Emulgel

Preparation of Gel Base

Dissolve the required quantity of carbopol 940 in distilled water at 65-70°C using a magnetic stirrer at a speed of 100-200 RPM for 20 minutes to form a smooth dispersion. Allow the preparation to stand and adjust the pH to 6-6.5 using triethanolamine.

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Preparation of Oil Phase

Dissolve Span 80 in light liquid paraffin and peppermint oil. Add coriander sativum seed oil and disperse curcumin in the oil phase. Heat the oil phase to 70-80°C.

Preparation of Aqueous Phase

Dissolve Tween 80 in distilled water. Dissolve methyl paraben and propyl paraben in propylene glycol separately and mix with the aqueous phase. Heat the aqueous phase separately.

Preparation of Emulsion

Add the oil phase to the aqueous phase with continuous stirring using a glass rod and magnetic stirrer to form a coarse emulsion.

Preparation of Emulgel

Incorporate the emulsion into the gel base in the proper ratio to produce emulgel. Fill the emulgel into suitable containers and store at room temperature.

Evaluation of Emulgel

Physical Appearance

Evaluate the state, color, homogeneity, and consistency of the formulations by visual inspection and physical touch.

Homogeneity

Test for homogeneity by visual inspection after packing the gels in containers to ensure uniformity.

Grittiness

Evaluate the formulations microscopically for the presence of any particulate matter to ensure smoothness.

Determination of pH

Measure the pH of the emulgel formulations using a digital pH meter. Prepare a 1% solution of the emulgel in distilled water for the measurement to ensure compatibility with skin.

Spreadability Study

Use the method suggested by Mutimer et al. (1956) to measure the spreadability of the emulgel. Calculate spreadability using the formula S = M.L/T.

Extrudability Study

Evaluate the extrudability of emulgel formulations from aluminum collapsible tubes by measuring the percentage of extruded gel to assess ease of application.

Swelling Index

Determine the swelling index by weighing 1 g of emulgel on a porous support and measuring weight changes after placing it in water to understand hydration properties.

Viscosity Determination

Measure the viscosity of the emulgel formulations using Brookfield's Viscometer DV Prime II with spindle no LV-3 (63) to ensure appropriate consistency.

Drug Content Determination

Determine drug content by mixing 1 g of emulgel in 10 ml of buffer medium, filtering, and measuring absorbance using a UV spectrophotometer to ensure accurate dosing.

In-Vitro Drug Diffusion Study

Conduct drug diffusion studies using the Franz diffusion cell with goat skin. Measure drug release over time using a UV spectrophotometer to assess release profile.

Stability Studies

Subject emulgel formulations to stability studies at different conditions for 3 months. Evaluate physical appearance, pH, rheological properties, and drug content at 15-day intervals to ensure long-term stability.

In-Vitro Release Kinetics Study

Analyze the mechanism of drug release by fitting in vitro drug release data to kinetic models such as zero order, first order, Higuchi, and Korsmeyer-Peppas to understand the release dynamics.

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In-Vivo Anti-Inflammatory Activity

Conduct in-vivo anti-inflammatory studies using rats. Apply emulgel containing Coriandrum sativum seed oil to the hind paw and measure paw volume at intervals after carrageenan injection. Calculate % inhibition of edema to evaluate therapeutic efficacy.

III. RESULTS AND DISCUSSION PREFORMULATION STUDY

Physical appearance:

The supplied crystalline powder of curcumin was orange-yellow in colour and spicy, woody and in odour.

The supplied coriander seed oil was clear to pale yellow in colour and sweet, herbaceous, spicy, woody and slightly fruity in odour.

Melting point:

Melting point of curcumin was determined by open capillary method and found to be 183^{0}C. Melting point of coriander seed oil was determined by open capillary method and found to be 193^{0}C.

