International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 4 July-Aug 2025, pp: 828-832 www.ijprajournal.com ISSN: 2456-4494

Formulation and Estimate of Aceclofenac Topical emulgels

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Date of Submission: 10-08-2025 Date of Acceptance: 20-08-2025

ABSTRACT

Topical gel preparation remains one of the most popular and important pharmaceutical dosage forms due to its ability to deliver therapeutic effects locally while minimizing systemic side effects. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including Aceclofenac, are widely used in treating inflammatory conditions like rheumatoid arthritis, but their oral administration often leads to gastrointestinal irritation and other systemic side effects. Topical application of NSAIDs offers targeted delivery to inflamed sites, thereby reducing adverse effects and improving patient compliance.Aceclofenac, a BCS class II drug belonging to the phenylacetic acid group, has shown significant anti-inflammatory and analgesic properties. Due to its lipophilic nature, it is well absorbed through tissues, enhancing its therapeutic potential in topical formulations. Additionally, Aceclofenac stimulates glycosaminoglycan (GAG) synthesis, improving skin permeation.This study explores the formulation and evaluation of topical gels of Aceclofenac using natural and synthetic polymers like guar gum and sodium alginate. Preformulation studies, drug-excipient compatibility (via FTIR), solubility enhancement, and drug release characteristics were conducted to ensure stability and efficacy. Aceclofenac demonstrates therapeutic efficacy in conditions such as rheumatoid arthritis, osteoarthritis, dysmenorrhea, and dental pain, and is considered safer and more tolerable than some other NSAIDs.

Keyword :- Aceclofenac, Topical gel formulation, Fast dissolving tablets, NSAIDs, Emulgel, Direct compression, Gelling agents, Guar gum, Sodium alginate, Drug delivery, Skin permeability, Anti-inflammatory

I. INTRODUCTION

Topical gel preparation has remains one of the most popular and important pharmaceutical dosage forms. As a result, the therapeutics effects of the drugs are achieved effectively whereas the systemic side effects can be avoided or minimized. The Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) have been widely used in the treatment of rheumatoid arthritis and other related condition .However, they carry the risk of undesirable systemic side effect and gastrointestinal irritation at the usual dose of oral administration[1]Considering the fact that most inflammatory diseases occur locally and near the surface of the body ,topical application of NSAID on the inflamed site can offer the advantage of delivering a drug directly to the disease site and producing its local effect .This occurs by avoiding gastric irritation and also reduced adverse systemic effect[2]Aceclofenac (2-[(2, 6-dichlorophenyl) amine] phenylacetoxyacetic acid) is a new NSAID of phenyl acetic acid group, demonstrated remarkable anti-inflammatory and analgesic properties. Structure of Aceclofenac is shown in (fig.1).Preliminary clinical studies have shown that Aceclofenac 1.5% applied topically for 4 days is as well tolerated as placebo.[3]Aceclofenac is an example of BCS class II compound, due to its lipophilic nature it will better absorbed by tissue and will show better action.[4]

Pharmacologically Aceclofenac stimulates glycosaminoglycan's (GAG) synthesis which results in enhancement of skin permeation of NSAIDs. Stratum corneum is the principal barrier for cutaneous penetration allowing slow absorption of the drug .[5]

The importance of Aceclofenac as a new generation NSAID has inspired development of topical drug delivery. Topical formulation of Aceclofenac gives the opportunity to deliver the drug directly to the diseased site.[6]Guar gum is made up of linear chains of (1–4)-b-D-manopyranosylunits with D galactopyranosyl unit linked by (1–6) linkages. The ratio ofD-galactose to

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Volume 10, Issue 4 July-Aug 2025, pp: 828-832 www.ijprajournal.com ISSN: 2456-4494

D-mannose is between 1: 1.4 and 1: 2. The USPNF 23defines guar gum as a gum that is obtained from endosperms of Cya-mopsistetragonolobus (L.) Taub (Fam. Leguminosae).It mainly has a high-molecular-weight hydro colloidal polysaccharide, comprised of galactanandmannan units linked through glycoside linkages, chemically knownas a-galactomannan.Sodium alginate involves mainly sodium salt of alginic acid (amixture of polyuronic acids which are residues of D-mannuronic acid andL-guluronic acid).[7]

TOPICAL DELIVERY INCLUDES TWO BASIC TYPES OF PRODUCTS

- External topical that are spread, sprayed or otherwise dispersed on to cutaneous tissues to cover the affected area.
- Internal topical that are applied to the mucous membrane orally, vaginally or on a rectal tissues for local activity

