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Formulation, Optimization And Evaluation Of Ibuprofen Herbal Emulgel.

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Abstract: Topical drug delivery system is dosage forms which are applied directly to skin to cure various disease. Compared to other semisolid formulations, gels offer more benefits in both cosmetic and pharmaceutical uses. Emulgel have become a promising option for delivering drugs that don't dissolve easily in water (hydrophobic drugs). Inflammation and rheumatism are still major health issues today. While there are many allopathic medicines gel available to treat inflammation, they often cause side effects such as skin irritation, Burning or Stinging sensation, Allergic reaction, Dryness or peeling of the skin. Herbal emulgels are generally considered to be safer alternatives compared to allopathic emulgels. This study focuses on formulating an herbal gel utilizing extracts of incarnating Turmeric (*curcuma longa*) for dermatological application. The herbal gel formulation was developed by combining aqueous phase and oil phase & base. The emulgel was tested using different parameters such as its physical appearance, pH level, spread ability, Viscosity and how well the drug diffuses. All the prepared emulgel batches showed good physical properties. Among them the batch labelled IBU-4 showed the highest drug release. This anti-inflammatory emulgel is useful for treating inflammation. Overall, the emulgel is proven to be safe & effective for treating inflammation.

Key Words: - Emulgel, Ibuprofen, Turmeric, Hydrophobic Drugs & Anti-Inflammatory Emulgel

I. INTRODUCTION

Emulsifying gels, commonly referred to as emulgels, are topical preparations that merge the benefits of emulsions and gels into a Single formulation, these semi-solid systems improve the stability of emulsions while offering better skin penetration and greasy feel. They're increasingly being used in a non-Cosmetics, dermatology and pharmaceutical products, especially for delivering poorly water- Soluble drugs.

Topical medications are used on the body to treat different health problems. Most often, these drugs are applied to the skin. They can either work directly on the area where they’re applied or get absorbed into the bloodstream through the skin layers. Topical drug delivery systems are meant to deliver medicine right to the affected area on the skin, especially for treating skin-related conditions. These systems are mainly used for infections on the skin and come in different forms—solid, semi-solid, and liquid.

Ibuprofen gel, when applied to the skin, typically begins to take effect within 1 to 2 days. However, for conditions such as arthritis, it may require up to 7 days of consistent application to the affected joint to experience the full therapeutic benefit. A gel is a solid or semi-solid formulation composed of at least two components, where a liquid phase is interspersed within a condensed network. Gels are widely utilized to enhance both cutaneous and percutaneous drug delivery, offering an effective alternative to oral administration. One of the key advantages of topical gel formulations over oral tablets is the avoidance of first-pass hepatic metabolism, which can improve drug bioavailability. Additionally, gels bypass gastrointestinal absorption challenges, such as variable pH conditions, and generally offer improved patient compliance due to ease of application and localized effect.

Herbal formulations usually have moderate effectiveness and are less toxic than many pharmaceutical drugs. Especially in Western countries, there's a growing belief that "natural" is better than "chemical" or "synthetic," which has given rise to Neo-western herbalism and boosted the herbal industry. According to the World Health Organization (WHO), around 80% of the global population (about 4 billion people) depends on traditional medicine for their basic health needs. Nearly 25% of modern medicines still include plant-based ingredients or synthetic versions based on plant-derived compounds.

Herbal medicine is a key part of traditional healthcare systems like Ayurveda, homeopathy, naturopathy, traditional Chinese medicine, Unani, and Siddha. The global demand for medicinal plants is rising as people become more aware of the benefits of natural products. In India, especially in rural and tribal areas, medicinal plants are valued not only for their cultural and spiritual significance but also for being safe and affordable. Major pharmaceutical companies are actively researching plants collected from forests and medicinal farms to explore their healing potential.

