



A REVIEW METHOD AND TYPES OF OINTMENT IN COSMECUTICALS

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ABSTRACT

Pharmaceutical semisolid preparation includes ointment, cream, paste emulsion gel and rigid foams. These preparations serve as a carrier for drugs. Ointment can adhere to the application surface for long period of time before they are washed off. These property of ointment helps for prolong drug delivery at the site of application. Ointments may be medicated or non-medicated. Oleaginous ointments are preferred for dry, chapped skin in the environment of low humidity because of its occlusive properties. Ointments are mainly evaluated by physical test like test for rate of absorption, test for non-irritancy, test for penetration, test of drug release, test of rheological property, test of content uniformity and also by microbiological test like microbial content and preservative efficacy.

KEYWORDS: semisolid, ointment, ointment bases, Brookfield viscometer, additives in ointment, penetrometer.

INTRODUCTION

Semisolid dosage forms such as ointments may be used for topical application to the skin,¹⁶ placement on the surface of the eye, or for nasal, vaginal, or rectal use for medicinal or protective activities or cosmetic purposes. These preparations are used for the limited effects they have on the skin or mucous membrane at the moment of application due to drug penetration, and they are why they are used.¹⁸ In the treatment of cutaneous illnesses, these devices are intended to deliver the medication directly into the skin, with the skin serving as the target organ. Emulsions of oil and water are used to create the semi-solid substance known as an ointment. Both oil-in-water (O/W) and water-in-oil (W/O) ointments are composed of very small droplets of oil and water that are distributed uniformly across a continuous oily or watery phase, respectively. Ointments may either be oil-in-water or water-in-oil, and this distinction is based on how the oil is distributed throughout the product. Because they are less oily and can be removed with water more readily, ointments that include oil and water are more pleasant to use and are appropriate for cosmetic use.



Fig: Ointment

It is more difficult to work with water-in-oil ointments, but because many of the medications that are included in ointments are hydrophobic, they will be released more easily from a water-in-oil cream than from an oil-in-water cream. Water-in-oil ointments have the disadvantage of being less stable. Because they create an oily barrier, water-in-oil ointments are also more moisturizing. This barrier helps to minimize the amount of water that is lost from the stratum corneum, which is the skin's outermost layer. Traditional medical practices are being championed by both the World Health Organization (WHO) and the United States of America due to the fact that they are less costly, readily accessible, and comprehensive, particularly in poor nations. In addition to this, it is a fact that just eight percent of the world's population receives the majority of their main medical treatment from plants. The significance of traditional medicine has been acknowledged on a global scale, especially in affluent nations; as a result, there are now treatment techniques, protocols, and standards in place for ethnomedicine.

There are many different signs and symptoms that may be caused by skin illnesses, and in many cases, the therapy must be maintained for an extended period of time. It is necessary to have a herbal skin cream that is both safe and effective in order to cure a variety of skin conditions, including wounds, acne vulgaris, fissures, psoriasis, and other sorts of skin illnesses. Although there are many different kinds of cream that are regarded for wound healing, it still seems that they have a limited capacity for the pace of tissue regeneration. As a result, after doing an in-depth study into the pathophysiology of wound healing and the many conventional and alternative treatments available. Homeopathic systems of medicine all provide a significant amount of information pertaining to skin care. In this day and age, the expertise and experience gained through the use of herbs is being combined with cuttingedge cosmetic technology in order to provide a product that is not only secure and efficient but also acceptable to a greater number of individuals.



Fig: Ointment as a Herbal

DEVELOPMENT OF HERBAL OINTMENT

According to survey report by WHO, about 25 per cent of prescribed human medicines are derived from plants and 80 per cent people still depend on traditional system of medicines. The herbal wealth of India and the knowledge of their medicinal properties have a long tradition, as referred in Rig veda and other ancient literature. The topography of India in the tropical belt with its varied climatic zones made it a vast storehouse of medicinal plants. The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicine. One of the major problems faced by the herbal industry is the unavailability of rigid quality control profiles for herbal materials and their formulations. Regulatory bodies have laid down the standardization procedures and specifications for Ayurvedic preparations. The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety, and efficacy.

<i>Difference between cream and ointment</i>	
<i>Cream</i>	<i>Ointment</i>
Water-based semisolid preparation	Oil-based semisolid preparation
Contains 50% oil and 50% water	Contains 80% oil and 20% water
Non-greasy, rich, and heavy	Greasy, smooth and soften
Thick liquid preparation	Soft semisolid preparations
White to off-white in color	Usually translucent
Thicker consistency	Thinner consistency
Easily spreadable	Less spreadable
Rapidly absorbed	Slower absorbed
Rapid onset of action	Slow onset of action
Easily washed off	Not easily washed off

Fig: Difference between Ointment and Cream

TYPES OF OINTMENT

Ointment may be medicated or non-medicated.

