OINTMENT BASES

P. SUGATHAN *

Summary

Local medications are important in any dermatological prescription. For optimum results at reasonable cost such medications are best ; 'tailor made'. Absolute dependence on commercially available preparations severely restricts the freedom of the practising dermatologists. Working knowledge of cosmetically elegant and therapeutically useful ointment bases are therefore essential for all of us. The varieties of such bases with details of making them locally by self or under guidance are described and their advantages and disadvantages compared.

KEY WORDS : Ointment bases — Classification — Formulas of ointment bases — Method of manufacture — Mode of action.

Ointments are semisolid preparations for external application, of such consistency that they may be readily applied to the skin by inunction[1]. In addition to serving as vehicles for the topical application of medicinal substances they are also useful protectives and emollients for the skin. Indeed the ointment base constitutes the major portion of a pharmaceutical preparation. It may thus influence the efficacy of the incorporated substances. The selection of ointment bases is therefore important to the practicing dermatologist.

The ideal ointment base should be compatible with the skin, stable, smooth and pliable, nonirritating, nonsensitizing, inert, able to absorb water or other liquid medicinal preparations and able readily to release these medicines on local application[2]. Ease of compounding, pharmaceutical elegance, long 'shelf-life' and lower cost are other desirable qualities. No single ointment base so far available possesses all these characteristics. The continued search for the ideal ointment base has resulted in numerous new ointment bases requiring some form of classification. Though there already exists classifications based on the degree of penetration or the mode of action, a more practical classification is the one that is based on their composition. Four classes of ointment bases are thus recognized : Oleagenous ointment bases, Absorption ointment bases, Emulsion ointment bases and Water soluble ointment bases.

I. Oleagenous Ointment Bases :

The oleagenous ointment bases comprise of three major groups. They are the oils of vegetable origin, fats of animal origin and solid hydrocarbons obtained from petrolatum. The vegetable oils are used as such or more often to lower the melting point of or soften the bases from a higher consistency. Any vegetable oil may be used

* Professor of Dermato-Venereology, Medical College Hospital, Calicut-673008.

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for this purpose but the most popular one is the olive oil. It is a pale yellow or light greenish yellow oily liquid obtained from the ripe fruits of Olea-europaea. Three grades of olive oil exist. Gentle crushing of fresh fruits without breaking the putamen and moderate pressure of the pulpy mass yields the highest grade of oil called the virgin oil or first expressed oil. Mixing the residue with water and further expression under higher pressure yields an oil of the second quality. The remaining cakes are then extracted with carbon disulphide and this is called Pyrene oil or bagasse oil. Olive oil is used as such as a vehicle or in the manufacture of other ointments.

Animal fats were popular once particularly lard and suet. These are only of historical interest now as they are almost completely replaced by hydrocarbon ointment bases. Vegetable oils and animal fats were once grouped under the term endodermic ointment bases because they were believed to penetrate deeper into the skin. Bees-wax is hardly ever used as such. It is used in combination with hydrocarbons.

The hydrocarbon ointment bases are bland, stable, chemically inert group of substances which will mix virtually with any chemical substances. However they do not release the incorporated substances with any degree of certainty and are thought to act primarily on the skin surface and hence also called epidermic ointment bases. The most popular and familiar bases in this group are the white and yellow petrolatum. Yellow petrolatum is obtained from the 'residuums' of petroleum distillation. It is purified by melting and treating with sulphuric acid and then percolating through recently prepared bone charcoal or adsorptive clays. White petrolatum is prepared from yellow petrolatum by repeating this process again. Repeated purification in this manner remove certain antioxidants naturally present and hence this purified product has a tendency to oxidize and develop an offensive odour. This is prevented by the addition of small quantities of alpha tocopherol or other antioxidants. Sometimes a mixture of paraffin and liquid petrolatum is sold as white petrolatum. This will be granular and the liquid portion often separates. The reason why petrolatum is also called 'Vaseline' makes interesting reading[3].

Addition of 5% beeswax (white or yellow) to white petrolatum produce a vehicle called "simple ointment". White wax is preferred to incorporate white substances and yellow wax is used when coloured substances are to be added to simple ointment. The quantity of wax may be altered to suit the consistency and climatic conditions. Simple ointment is compatible with a number of substances used as ointments in therapeutics. It is ideal for compounding ophthalmic ointments and for incorporation of antibiotics like bacitracin and tetracyclines which are unstable in the presence of water.

