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FORMULATION AND EVALUTION OF ANALGESIC OINTMENT CONTAINING DICLOFENAC SODIUM

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ABSTRACT

Diclofenac sodium ointment is one of the most widely used topical non-steroidal anti-inflammatory drug (NSAID) formulations for the management of pain and inflammation associated with musculoskeletal disorders, osteoarthritis, sprains, strains, sports injuries, and localized soft tissue conditions. Topical administration offers a targeted therapeutic approach by delivering the drug directly to the affected site while minimizing systemic absorption, thereby reducing the risk of gastrointestinal, cardiovascular, and renal adverse effects commonly associated with oral NSAIDs. The effectiveness of diclofenac sodium ointment depends on several formulation factors, including the selection of suitable ointment bases, penetration enhancers, stabilizers, preservatives, and other excipients that influence drug release, skin permeation, stability, and patient acceptability. This review summarizes the physicochemical and pharmacological properties of diclofenac sodium, its mechanism of action through cyclooxygenase (COX) inhibition, and the formulation strategies employed in topical ointment development. In addition, the article discusses various evaluation parameters such as appearance, pH, viscosity, spreadability, drug content, in vitro drug release, skin irritation, stability, and therapeutic efficacy. Recent advances in topical drug delivery systems and current research trends aimed at improving skin penetration and bioavailability are also highlighted. Overall, diclofenac sodium ointment remains a safe, effective, and patient-friendly topical dosage form for localized pain management, with ongoing research focused on enhancing its clinical performance and therapeutic outcomes.

1. INTRODUCTION

1.1Semi solid dosage form: Topical semi solid dosage form is normally presented in the form of creams, gels, ointments, or pastes. They contain one or more active ingredients dissolved or uniformly dispersed in a suitable base and any suitable excipients such as emulsifiers, viscosity increasing agents, antimicrobial agents, antioxidants or stabilizing agents.[1]

Examples: Ointment, pastes, creams, gel.[2]

1.2 Advantages of semi - solid dosage form

- It is used externally.
- Probability of side effect can be reduced.
- First pass gut and hepatic metabolism is avoided.
- Convenient for comatose patients or patients having difficulty on oral administration.
- Convenient dosage form for bitter drugs
- More stable than liquid dosage form.

1.3 Disadvantages of semi - solid dosage form

- There is no dosage accuracy in semi solid dosage forms.
- The base which is used in the semisolid dosage form can be easily oxidized.
- May cause staining.
- They are bulky to handle.
- Application with finger may cause contamination.
- Physio - chemically less stable than solid dosage form[3]

1.4 Transdermal drug delivery system

Transdermal drug delivery systems (TDDS) refer to formulations created to administer an appropriate medicinal dosage through a patient's skin, ensuring the delivers of a therapeutic dose of the drug into the body. To achieve systemic effects by transmitting therapeutic substances through human skin, it is essential to consider the skin's biophysical, morphological, and physicochemical properties comprehensively. Transdermal drug delivery presents notable advantages compared to injectables and oral routes, as it improves patient compliance and circumvents the first-pass metabolism.[4]

1.5 Objective

1. **E**nhance bioavailability and efficacy.
2. Reduce system side effects.
3. Improve patient compliance and adherence.
4. Overcome skin barrier limitation.[5]

1.6 Advantages of transdermal drug delivery

- Avoiding first-pass metabolism, reducing side effects, and minimizing fluctuations in plasma levels.
- Utilizing drug candidates with short half-lives and low therapeutic indices.
- Easy elimination of drug delivery in case of toxicity.
- Reduced dosing frequency, enhancing patient compliance.

