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A REVIEW ON OINTMENT FORMULATION

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ABSTRACT

Ointments are semisolid preparations designed for external application, where the drug is uniformly dispersed in a suitable base, often incorporating emulsions for better drug delivery and skin absorption. They typically include active medicinal substances and are meant for external use on the body to achieve a therapeutic outcome. Numerous medications intended for topical use on healthy or damaged skin and mucosa are formulated as semisolid preparations like ointments. As a result, ointment formulations have become a significant focus in modern pharmaceutical research due to their ease of application, physical stability, favorable dissolution characteristics, and overall therapeutic effectiveness. The ointment was formulated by blending active ingredients into the prepared base using trituration in an optimized ratio, and its quality was evaluated based on parameters like non-irritancy, ease of spreading, drug diffusion, and overall stability.

KEYWORDS: Ointments, cleansing agent, emulsification method, fusion method, non irritancy test.

INTRODUCTION

Ointments are semisolid preparations that behave like viscoelastic materials under pressure, usually containing medicines for external application on skin. Non-medicated ointments serve as bases or emollients and are similar to products. They are used for a variety of purposes including protecting, soothing, and treating skin conditions.[1]

Pharmaceutical semisolid dosage forms such as ointments and foams are designed for topical application and consist of one or more active pharmaceutical ingredients that are either dissolved or uniformly dispersed in suitable bases, along with functional excipients like emulsifiers, viscosity enhancers, antimicrobial agents, antioxidants, and stabilizers — all of which help to ensure the product's stability, effectiveness, and ease of application for therapeutic, protective, or cosmetics purpose through skin or mucosal surface include nasal, rectal, or vaginal routes.[2]

Ointments are topical formulations that not only provide protective and lubricating effects on the skin but also deliver active drugs directly to the affected area or into systemic circulation via transdermal absorption, and are widely preferred in pharmaceutical practice due to their ability to maintain stable and prolonged drug levels in the blood, ensure patient safety, deliver faster therapeutic action, offer ease of application without the need for extensive procedures, and allow for greater patient compliance and broader acceptance in both clinical and home care settings.[3]

Ointments, which heal, protect, or soothe the skin upon direct application, function as both protective and therapeutic agents by effectively delivery medication to the affected area, and due to their occlusive nature, oleaginous ointments are particularly suitable for treating dry, chapped skin in low. humidity condition, while their safety, efficiency, and quality are evaluated through various physical, tests like absorption rate, Non-irritancy, as well as microbiological assessment such as microbial content and preservative effectiveness, with their simple composition are primary a base oil, fat and additional ingredients. That helping reduces the risk of sensitization or discomfort in use.[4]

Ointments hydration to the skin, form a protective layer against environmental irritants, and deliver active pharmaceutical ingredients that effectively treat localized conditions such as bacterial infections, eczema, psoriasis, or fungal diseases, while their occlusive nature enhances absorption and ensures sustained therapeutic effect.[5]

ADVANTAGES

◊ More stable than liquid dosage forms.

◊ They avoid first-pass metabolism of drugs.

◊ They are suitable dosage forms for bitter-tasting drugs.

◊ Easy to apply on localized areas.[6]

◊ Not fast drying.

◊ It possesses good keeping quality.

◊ They are chemically more stable than liquid dosage forms.

◊ Ointments are well-tolerated topical drug delivery systems that can be used for treatment of a variety of conditions.

◊ Easily washable and non-greasy.[7]

DISADVANTAGES

◊ Not suitable for hairy areas.

◊ Some people may be allergic to additives in ointments.

◊ Less effective for active or outdoor use.

◊ Oily semisolid product, which can stain and is cosmetically less appealing.[8]

◊ May block skin pores.

◊ Sometimes have a short shelf life once opened.

◊ May possess an unpleasant odor.

◊ Dosage regimen is not always possible to control.

◊ Using fingertips to apply may lead to contamination or cause skin discomfort and irritation.[9]

◊ They are often large and hard to carry.

