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Research

Development and Physicochemical Evaluation of Ceclofenac-Loaded Emulgel

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Abstract:
The emulgel formulation has emerged as one of the most efficient and effective strategies for the delivery of hydrophobic drugs. Emulgels represent a hybrid dosage form that combines the characteristics of both emulsions and gels. Owing to this dual property, they enhance the solubility of poorly water-soluble drugs, thereby improving their bioavailability, while also offering a patient-friendly approach to topical drug delivery. In this study, aceclofenac, a nonsteroidal anti-inflammatory drug (NSAID) derived from diclofenac, was selected as the model drug. Being a BCS class II compound (low solubility and high permeability), aceclofenac is well-suited for formulation as an emulgel, where even smaller doses can achieve therapeutic efficacy in topical applications. Two different gelling agents, carbomer 934 and HPMC K4M, were used separately at a concentration of 1% w/w to prepare the emulgels. Linseed oil served as the penetration enhancer. The prepared formulations were evaluated for rheological properties, pH, and in vitro drug release profile. The findings revealed that the emulgel prepared with carbomer 934 exhibited a superior drug release profile compared to the formulation containing HPMC K4M. These results suggest that carbomer 934 is a more suitable gelling agent for the development of aceclofenac emulgel formulations, providing enhanced drug release and potentially better therapeutic outcomes.

Keywords: Aceclofenac, Topical Drug Delivery System, Emulgel, HPMC

1. Introduction:

Drugs have been administered to the human body through a variety of routes over the last few decades, including oral, sublingual, rectal, and parental routes. Topical drug delivery systems are generally used in cases of failure of other systems or when local skin infections, such as fungal infections occur.[1-3] Skin delivery of drugs is an effective and targeted treatment for local dermatological conditions. Due to its ability to avoid first pass effects, gastrointestinal irritation, and metabolic degradation associated with oral administration, this route of drug delivery has gained popularity.[4-6] Only 25-45% of a dose administered orally reaches the bloodstream because of presystemic metabolism. These disadvantages can be overcome by applying gel formulations topically.[7] In dermatology, topical drug delivery refers to applying a drug-containing formulation directly to the skin, thereby treating cutaneous formulation disorders.[8-10] The most popular skin care products are semisolid preparations, such as ointments, creams, pastes, gels, which range in formulation & consistency from liquid to powder. Due to their less greasy nature and easy removal from the skin, topical gel formulations are suitable for drug delivery.[11] In precutanous absorption, drugs are released from the formulation and permeated through the skin to reach the target tissues. Pharmacokinetic properties of the drug and the vehicle determine how well it will be

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released from topical preparations. Studies have been conducted to enhance drug and skin permeation by selecting appropriate vehicles or co-administering chemical enhancers.[12-13]

The factors that affect precutanous absorption need to be understood when using topical agents. It is possible for molecules to penetrate the skin through three different routes: intact stratum corneum, sweat glands, or sebaceous follicles. It is estimated that over 99% of the skin surface is accessible for precutanous drug absorption through the stratum corneum. In order for precutanous absorption to take place, it must pass through this outermost layer.[14-16] A concentration gradient is established during precutanous absorption as a driving force for drug movement across the skin, and the drug is released from the vehicle (penetration coefficient); and the drug diffuses across the skin layers (diffusion coefficient). Low molecular mass (400 Daltons) and adequate solubility in oil and water are preferred characteristics of topical drugs.[17-20] In contrast to creams and ointments, gel formulations generally provide faster drug release compared to liquids. They are created by encapsulating large amounts of liquid in a network of colloidal particles. In topical dosage forms, hydrophobic drugs are delivered by diffusion, and hydrophilic drugs are delivered by permeation through the stratum corneum. Emulgels are therefore prepared to overcome this limitation.

2. Materials and Methods:

Aceclofenac was a gift sample from Cipla Pharmaceuticals Ltd. - Ahmedabad. All the other chemicals used in the experiment were of the analytical grades. The emulgel formulations were prepared using method as depicted in the flow diagramme Fig 1.Also the composition of various emulgel formulations are shown in Table 1.

