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FORMULATION AND EVALUATION OF POLYHERBAL OINTMENT

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Abstract :

Ointments are semisolid dosage forms that, under shear stress, often behave like visco-elastic materials. They are often used externally to the body for therapeutic purposes and include medicinal substances. Numerous medicinal substances that are applied topically to either intact or damaged skin or mucous membranes come in semisolid consistency and are referred to by different names, such as ointments, creams, pastes, etc. It is mostly applied to the skin as an emollient or protective layer. The screening of plants used in popular medicine is the first step towards achieving the goal. Herbal medications are also utilised as ointments in addition to other dosage forms.

Keywords – Ointment, Semi-Solid, Homogenous, Polyherbal

Introduction

An ointment is a thick, homogenous, semi-solid preparation with a high viscosity that is typically greasy and used for external application to the skin or mucous membranes. Its composition is oil 80% water 20%. The maximum amount of water that an ointment can contain is indicated by its water number. They are applied to the skin as emollients or when a certain level of occlusion is required, along with other protective, therapeutic, or preventive uses.An ointment is a thick, homogenous, semi-solid preparation with a high viscosity that is typically greasy and used for external application to the skin or mucous membranes.

Its composition is oil 80% water 20%. A cream's water number indicates the utmost volume of water it can they are usually meant to be applied topically to the body or to the mucous membrane and contain medications.There are two types of ointments: medicated and non-medicated. Non-medicated ointments, also known as ointment bases, are used as such to have lubricating or emollient properties, or they can be prepared and used as medicated ointments. Other terminology, such as "creams," "pastes," and "cerates," are frequently used interchangeably with "emollient" in the context of prescription medicine.Non-medical ointments are used as lubricants, emollients, and protectants, while medicated ointments are used to treat infections, inflammations, and itch. The ointments can be classified as hydrophobic, water-emulsifying, or hydrophilic, and are often made up of ointment bases with a high concentration (often 50% w/w) of dispersed medicines.

Many medications intended for topical administration to mucous membranes or to skin that is intact or injured have been offered in semisolid consistency and are primarily utilised as skin protectants or emollients. They are also sometimes referred to as ointments, creams, salves, or pastes. Today's ointments accomplish the same thing, but they also deliver the medication into the bloodstream. Consequently, they are referred to as

a) Epidermatic: Applied to the epidermis.

b) Endodermatic, which refers to activity on the skin's deeper layers.

c) Diadermic: Designed to reach deep into the body and distribute medication into bodily fluids (systemic circulation)

Every ointment has a foundation that serves primarily as a vehicle for the medications. Its performance is also dictated by the nature of the base. Therefore, choosing an ointment base is a crucial step in the formulation process. Understanding skin anatomy in relation to medication absorption is crucial for a scientific understanding of the percutaneous absorption of ointment bases.Every ointment has a foundation that serves primarily as a vehicle for the medications. Its performance is also dictated by the nature of the base. Therefore, choosing an ointment base is a crucial step in the formulation process. Understanding skin anatomy in relation to medication absorption is crucial for a scientific understanding of the percutaneous absorption of ointment bases. Additionally, herbal medications are prepared as ointments. After preparing the ointment base, the active components are added to it via trituration to create the ointment's optimal ratio.

Once the formulation is finished, the ointment's irritancy, spreadability, diffusion, and stability are evaluated. An important source of novel chemicals with potential utility for the development of chemotherapeutic medicines is traditional medicine. The screening of plants used in popular medicine is the first step towards achieving this goal. Ointments are another formulation for herbal medications, in addition to other dosage forms. A viscous semisolid preparation used topically to various body surfaces is called an ointment. These consist of the skin as well as the mucous membranes of the nose, eyes, vagina, and anus. An ointment could contain medication or not. Medicated ointments have a medication that has been emulsified, suspended, or dissolved in the base. Ointments have a variety of topical uses, including keratolytic, astringent, antiseptic, emollient, protestant, and antipruritic.