Sl. No	Name	Manufacturer	Applications
1	Povidone-Iodine ointment USP 10% w/w	Luxica Pharma Inc	For infection in wounds and cuts.
2	Neomycin and polymyxin B sulfates and bacitracin zinc ointment USP	Akorn Inc	To prevent bacterial skin infection due to minor cuts, scrapes or burns on the skin.
3	Mupirocin ointment IP 2% w/w.	Zydus Cadila	To treat bacterial skin infection.
4	Graphitis ointment	Boiron Laboratories	For various skin conditions, such as eczema, dermatitis, cracked skin, and old scars.
5	Tobramycin ointment USP	Advacare Pharma	To treat bacterial infections of the eye, such as conjunctivitis and blepharitis.
6	Tacrolmus ointment 0.03% w/w.	Healing Pharma India Pvt. Ltd	To relive symptoms of allergic eye diseases such as pain, inflammation, redness and itching.
7	Fluticasone ointment IP	GlaxoSmithKline	As a broad- spectrum antiseptic

		Pharmaceuticals Ltd	to treat inflammation and itching.
8	Wound Healing ointment	Medilife Impex Pvt Ltd	To support the healing of minor superficial wounds and damaged skin
9	Sodium fusidate ointment BP	Sun Pharmaceutical Industries Limited	To treat various bacterial skin infections, including impetigo, infected cuts and abrasions, and infected eczema.
10	Hypericum ointment	SBI Pharmaceuticals Co., Ltd.	To relieve nerve pain from injuries, puncture wounds, and post-surgical discomfort

APPLICATIONS

◊ Ointments protect the skin from irritants such as moisture, sun, and air.

◊ Ointments moisture and soften rough, dry skin effectively.

◊ Ointments help deliver drug straight to the problem area, reducing side effects on the rest of the body.

◊ Ointments can sooth inflamed skin by delivering anti-inflammatory drug directly.[10]

◊ Ointments fight infection burns and skin diseases.

◊ Ointment helps to remove dead skin by softening it, adding in treating psoriasis and warts.

◊ Hydrocarbon based ointment like petroleum deeply moisture and shield the skin from dryness.

◊ Ointments with pain relief sooth targeted areas and reduce discomfort effectively.

◊ Steroids based ointments helps clam skin irritation and control information.

◊ Ointment helps improve skin look by cleaning and adding smoothness.[11]

IDEAL CHARACTERISTICS

◊ It should be physically and chemical stable.

◊ It should be smooth and free from grittiness.

◊ It should be easy to apply.

◊ The medicament should be finely divided and uniformly distributed throughout the base.

◊ It should melt or soften at body temperature.

◊ Should be efficient on all types of skin.[12]

◊ The base of ointment should be not posses any therapeutic action.

◊ The ointment should have a skin friendly pH.

◊ It should be free from microbial contamination to ensure safety and effectiveness.

◊ Easy to package and store.

TYPES OF OINTMENTS

Ointments are classified into

* Non-medicated ointment

* Medicated ointment[13]

Non-medicated ointment

These ointments are drug free and are mainly used to hydrate, protect, and relieve irritation on the skin by forming a soothing barrier.

Medicated ointment

These products include one or more active pharmaceutical ingredients and are designed to deliver therapeutic either at the site of application or throughout the body.

FORMULATION

A typical ointment requires active pharmaceutical ingredients, emollient, cleansing agent, antioxidants, emulsifier, preservative, surfactant, polymer and solvent for its formulation.[14]

Active pharmaceutical ingredients (API):

To treat acne and rosacea. Clindamycin to treat certain type of bacterial infection.[15]

Example: Azelaic acid , clindamycin.

Emollient

It works by preventing water loss from the outer layer of skin.

Example: liquid paraffin, wax, beeswax.

Cleansing agent

Its effective at removing dirt, oils, and other impurities from skin, hair, and surface.

Example: sodium lauryl sulphate.

Antioxidants

It substance that can protect cells in from damage caused by unstable molecules called free radicals.

Example: Gallic acid, ferullic acid.

Emulsifier

It is a substance that helps mix two immiscible liquid like oil and water by stablizing the emulsion.[16]

Example: lecithin.