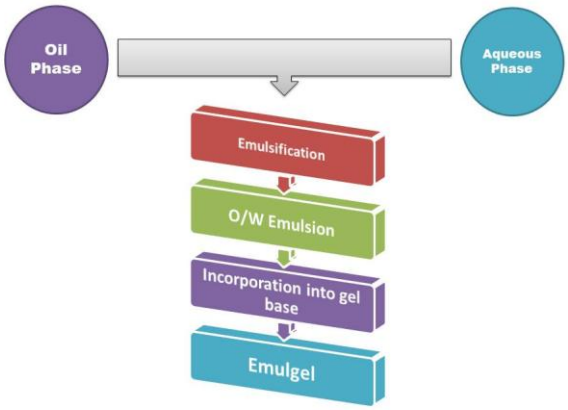

Fig.1: Flow sheet diagramme of emulgel formation

2.1 Composition of various formulations of emulgel

Table 1: Different batches of Emulgel

Ingredients (%w/w)	**Emulgel 100 gm. Formulation**							
	F1	F2	F3	F4	F5	F6	F7	F8
Aceclofenac	1	1	1	1	1	1	1	1
Linseed oil	3	3	3	3	3	3	3	3
Menthol	5	5	5	5	5	5	5	5
Methyl Salicylate	10	10	10	10	10	10	10	10
Propylene Glycol	10	10	10	10	10	10	10	10
Methyl Paraben	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Propyl Paraben	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Tween 80	2	2	2	2	2	2	2	2
Carbomer 934	1	1	1	1	1	1	1	1
HPMC K4M				0.5	1	1.5		1
Ethyl Acetate	7	7	7	7	7	7	7	7
Distilled Water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

3. Evaluation Parameters:

3.1. Physical Appearance:

The prepared emulgels underwent a thorough visual inspection to assess their clarity, color, and absence of particulate matter. This evaluation is critical as the physical attributes of the emulgel significantly influence patient compliance and acceptance of the topical treatment, ensuring it meets aesthetic and functional standards for therapeutic use.

3.2. pH:

The pH of the emulgel was determined using a calibrated digital pH meter to ensure compatibility with skin physiology. The gel sample was gently stirred in 50 ml of distilled water for approximately one minute to achieve a uniform suspension, facilitating accurate pH measurement. This step is essential to confirm the formulation's suitability for topical application, minimizing potential irritation or discomfort.

3.3. Spreadability:

Spreadability was evaluated using a wooden block apparatus connected to a pulley system, designed to quantify the emulgel's 'Slip' and 'Drag' properties. A fixed glass slide on the block served as the base, where approximately 2 g of emulgel was applied. A second glass slide, equipped with a hook, was placed over the sample to sandwich it, and a 500 mg weight was added to eliminate air pockets and ensure a uniform thin film. A predetermined weight was then placed in the pulley pan, and the time required for the slides to separate was recorded. Shorter separation times indicate superior spreadability, reflecting the emulgel's ease of application and coverage on the skin, which is vital for effective therapeutic delivery[21].

It is calculated by using the following formula.

$S = M^* L / T$

Where, M = wt. tied to upper slide; L = length of glass slides; T = time taken to separate the slides

3.4. Extrudability Study

The success of a gel formulation hinges on its ability to extrude effortlessly from its container, ensuring ease of use for patients. This study assessed extrudability by applying a standardized procedure: a collapsible tube filled with gel had its crimped end pressed firmly to initiate extrusion[22]. Upon removing the cap, the gel was allowed to extrude naturally until the applied pressure subsided. The time required to dispense a 0.5 cm ribbon of gel under a consistent 500 gm force was meticulously recorded in seconds for each formulation. This metric is crucial for evaluating the formulation's practical applicability and patient convenience.

3.5. Rheological Study:

The viscosity of various emulgel formulations was measured using a Brookfield Viscometer DV III+ equipped with spindle number 4, set at a controlled temperature of 37°C to mimic physiological conditions. The spindle was carefully lowered perpendicularly into the center of the emulgel sample within its container, avoiding contact with the jar's bottom to ensure accurate readings. The spindle rotated at 100 revolutions per minute for 10 minutes, allowing the formulation to stabilize and providing a comprehensive assessment of its rheological properties[23]. This analysis is vital for understanding the gel's texture, spreadability, and stability under application conditions.

3.6. Drug content study:

The drug content within the emulgel was quantified by dissolving 1 gm of gel in a 100 ml flask with ethanol, agitating the mixture until fully dissolved, and then adjusting the volume to 100 ml with additional ethanol. The solution was filtered using Whatman filter paper to remove any undissolved particles. For further dilution, 5 ml of the filtrate was transferred to a 50 ml volumetric flask and brought to volume with ethanol. The absorbance of this diluted solution was measured at 275 nm using a UV-visible spectrophotometer, providing a precise determination of the drug concentration and ensuring the formulation's potency and uniformity[24].