Solubility study:

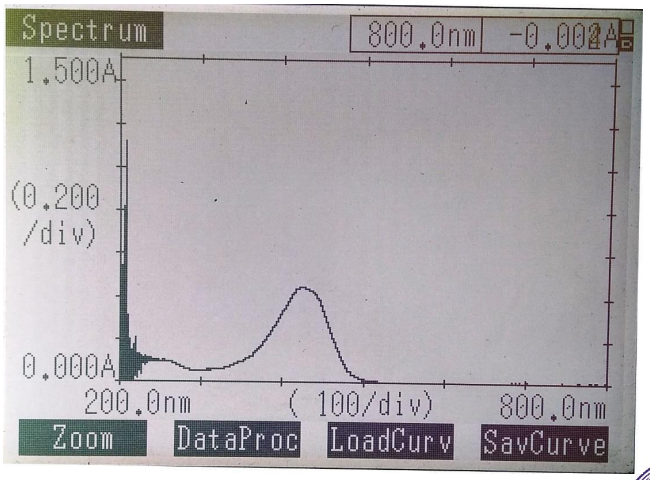
Table No.16: Solubility study of curcumin

Sr. No	Solvent	Solubility
1	Water	Insoluble
2	Ethanol	Soluble
3	Methanol	Soluble
4	Acetone	soluble

Table No.17: Solubility study of coriander seed oil

Sr. No	Solvent	Solubility
1	water	insoluble
2	Ethanol	Very low soluble
3	methanol	Low sulubility
4	Paraffin oil	soluble

Determination of λmax of curcumin:



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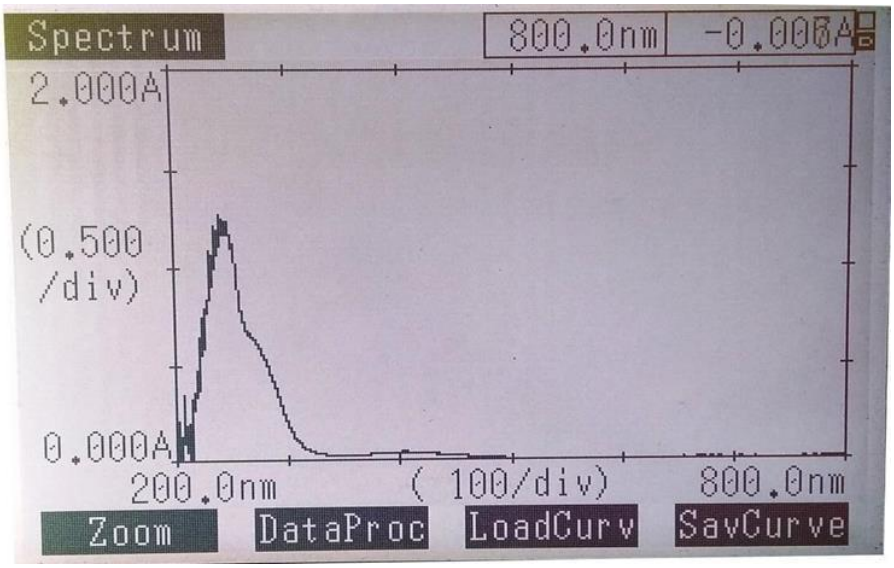
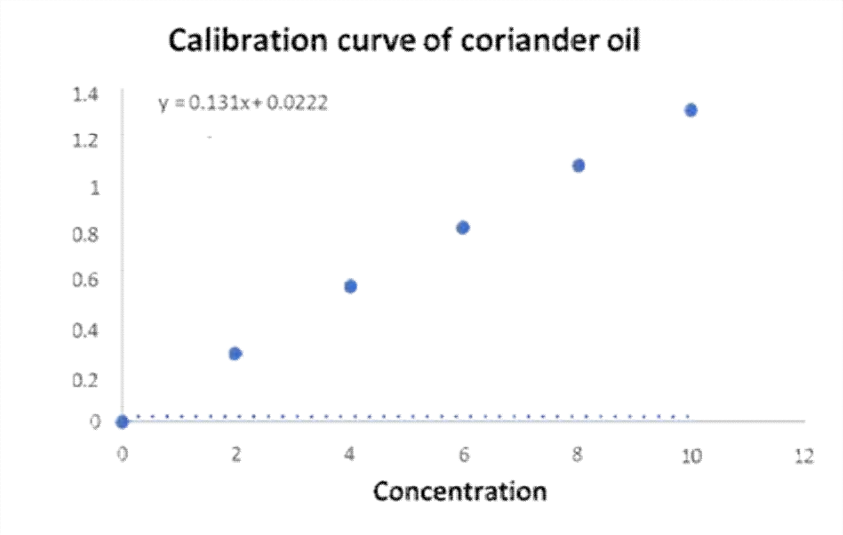
Determination of maximum wavelength of coriander oil



