LESSON ASSIGNMENT

LESSON 5
Medicated Applications.

LESSON ASSIGNMENT
Paragraphs 5-1 through 5-11.

LESSON OBJECTIVES
After completing this lesson, you should be able to:

5-1. Given a group of definitions, select the definition of the term ointment as presented in Lesson 5.

5-2. Given several types of substances, select the type of substance that should be used as an ointment base.

5-3. Given a group of preparation procedures, select the procedure that should be used to prepare an ointment using the Fusion Method as discussed in Lesson 5.

5-4. Given a list of auxiliary labels, select the auxiliary label that should be placed on a container in which an ointment is dispensed.

5-5. From a group of definitions, select the definition of the term suppository.

5-6. From a list of possible uses for suppositories, select a common use of suppositories.

5-7. Given a group of statements, select the statement that best describes the relationship between the rectal and the oral dose of a medication.

5-8. Select, from a list of auxiliary labels, the auxiliary label that should be placed on a prescription bottle or box containing suppositories to be dispensed to a patient.

SUGGESTION
After completing the assignment, complete the exercises at the end of this lesson. These exercises will help you to achieve the lesson objectives.
LESSON 5
MEDICATED APPLICATIONS
Section I. OINTMENTS, PASTES, AND CREAMS

5-1. INTRODUCTION

Ointments are semisolid preparations intended for external application that usually contain medicinal substances. Pastes, ointment-like preparations that contain a greater amount of solids, generally are thicker and do not melt when applied to the body. Creams are semisolid emulsions very much like ointments in consistency but are opaque rather than translucent. For purposes of dispensing, because the methods of preparation and packaging and labeling are so similar, we will discuss these three forms of medication together.

a. Purpose of Ointments. Ointments have several purposes. They act as vehicles for medicinal agents for topical application. They may protect, or act as emollients to, the skin. A few are counterirritants. Ointments are limited only by the number of medicinals that can be incorporated into them and, to some extent, by their absorption into the body.

b. Desirable Qualities in Ointments. Ointments, creams, and pastes must be smooth, never gritty. More trituration is necessary in preparing powders for incorporation into ointments than powders to be used in tablets or capsules. Since ointments, creams, and pastes are often applied to broken skin and may be absorbed into the body, extra measures of cleanliness must be taken in preparing them. Spatulas, ointment slabs, and all the equipment used to make ointments must be immaculate. The choice of an ointment base is of the utmost importance, and although it may be impossible for any single base to be ideal in every respect, the following are standards for which we strive:

(1) The base in no way adversely affects a wound to which it is applied.

(2) It is pharmaceutically elegant.

(3) It does not cause sensitization or irritation, either to unabraded or traumatized skin.

(4) It is prepared with relatively little difficulty.

(5) It is neutral (neither acidic nor basic).

(6) It does not dehydrate the area to which it is applied.

(7) It is nongreasy and nonstaining.
(8) It has permanency, good keeping qualities, and neither becoming rancid nor supporting microbial growth.

(9) It is compatible with a wide range of medicinal substances and with other bases with which it is likely to be mixed.

(10) It releases the incorporated medication effectively to the site of application, and if so intended, passes into or through the skin.

(11) It is washable. Unfortunately, not all ointments, creams, and pastes meet this requirement.

5-2. CLASSIFICATION OF OINTMENT BASES

Ointment bases can be classified according to composition and general characteristics. The ointment base or vehicle may or may not be therapeutically active. It may be used without active ingredients if only protection or emollient properties are desired. Ointment bases fall into one of these classes: oleaginous, absorption, emulsion, or water-soluble.

a. Oleaginous Ointment Bases. Oleaginous ointment bases include not only vegetable oils and animal fats, but also hydrocarbons derived from petroleum. Because of their nature, oils and fats become rancid and foul smelling on exposure to the atmosphere and to light. Preservatives and antioxidants are necessary ingredients in these bases. The hydrocarbon bases may include liquid petrolatum to lower viscosity or white wax to raise it. White Ointment, USP is a typical combination of hydrocarbons.

(1) Petrolatum (Vaseline). Petrolatum is a tasteless, odorless, yellowish, greasy solid with a melting point between 38º C and 60º C. White petrolatum is decolorized petrolatum. It is used more frequently than yellow petrolatum. Petrolatum is very stable, very compatible with most substances, and emollient to the skin. The consistency can easily be varied by the incorporation of mineral oil (liquid petrolatum) or white wax. Petrolatum-type ointment bases are more stable than vegetable- or animal-type bases. However, all of these bases are greasy. The degree to which they release the incorporated medication is questionable. They are able to absorb only very small amounts of water, unless treated with cholesterol.