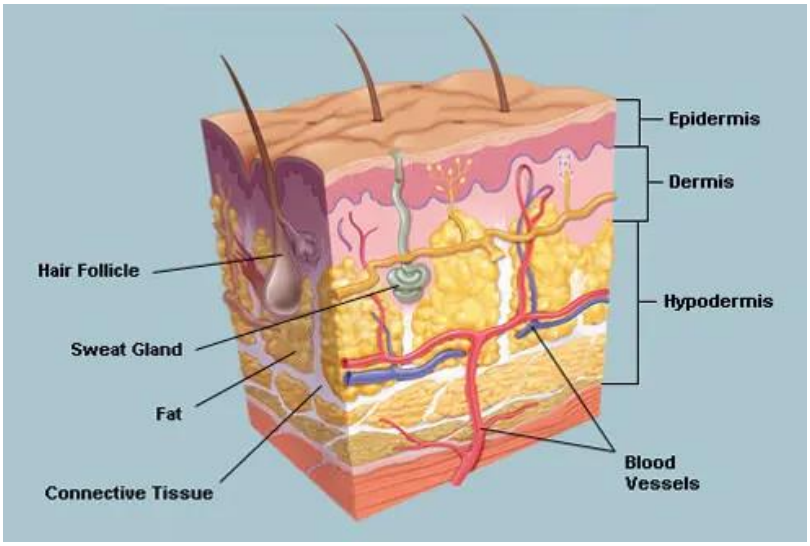
1.7 Disadvantage of transdermal drug delivery system

- TDDS cannot deliver ionic drugs.
- TDDS cannot achieve high drug levels in blood/plasma
- It cannot develop for drugs of large molecular size.
- TDDS cannot deliver drugs in a pulsatile fashion.
- TDDS cannot develop if drug or formulation causes irritation to skin.[6]

1.8 Physiology of skin

The skin is the largest organ in the body, covering its entire external surface. The skin has 3 layers-the epidermis, dermis, and hypodermis, which have different anatomical structures and functions. The skin's structure comprises an intricate network that serves as the body's initial barrier against pathogens, ultraviolet (UV) light, chemicals, and mechanical injury.[7]

The skin is the largest organ of the body, accounting for about 15% of the total adult body weight. It performs many vital functions, including protection against external physical, chemical, and biologic assailants, as well as prevention of ex- cess water loss from the body and a role in thermoregulation. The skin is continuous, with the mucous membranes lining the body’s surface. The integumentary system is formed by the skin and its derivative structures.[8]



1.9 OINTMENTS

Ointments are semisolid dosage form which usually act as viscos-elastic materials when shear stress is applied. They generally contain medicinal ingredients and are used to be applied externally to the body for therapeutic effect. Many therapeutic agents used for topical application to intact or broken skin or to mucous membranes are presented in the form of semisolid consistency variously designated as ointments, creams, pastes etc. It is used mainly as protective or emollient for the skin.[9]

Ointment has very moisturizing characteristic and are effective for dry skin. They have very low risk of sensitization due to having few ingredients beyond the base oil or fat and low irritation risk.[10]

1.10 Types of Ointments

Ointment may be medicated or non-medicated.

a) **Medicated ointments**: For the application of API to skin for protective, therapeutic, or prophylactic purpose.

b) Non-medicated ointments: These are used for physical effect. They are use as protectant, emollient, or lubricants.[11]

1.11 Characteristics of an ideal ointment

1**)** It should be physically and chemically stable.

2) In ointment base, finely divided active ingredients should be uniformly distributed.

3) The base of ointments should not possess any therapeutic action.

4) The ointment should be smooth and free from grittiness.

1.12 Advantages of ointment

1. They avoid first pass metabolism of drug.
2. Suitable for incorporating bitter tasting drugs.
3. Better patient compliance as easily acceptable by paediatrics and geriatrics.
4. Provide target delivery of drug to a specific site.
5. Comparatively more stable chemically.