Preservative

To prevent microbial growth and ensure product safety and stability.[17]

Example: paraben, phenoxyethanol, benzyl alcohol.

Surfactant

It is surface-active agents, reduce the surface tension of liquids, allowing them to spread and wet surfaces more effectively.

Example: sulfonates, soap, sodium laureth sulfate.

Polymer

These polymer can enchance drug release, improve stability and affect the ointments texture and spreadability.

Example: polyethylene glycol, Hydroxypropyl methylcellulose.

Solvent

Solvent is a liquid substance used to dissolve or dilute other substances, facilitating the creation of solution, suspension or emulusions for drug formulation.[18]

Example: Ethanol, methanol.

METHODS OF PREPARATION

Fusion method

When ointment contains a number of solid ingredients with different melting points, it is necessary to melt them in decreasing order to their melting point. The entire components are melted accordingly.[19]

Chemical reaction method

The preparation of strong mercuric nitrate ointment, where a chemical reaction between mercury, nitric acid, and other components is essential.

Emulsification method

All the component are taken required quantity. The fats, oil and waxes are melted together on water bath at a temperature of 70c. The aqueous solution of all heat stable components is heated at same temperature.[20]

Trituration method:

Triturations method for ointments preparation involves grinding solid medications with a small amount of ointment base on a slab or in a mortar using a spatula until a smooth, homogeneous mixture is achieved.[21]

EVALUATION PARAMETERS FOR OINTMENTS

Test for rate of absorption

In diadermatic ointment, it should be evaluated for the rate of absorption of drug into the blood stream. This test can be done in-vivo only. The ointments should be applied over a definite area of the skin by running. The rate of absorption i,e the amount durg absorbed per unit time should be more.[22]

Test for non irritancy

The base used in the formulation of ointment may cause irritation or allergic reaction. Non-irritancy of the preparation is evaluated by patch test. In this test 24 human volunteers are selected. Definite quantity of ointment is applied under conclusion daily on the back or volar fore arm for 21 days. Daily the type of pharmacological action observed and noted. No visible reaction or erthema or intense erythema with edema and vesicular erosion should occour. A good ointment base shows no visible.

Test for rate of penetration

The rate of penetration of a semisolid dosage forms crucial in the onset and duration of action of the drug. Weighted quantity of the preparation should be applied over selected area of the skin for a definite period time. Then the preparation let over is collected and weighed. The difference between the initial and the final weight of the preparation gives the amount of preparation penetrated through the skin and this when divided by the area and time period of application gives the rate of penetration of the preparation the test should be replaced twice or thrice.[23]

The rate of rheological properties:

Viscosity is the one of the most important parameter of semisolid preparation. It should be the product can be easily removed from the container and easy to apply in skin. Cone and plate viscometer and Brookfield viscometer is used to determined the viscosity of the preparation.[24]

Test for content uniformity

The net weight of content of filled ointment containers is determined. The results should match each other and with the label quantity. The test is also called minimum fill test.[25]

Test for preservation efficiency

Using pore plate technique the number of microorganisms initially present in the preparation are determined. Solution of different samples of the preparation are made and mixed with Tryptone Azolectin (TAT) broth separately. All cultures of microorganisms are added into each mixture, under aseptic condition, all mixture is incubated. The number of microorganisms in each sample is counted on 7^{th}, 14^{th}, 21^{st}, and 28^{th} days of inoculation.

CONCLUSION

Ointments are semisolid dosage forms which contain medicament and are applied topically. Ointments have several advantages as they are easy to apply on localized areas and possess good keeping quality. Some of the disadvantages of ointments include being less effective for active/outdoor use, not suitable for hairy areas, etc. The formulation of ointments requires emollients, antioxidants, emulsifiers, cleansing agents, preservatives, surfactants, and polymers. Various methods of preparation in ointments are fusion method, emulsification method, chemical reaction method, and extraction methods. Ointments are evaluated by tests for rate of absorption, test for non-irritancy, test for rate of penetration, test for the rate of rheological properties, test for content uniformity. Ointment formulation not only improves skin health but also enhances the patient's overall comfort and quality of life.

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