(2) Jelene (Plastibase). Jelene, a mixture of hydrocarbons in the liquid and wax ranges, has a jelly-like consistency. It is better than petrolatum in many respects. It maintains its consistency over a wide range of temperature without additives. It releases medication more reliably and provides a better appearing ointment.

(3) Silicones. Silicones, polymers of silicon and oxygen, make good ointments for protecting the skin from moisture.
(4) **Summary of oleaginous bases.** We can sum up the oleaginous ointment bases as follows:

(a) Properties. Not good water absorbers, insoluble in water, not washable, not greasy.

(b) Examples. Fats and fixed oils such as lard olive oil, cottonseed oil, petrolatum, white ointment, plastibase, and silicon bases.

(c) Advantages. Highly compatible; all but the fats and oils are stable; good emollients.

(d) Disadvantages. Difficult to remove from skin and clothing; uncertain as to yield of medicament.

b. **Absorption Bases.** An absorption base absorbs water or aqueous solutions of medicinals. These bases are generally anhydrous (waterless), hydrophilic (water loving) bases.

   (1) **Constituents.** The most common absorption bases are composed of petrolatum mixed with animal sterols such as cholesterol. Aquaphor is a widely used and excellent example of an absorption base. Hydrophilic Petrolatum, USP is another.

   (2) **Summary of absorption bases.** We can sum up the absorption bases as follows:

   (a) Properties. Anhydrous; will absorb water; most are not washable.

   (b) Example. Hydrophilic Petrolatum, USP; aquaphor; Anhydrous Lanolin, USP.

   (c) Advantages. Highly compatible; relatively stable to heat; can be used in anhydrous form or water can be added when emolliency is desired.

   (d) Disadvantage. Greasy.

c. **Emulsion Bases.** Emulsion ointment bases consist of an aqueous phase, an oleaginous phase, and an emulsifying agent. They are true, solid emulsions. Emulsion bases may be either oil-in-water (o/w) or water-in-oil (w/o), usually depending upon the phase in which the emulsifier is more soluble. The water phase varies from 10 percent to 80 percent of the completed ointment base.
(1) **Preparation.** Emulsion bases are made by melting the greasy and oily materials together in one container and heating the water and water-soluble materials in another container. At the temperature of 75º C, they are mixed together until a smooth cream results. While the mixture is still warm and thin, it may be passed through a homogenizer to improve the appearance and quality of the base. The mixture is then stirred until it congeals.

(2) **Summary of emulsion bases.** We can sum up the important aspects of emulsion bases as follows:

(a) **Properties.** The w/o emulsion bases are insoluble in water and are not washable; the o/w emulsion bases are washable and nongreasy.

(b) **Example.** Lanolin, USP (w/o); Hydrophilic Ointment, USP (o/w); vanishing creams (o/w).

(c) **Advantages.** Washable and nongreasy if oil-in-water (o/w).

(d) **Disadvantages.** Subject to water loss if o/w, greasy and unwashable if water-in-oil (w/o), unless, a preservative is added, the emulsion bases are subject to mold growth.

d. **Water-Soluble Bases.** The polyethylene glycol polymers, or Carbowaxes, are of great importance in ointments. The names of the Carbowaxes include numbers that roughly indicate their average molecular weight. Carbowaxes with a molecular weight in the area of 1,000 are soft, ointment-like substances. As the molecular weight increases, they become harder and they finally become waxes. They are water-soluble, nonvolatile, and do not deteriorate or support mold growth.

(1) **Formulations.**

(a) The most suitable Carbowax ointment bases are formulations of heavy and light molecular-weight polyethylene glycols, such as the formula below for Polyethylene Glycol Ointment, USP:

<table>
<thead>
<tr>
<th>Polyethylene Glycol 4,000</th>
<th>40%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene Glycol 400</td>
<td>60%</td>
</tr>
</tbody>
</table>

(b) This base is so water-soluble that not more than 5 percent water can be added in making ointments. When greater volumes of water must be added to the ointment, the following formulation is recommended:

<table>
<thead>
<tr>
<th>Polyethylene Glycol 4,000</th>
<th>47.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene Glycol 400</td>
<td>47.5%</td>
</tr>
<tr>
<td>Cetyle Alcohol</td>
<td>5.0%</td>
</tr>
</tbody>
</table>
(c) Up to 20 percent of water or 5 percent of alcohol can be added to this ointment.