Oleagenous vehicles are occlusive and induces hydration of the stratum corneum through sweat accumulation[4,5]. Hence they can be solely used for their physical effect on the skin surface such as control of hydration. The only undesirable quality of the hydrocarbon ointment bases is that they are greasy and difficult to remove from skin and clothings.

Plastibase is a soft, unctuous, colourless jellylike substance developed by Squibb (USA) and consists of mineral oils with heavy hydrocarbon waxes having a molecular weight of 1300. It maintains a desirable consistency over a wide range of temperature (–15°

to 60°C). It releases the incorporated drugs well and has a long shelf life. However, this is not available to the dermatologists in India.

Silicones are synthetic polymers in which the basic structure is not carbon as in the usual type of synthetic polymers but an alternate chain of silicone and oxygen atoms (-Si-o-Si-o-Si-). Depending on the number and type of organic group attached to the silicone and the method of their preparation the material may be a liquid, resin or rubber. Silicones commonly used in pharmaceutical and cosmetic industries are dimethylpolysiloxane 200, methylphenylpolysiloxane and a stearyl ester of dimethylpolysiloxane. All are insoluble in water and are water repellent. These are clear fluids available in a wide range of viscosities. Dimethylpolysiloxanes are physiologically inert and virtually nontoxic and hence widely used in cosmetic industry and in the manufacture of barrier creams[6]. In addition to topical use silicones have been used successfully in the treatment of plantar callosities[7], corns[8], facial hemiatrophy[9] and for soft tissue augmentation[10]. A good ointment base incorporating the silicones is as below:

Silicone Gibson base

Cetyl alcohol	15	Gm.
Sodium Lauryl Sulphate	1.0	Gm.
Dimethylpolysiloxane polymer	40.0	Gm.
Purified water	43.0	ml.
Methyl paraben	0.25	Gm.
Propylparaben	0.15	Gm.

(The aqueous mixture of sodium lauryl sulphate and the parabens is warmed to 75°C and slowly add it to warmed (25°C) cetyl alcohol–silicone mixture. Stir the ointment until it congeals).

Spermaceti is a white, somewhat translucent waxy substance obtained from the head of sperm whale, *Physeter macrocephales*. It is used to give consistency and texture to cold creams and ointments. Due to the severe restrictions imposed on whale hunting spermaceti is in short supply.

Starch glycerite is an elegant emollient and can be used in the place of fatty ointment vehicles. It is also easily removed from the site of application.

Starch	—	100 Gm.
Benzoic acid	—	2 Gm.
Purified water	—	200 ml.
Glycerine	—	700 ml.

(Rub the starch and benzoic acid with water in a porcelain dish until a smooth paste is produced. Add glycerine and mix well. Heat this mixture in a sand bath to 140°C with constant and gentle stirring until a translucent jellylike mass results. Strain through muslin.)

II. Absorption Ointment Bases:

The term absorption bases denotes the property of such bases and not their action when applied on the skin. They are generally anhydrous substances capable of absorbing considerable quantity of water and still retain their ointment-like consistency. Antiseptic aqueous solutions exhibit higher potency in these bases than in oleagenous bases. Further, cutaneous penetration of the incorporated medicinal substances is better in them. Anhydrous lanolin was a popular absorption ointment base of yesteryear. It is seldom used now because of the frequent occurrence of contact allergic dermatitis. Two other excellent formulae of absorption bases are:

Hydrophilic Petrolatum

Cholesterol	—	30 Gm.
Stearyl alcohol	—	30 Gm.
White wax	—	80 Gm.
White petrolatum	—	860 Gm.

(Melt stearyl alcohol, white wax and white petrolatum together on a steam bath and add cholesterol and stir until it completely dissolves. Remove from the bath and stir until the mixture congeals.)

Aquabase Ointment

Cholesterol	—	30 Gm.
Cottonseed oil	—	30 ml.
White petrolatum	—	940 Gm.

(Heat the petrolatum and cottonseed oil to 145°C. Remove from heat and add cholesterol and stir until congeals.)

Both the above bases are heat stable and ideal for making ophthalmic ointments. Almost all the topical medicaments are compatible with these. These are best for making ointments of tetracyclines and bacitracin which are unstable in the presence of water.

