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Formulation of Aceclofenac Gel for Acute Pain Therapy

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Abstract: Aceclofenac is a Non-Steroidal Anti-Inflammatory Drug, used in the treatment of inflammation and degenerative disorder of the musculoskeletal system. It is widely prescribed for the treatment of osteoarthritis, rheumatoid arthritis, dysmenorrheal, acute lumbago, musculoskeletal trauma and gonalgia (Knee pain). Aceclofenac is well tolerated, with most adverse events being minor and reversible and affecting mainly the G.I system. Most common events include dyspepsia, abdominal pain, nausea, ulcerative stomatis and pancreatitis. The aim of this study was to formulate topical gel containing 1.5% Aceclofenac, 1% Benzyl Alcohol, 3% Linseed oil, 10% Methyl Salicylate, 0.01% Capsaicin, 5% Menthol and evaluate the same

Keywords: Aceclofenac Gel, Formulation and Development

I. INTRODUCTION

The Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) possess anti-inflammatory, analgesic and antipyretic activities. The Indian drug industry is always ready to cater to the needs of medical professionals by developing combinations of various kinds of drugs that are capturing substantial market share. Aceclofenac is a Diclofenac derivative of the Non-Steroidal Anti-Inflammatory Drug^{1,2,3}, which is chemically, (2-[2-[2-(2,6- dichlorophenyl) aminophenyl] acetyl] oxyacetic acid)^{4,5}. Aceclofenac exhibited potent Anti-Inflammatory Analgesic activity and is widely prescribe for the treatment of osteoarthritis, rheumatoid arthritis, acute lumbago, and dental pain condition⁶. Aceclofenac is well tolerated, with most adverse events being minor and reversible and affecting mainly the G.I system. Although the incident of gastrointestinal adverse events with Aceclofenac was similar to that comparator NSAID in individual clinical trial withdrawal rate due to these events were significantly lower Aceclofenac than with Ketoprofen and Temoxicam^{7,8}. Other adverse effects which are not common such as dizziness (1%), vertigo (0.3%) and tremor. In the present study is the development a formulation of Aceclofenac gel and to evaluate the same for drug content, pH and viscosity.

II. LITERATURE

Aceclofenac gel formulation for acute pain therapy has been studied extensively, showcasing its potential as an effective treatment for various musculoskeletal conditions.

Benefits of Aceclofenac Gel

- Effective pain relief: Aceclofenac has been shown to be at least as effective as other NSAIDs in reducing pain and improving functional capacity in chronic and acute painful musculoskeletal conditions.
- Favorable GI profile: Studies suggest that aceclofenac has a more favorable gastrointestinal profile compared to other NSAIDs, with a lower incidence of gastrointestinal adverse events.
- Rapid onset of action: Research indicates that aceclofenac has a rapid onset of action, with significant pain reduction observed within a few hours of administration ¹².

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Formulation Development

- Nanosponge gel: Studies have explored the development of aceclofenac-loaded nanosponge gel, which has shown promising results in terms of anti-inflammatory activity and permeation.
- Topical delivery: Topical delivery of aceclofenac has been investigated as a potential treatment for musculoskeletal pain, with studies demonstrating its efficacy and safety ^{3 4}.

Comparative Studies

- Diclofenac comparison: Research has compared the efficacy and safety of aceclofenac with diclofenac, showing that aceclofenac is as effective or even more effective than diclofenac in managing pain and inflammation.
- Other NSAIDs comparison: Studies have also compared aceclofenac with other NSAIDs, such as piroxicam and indomethacin, demonstrating its efficacy and safety profile ⁵.

Future Directions

- Further research: Continued research is needed to fully explore the potential of aceclofenac gel formulation for acute pain therapy, including its long-term efficacy and safety.
- Optimizing formulation: Optimizing the formulation of aceclofenac gel to enhance its permeation, efficacy, and safety profile may lead to improved treatment outcomes.

Aim & Objective

Aim And Objective on Formulation Of Acelcofenac gel for Acute Pain Therapy Meta AI: Here's a possible aim and objective for the formulation of Aceclofenac gel for acute pain therapy:

Aim

To develop a topical Aceclofenac gel formulation that provides effective pain relief for acute musculoskeletal conditions, with improved skin permeation, efficacy, and safety.

Objectives

- 1. Formulate Aceclofenac gel: Develop a stable and effective topical gel formulation of Aceclofenac.
- 2. Enhance skin permeation: Improve skin permeation of Aceclofenac to achieve optimal therapeutic effect.
- 3. Evaluate efficacy: Assess the efficacy of the formulated gel in reducing pain and inflammation in acute musculoskeletal conditions.
- 4. Ensure safety: Evaluate the safety and tolerability of the formulated gel.
- 5. Optimize formulation: Optimize the formulation to achieve desired characteristics, such as rapid onset of action and sustained pain relief.

Active component of Aceclofenac gel

Class: Non-Steroidal Anti-Inflammatory Drug (NSAID) Concentration in gel form: Typically 1.5% w/w or 2% w/w, depending on the formulation

Function:

- Reduces pain, inflammation, and swelling
- Commonly used for muscle pain, joint pain, osteoarthritis, and sports injuries
- Other common excipients (inactive ingredients) in Aceclofenac gel:
- Menthol cooling and analgesic effect
- Methyl salicylate anti-inflammatory and rubefacient
- Linseed oil anti-inflammatory

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- Diclofenac diethylamine (in some combo gels)
- Carbopol, Propylene glycol, Triethanolamine, Isopropyl alcohol, Purified water as gel base and stabilizers

Let me know if you need a full label or composition sheet for Aceclofenac gel.