- a) Medicated ointment: For the application of API to skin for protective, therapeutic, or prophylactic purpose.
- b) Non-medicated ointment: These are used for physical effect. They are use as protectant, emollients, or lubricants.

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 ointment should not possess any therapeutic action.
- 4) The ointment should be smooth and free from grittiness.

Advantages of an ointment

- 1) They have site specific application of drug on affected area, which avoids unnecessary non target exposure of drug thereby avoiding side effect i.e. site-specific action with less side effect.
- 2) They avoid first pass metabolism of drug.
- 3) Convenient for unconscious patients having difficulty in oral administration.
- 4) Comparatively they are chemically more stable and easier to handle than liquid dosage forms.
- 5) They are suitable dosage forms for bitter taste drugs.

Disadvantages of an ointment

- 1) These oily semisolid preparations are staining and cosmetically less aesthetic.
- 2) Application with finger tip may contaminate the formulation or cause irritation when applied.
- 3) As compared to solid dosage forms, semisolid preparation are more bulky to handle.
- 4) Though semisolid allow more flexibility in dose, dose accuracy is determined by uniformity in the quantity to be applied.
- 5) Physio-chemically less stable than solid dosage form.

OINTMENT BASES

Ointment bases are anhydrous and generally contain one or more medicaments in suspension or solution or dispersion. On the basis of their level of action, they are classified as: epiderma tic, endodermic and diaromatic (Carter, 1987). An antiseptic ointment is aimed to destroy or inhibit the growth of bacteria. Several antimicrobial herbal ointments have been formulated using medicinal plants. There is typically little variability between brands of generics and name brand drugs. They are often disliked by patients due to greasiness. The vehicle of an ointment is known as the ointment base.

Advantages of ointment bases

- Washable and non-greasy if oil-in-water (o/w)
- Wide range of compatibility
- Do not become rancid or support microbial growth;
- No irritating (to the same degree as lanolin, petrolatum, etc)
- Adhere well to skin
- Easily washed off
- Low incidence of sensitization
- Have a low index of irritation on storage
- Easy to compound and remain stable on storage
- Economic and easy to transport.
- Possess good keeping qualities.
- Pharmaceutically elegant.

Disadvantages of ointment bases:

- Subject to water loss if o/w,
- Greasy and un-washable if water-in-oil (w/o),
- Unless, a preservative is added, the Emulsion bases are subject to mold growth, sometimes undergo gradual discoloration with certain drugs.
- Unless acetyl alcohol is added, an aqueous solution can be added only to the extent of 5 percent.

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 base
- 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 base do not dry out.
- e) These base 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 base

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 base 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.

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

IDEAL PROPERTIES OF OINTMENT BASES

- 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.

METHOD OF PREPARATION OF OINTMENT

Ointments can be prepared either by mechanical incorporation or by fusion methods. Irrespective of the method employed for preparation, ointments should be smooth and free from granular or gritty particles. In compounding of ointments, the following general aspects should be considered.

- (i) If insoluble substances are to be incorporated in the ointment base then they should be in impalpable powder form.
- (ii) For efficient incorporation of insoluble substances they should first be levigated with a little quantity of base to form a smooth cream and then incorporated into the remainder of the base.
- (iii) Water-soluble salts are best incorporated by dissolving them in a small quantity of water and then incorporating in the base. (iv) Drugs soluble in ointment bases may also be incorporated by fusion (melting the highest melting point ingredient of the base and mixing the medicament into it). Remaining ingredients are then added and mixed by stirring.

Preparation of ointment mainly depend on nature of ingredients. Ointments are mainly prepared by two general method:

- a) Incorporation
- b) Fusion

a) Incorporation In this finely subdivided insoluble medicaments are evenly distributed by grinding with a small amount of the base followed by dilution with gradually increasing amounts of the base.

b) Fusion In this method the ingredients are melted together in descending order of their melting points and stirred to ensure homogeneity.

OTHER ADDITIVES IN OINTMENT

1. Preservatives In Ointment

The antimicrobial compounds and their quantities should be carefully decided upon if the same are to prevent contamination, deterioration or spoilage of ointment bases by bacteria and fungi. The first consideration in selection is the irritancy or toxicity of the compound to the tissue to which the ointment is to be applied. For instance, methyl and propyl parabens are irritant to nasal passages. Boric acid may also get absorbed through the nasal passages in sufficient amounts to be toxic. Quaternary ammonium compounds or phenylmercuric nitrates are better tolerated by nasal tissues. On occasions the plastic containers or rubber closures may 'take up' some amount of the preservatives thus reducing their availability for antimicrobial action. Sometimes the preservatives get complexed by other ingredients and are thus not available in sufficient concentration for antimicrobial action. In the presence of tween 80, methylparaben, benzalkonium chloride, benzoic acid etc. get inactivated to appreciable extents. The bactericidal activity also depends upon partition coefficient of the antimicrobial compound between aqueous and oily phases. If both the phases are to be protected additional amounts may be needed. Hence, a practical man should make viable counts on his products after a period of storage in order to judge preservative qualities of the antimicrobial compounds used.