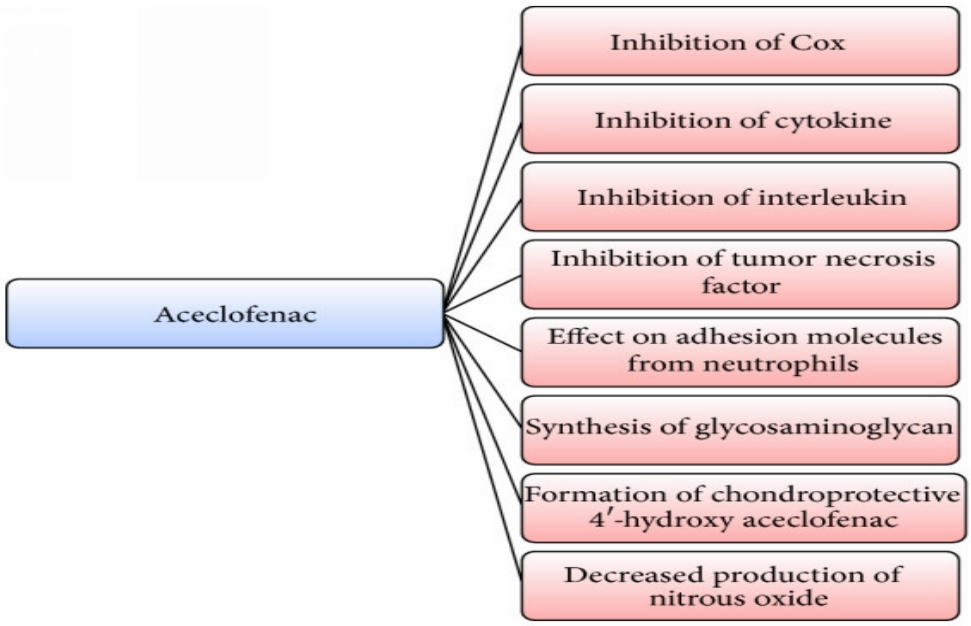

Fig No. 1 Targets of ACE resulting in decrease of pain and inflammation.

A Factors Affecting Topical Absorption of Drug
Physiological Factors:

- ✓ Skin thickness.
- ✓ Lipid content.
- ✓ Density of hair follicles.
- ✓ Density of sweat glands.
- ✓ Skin pH.
- ✓ Blood flow.
- ✓ Hydration of skin .
- ✓ Inflammation of skin.

Physiochemical Factors:

- ✓ Partition coefficient
- ✓ Molecular weight (<400 dalton).
- ✓ Degree of ionization (only unionized drugs

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gets absorbed well)
- Effect of vehicles

Advantages of Topical Drug Delivery System:
- ✓ Avoidance of first pass metabolism.
- ✓ Avoidance of gastrointestinal incompatibility.
- ✓ More selective to a specific site.
- ✓ Improve patient compliance.
- ✓ Suitability for self medication.
- ✓ Providing utilization of drug with short biological half life and narrow therapeutic window.
- ✓ Ability to easily terminate medication when needed.

Disadvantages of Topical Drug Delivery System
- ✓ Skin irritation on contact dermatitis.
- ✓ Possibility of allergenic reactions.
- ✓ Poor permeability of some drug through skin.
- ✓ Drug of large particle size not easy to absorb through the skin.

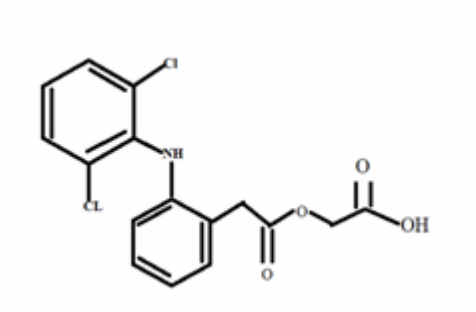

Fig 01. Structure of Aceclofenac

IUPAC Name of Aceclofenac:-
2-[2-{2-(2,6-dichloroanilino)phenyl]acetyl} oxyacetic acid

Chemical Formula:-
C16-H13-Cl2-NO4

Molecular weight:-
354 g·mol^{-1}

Therapeutic Categories:-
- ➢ Analgesic, antipyretic and anti-inflammatory agent
- ➢ Non-steroidal anti-inflammatory drug, NSAID

Chemical Name:-
Glycolic acid, [o-(2,6-dichloroanilino)phenyl] acetate (ester) (WHO)

II. MATERIALS AND METHODS

1.Experimental Requirements :-[8]
The following are the Equipment, Instrument, and Materials that were used for the formulation and evaluation of Drug-
- ♦ Aceclofenac, carbopol 934, Tween 80, Span 80, Propylene glycol, ethanol, clove oil, Methyl paraben.
- ♦ Digital balance, magnetic stirrer, Spectrophotometer, compound microscope, Dissolution test apparatus, pH meter.

2.Preformulation Studies :-[8]
Preformulation studies are performed for the improvement of Emulgel before the initiation of plan advancement, and the significant objective of the investigation is to create or foster steady, safe, and restoratively powerful and effectual dose frames that are essentially identified with the portrayal of the physicochemical properties of the medication substance. The major aim of the pre-formulation studies before product development are :
- ♦ To establish the important physicochemical nature & characteristics of the drug.
- ♦ For the determination of drug compatibility with different excipients used in the formulation.

3. Characterization of Aceclofenac:-[8]
For pre-formulation studies, the micronized form of Aceclofenac was subjected to physical tests.

