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Formulation and Evaluation of Aceclofenac Emulgel

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Abstract: *Aceclofenac is a widely used non-steroidal anti-inflammatory drug (NSAID) for the management of pain and inflammatory conditions such as arthritis. However, its oral administration is associated with gastrointestinal side effects and poor patient compliance. The present study aims to formulate and evaluate a topical emulgel containing Aceclofenac to enhance drug delivery and minimize systemic adverse effects.*
The emulgel was prepared by incorporating an oil-in-water emulsion into a gel base using Carbopol 934 as a gelling agent. Suitable emulsifying agents such as Tween 80 and Span 80 were used to stabilize the formulation. The prepared emulgel was evaluated for various physicochemical parameters including appearance, pH, viscosity, spreadability, drug content, and in-vitro drug release.
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Keywords: Aceclofenac, Emulgel, Topical delivery, NSAID, Carbopol, Drug release, Anti-inflammatory, Skin permeation, Evaluation parameters, Controlled release

I. INTRODUCTION

Aceclofenac is a widely prescribed non-steroidal anti-inflammatory drug (NSAID) belonging to the phenylacetic acid class, primarily used in the management of pain and inflammatory conditions such as osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. It exerts its pharmacological action by inhibiting cyclooxygenase (COX) enzymes, particularly COX-2, thereby reducing the synthesis of prostaglandins responsible for inflammation pain, and swelling. Despite its efficacy, oral administration of Aceclofenac is often assoCIATES with gastrointestinal side effects including gastric irritation, ulceration, and bleeding, along with hepatic first-pass metabolism that reduces drug bioavailability.,

1. Aceclofenac

Aceclofenacis a non-steroidal anti-inflammatory drug (NSAID) widely used for its analgesic (pain-relieving) and anti-inflammatory properties. It is commonly prescribed in conditions involving pain and inflammation such as arthritis and musculoskeletal disorders.

Chemical Information :
Drug Name: Aceclofenac
Category: NSAID
Molecular Formula: C16H13Cl2NO4
Molecular Weight: 354.18 g/mol
IUPAC Name: [2-[(2,6-dichlorophenyl) amino] phenyl] acetoxyacetic acid

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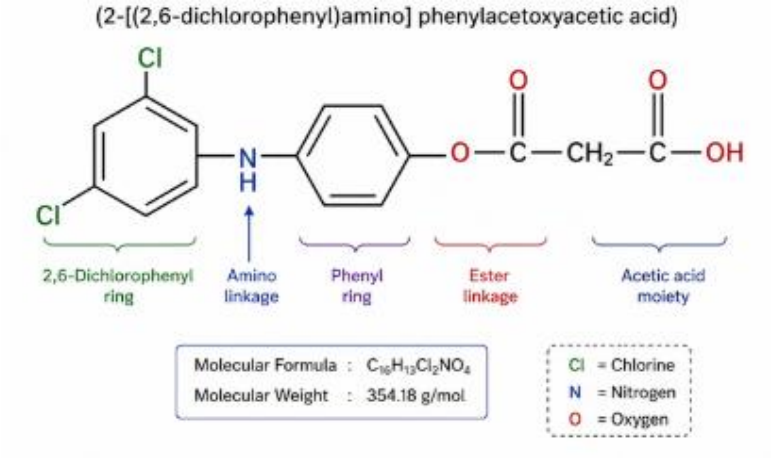
2. Mechanism of Action

Aceclofenac inhibits cyclooxygenase (COX) enzymes
responsible for prostaglandin synthesis. Reduction of prostaglandins leads to decreased pain and inflammation.

3. History of Aceclofenac

Aceclofenac was developed from diclofenac in the 1980s to create a more effective and better-tolerated NSAID. Since its introduction in the 1990s, it has become an important drug in managing pain and inflammation, with ongoing research focusing on improved delivery systems like emulgels.

The development of aceclofenac is linked to the evolution of non-steroidal anti-inflammatory drugs (NSAIDs). Early NSAIDs like aspirin were effective but caused significant gastrointestinal side effects. This led researchers to develop safer and more tolerable alternatives.



Advantages of Aceclofenac

Anti-inflammatory Action Improved Patient Compliance
Effective Pain Relief (Analgesic Effect) Better Gastrointestinal Tolerability Versatile Formulations
Useful in Combination Therapy Good Safety Profile Chondroprotective Effect

4. Emulgel

An emulgel is a biphasic system in which an emulsion (oil + water phase) is incorporated into a gel base using a suitable gelling agent.

Advantages of emulgel

Improves drug solubility Enhanced skin penetration Controlled drug release Easily Spreadable
Better patient compliance

PLAN OF WORK

The Present work was planned in the following manner:
1. Literature review
2. Preformulation studies
3. Selection of excipients
4. Preparation of gel base
5. Preparation of emulgel

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6. Evaluation studies
7. Optimization
8. Stability studies
9. Data analysis
10. Conclusion

LITERATURE REVIEW

Aceclofenac Emulgel focuses on enhancing the topical delivery of Aceclofenac—a potent Non-Steroidal Anti-Inflammatory Drug (NSAID) commonly used for arthritis, pain, and inflammation—while minimizing the gastric side effects associated with its oral consumption.