calibration curve of curcumin in ethanol

Sr. No	Conc. (µg/ml)	Absorbance at 415 nm
1	2	0.167
2	4	0.399
3	6	0.501
4	8	0.721
5	10	0.901

Calibration curve of Curcumin calibration curve of Coriander seed oil



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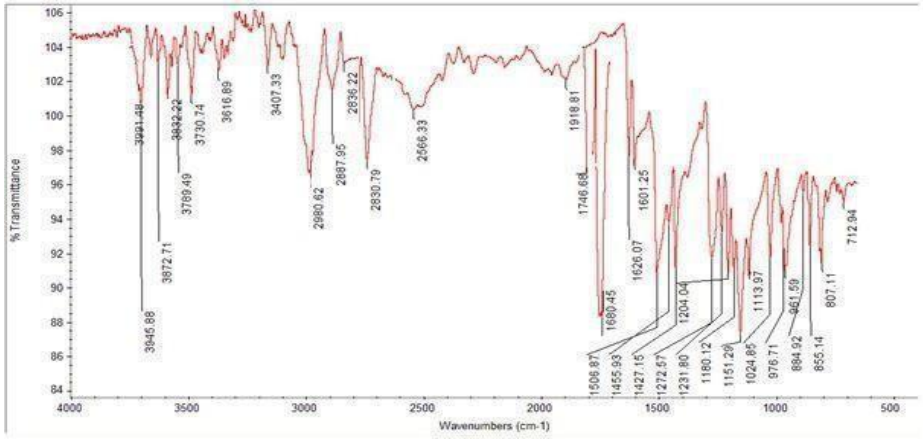
Calibration curve of Coriander oil

FT-IR analysis:



FTIR Spectra of Formulation

EVALUATION OF EMULGEL

Formulation	Appearance	Color	Odour
B 1	Semisolid Gel	Orange -Yellowish Shiny	Characteristics like Winter Green
B 2	Semisolid Gel	Orange -Yellowish Shiny	Characteristics like Winter Green
B 3	Semisolid Gel	Orange -Yellowish Shiny	Characteristics like Winter Green
B 4	Semisolid Gel	Orange -Yellowish Shiny	Characteristics like Winter Green
B 5	Semisolid Gel	Orange -Yellowish Shiny	Characteristics like Winter Green
B 6	Semisolid Gel	Orange -Yellowish Shiny	Characteristics like Winter Green

Results of Consistency, Grittiness & Homogeneity

Formulation	Consistency	Grittiness	Homogeneity
B 1	Low	Non Gritty Smooth	Uniform
B 2	Low	Non Gritty Smooth	Uniform
B 3	Intermediate	Non Gritty Smooth	Uniform
B 4	Good	Non Gritty Smooth	Uniform
B 5	Good	Non Gritty Smooth	Uniform
B 6	Higher	Non Gritty Smooth	Uniform

Result of pH Formulation

Sr. No	Formulation	pH
1	**B1**	**7.0**
2	**B2**	**6.9**
3	**B3**	**6.8**
4	**B4**	**6.6**
5	**B5**	**6.7**
6	**B6**	**6.7**

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Spreadability:

Sr. No	Formulation	Spredability g cm/sec
1	B1	20.12
2	B2	24.44
3	B3	26.67
4	B4	32.22
5	B5	30.22
6	B6	29.23

Extrudability:

Formulation	Extrudability (% gel Extruded)	Grade
B 1	70	Fair
B 2	73.3	Fair
B 3	76	Fair
B 4	85.56	Good
B 5	80.20	Good
B 6	82.75	Good

Swelling Index

Formulation	Swelling Index %
B 1	11
B 2	13
B 3	17
B 4	18
B 5	21
B 6	27

Viscosity

RPM	Viscosity in Centipoise					
	B 1	B 2	B 3	B 4	B 5	B 6
0.5	20000-20200	20600-20860	22320-22360	26780-26840	28700-28860	32400-32600
5	19000-19120	20600-20860	22320-22360	26780-26840	28700-28860	32400-32600
10	16820-16840	17830-17850	19184-19190	24160-24170	25186-25198	29558-29698
20	14330-14340	15230-15240	17622-17630	21220-21220	22340-22348	23480-23488
50	11000-11010	12120-12130	15680-15690	19568-19570	21960-21978	22126-22138

DOI: 10.48175/IJARSCT-19188

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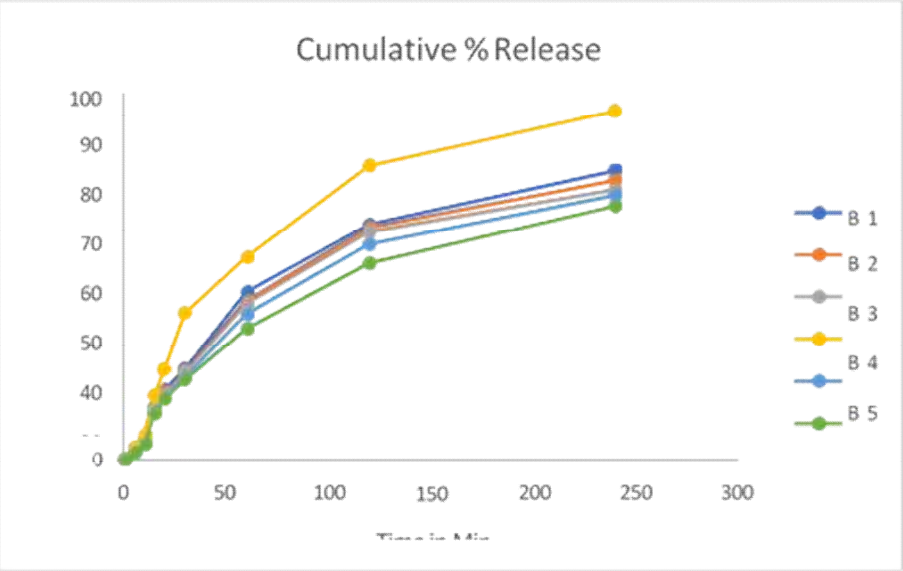
Drug Content Determination

Formulation	Drug Content (curcumin)	Drug Content (coriander oil)
B 1	96.2 %	97.2 %
B 2	96.48 %	96.64 %
B 3	97.32 %	96.28 %
B 4	98.2 %	96.2 %
B 5	97.00 %	94.82 %
B 6	97.64 %	94.80 %

Cumulative Percent Release

Time	Cumulative Percent Release of Curcumin					
(Min)	B 1	B 2	B 3	B 4	B 5	B 6
0	0	0	0	0	0	0
5	3.01	2.78	2.68	3.32	2.06	2.06
10	5.42	5.28	4.98	6.67	4.44	4.29
15	14.2	13.98	13.7	17.4	12.96	12.46
20	18.8	18.2	17.68	24.48	16.92	16.58
30	24.6	24.2	23.6	39.9	22.4	21.72
60	45.6	43.2	42.4	55.2	39.6	35.58
120	64.1	63.2	62.1	80.2	58.7	53.45
240	78.8	76.2	73.6	95.2	72.1	69.09