1.13 Disadvantages of ointment

1. Due to oily preparation these formulations produce stains.
2. On application it may cause itching or might cause contamination.
3. Physio-chemically less stable than solid dosage form.
4. Bulky to handle.
5. Phase separation or cracking may occur.[12]

1.14 Application

- Treatment of skin Diseases
- Antimicrobial Action
- Emollient Action
- Protection
- Anti analgesic action
- Anti-inflammatory Action
- Pain Relief
- Wound healing
- Systemic Drug delivery
- Ophthalmic use[13]

1.16 OINTMENT BASES WITH EXAMPLE

Type of Ointment bases (according to USP)

Mainly ointment bases are of following types:

1) Oleaginous ointment base or hydrocarbon ointment base

2) Absorption ointment bases

3) Water removable bases or water washable bases

4) Water soluble base

1) Oleaginous ointment base or hydrocarbon ointment base (water in Oil)

These bases have following properties

a) Small amount of aqueous component can be incorporated into these bases.

b) These bases have emollient effect.

c) These bases are difficult to wash off as these are w/o type of bases.

d) These bases do not dry out.

e) These bases keep the medicament in prolonged contact with skin.

f) These bases act as occlusive dressing. Examples: white petrolatum, yellow ointment, white ointment.

2) Absorption ointment bases

These bases categorize into two groups:

A) Permit the incorporation of aqueous solution with the formation of water in oil type of bases. Example: Hydrophilic petrolatum Lanolin

B) These are already w/o type of bases and permit the additional amount of aqueous solution. Example: Anhydrous lanolin These bases have following properties:

3) Water removable bases or water washable bases

These bases are also called as emulsifying bases or oil in water type of emulsion bases. These are water washable bases. Mostly these bases are preferred for cosmetic purpose. Advantages of these bases are:

a) Some medicaments are more effective in these bases.

b) These bases may be diluted with water. Example: Hydrophilic ointment, Vanishing cream.

4) Water soluble base

These bases are greaseless bases containing water soluble constituents. These are oil-in-water emulsions that are capable of being washed from skin or clothing with water. For this reason, they are frequently referred to as

“Water-washable” ointment bases.

1.17 Characteristics

a. Resemble creams in their appearance

b. May be diluted with water or with aqueous solution

c. From therapeutic viewpoint, no ability to absorb serous discharge in dermatologic conditions

d. Certain medicinal agents may be better absorbed in the skin

e. Insoluble in water

1.18 Ideal characteristics

1) Should not retard wound healing,

2) Have a low sensitization index,

3) Pharmaceutically elegant,

4) Release the medicament efficiently at the site of application,

5) Have a low index of irritation,

6) Non-dehydrating, non-greasy and neutral in reaction,

7) Compatible with common medicaments and also with the skin,

8) Easily washable with water,

9) Have minimum number of ingredients,

10) Easy to compound and remain stable on storage.[14]

CONCLUSION

Diclofenac sodium ointment is an effective topical non-steroidal anti-inflammatory drug (NSAID) widely used for the management of pain, inflammation, and musculoskeletal disorders. Its topical route of administration provides targeted drug delivery at the site of inflammation while minimizing systemic exposure and reducing the risk of gastrointestinal and cardiovascular adverse effects commonly associated with oral NSAIDs. The formulation of diclofenac sodium ointment with suitable excipients enhances drug stability, skin penetration, patient acceptability, and therapeutic efficacy. Recent advances in topical drug delivery systems, including the use of penetration enhancers, nano-based carriers, and optimized ointment bases, have further improved the bioavailability and clinical performance of diclofenac sodium formulations. Numerous preclinical and clinical studies have demonstrated the safety, efficacy, and tolerability of diclofenac sodium ointment in the treatment of osteoarthritis, sports injuries, sprains, strains, and other localized inflammatory conditions. However, challenges such as limited skin permeability, formulation stability, and occasional local skin irritation still require continued research and optimization. Overall, diclofenac sodium ointment remains a valuable and patient-friendly therapeutic option for localized pain management. Future research should focus on developing novel formulation strategies that enhance skin penetration, prolong drug release, improve patient compliance, and maximize therapeutic outcomes while maintaining a favorable safety profile. Such

advancements will further strengthen the clinical utility of diclofenac sodium ointment in modern topical drug delivery.

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