1.1. Advantage

1. First pass metabolism is not occurred
2. Avoid gastro intestinal incompatibility
3. Selective to a selected site
4. Enhance patient compliance
5. Integration of hydrophobic drugs
6. Higher loading capability
7. Better penetration and stability
8. Economical
9. Termination of medication is easy when needed
10. Easily apply
11. No intensive sonication is required

1.2. Disadvantages

1. Skin inflammation on contact scale/sores
2. Hyper sensitivity
3. Poor absorbance of few drugs through the pores and skin
4. Large molecule size of drug does not absorb via skin
5. Chances of allergic reaction

2. MATERIAL / INGREDIENT: -

2.1. Aqueous Phase Components:

The aqueous phase forms the continuous phase of the emulsion and serves as the medium for water-soluble constituents. Common examples include purified water.

2.2. Oil Phase Components:

Oils constitute the dispersed phase in emulsions and aid in the delivery and absorption of lipophilic active ingredients. Typical oil used include Liquid paraffin, Nilgiri oil.

2.3. Anti-inflammatory agent:

Ibuprofen is an Anti-inflammatory agent it is a class of medication called NSAIDs. It works by stopping the production of a substance in a body`s that causes pain, fever and inflammation.

2.4. Herbal combination for Anti-inflammatory agent:

An herbal combination for anti-inflammatory action often includes turmeric. These herbs work synergistically to reduce inflammation, ease joint pain, and support overall wellness. Rich in natural compounds like curcumin they help block inflammatory pathways without the side effects of synthetic drugs. Such blends are commonly used in traditional and modern herbal medicine to manage chronic inflammatory conditions naturally.

2.5. Emulsifying Agents:

Emulsifiers are incorporated to stabilize the emulsion by reducing interfacial tension between the aqueous and oil phases, thus ensuring homogeneity and shelf-life stability. Common emulsifying agents include Polyoxyethylene sorbitan monooleate (Tween 80), Propanediol.

2.6. Gelling Agents:

Gelling agents are used to impart the semi-solid consistency characteristic of emulgels and to enhance drug retention at the site of application. Frequently used gelling agent include Xanthan gum, Bees wax.

2.7. Preservatives:

Preservatives are essential to inhibit microbial growth and prevent formulation degradation during storage. Commonly employed preservatives include methylparaben.

2.8. pH Adjusting Agents:

These agents are added to maintain the pH within an optimal range to ensure the stability and efficacy of the formulation. Triethanolamine is commonly used for this purpose.

3. METHODS: -

Fusion Method: -The fusion method of preparing an emulsifying gel involves melting and mixing. ingredients especially those with different phases oil and water to form a stable emulsion that has a gel-like consistency.

Fusion method process:

a. Preparation of the oil phase

b. preparation of the aqueous phase

c. mixing of phases.

d. Addition of Gelling agent

e. PH adjustment (if needed)

f. Cooling & Packaging

3.1. Formulation of Emulsion:

a. Preparation of the Aqueous Phase:

The aqueous phase was prepared by dissolving Tween 80 in purified water. Methyl paraben and ibuprofen were separately dissolved in propylene glycol after dissolved the mixture mix together then heated to a temperature of 70°C to 80°C with continuous stirring. Turmeric and xanthan gum (used as a base) were subsequently added under continuous stirring and heating. Purified water was added dropwise at regular intervals during the heating and stirring process to ensure uniform dispersion.

b. Preparation of the Oil Phase:

The oil phase was prepared by dissolving beeswax in a mixture of Tween 80 and liquid paraffin under heat. The resulting oily phase was then gradually added to the aqueous phase, followed by the addition of triethanolamine, with continuous.

c. Essential oil incorporation

Allow the emulsion to cool to room temperature after thorough mixing. Once cooled, add Nilgiri (eucalyptus) oil and stir well to ensure uniform distributions stirring and heating throughout the process.