3.7. In-vitro drug release kinetics:

In-vitro drug release kinetics were evaluated using Franz Diffusion cells, a robust system for simulating transdermal delivery. The emulgel formulation was applied to egg membranes positioned between the donor and receptor compartments of the cell. The receptor compartment was filled with a dissolution medium consisting of sodium phosphate buffer (pH 7.2) and ethanol in an 80:20 ratio, mimicking physiological conditions. The cell temperature was maintained at 37 ± 0.5°C using a water bath to reflect body temperature. A magnetic bead and stirrer operated at 50 rpm ensured continuous and uniform mixing of the medium. Samples (1.0 ml) were periodically withdrawn, appropriately diluted, and analyzed for drug content at 275 nm using a UV-visible spectrophotometer, enabling a detailed assessment of the release profile and therapeutic efficacy over time.

4. Result and Discussion

4.1. Physical Appearance

The aceclofenac emulgel formulations exhibited a homogenous consistency, devoid of clogging or lumps, suggesting an optimal texture that ensures uniform application and effective drug distribution. The emulgels presented as white, viscous, creamy preparations, reflecting a smooth and aesthetically pleasing texture suitable for topical use. In contrast, all formulation batches displayed a homogenous yellowish milky emulsion, likely due to the presence of active ingredients and excipients that contribute to the coloration and emulsion stability. This uniformity and visual appeal enhance patient compliance and indicate a well-stabilized system, where the emulsification process effectively integrated the oil and aqueous phases, preventing phase separation or aggregation.

4.2 pH

The pH values of all formulations ranged from 6.1 to 6.5, aligning closely with the human skin's natural pH of approximately 5.5 Table 2. This slight alkaline shift is advantageous, as it minimizes the risk of skin irritation while maintaining compatibility with the skin's acidic mantle. The observed pH range suggests that the formulation components, including emulsifiers and active ingredients, were balanced to create a skin-friendly environment. This compatibility is critical for prolonged topical application, as it reduces the likelihood of disrupting the skin barrier or eliciting adverse reactions, thereby supporting the formulation's safety and efficacy for therapeutic use.

Table 2: pH of the various formulations

Formulations	*pH*			Mean(n=3)
F1	6.2	6.4	6.1	6.3
F2	6.6	6.0	6.5	6.4
F3	6.2	6.2	6.0	6.1
F4	6.6	6.0	6.3	6.3
F5	6.5	6.6	6.2	6.4
F6	6.7	6.4	6.5	6.5
F7	6.7	6.2	6.4	6.4
F8	6.6	6.1	6.5	6.4

4.3. Spreadability

The spreadability of an emulgel is deemed optimal when it requires minimal time to distribute evenly across a surface, facilitating ease of application. Among the evaluated formulations, the F3 emulgel demonstrated superior spreadability, attributed to its efficient response to minimal shear force. The recorded spreadability values suggest that F3 can be easily applied with gentle pressure, enhancing patient convenience and ensuring uniform drug distribution Table 3. This improved performance likely stems from an optimal balance of emulsifiers and gelling agents, which reduces internal resistance and promotes a smooth, consistent spread, critical for effective topical therapy.

Table 3: Spreadability of the Formulations

Formulations	Time (sec.)			Mean(n=3)
F1	12	13	15	13
F2	14	12	11	12
F3	10	11	13	11

F4	11	13	12	12
F5	16	14	15	15
F6	15	17	13	15
F7	13	16	15	14
F8	18	16	15	16

4.4 Extrudability Study:

The extrudability of the various formulations ranged from 13 to 18 seconds, indicating that all samples were readily extruded from their containers with moderate pressure Table 4. This narrow time range reflects a consistent and user-friendly extrusion profile, essential for practical application. The ease of extrusion suggests a well-formulated gel matrix, where the interaction between the gelling agent and active ingredients minimizes resistance, ensuring reliable delivery from the tube. This property enhances patient adherence by simplifying the dispensing process without requiring excessive force.

Table 4: Extrudability study of formulations

Formulations	Time (sec.)			Mean(n=3)
F1	14	18	17	16
F2	13	15	16	14
F3	13	12	15	13
F4	18	16	19	17
F5	15	19	18	17
F6	16	20	19	18
F7	18	17	21	18
F8	16	15	19	16

4.5. Rheological Study:

Viscosity assessments were conducted using a Brookfield Viscometer with spindle number 4 at 100 rpm and 37°C, simulating physiological conditions. The measured viscosity values provide insight into the formulations' flow behavior and structural integrity, which are vital for maintaining stability and ease of application Table 5. The consistent viscosity across samples indicates a robust gel network, likely due to the effective incorporation of thickening agents, ensuring the emulgel remains stable under shear stress while being suitable for topical use.