➢ Characteristics of an ideal ointment -

1. It should be physically and chemically stable.
2. The base of ointment should possess no therapeutic action.
3. In ointment base, finely divided active ingredient should be uniformly distributed.
4. The ointment should be sooth and free from grittiness

➢ Advantages of ointment -

1. They provide means of site specific application of drug on affected area, which avoids unnecessary non target exposure of drug thereby avoiding side effects.
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 easy to handle than liquid dosage forms.
5. They are suitable dosage forms for bitter taste drugs

➢ Disadvantages of 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 preparations are bulky to handle.

4. Though semisolids allow more flexibility in dose, dose accuracy is determined by uniformity in the quantity to be applied.
5. Physico-chemically less stable than solid dosage forms.

Ointment Bases -

Ointment bases are anhydrous and generally contain one or more medicaments in suspension or solution or dispersion.

They are divided into three categories based on the degree of action they exhibit: diadermatic, endodermatic, and epidermatic (Carter, 1987). The goal of an antiseptic ointment is to either eradicate or stop the growth of bacteria. Many herbal ointments with antibacterial properties have been created with the aid of medicinal herbs. Generally speaking, there is not much difference in quality between name brand and generic medications. Patients frequently dislike them because of their greasiness. The term "ointment base" refers to the vehicle of an ointment.

Types of Ointment Bases :

There are five (5) classes or types of ointment bases, which are differentiated on the basis of their physical composition. These are:

• Oleaginous bases

• Absorption bases

• Water-in-oil emulsion bases

• Oil-in-water emulsion bases

• Water soluble or water miscible bases

➢ Advantages of ointment bases –

1. Washable and non-greasy if oil-in-water (o/w).
2. Wide range of compatibility.
3. Do not become rancid or support microbial growth.
4. Nonirritating (to the same degree as lanolin, petrolatum, etc).
5. Have a low index of irritation on storage.

➢ Disadvantages of ointment bases –

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

➢ Characteristics of ointment bases -

1. Insoluble in water
2. Not water washable
3. Contains water (Limited)
4. Emollient
5. Occulsive
6. Greasy

Selection of the appropriate base depends on –

1. Desired release rate of the particular drug substance from the ointment base.
2. Desirability for enhancement by the base of the percutaneous absorption of the drug.
3. Advisability of occlusion of moisture, from the skin by the base.
4. Short term and long term stability of the drug in the ointment base.
5. Influence, if any, of the drug on the consistency or other features of the ointment base.

Other additives in ointments -

Besides base and medicaments, the ointments may contain one or other of following groups of additives:

A. Preservatives :

If microbial compounds are being used to stop bacteria and fungus from contaminating, deteriorating, or spoiling ointment hases, then the selection of these compounds and their amounts needs to be done with great care. The first factor in choosing an ointment is whether or not the ingredient will irritate or be hazardous to the area where it will be applied. For example, propyl and methyl parabens can cause irritation to the nasal passages. Boric acid might be harmful. Nasal tissues are more tolerant of phenyl mercuric nitrates or quaternary ammonium compounds. Occasionally, preservatives may be absorbed by plastic containers or rubber closures, decreasing their availability forantibacterial activity. Preservatives can occasionally become complexed by other components, which makes them less concentrated and less available for microbial activity. Benzalkonium chloride, benzoic acid, methyl paraben, and ete become significantly inactivated when tween 80 is present. The antibacterial compound's partition coefficient between the oily and aqueous phases affects the bacterial activity as well. An additional sum would be required if both phases need to be protected.

B. Antioxidants:

Whenever oxidative base degradation is a possibility, antioxidants should be added. It might be preferable to choose two antioxidants rather than just one. The partition coefficients of the two pluses that are present in a house between the aqueous and oil phases determine the concentration of antioxidants.

C. Chelating agents:

Tiny amounts of compounds like citric acid, maleic acid, phosphoric acid, etc. can be added to chelate metallic ions if it is thought that their traces may catalyse oxidative degradations.