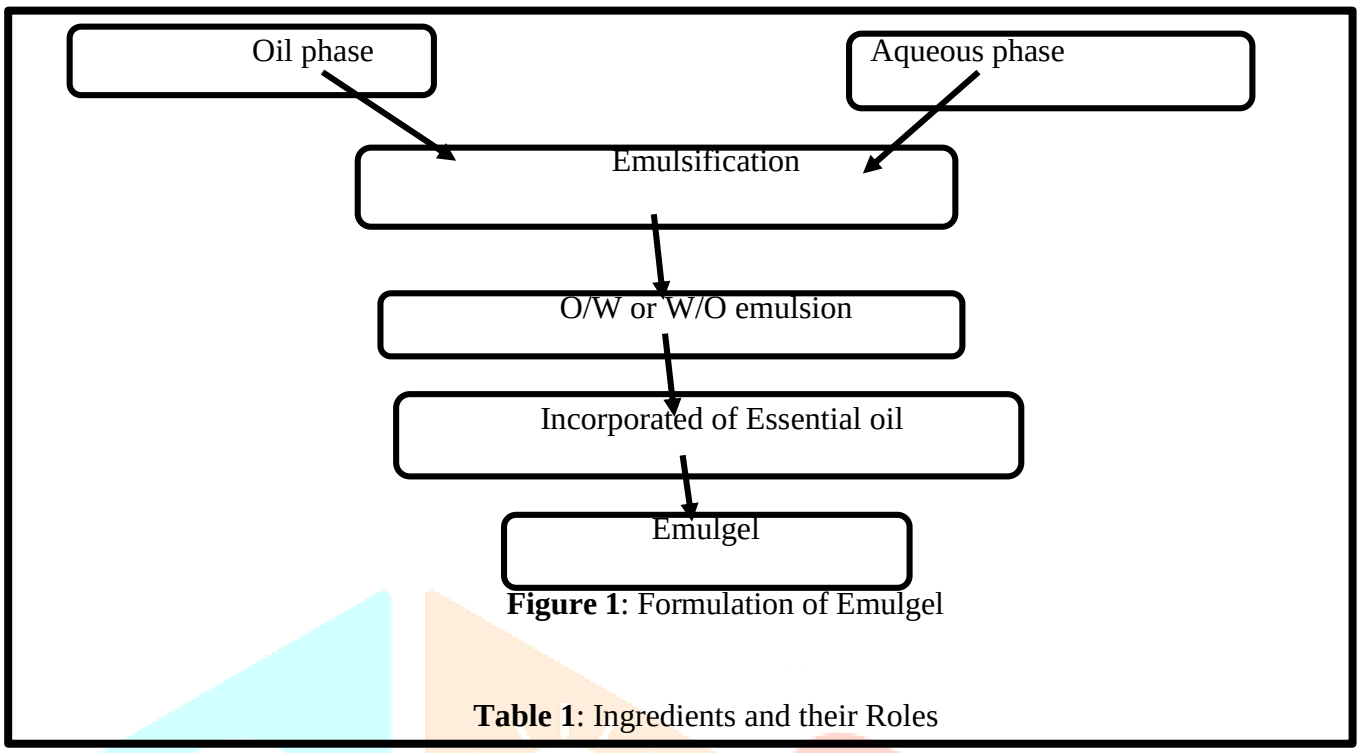


Figure 1: Formulation of Emulgel

Table 1: Ingredients and their Roles

Sr. No.	Ingredients	Role in formula
1.	Ibuprofen	NSAID`s
2.	Turmeric	Anti-inflammatory
3.	Xanthan gum	Gelling agent
4.	Bees wax	Gelling agent
5.	Liquid paraffin	Oil base
6.	Tween 80	Emulsifier
7.	Propanediol	Emulsifier
8.	Methyl paraben	Preservative
9.	Triethanolamine	pH adjuster
10.	Eucalyptus oil	Essence
11.	Water	Solvent

4. EXPERIMENTAL WORK: -

Formulation of Curcumin Longa Emulgel Preparation on the trial basis

Table 2: - Formulation of preliminary trial batches of Curcumin Longa Emulgel Preparation