Table 5: Rheological study of formulations

Formulations	Viscosity (cPs)			Mean(n=3)
F1	1252	1089	1467	1269
F2	1029	1287	1445	1253
F3	955	1189	1076	1073
F4	1023	1187	1654	1288
F5	1286	1837	1342	1488
F6	1314	1764	1456	1511
F7	1048	1421	983	1150
F8	1363	1678	1710	1583

4.6. Drug Diffusion Study:

Drug diffusion was evaluated by sampling different formulations at various time intervals, with absorbance measured using a UV Shimadzu 1800 spectrophotometer at 275 nm. This wavelength was selected based on the drug's maximum absorbance, ensuring accurate quantification Table 6. The results reflect the rate at which the active ingredient diffuses through the gel matrix, influenced by factors such as drug solubility and matrix porosity. Variations in diffusion rates across formulations highlight differences in formulation composition, providing a basis for optimizing drug release profiles.

Table 6: % Drug diffusion of formulations

Formulations	% Drug diffusion
F1	94.3
F2	87.6
F3	96.9
F4	93.3
F5	97.4
F6	98.5
F7	95.1
F8	91.3

4.7. In-Vitro Drug Release Kinetics:

In-vitro drug release was monitored over 12 hours at hourly intervals, revealing that F3 and F6 formulations exhibited superior release profiles Table 7 Fig.2. The enhanced release in these formulations is likely due to an optimal combination of emulsifiers and penetration enhancers, which facilitate sustained drug liberation. This controlled release pattern, extending up to 12 hours, suggests a prolonged therapeutic effect, reducing the frequency of application and improving patient compliance. The superior performance of F3 and F6 may be attributed to their refined composition, balancing drug solubility and matrix stability for effective delivery.

Table 7: Drug release kinetics of different formulations

Time (hrs.)	F1	F2	F3	F4	F5	F6	F7	F8
1	5.17	4.10	5.56	5.76	3.94	8.80	4.10	5.18
2	12.02	7.25	13.61	7.51	6.15	16.51	7.25	7.93
3	16.54	10.93	21.25	11.05	9.37	29.72	10.93	12.45
4	25.16	12.28	32.13	16.54	11.20	38.64	12.28	17.62
5	33.47	23.68	39.58	25.93	22.46	47.38	23.68	26.01
6	41.31	28.41	46.40	30.24	25.34	55.13	28.41	32.85
7	49.67	33.06	51.79	38.85	29.81	63.02	33.06	42.65
8	58.46	37.12	62.83	40.69	34.65	70.61	37.12	46.42
9	60.02	42.62	68.32	45.65	40.65	83.45	42.62	49.83
10	68.32	49.53	74.82	52.25	46.74	77.54	49.53	52.64
11	74.60	53.62	81.25	55.48	50.15	90.05	53.62	57.45
12	76.77	60.31	89.53	63.42	58.09	98.86	60.31	62.06

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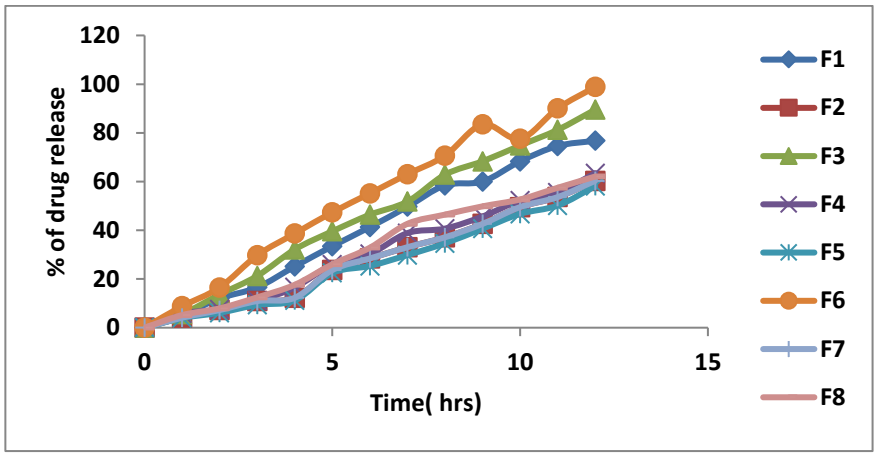

Fig 2: Drug release profile

4.8 Discussion:

Topical delivery systems are poised to revolutionize the pharmaceutical landscape, emerging as the preferred modality over traditional oral, parenteral, and other administration routes. This shift is driven by several inherent limitations of conventional methods—such as gastrointestinal degradation and first-pass metabolism in oral delivery, pain and infection risks in parenteral administration, and variable absorption rates in alternative routes—coupled with the significant advantage of heightened patient compliance. Topical formulations offer a non-invasive, convenient application method that aligns with patient preferences, reducing the need for frequent dosing and minimizing systemic side effects, thereby fostering adherence to treatment regimens.