D. Fragrances:

Due to the use of specific blends, the majority of ointment bases these days have a pleasing scent. Choosing the right perfume blend is a really difficult task, and every manufacturer wants to give their product a unique odour.

Method of Preparation of Ointment :

Preparation of Ointments by Fusion Method :

In the fusion technique, drugs and other solids are dissolved in an ointment base and then combined. By melting the ingredient into the base, the soluble constituents are dissolved. After speculation or trituration, the congeal mixture is smoothed out.

Preparation of Ointments by Trituration :

Trituration, in which finely subdivided insoluble medicaments are evenly distributed by grinding with a small amount of the base or one of its ingredients followed by dilution with gradually increasing amounts of the base.

Preparation of Ointments by Chemical Reaction :

Sublimed sulphur is sieved through no. 180 sieves. Then sublimed sulphur is triturated with a small amount of simple ointment. Then the remaining amount of simple ointment is added and the mixture is levigated until a smooth and homogenous mass is obtained.

Preparation of Ointments by Emulsification :

An emulsion system contain an oil phase, an aqueous phase and an emulsifying agent. For o/w emulsion systems the

following emulsifying agents are used :

(i)water soluble soap

(ii) cetyl alcohol

(iii)glyceryl monostearate

(iv) combination of emulsifiers: triethanolamine stearate + cetyl alcohol

(v) non-ionic emulsifiers: glyceryl monostearate, glyceryl monooleate, propylene glycol stearate.

For w/o emulsion creams the following emulsifiers are used :

(i)polyvalent ions e.g. magnesium, calcium and aluminum are used.

(ii) combination of emulsifiers: beeswax + divalent calcium ion.

The viscosity of this type of creams prevents coalescence of the emulsified phases and helps in stabilizing the emulsion.

Formulation :

1) Simple Ointment (B.P.) Base

Ingredients (10gm)

Wool Fat.....0.5gm

Cetostesryl Alcohol.....0.5gm

Hard Paraffin.....0.5gm

Soft Paraffin.....8.5gm

Method of Preparation :

The simple ointment base was prepared by mixing the wool fat, hard paraffin, Cetostearyl alcohol and yellow soft paraffin with gentle heating with stirring. The obtained ointment base is then cooled and stored.

2) Herbal ointment:

Ingridents :

1.TUEMERIC :

Synonyms : Haldi, Manjal, Haridra

Biological Name : Curcuma longa

Family : Zingiberaceae

Uses : Antibacterial, Anti- Inflammatory, Antimicrobial

Fig : Turmeric

2.ALOE VERA :

Synonym : Ghikumari, Kala Banda, Korphad

Biological Name : Aloe Vera

Family : Asphodelaceae

Uses : Antifungal, Anti-inflammatory

Fig : Aloe Vera

3.NEEM OIL :

Synonyms : Arishth, Azadirachta Indica, Margosa, Melia, Azadirachta, Neem Tree, Nim Tree.

Biological Name : Azadirachta Indica

Family : Meliaceae

Uses : Skin Ulcer

Fig : Neem Oil

4.BHIMSENI KAPOOR :

Uses : Antibacterial and Antifungal

Fig : Bhimseni Kaoor

5.KARANJA OIL :

Synonym : Pongamia glabra.

Biological Name : Millettia pinnata

Family : Fabaceae

Uses : Antioxident

Fig Karanja Oil

6.KOKUM BUTTER :

Synonyms : Goa butter, Kokum butter, Kokum oil, Mangosteen oil.

Biological Source : Garcinia indica or G. Purpure

Family : Zamiaceae

Uses : Antioxidant

Fig : Kokum Butter

Preparation Of Turmeric Extract –

Preparation of Turmeric Extract Dried rhizomes of turmeric were ground and the powder obtained was followed for extraction same as that for neem leaves extract. The extract with crimson red color was obtained and stored at cool and dark place in air tight container.

Extraction –

Curcumin is a yellow-orange crystalline powder. It is a hydrophobic natural phenolic material. It is stable at high temperatures and at acidic pH but, it is unstable in alkaline conditions and in the presence of light.