Sr. No.	Name of Ingredients	F1	F2	F3	F4	F5
1.	Ibuprofen	1gm	1gm	1gm	1gm	1gm
2.	Turmeric	0.4gm	0.6gm	0.4gm	0.04gm	0.04gm
3.	Xanthan gum	1gm	1gm	1gm	1gm	1.5gm
4.	Bees wax	1gm	1gm	0.8gm	2gm	2gm
5.	Liquid paraffin	0.5gm	0.5gm	0.6gm	0.5gm	0.5gm
6.	Tween 80	1ml	1ml	2ml	2ml	2ml
7.	Propanediol	1ml	1ml	1ml	1ml	1ml
8.	Methyl paraben	0.2gm	0.2gm	0.2gm	0.2gm	0.2gm
9.	Triethanolamine	0.5gm	0.5gm	0.5gm	0.6gm	0.6gm
10.	Eucalyptus oil	0.5ml	0.7ml	1ml	1ml	1ml
11.	Water	q.s	q.s	q.s	q.s	q.s

Evaluation Parameters for of Preliminary Trial Batches

Physical Examination:

Prepared topical Ibuprofen Herbal emulgel formulations were observed for their colour, odour Taste.

Table 2: - Physical Evaluation Parameters

Sr. No.	Parameter	Observation
1.	Colour	Yellowish
2.	Odour	Pleasant Smell
3.	Taste / Appearance	Smooth

Determination of pH:

The pH of emulgel formulations was determined by means of the use of a digital pH meter. 1 gram of emulgel dissolved in 100 ml. of distilled water and stored for two hours. The measurement of pH of all formulation was done in triplicate, and average values were calculated.

Rheological Studies:

The viscosity of different Ibuprofen emulgel formulations was determined at 25°C using a Brook- filled Viscometer.

Viscosity was measured by using spindle (62).

Spreading coefficient

Spreadability was suitably modified in the laboratory and used for the study. It consists of a wooden block, which is attached to a pulley at one end. Spreading coefficient was measured on the basis of "Slip' and Drag characteristics of emulgel. A ground glass slide was fixed on the wooden block. An excess of emulgel (about 2 g) under study was placed on this ground slide. The emulgel preparation was then sandwiched between this slide and second glass slide having same dimension as that of the food ground slide. The second glass slide is provided with the hook. Weight of 500 mg was placed on the top of the two slides for 5 min to expel air and to provide a uniform film of the emulgel between the two slides measured quantity of weight was placed in the pan attached to the pulley with the help of hook. The time (sec) required by the top slide to cover a distance of 5 cm was noted. A shorter interval indicates better spreading coefficient.

$$S = M \frac{L}{T}$$

Where,

M= Weight tide to upper slide

L= Length of glass slide

T=Time taken to separate the slide

OPTIMIZATION:

Optimization is an act, process or methodology of making design, system or decision as fully perfect, functional or as
effective as possible. Optimization of a product or process is the determination of the experimental conditions resulting in
its optimal performance.

Parameters of Optimization:

1. Variable types:
   a) Independent: The independent variables are under the control of the formulation. These might include the compression force or the die cavity filling or the mixing time.
   b) Dependent: The dependent variables are the characteristics that develop in response to the independent variables. The more the variable that are present in the system the more the complications that are involved in the optimization.
2. Factors: Independent variables will form factors. Variables which can be controlled by an experimenter.
3. Levels: Range of each factor in the study or grade of excipients.
4. Response: Output of the experiment.

Central Composite Design (CCD): (Box –Wilson design)

Central composite design (CCD) is a statistical optimization method commonly used in pharmacy and pharmaceutical
research. It is a subset of response surface methodology (RSM) and is widely used to study the relationship between
multiple variables and their effect on the response or outcome of interest.

