3. Stability of the drug in the ointment base.
4. Effect of the drug on the consistency of the ointment base.
5. The desire for a base that is easily removed by washing with water.
6. Characteristics of the skin surface to which it is applied.

Preparation of ointments

Ointments are prepared by two general methods:

1. Incorporation
2. Fusion

The method used depends primarily on the nature of the ingredients.

Incorporation

By the incorporation method, the components are mixed until a uniform preparation is attained, on a small scale the pharmacist may mix the components using a mortar and pestle or a spatula and slab (a glass or porcelain plate).

Incorporation of solids

When preparing an ointment by spatulation, the pharmacist works the ointment with a stainless steel spatula having a long, broad blade. If the components of an ointment are reactive with the metal of the spatula (e.g. as in the case of phenol), hard rubber spatula may be used.

The ointment base is placed on one side and the powdered components previously reduced to fine powders on the other side. A small portion of the powder is mixed with a portion of the base until uniform mixture is obtained. The process is continued until all portions of the powder and the base are combined and thoroughly and uniformly blended.

It is often desirable to reduce the particle size of a powder or crystalline material before incorporation into the ointment base, so that the final product will not be gritty. This may be done by levigation process (i.e. mixing the solid material in a vehicle to make a smooth dispersion).

The levigating agent used should be physically and chemically compatible with the drug and base.

The levigating agent for example is mineral oil for oleaginous bases or the bases where oils are the external phase and glycerine for bases where water is the external phase.

The amount of levigating agent used should be about equal in volume to the solid material. A mortar and pestle is used for levigation, this allows both reduction of particle size and the dispersion of the substance in the vehicle. After levigation, the dispersion is incorporated into the ointment base by spatulation or with the mortar and pestle until the product is uniform.

Incorporation of liquids

Liquid substances or solutions of drugs are added to an ointment according to ointment base's capacity to accept the volume required. For example, only very small amounts of an aqueous solution may be incorporated into an oleaginous ointment, whereas hydrophilic ointment bases readily accept aqueous solutions.

When it is necessary to add an aqueous preparation to a hydrophobic base, the solution first may be incorporated into a minimum amount of a hydrophilic base and then that mixture added to the hydrophobic base. However, all bases even if hydrophilic have their limit to retain liquids beyond which they become too soft or semiliquid. Alcoholic solutions of small volume may be added well to oleaginous vehicles or emulsion bases.

- On large scale, roller mills force ointments through stainless steel rollers to produce ointments that are uniform in composition and smooth in texture.

Fusion

By the fusion method, all or some of the components of an ointment are combined by being melted together and cooled with constant stirring until congealed. Components not melted are added to the congealing mixture as it is being cooled and stirred.

Naturally, heat-labile substances and any volatile components are added last when the temperature of the mixture is low enough not to cause decomposition or volatilization of the components.

Substances may be added to the congealing mixture as solutions or as insoluble powders levigated with a portion of the base. On a small scale, the fusion process may be conducted in a porcelain dish or glass container.

Medicated ointments and ointment bases containing components as bees wax, paraffin, stearyl alcohol and high molecular weight PEG which do not lend themselves well to mixture by incorporation are prepared by fusion.

In the preparation of ointments having an emulsion base, the method of manufacture involves both a melting and an emulsification process.

The water-immiscible components such as the oil and waxes are melted together in a steam bath to about 70-75 °C, and an aqueous solution of the heat-stable water soluble components is prepared and heated to the same temperature as the oleaginous components, then the aqueous solution is slowly added with mechanical stirring to the melted oleaginous mixture. The temperature is maintained for 5-10 minutes and the mixture is slowly cooled with the stirring continued until congealed.

If the aqueous solution were not the same temperature as the oleaginous melt, there would be solidification of some of the waxes upon the addition of the colder aqueous solution to the melted mixture.