Method of Preparation :

The Hard paraffin and cetostearyl alcohol taken in a china dish kept on water-bath at 700C. Wool fat and white soft paraffin are added to this mixture and stirred until all the ingredients are melted and then added the extracts with continuous stirring. Ointment was prepared by using extracts of Turmeric and Aloe-vera, Bhimsen Kapoor, Karanj oil, Neem oil, Kokum butter taking in different proportions of extracts.

Evaluation Test for Ointment :

The prepared poly-herbal ointment formulations were evaluated by various physio chemical characterization.

1.Color and Odor

Physical parameters like color and odor were examined by visual examination.

2.pH

pH of prepared herbal ointment was measured by using digital pH meter. The solution of ointment was prepared by using 100 ml of distilled water and set aside for 2 h. pH was determined in triplicate and average value was calculated.

3. Consistency

Smooth and no grittiness were observed.

4. Spreadability

The spreadability was determined by placing excess of sample in between two slides which was compressed to uniform thickness by placing a definite weight for definite time. The time required to separate the two slides was measured as Spreadability.

5. Extrudability

The formulation was filled in collapsible tube container. The extrudability was determined in terms of weight of ointment required to extrude 0.5 cm of ribbon of ointment in 10. seconds. Diffusion studies. The diffusion study was carried out by preparing agar nutrient medium. A hole has made on a board at the center and poly-herbal ointment was by placed in it. The time taken by ointment to get diffused through was noted after 1h.

6.Loss on drying (LOD)

LOD was determined by placing the poly-herbal ointment formulation in Petri dish on water bath and dried at 105°C temperature.

7.Solubility

Solubility is main criteria for the ointment formulation to check the cleansing properties solubility has determined in boiling water, distilled water and other solvent including alcohol, ether and chloroform.

8. Washability

Formulation was applied on the skin and then ease extend of washing with water was checked.

9.Non irritancy Test

Herbal ointment prepared was applied to the skin of human being and observed for the effect.

10.Stability study

Physical stability test of the herbal ointment was carried out for four weeks at various temperature conditions like 2°C, 25°C and 37°C. The herbal ointment was found to be physically stable at different temperature i.e., 2°C, 25°C and 37°C within four weeks.

Results :

The present study was done to prepare and evaluate the polyherbal ointment.For this, the herbal extracts were prepared by using simple maceration process to obtain a good yield of extract and there was no any harm to the chemical constituent and their activity.

The levigation method was used to prepare ointment so that uniform mixing of the herbal extract with the ointment base was occurred which was stable during the storage.

The Physicochemical properties were studied which shows satisfactory results for spreadability,extrudability, washability,solubility and others. Also the formulation was placed for stability studies at different condition within four weeks.

Conclusion :

The interest of herbal medicines and their uses have been increased rapidly in recent years even though there are lot of modern medicines are available in market. Substances derived from plants have been attracted many people in recent years for various Medicinal applications. Herbal plants are the richest source of bioactive compounds used in traditional and modern medicine. The present work is to evaluate and formulate the ointment of turmeric extract.

Soxhlet extraction was used for the extraction of turmeric. The simple ointment base was prepared by mixing wool fat, hard paraffin, cetostearyl alcohol and yellow soft paraffin by gentle heating with stirring. Herbal ointment was prepared by mixing hard paraffin and cetosteryl alcohol in china dish on a water bath at 700°C. Wool fat and white soft paraffin are added to this mixture and stirred until all the ingredients are melted and the extracts such as turmeric, aloevera, and bhimseni kapoor, karanj oil, neem oil and kokum butter by using leviagation method taken in different proportions of extracts.

Once the ointment is prepared, it was evaluated for its physicochemical parameters such as color, odor, pH, consistency, spreadability, excrudability, loss on drying, washability, solubility, irritancy.

Thus it could become a media to use the medicinal properties of turmeric effectively and easily as a simple dosage form for the treatment of Skin Infection.

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