The Central Composite Design (CCD) was employed to systematically study the experimental design to investigate the effect of two independent variables (factors). i.e., concentration of xanthan gum (X1), Concentration of light Bees wax (X2) on the dependent variables, i.e., Percentage drug release (Y1), viscosity (Y2). In these study conc. of xanthan gum (X1), conc. of light Bees wax (X2) was considered as formulation variables which varied, as required by experimental design & the number of other excipients were kept constant. Percentage drug release (Y1), viscosity (Y2) was selected as response variables. All analysis were performed by using the Design Expert
Version 13.0.5.0 software

Advantages:

1. CCD can be run sequentially
2. Run factorial and center points
3. Axial points can be added if needed.

Applications of Optimization:

1. Used in the formulation & processing
2. Clinical chemistry
3. Medicinal Chemistry
4. High performance liquid chromatographic analysis
5. Study of pharmacokinetic parameters

1. Types of CCD
   * Central composite design (CCD)
   * Axial points - Sequential experimentation
2. full factorial design
   * Center points – check for lack of fit or adequacy of fit
   * Axial points – estimating Quadratic effects

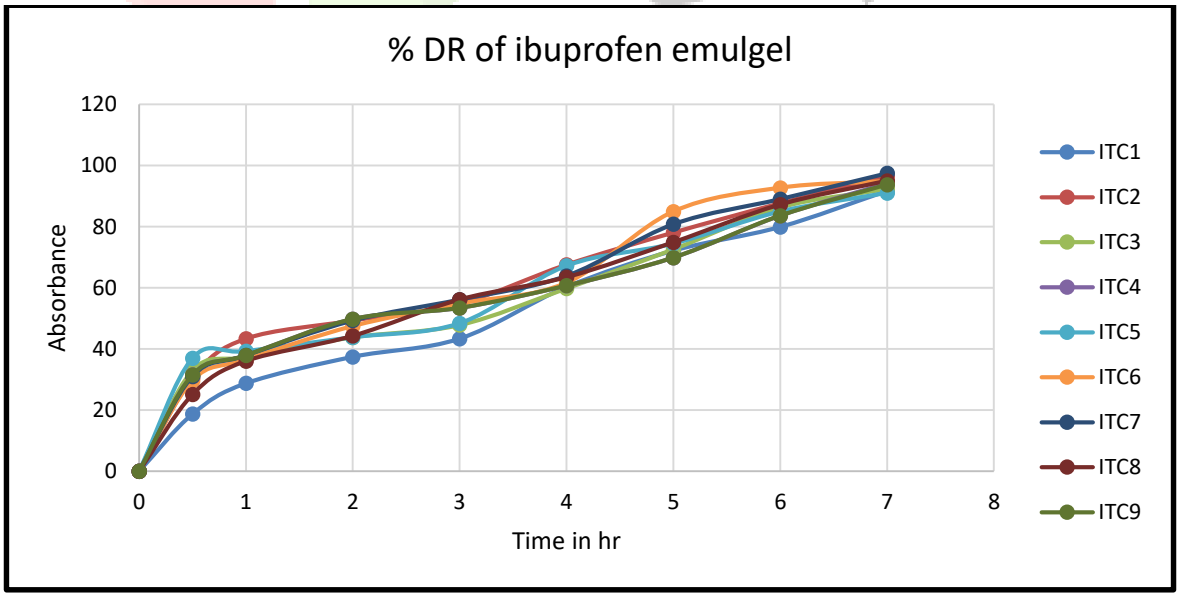
Formulation of Optimization batches of Curcumin Longa Emulgel Preparation

Sr. No.	Name of Ingredients	F1	F2	F3	F4	F5
1.	Ibuprofen	1gm	1gm	1gm	1gm	1gm
2.	Turmeric	0.4gm	0.6gm	0.4gm	0.04gm	0.04gm
3.	Xanthan gum	1gm	1gm	1gm	1gm	1.5gm
4.	Bees wax	1gm	1gm	0.8gm	2gm	2gm
5.	Liquid paraffin	0.5gm	0.5gm	0.6gm	0.5gm	0.5gm
6.	Tween 80	1ml	1ml	2ml	2ml	2ml
7.	Propanediol	1ml	1ml	1ml	1ml	1ml
8.	Methyl paraben	0.2gm	0.2gm	0.2gm	0.2gm	0.2gm
9.	Triethanolamine	0.5gm	0.5gm	0.5gm	0.6gm	0.6gm
10.	Eucalyptus oil	0.5ml	0.7ml	1ml	1ml	1ml
11.	Water	q.s	q.s	q.s	q.s	q.s