2. Antioxidants In Ointment

Antioxidants should be included to avoid the oxidative degradation of the base. It may be more desirable to select two antioxidants instead of one. The concentration of antioxidants depends upon their partition coefficients between the aqueous and oil phases if both the phases are present in a base. Generally compounds like butylated hydroxy anisole, propyl gallate, nor dehydroabiatic acid etc. are used in ointment bases.

3. Chelating Agents

Whenever it is anticipated that traces of metallic ions are likely to catalyse oxidative degradations small amounts of substances such as citric acid, maleic acid, phosphoric acid etc. may be added to chelate the metallic ions.

4. Perfumes

Most ointments have a pleasant smell imparted by incorporation of selected perfume blend. The selection of a perfume blend is a very critical. The blends selected must be compatible with other ingredients. Essential oils from plant materials used as perfumes. The floral group blends such odours as jasmine, rose, lily and gardenia. The woody is group characterize by sandal wood, cedar wood.

PHYSICAL METHODS

1) Test of Rate of Absorption

In diadermic ointments, drug moves deeper in the skin tissues and finally into the systemic circulation. Such ointments should be evaluated for the rate of absorption of drugs. The ointment should be applied over a definite area of skin by rubbing. At regular interval of times, serum and urine samples should be analysed for the quantity of drug absorbed. The amount of drug absorbed per unit time should be more.

2) Test of Non-irritancy

The bases used for formulation of ointment may causes allergic reactions. Patch test is used for evaluation of non-irritancy. 24 human volunteers are selected for this test. Observation of type of pharmacological action is noted. No visible reaction or erythema or intense erythema with edema and vesicular erosion should occur. A good ointment base should shows no visible reaction.

3) Test of Rate of Penetration

Onset and duration of action of drug is mainly affected by rate of penetration of a semisolid dosage form. Weighed quantity of the ointment should be applied over a definite area of skin for a definite period of time. Then the preparation left over is collected and weighed. The difference between the initial and the final weights of the preparation gives the amount of preparation penetrated through the skin and this when divided by area and time period of the application gives the rate of penetration of the preparation. Flow-through diffusion cell or microdialysis method is used for estimation of rate of penetration of the preparation. Animal and human skin of definite area should be collected and tied to the holder present in a diffusion cell. The diffusion cell is placed in a fluid bath. Measured quantity of the preparation is applied over the skin and the amount of drug passed into the fluid is measured at regular interval of time by analysing the aliquots of the fluid using a spectrophotometer.

4) Test of Rate of Drug Release

Internal surface of test tube is coated with the preparation as a thin layer. Saline or serum is poured into the test tube. After a certain period of time, the saline is analyzed for the quantity of the drug. The amount of drug when divided by the time periods gives the rate of drug release.

5) Test of Rheological Properties

Viscosity is one of the important parameter of semisolid preparation. It should be such that the product can be easily removed from the container and easily applied to the skin. Cone and plate viscometer or brookfield viscometer is used to determined the viscosity of the preparation.

6) Test of Content Uniformity

The net weight of the content of ten filled ointments containers is determined. The result should match each other and with the labelled quantity. This test is also called minimum fill test.

MICROBIOLOGICAL METHODS

1) Test of Microbial Content

Micro-organism like pseudomonas aeruginosa and staphylococcus aureus may contaminate the preparation and finally infect the skin. So ointments should be tested for the absence of such micro-organisms. Solution of different samples of the preparation are made, Each sample is inoculated into separate volume of 0.5ml of rabbit's plasma under aseptic condition and incubated at 37 C for 1-4 hours. No formation of the clot in the incubated mass indicates the absence of the microorganism.

2) Test of Preservative

Efficacy Pour plate technique is used to determine the number of micro-organisms present in the preparation. Solution of different samples of the preparation are made and mixed with Tryptone Azolectin (TAT) broth separately. All cultures of the micro-organisms are added into each mixture, under aseptic conditions. All mixtures are incubated. The number of micro-organisms in each sample are counted on 7th, 14th, 21st and 28th days of inoculation.

3) Microbial Limits

On 14th day, the number of vegetative cells should not be more than 0.1% of initial concentration. On 28th day, the number of organism should be below or equal to initial concentration.

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