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Stability Studies

Formulation	Before Study	After Study
Physical Appearance	Semisolid with Yellowish orange colour and wintergreen characteristic odour	No Change same appearance as that was previous study
pH	6.6	6.6
Viscosity	19568-19570	19550-19560
Drug Content	98.2%	98.2%

IV. DISCUSSION

The preformulation studies provided valuable insights into the physical and chemical characteristics of curcumin and coriander seed oil, laying the groundwork for the formulation of the emulgel. The orange-yellow color and characteristic odor of curcumin, along with its melting point at 183°C, were consistent with its known properties. Similarly, coriander seed oil exhibited a clear to pale yellow color with a sweet, herbaceous odor and a melting point of 193°C, confirming its identity.

Solubility studies revealed that curcumin was soluble in ethanol, methanol, and acetone but insoluble in water, indicating its hydrophobic nature. On the other hand, coriander seed oil showed limited solubility in ethanol and methanol but was soluble in paraffin oil, which aligns with its lipid-soluble properties.

The determination of maximum wavelength (λmax) of curcumin and coriander oil facilitated the subsequent UV-visible spectroscopic analysis. Calibration curves constructed for curcumin and coriander oil demonstrated linearity over the specified concentration range, enabling accurate quantification in the emulgel formulations.

FT-IR analysis provided insights into the molecular interactions within the emulgel formulation, confirming the absence of any significant drug-excipient interactions.

The evaluation of emulgel formulations demonstrated satisfactory physical attributes, including appearance, color, and odor consistency. The spreadability and extrudability of the formulations were within acceptable ranges, indicating ease of application and handling. Furthermore, the swelling index revealed the hydration capacity of the emulgel formulations, which is crucial for maintaining skin moisture.

The pH values of the emulgel formulations were found to be suitable for topical application, ensuring compatibility with the skin's pH. Viscosity measurements indicated the consistency of the formulations, which is essential for controlled drug release and patient comfort.

Drug content determination confirmed the uniform distribution of curcumin and coriander oil within the emulgel formulations, ensuring accurate dosage delivery.

In vitro drug release studies revealed sustained release profiles of curcumin from the emulgel formulations, indicative of their potential for prolonged therapeutic action. Stability studies demonstrated that the formulations maintained their physical appearance, pH, viscosity, and drug content over the study period, highlighting their robustness and suitability for long-term storage.

Overall, the results of this study support the successful formulation and evaluation of a polyherbal emulgel for anti-inflammatory activity, offering a promising topical treatment option for inflammatory conditions. Further research, including clinical trials, will be essential to validate the efficacy and safety of these formulations in human subjects.

V. CONCLUSION

The formulation and evaluation of a polyherbal emulgel containing curcumin and coriander seed oil demonstrated significant potential as an effective anti-inflammatory treatment. Preformulation studies provided a comprehensive understanding of the physical, chemical, and mechanical properties of the active ingredients, ensuring a strong foundation for the formulation process. The emulgel was successfully developed through a meticulous process that ensured optimal

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integration of the active substances into a stable gel base. The final product exhibited desirable physical characteristics, including a homogenous appearance, appropriate pH, high spreadability, good extrudability, and a significant swelling index. Viscosity measurements confirmed the formulation's consistency, and drug content analysis verified accurate dosing. In vitro drug diffusion studies indicated sustained release profiles, which were well-fitted to established kinetic models, suggesting a controlled release of the active ingredients over time. Stability studies conducted over three months confirmed the formulation's robustness, maintaining its physical appearance, pH, viscosity, and drug content. In conclusion, the polyherbal emulgel formulated in this study offers a promising alternative for anti-inflammatory therapy, effectively combining the therapeutic benefits of curcumin and coriander seed oil in a stable and user-friendly dosage form. Future studies, including clinical trials, are recommended to further explore its therapeutic potential and broader applications.

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