Emulgel technology addresses a critical challenge in topical drug delivery by effectively incorporating hydrophobic drugs into a hydrophilic gel matrix, creating a versatile and stable delivery platform. This hybrid system leverages the emulsifying properties of oil-in-water emulsions with the structural integrity of gels, enabling the encapsulation and sustained release of lipophilic active ingredients that are otherwise difficult to formulate. The study revealed that emulgels exhibit exceptional bioadhesion, allowing them to adhere firmly to the skin surface, which enhances drug residence time and improves therapeutic efficacy. Additionally, their high viscosity ensures a smooth, uniform application, while their long-term stability prevents phase separation or degradation over extended periods, further boosting patient acceptance and product shelf-life.

Among the various gel-forming polymers evaluated, emulgels formulated with Carbomer 934 demonstrated superior performance and enhanced stability compared to those prepared with two alternative polymers. This improved outcome can be attributed to Carbomer 934's robust gelling capacity and its ability to form a dense, cohesive network that stabilizes the emulsion system. The polymer's pH-dependent swelling behavior and excellent rheological properties contribute to a consistent texture and prolonged structural integrity, ensuring the emulgel remains effective under varying environmental conditions. These findings underscore Carbomer 934's potential as an optimal choice for developing stable, patient-friendly emulgel formulations, paving the way for its broader adoption in future topical drug delivery innovations.

5. Conclusion:

The gel formulation incorporating Carbomer 934 exhibited exceptional clarity and prolonged stability, outperforming two alternative gel-forming polymers evaluated in this study. This superior performance is likely due to Carbomer 934's robust gelling properties, which enhance structural integrity and resist degradation over time. The investigation revealed that variations in the concentrations of Tween 80 and linseed oil significantly influenced key properties, including viscosity, spreadability, and in vitro drug permeability, highlighting their critical roles in optimizing the formulation's performance. All prepared formulations demonstrated excellent spreadability and maintained pH levels closely aligned with human skin (approximately 5.5), ensuring compatibility and minimizing irritation potential. Drug permeation studies underscored the F6 formulation as the most effective, releasing the active ingredient at a higher rate compared to other batches, establishing it as the optimized formulation.

These findings collectively affirm the successful development and comprehensive evaluation of the Aceclofenac emulgel, positioning it as a promising candidate for topical therapeutic applications.

6. Future prospects of aceclofenac emulgel

The successful development and optimization of Aceclofenac emulgel, particularly the F6 formulation with Carbomer 934, open promising avenues for advancing topical drug delivery systems. In the coming years, this emulgel platform could be expanded to deliver a broader range of non-steroidal anti-inflammatory drugs (NSAIDs) and other therapeutic agents, catering to conditions such as arthritis, musculoskeletal pain, and chronic inflammation. The formulation's superior clarity, stability, and skin-compatible pH suggest potential for scaling up production, enabling commercialization and wider accessibility in pharmaceutical markets.

Further research could explore the incorporation of novel penetration enhancers and bioadhesive polymers to enhance drug permeation and prolong release profiles, potentially reducing dosing frequency and improving patient adherence. The observed influence of Tween 80 and linseed oil on viscosity and spreadability provides a foundation for fine-tuning these excipients, possibly integrating natural oils or nanotechnology-based carriers to boost efficacy and target deeper dermal layers. Clinical trials could validate the emulgel's performance in diverse patient populations, including those with sensitive skin or chronic conditions, paving the way for personalized medicine approaches.

Additionally, the emulgel's versatility as a scaffold biomaterial could be leveraged for wound healing applications, combining anti-inflammatory effects with regenerative properties through the addition of growth factors or antimicrobial agents. Regulatory approval and patenting of the optimized F6 formulation could position it as a competitive alternative to existing topical therapies, driving innovation in the pharmaceutical industry. Long-term studies may also investigate its environmental impact and sustainability, aligning with global trends toward eco-friendly healthcare solutions. As topical delivery gains prominence, this emulgel platform holds the potential to set new standards in patient-centric, effective, and safe treatment modalities.

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