Emulgels are considered a "novel" approach that combines emulsions and gels, offering improved stability, drug loading, and penetration compared to conventional gels or creams.

Aceclofenac is a phenylacetic acid derivative NSAID widely used for treating pain, inflammation, and musculoskeletal disorders. It has pharmacological effects similar to diclofenac but shows reduced gastrointestinal toxicity, making it safer for chronic therapy

AIM AND OBJECTIVES

AIM :-

To formulate and evaluate Aceclofenac emulgel for topical anti-inflammatory activity.

OBJECTIVES :-

1. To develop a stable emulgel formulation
2. reduce systemic side effects
3. improve skin penetration
4. enhance solubility of Aceclofenac
5. study in-vitro drug release profile
6. To achieve controlled drug release
7. evaluate physicochemical properties
8. To assess stability of formulation
9. improve patient compliance

MATERIALS AND METHODS

Composition of Aceclofenac Emulgel :-

INGREDIENTS	QUANTITY (%)	QUANTITY (gm)
Aceclofenac	1%	1gm
Carbopol 934	1%	1gm
Liquid paraffin	7.5%	7.5gm
Tween 80	1%	1gm
Span 80	1%	1gm
Methyl paraben	0.03%	0.03gm
Propyl paraben	0.01%	0.01gm
Propylene glycol	5%	5gm
Triethanolamine	q.s.	~0.5gm
Water	q.s. To 100 %	~83ml

Table 1 : Required Ingredients

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MATERIALS USED :-

Materials	Category	Function
Aceclofenac	Drug	Anti-inflammatory agent
Carbopol 934	Polymer	Gelling agent
Liquid paraffin	Oil phase	Emollient
Tween 80	Surfactant Co-	Emulsifying agent
Span 80	surfactant	Emulsifying agent
Propylene glycol	Penetration enhancer	Solvent
Methyl paraben	Preservative	Antimicrobial agent
Propyl paraben	Preservative	Antimicrobial agent
Triethanolamine	pH adjuster	Neutralizer
Purified water	Vehicle	Solvent

Table 2 : Materials Use

EQUIPMENT USED

Equipment	Use
Digital balance	Weighing
Beaker	Mixing
Magnetic stirrer	Stirring
Brookfield viscometer	Viscosity measurement
pH meter	pH determination
UV spectrophotometer	Drug content analysis

Table 3 : Equipment Used

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PREPARATION OF ACECLOFENAC EMULGEL

STEP 1 : GEL PREPARATION

Disperse Carbopol 934 in water

Allow swelling for 24 hours

Adjust pH with Triethanolamine

STEP 2 : EMULSION PREPARATION

Oil phase: paraffin + spam 80

Aqueous phase: water + Tween 80 + (methyl paraben, propyl paraben)

Heat (70-75°c) and mix both phases

STEP 3 : EMULGEL PREPARATION

Mix gel and emulsion (1:1 ratio) Add propylene glycol

Stir to obtain uniform emulgel

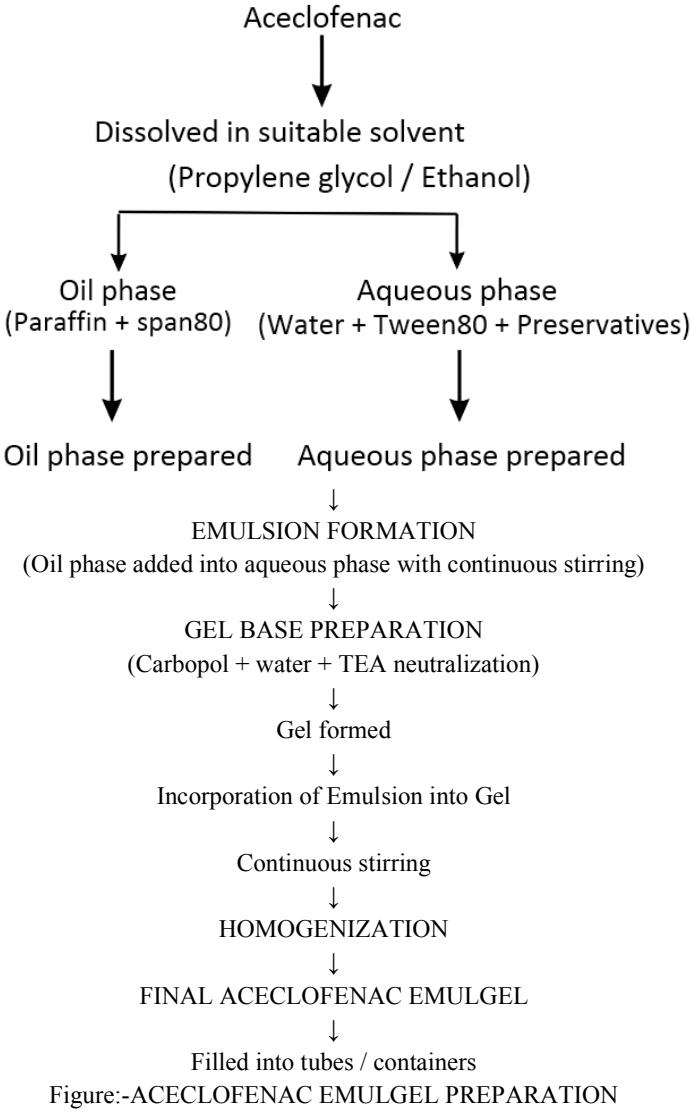

Figure:-ACECLOFENAC EMULGEL PREPARATION

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EVALUATION PARAMETERS

1. PHYSICAL APPEARANCE

The emulgel is visually checked for: Color
Odor Consistency Homogeneity
It should be smooth, uniform, and free from lumps
or phase separation.