In Vitro Drug Release Studies:

Table No. In vitro Diffusion Study of Optimized Formulation (ITC1-ITC9)

Sr. No.	Time (min)	Batches (%)								
		ITC1	ITC2	ITC3	ITC4	ITC5	ITC6	ITC7	ITC8	ITC9
1	00	00	00	00	00	00	00	00	00	00
2	30	18.71	30.58	32.87	**31.50**	36.93	29.67	31.04	25.10	31.50
3	60	28.76	43.37	37.43	**37.89**	39.26	36.52	37.89	36.06	37.89
4	120	37.43	49.30	43.82	**49.76**	43.82	47.47	49.30	44.28	49.76
5	180	43.37	54.78	47.82	**53.41**	48.39	54.78	56.15	56.15	53.41
6	240	60.26	67.56	59.80	**60.71**	67.17	61.63	63.91	63.45	60.71
7	300	72.13	78.06	72.58	**69.84**	74.41	84.91	80.80	74.87	69.84
8	360	79.89	87.65	86.28	**83.54**	84.91	92.67	89.02	87.19	83.54
	420	91.65	96.5	92.32	**94.13**	90.98	94.86	97.45	94.98	93.69



Figer No. : % Drug Release of Ibuprofen emulgel

*** DF indicates degree of freedom; SS (Sum of Square); MS (Mean Sum of Square) and F is (Fischer's Ration).**

A) % Drug Release

Final equation in terms of coded form, % DR= +96.79-0.7876X1-1.64X2
Final equation in terms of Actual factor %DR=+102.43462-1.57521X1-1.63979X2

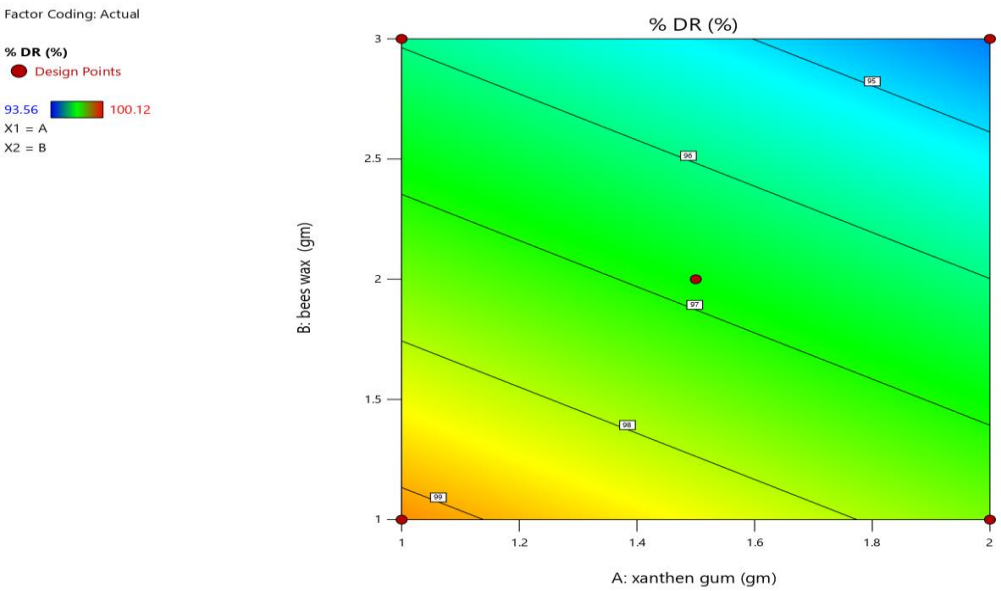


Figure 4: Response Surface Contour Graph Showing the Influence of Xanthan Gum (X1) and Bees Wax (X2) on % Drug Release of Ibuprofen.