C. Emulsion Ointment Bases:

Preparations coming under this classification are also called hydrophilic or water removable ointment bases because these bases and the resulting ointments can be removed from skin and clothings easily with water. The availability of a number of organic compounds for use as wetting agents, dispersing agents, emulsifiers, penetrants, emollients, detergents, preservatives etc., has given a much greater degree of flexibility to ointment formulation.

In general, an emulsion ointment base contains an aqueous phase, an emulsifying agent and an oleagenous phase. The water phase may vary from 10 to 80% of the total base. Addition of water or medicinal solutions will not seriously affect the consistency of a soft cream. Hydrophilic ointment USP is an excellent example of this group.

Hydrophilic Ointment USP

Methylparaben	–	0.25 Gm
Propylparaben	–	0.15 Gm
Sodium lauryl sulphate	–	10.0 Gm
Propylene glycol	–	120.0 ml
Stearyl alcohol	–	250.0 Gm
White petrolatum	–	250.0 Gm
Purified water	–	370.0 ml

(Stearyl alcohol and white petrolatum are melted together in a water bath at about 75°C. All the other ingredients are dissolved in water warmed to about 75°C and the former mixture is strained into this with gentle stirring till it congeals.)

The quality of the ingredients, the order, speed and type of mixing and the temperature at which the emulsion is made are all important. The finished product will have a pH of 5.5 to 7. Hydrophilic ointment has a cosmetic-like appearance. This fact together with its ease of application and simplicity of removal produces a psychological effect in the patient which insure better patient co-operation and hence more efficacious therapy. Release of the medicinal agents in this base is better because of the presence of the water phase and the surface tension reducing properties of the emulsifiers and the adjuant agents. Compared to the oleagenous bases keratolytics incorporated in the hydrophilic ointment exert their effect in a shorter time. It is easily made and can be stored well. However, on prolonged standing it may lose water and also tend to support the growth of mold. The addition of propylene glycol has improved this to some extent. The occurrence of allergic contact dermatitis to paraben[11] may make this excellent base less popular in the years to come. When applied as such immediately after a bath hydrophilic ointment is very useful for the treatment of dry skin. It can also be used as a base for urea creams. Another useful emollient, cleansing cream and ointment base is the cold cream.

Cold Cream USP

Spermaceti	–	125 Gm
White wax	–	120 Gm
Mineral oil	–	560 ml
Sodium borate	–	5 Gm
Purified water	–	190 ml

(Reduce spermaceti and white wax to small size and melt together in a water bath with mineral oil till the temperature reaches 70°C. Sodium borate is dissolved in water and warmed to 70°C. Mix these together stirring rapidly and continuously until it congeals.)

Replacing the mineral oil with almond oil or any other vegetable oil and the addition of a perfume makes this Galen's cold cream. An electric hand blender is helpful for proper, effortless and smooth blending.

IV. Water Soluble Ointment Bases :

These are prepared from higher ethylene glycol polymers known as carbowax compounds. These have a wide range in molecular weight. Those with molecular weight ranging from 200-700 are liquids and those above 1000 are wax-like solids. These are water soluble, nonvolatile, inert, unctuous agents which do not hydrolyze, deteriorate or support mold growth. These are widely used in the formulation of water soluble washable ointments but are not available for compounded prescriptions in India. Other semisolid preparations containing pectin, glyceryl monostearate, cellulose derivatives, sodium alginate, bentonite and colloid magnesium aluminium silicate may also be included under the category of water soluble ointment bases. One particular base called 'universal ointment base' requires special mention.

Universal Ointment Base

Calicium citrate	—	0.05 Gm
Sodium alginate	—	3.0 Gm
Methyl paraben	—	0.20 Gm
Glycerine	—	45.0 ml
Distilled water	—	52.0 ml

(Dissolve calcium citrate and methylparaben in water. Mix glycerine with sodium alginate to form a smooth paste. Add the aqueous mixture to this and stir until a smooth, stiff preparation is obtained. Set aside for several hours till thickening is complete.)

This is stable for over a year at room temperature and compatible with a number of medicaments. It can be sterilized by autoclaving and has a pH of 6.3.

Times have changed. Patients expect and often demand cosmetically acceptable and elegant local medications. To comply with this demand you don't have to be a slave of the manufacturers. Modern research has made availble to us a number of excellent, easy to compound ointment bases to meet every demand of the patient and any therapeutic situation. The plea for reviving the art of dispensing is, therefore, timely and meaningful[18]. Understanding the spectrum of ointment bases is the first step in this direction.

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