2. PH DETERMINATION

Measured using a pH meter. Ideal skin pH range: 5.5 – 7.0 Important because:
Ensures skin compatibility
Prevents irritation

3. VISCOSITY

Measured using a Brookfield viscometer.
Determines flow behavior of emulgel. A good emulgel should have:
Moderate viscosity
Easy spreadability

4. SPREADABILITY

Indicates how easily the gel spreads on skin. Measured using glass slide method.
Formula used:
Spreadability = M × L / T
where;
M = weight applied L = length moved
T = time taken
Higher spreadability = better patient acceptability.

5. DRUG CONTENT UNIFORMITY

Ensures uniform distribution of aceclofenac in formulation.
Sample is dissolved and analyzed using UV spectrophotometer.
Should be within acceptable range (usually 90–110%).

6. IN VITRO DRUG RELEASE STUDY

Performed using Franz diffusion cell. Measures how drug is released over time. Shows:
Sustained release behavior
Efficiency of emulgel system

7. STABILITY STUDIES

Stored under different conditions (room temperature, humidity, heat).
Evaluated for:
Phase separation Color change Drug degradation

ADVANTAGES OF EMULGEL

1. Better Patient Compliance
2. Enhanced Drug Penetration
3. Reduced Gastrointestinal Side Effects
4. Controlled and Sustained Release
5. Targeted Local Action
6. Improved Stability
7. Dual Action System
8. Non-Greasy and Easily Washable
9. Good Spreadability

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10. Easy to apply

APPLICATIONS

1. Anti-Inflammatory use
2. Arthritis Treatment
3. Management of Musculoskeletal pain
4. Post-traumatic pain Relief
5. Post-operative Pain(Mild Cases)
6. Localized Drug delivery
7. Local Inflammatory Conditions
8. Pain Relief

RESULT AND DISCUSSION

Organoleptic Properties :-

1. PHYSICAL EVALUATION

Color	White or off-white
Odor	pleasant or odorless
Texture	smooth and non-gritty
Homogeneity	Good
pH	~6.5
Consistency	semi-solid and smooth consistency
Wash ability	Washable

Table 4 : Physical evaluation

2. HOMOGENEITY

Homogeneity refers to the uniform distribution of drug and other ingredients throughout the emulgel system, ensuring that each part of the formulation has the same composition and consistency.

3. STABILITY STUDY

Visible appearance	off-white
Phase separation	Stable
Homogeneity	Good

Table 5 : Stability study

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4. DETERMINATION OF PH

The pH of aceclofenac emulgel is measured using a calibrated pH meter, which detects hydrogen ion concentration in the formulationCalibrate the pH meter using standard buffer solutions (pH 4.0 and 7.0).

5. DETERMINATION OF SPREADABILITY

Spreadability is based on the sliding time of two glass slides when a fixed amount of emulgel is placed between them under a specific weight.

Better spreadability = less time taken for separation of slides

6. DETERMINATION OF VISCOSITY

Viscosity is an important parameter that indicates the flow behavior and consistency of the emulgel. It directly affects spreadability, application, and drug release.Viscosity is determined by measuring the resistance offered by emulgel to flow using a viscometer (commonly Brookfield viscometer).

7. STORAGE CONDITIONS

Room Temperature	25°c ± 2°c
Accelerated condition	40°c ± 2°c
refrigerated condition	Required

Table 6 : Storage condition

II. CONCLUSION

The developed emulgel showed satisfactory physical characteristics such as smooth texture, homogeneity, and acceptable pH suitable for skin application.The present study successfully formulated and evaluated a topical emulgel containing Aceclofenac for the management of pain and inflammation.

Aceclofenac emulgel is effective topical formulation.Aceclofenac emulgel is a topical semisolid dosage form developed by combining the properties of both emulsion and gel systems to enhance drug delivery through the skin. It provides an effective approach for the treatment of localized pain and inflammation associated with musculoskeletal disorders such as rheumatoid arthritis, sprains, and strains.

The formulation offers several advantages such as improved drug penetration, controlled and sustained drug release, non-greasy nature, better patient compliance, and reduced gastrointestinal side effects compared to oral therapy. The evaluation studies like pH, viscosity, spreadability, drug content, and stability confirm that the formulation is stable, safe, and suitable for topical application. Thus, aceclofenac emulgel represents an efficient and patient-friendly alternative for topical anti-inflammatory therapy, ensuring targeted action at the site of inflammation with enhanced therapeutic efficacy.