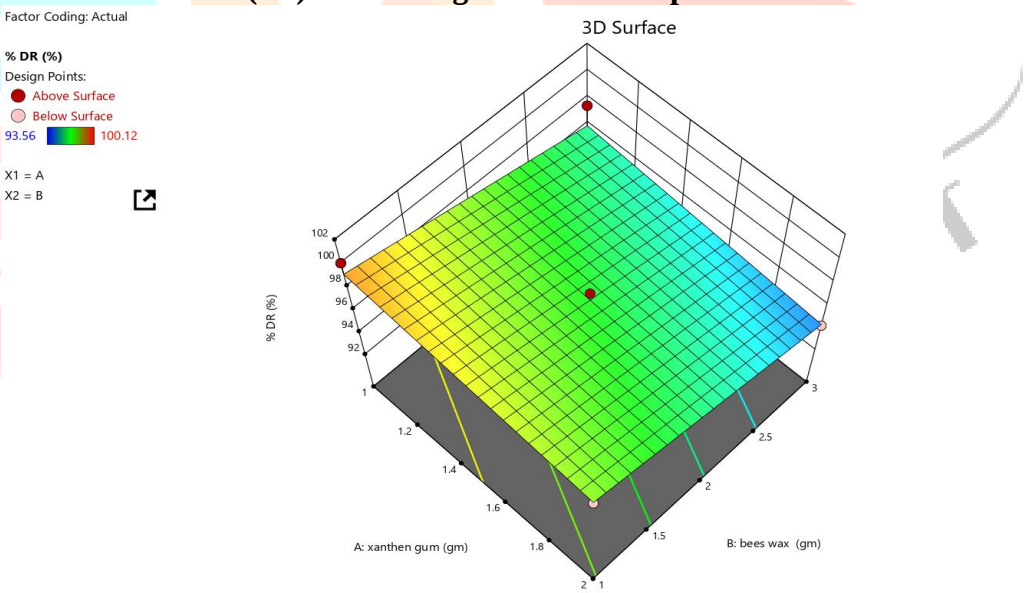


Figure 5: 3D Response Surface Graph Showing the Influence of Xanthan Gum (X1) and Bees wax (X2) on % Drug Release of Ibuprofen.

B) Viscosity

Final equation in terms of coded form, Viscosity = +36.15+2.86X1-1.56X2
Final equation in Actual factor Viscosity = +30.68133+5.72207X1-1.55888X

.

Table No.: Result of Analysis of Variance for Batches by CCD of Ibuprofen

Sr.No	Source	Sum of Squares	df	Mean Square	F-value	p-value	
1.	Model	26.47	2	13.24	10.57	0.0108	Significant
2.	A-Xanthan gum	4.96	1	4.96	3.96	0.0936	
3.	B-bees wax	21.51	1	21.51	17.18	0.0060	
4.	Residual	7.51	6	1.25			
	Cor Total	33.99	8				