4. Drug – Excipients Compatibility Studies :-
For the selection of suitable additives or excipients while developing a pharmaceutical formulation it's necessaryto check the drug-excipients compatibility. Various organoleptic (macroscopic) properties were observed using this study. Drug excipients compatibility tests give the assurance of the stability of formulation. The active drug was mixed with Potassium bromide (KBr) and spectra were plotted on FT-IR. Accordingly, the excipient and Potassium bromide mixed in the same ratio as 9:1 ratio and spectra were plotted. The FT-IR band of Aceclofenac was checked with FT-IR spectra of Aceclofenac with other additives used. Shifting or Disappearance of Aceclofenac peak in spectra was examined.[9]

5.Material
Aceclofenac was a kind gift from Mepro Pharmaceuticals Pvt. Ltd. Surendranagar, Gujarat and Aroff SR tablet (marketed product) was purchased from a local market in India. Each tablet was labeled to contain 200 mg of Aceclofenac BP. Table 1 lists the formulations evaluated for this study. The excipients were present in the tablets: hydroxypropyl methylcellulose-K4M (HPMC;

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Methocel K4M Premium, Colorcon Asia Pvt. Ltd., Singapore), hydroxypropyl methylcellulose-K15M (HPMC; Methocel K4M Premium, Colorcon Asia Pvt. Ltd., Singapore), hydroxypropyl methylcellulose-K100M (HPMC; Methocel K100M Premium, Colorcon Asia Pvt. Ltd., Singapore) Guar gum, ethyl cellulose 20cps, hydroxypropyl methylcellulose 15cps (Colorcon Asia Pvt. Ltd., Singapore), lactose (DMV International, U.S.A.), PVPK-30 sodium propyl paraben, fumaric acid microcrystalline cellulose (MCC; Avicel pH102, FMC biopolymer, U.S.A.), magnesium Stearate , talc, Isopropyl alcohol, methyllene chloride, titanium dioxide,PEG-6000, castor oil and Ponceau 4 R supra. All other chemicals used were of analytical grade.[10]

THERAPEUTIC USES OF ACECLOFENAC

Aceclofenac is successively used as anti-rheumatic, anti-inflammatory (both acute and chronic), analgesic (effective pain killer in lower backache, dental or gynecological pain) and antipyretic [11].

Dysmenorrhea

It is effective to treat dysmenorrheal pain. A single oral dose of aceclofenac 100 mg is sufficient to reduce primary dysmenorrhoea. In addition combination of aceclofenac and drotaverine is also functional and well tolerated treatment choice for primary dysmenorrhoea[12]

Dental Pain Management

NSAIDs are widely used in managing pain and postoperative discomfort in dental surgeries. Drugs of this group effectively block the prostaglandin synthesis in pain and inflammation [13]. Twice-daily of aceclofenac (100 mg) is effective in controlling post extraction pain [14].

Pharyngoamygdalitis

The aceclofenac improves the signs and symptoms of viral pharyngoamygdalitis. A study was conducted to compare the response of aceclofenac with paracetamol. The patients who had given aceclofenac showed better and earlier improvement in the clinical symptoms of acute viral pharyngoamygdalitis than those treated with paracetamol[15].

Rheumatoid Arthritis (RA)

NSAIDs are well accepted for a variety of chronic arthritis pain syndromes and inflammatory conditions, most commonly rheumatoid arthritis and osteoarthritis [16]. Aceclofenac has been used to treat inflammatory diseases in greater than 75 million patients universally. The pain-killing action of aceclofenac 100mg is more prolonged than that of paracetamol (acetaminophen) 650mg [17].

Osteoarthritis Arthritis (OA)

Aceclofenac has been widely used in osteoarthritis (OA) especially of knee in doses of 100mg twice daily [18]. It possesses comparable efficacy and a superior tolerance than other commonly marketed NSAIDs in the treatment of OA [19]. Aceclofenac has better and reliable effects in OA of knee than paracetamol having same tolerability [20]. In addition the response of acceclofenac alone and acceclofenacparacetamol combination was investigated in patients with OA flare-up. The combination provided more rapid pain relief but mono-drug was also effective [21]

III. CONCLUSION

Topical gels are widely used in drug delivery for localized action and reduced systemic side effects. Aceclofenac, a BCS class II NSAID, effectively treats inflammation but poses GI risks when taken orally. Topical application targets inflamed areas directly, minimizing adverse effects. However, skin permeability limits drug absorption. Permeation enhancers like glycosaminoglycan stimulators help overcome this. Gelling agents such as guar gum and sodium alginate aid in forming gels, offering faster release than creams. Emulgels, combining emulsions and gels, enhance drug diffusion and skin penetration, improving efficacy. Additionally, fast-dissolving Aceclofenac tablets were prepared via direct compression. Evaluations confirmed uniform weight, consistent thickness, sufficient hardness, and low friability (<1%), indicating good mechanical strength and durability. These formulations improve drug delivery efficiency and patient compliance in managing inflammatory conditions.

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