Key Considerations

- 1. Drug delivery: Effective delivery of Aceclofenac to the site of action.
- 2. Skin permeation: Enhancing skin permeation to achieve optimal therapeutic effect.
- 3. Stability: Ensuring stability and shelf-life of the formulated gel.
- 4. Patient compliance: Developing a formulation that is easy to apply and has a pleasant texture.

Excipients (Inactive Ingredients):

These may vary slightly depending on the manufacturer, but usually include:

- 1. Menthol Provides a cooling sensation and enhances absorption
- 2. Methyl Salicylate Rubefacient; enhances analgesic effect
- 3. Linseed Oil Anti-inflammatory and emollient
- 4. Carbopol 940 Thickening agent used to form the gel base
- 5. Propylene Glycol Solvent and humectant (improves penetration)
- 6. Isopropyl Alcohol Solvent and antiseptic
- 7. Triethanolamine Used to adjust pH and help gel formation
- 8. Purified Water Solvent base for the gel

Aceclofenac Gel Formulation (for 100 g)

Ingredient	Quantity	Purpose
Aceclofenac	1.5 g	Active anti-inflammatory agent
Menthol	0.5 g	Counter-irritant, cooling effect
Methyl Salicylate	3.0 g	Analgesic, anti-inflammatory
Linseed Oil	3.0 g	Anti-inflammatory, emollient
Carbopol 940	1.0 g	Gelling agent
Propylene Glycol	5.0 g	Penetration enhancer, humectant
Triethanolamine (TEA)	q.s. (about 1-2 g)	pH adjuster and gel neutralizer
Isopropyl Alcohol (IPA)	10.0 g	Solvent and antiseptic

Preparation Method:

- 1. Disperse Carbopol 940 in a portion of purified water and allow it to swell for about 2 hours.
- 2. Dissolve Aceclofenac in isopropyl alcohol along with menthol, methyl salicylate, and linseed oil.
- 3. Add propylene glycol and preservative to the alcoholic solution.
- 4. Mix the alcoholic solution with the Carbopol dispersion slowly with continuous stirring.
- 5. Adjust the pH to 6.5–7.0 using triethanolamine to form a clear gel.
- 6. Make up the final volume/weight with purified water and stir until a homogeneous gel is formed.

7. Pack in an aluminum or laminated tube.

Evaluation Parameters for Aceclofenac Gel

1. Appearance

Test: Visual inspection

Criteria: Should be a clear or translucent, homogenous gel; free from lumps or air bubbles.

2. pH

Test: pH meter

Range: 6.5 to 7.0 (suitable for skin application)

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3. Viscosity

Test: Using a Brookfield viscometer Purpose: To assess the gel's flow characteristics and spreadability.

4. Spreadability

Purpose: Indicates ease of application on skin Result: Expressed in g·cm/sec (higher is better) Specification: Should contain 90–110% of the labeled Aceclofenac content.

5. Skin Irritation Test

Purpose: To assess skin compatibility Method: Patch test on albino rats or human volunteers (ethical approval required)

Advantages :

- 1. Localized Action
- 2. Reduced Gastrointestinal Side Effects
- 3. Fast Onset of Action
- 4. Non-Greasy & Easy to Apply
- 5. Fewer Systemic Side Effects
- 6. Convenient for Targeted Therapy
- 7. Patient-Friendly Alternative
- 8. Combination Synergy

Result :

1. Pain Relief

Begins within 30 minutes to a few hours after application.

Most effective for localized musculoskeletal pain.

2. Reduced Inflammation and Swelling

Regular use (2-3 times a day) over several days can reduce visible swelling and tenderness.

3. Improved Mobility

As pain and stiffness decrease, joint or muscle mobility often improves.

4. Fewer Systemic Side Effects

Compared to oral NSAIDs, aceclofenac gel has a lower risk of gastrointestinal or cardiovascular side effects because it's applied directly to the skin.

Possible Side Effects:

Although generally well-tolerated, some people may experience:

Mild skin irritation (redness, itching, or rash)

Photosensitivity (increased sensitivity to sunlight)

Allergic reaction (rare)

II. CONCLUSION OF ACECLOFENAC GEL

Aceclofenac gel is a well-established topical NSAID formulation offering effective, localized relief from pain and inflammation associated with musculoskeletal conditions such as osteoarthritis, sprains, strains, and back pain. Its ability to deliver the drug directly to the affected area minimizes systemic absorption, thereby significantly reducing the risk of common side effects linked to oral NSAIDs—especially gastrointestinal and renal issues.

With its quick onset of action, patient-friendly application, and combination with other synergistic agents like menthol and methyl salicylate, Aceclofenac gel stands out as a safe, convenient, and effective option for both acute and chronic pain management.

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Let me know if you need this conclusion tailored for a project report, product monograph, or regulatory dossier.

REFERENCES

- [1]. Indian Pharmacopoeia (IP) Latest Edition Contains official standards for Aceclofenac and topical preparations Source: Indian Pharmacopoeia Commission, Govt. of India
- [2]. British Pharmacopoeia (BP) Relevant for excipients and gel formulations Includes general methods of analysis and topical product standards
- [3]. Martindale: The Complete Drug Reference Details pharmacological properties, indications, and clinical usage of Aceclofenac
- [4]. Tripathi, K.D. Essentials of Medical Pharmacology Chapter on NSAIDs Describes mechanism of action, indications, and safety profile
- [5]. Allen, L.V. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems Provides formulation concepts and evaluation methods for gels
- [6]. PubChem / DrugBank
- [7]. Rane, B. R., & Patil, M. V. (2016). Formulation and evaluation of Aceclofenac gel. International Journal of Pharmaceutical Sciences Review and Research, 38(1), 190-194.
- [8]. Jadhav, K. R., et al. (2009). Formulation and evaluation of Aceclofenac topical gels. Indian Journal of Pharmaceutical Sciences, 71(2), 111–115