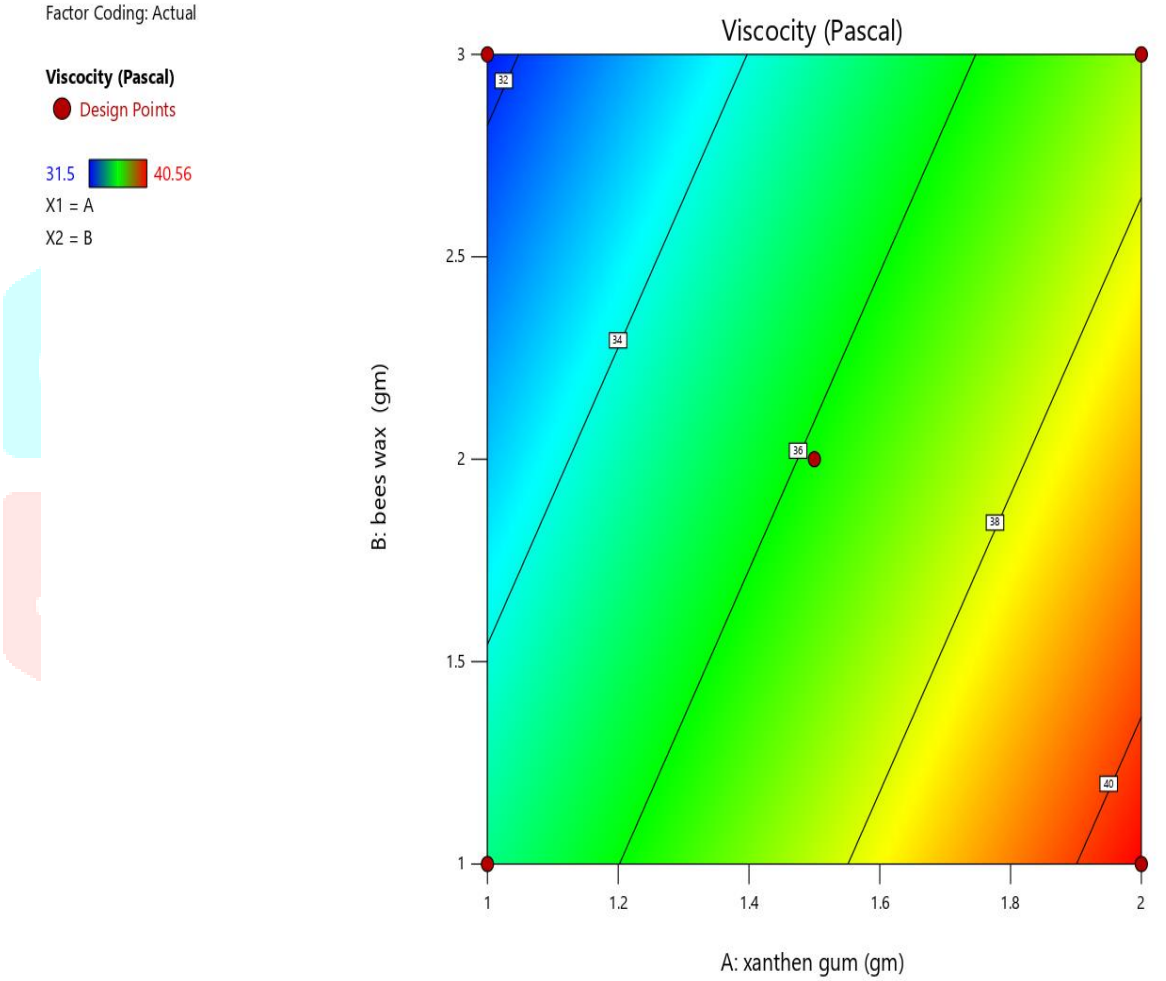


Figure 6: Response Surface Contour Graph Showing the Influence of Xanthan Gum (X1) and Bees wax (X2) on Viscosity of Ibuprofen.

CONCLUSION: -

The herbal emulsifying gel formulated with Ibuprofen demonstrated desirable physicochemical properties such as appropriate pH (5.5–6), homogeneity, spread ability, and viscosity, making it suitable for topical application. The incorporation of herbal components, such as turmeric and eucalyptus oil, may enhance the anti-inflammatory efficacy and provide synergistic therapeutic effects. The formulation ensures localized drug delivery, potentially reducing systemic side effects associated with oral NSAIDs. Overall, the prepared herbal emulgel presents a promising alternative for the topical treatment of inflammatory conditions, combining the benefits of conventional Ibuprofen with the healing properties of herbal ingredients.

RESULT: -

The herbal emulsifying gel formulated with Ibuprofen exhibited satisfactory physicochemical characteristics, including appropriate pH (5.5–6.0), smooth texture, good spread ability, and homogeneity. The formulation ensured effective drug incorporation and was stable under standard storage conditions. The pH range was within acceptable dermal limits, minimizing the risk of skin irritation. The presence of herbal components, such as turmeric and eucalyptus oil, may provide synergistic anti-inflammatory benefits alongside Ibuprofen.

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