(2) Summary of water-soluble bases. We can sum up the important aspects of the water-soluble ointment bases as follows:

(a) Properties. Anhydrous, but will absorb water and dissolve in water; washable; nongreasy.

(b) Examples. Carbowax compounds such as the polyethylene glycol ointment already mentioned, water-soluble ointment base (a federally stock-listed item of supply procurement), and bases containing pectin, cellulose, bentonite, and gelatin.

(c) Advantages. Wide range of compatibility; do not become rancid or support microbial growth; nonirritating (to the same degree as lanolin, petrolatum, etc); adhere well to skin; easily washed off; low incidence of sensitization.

(d) Disadvantages. Sometimes undergo gradual discoloration with certain drugs. Unless cetyl alcohol is added, an aqueous solution can be added only to the extent of 5 percent.

5-3. PREPARATION OF OINTMENTS

Ointments are prepared in the pharmacy by either incorporating the active ingredient(s) into the chosen base or by melting the base and active ingredient(s) together. The two methods are presented below:

a. Incorporation Method.

(1) Equipment. Most ointments made in the pharmacy are prepared simple incorporation, in a mortar either with a pestle or on an ointment slab with a spatula. An ointment slab is a heavy piece of glass with a rough surface on one side to help reduce the size of solid particles.

(2) Procedure. Triturate solid ingredients in a mortar until they are very fine. Then, in a mortar or on an ointment slab, make a paste of the powder with an equal amount of base. This is called levigation. Thoroughly mix the paste with another volume of base equal to that of the paste. Then continue this routine of mixing equal amounts of paste and base until the entire base has been added and you have a uniform preparation with a very small particle size. A mortar and pestle should be used for incorporating liquids into a base or for preparing larger quantities of an ointment.
b. **Fusion Method.** The fusion method is particularly useful when solid waxes are included in the ointment to add viscosity. In this method, first melt the substance with the highest melting point by using a water bath, but use as little heat as necessary. Then add the other ingredients on the basis of their decreasing melting points. When the entire mixture is liquefied, remove it from the water bath. Then stir the mixture until it congeals, to prevent possible separation and crystallization.

5-4. **DISPENSING OINTMENTS**

Ointments are traditionally packaged in jars and collapsible tubes. The jars are made of glass that is either green or opaque white. Ordinary tin tubes are convenient to the patient because they are easier to carry and do not break when they are dropped. They are especially valuable for ointments that lose moisture or decompose on exposure to the atmosphere.

a. **Filling Ointment Jars.** Ointment jars, available in many sizes ranging from 1/4 ounce to a pound and larger, may be filled by packing the ointment into them with a small spatula. In packing, the sides and bottom all the way around should be covered first, adding the final portions to the center and top in order to minimize air pockets. Melted ointments containing no material likely to settle out may be poured into containers while still warm and fluid. In either case, the ointment should be smoothed off at the top before the lid is closed.

b. **Filling Ointment Tubes.** You can fill ointment tubes at the pharmacy by first rolling the ointment into a glassine powder paper to make a cylinder just smaller than the base of the tube. Remove the cap of the tube so that air will not be trapped when the ointment is inserted. Insert the roll, ointment and paper combined, as far into the tube as the roll will go and close it by carefully flattening the end of the tube. Hold the end of the tube closed with firm pressure from the side of a spatula and carefully pull the glassine paper out of the tube. The ointment is left in the tube. Fold the end of the tube over twice, crease it tightly, and score it several times with the spatula edge to prevent it from opening during use.

c. **Labeling.** Select a label corresponding in size to the size of the jar being used. Metal ointment tubes should be moistened with tincture of benzoin before the label is applied to help the label adhere. When the label has been put into place, it should be covered with a strip of cellophane tape. The auxiliary label "For External Use Only" is required on all ointments, pastes, and creams.

Section II. **SUPPOSITORY**

5-5. **INTRODUCTION**

Suppositories are solid bodies of various weights and shapes, adapted for introduction into different orifices of the human body, usually the rectum or vagina. Suppositories usually dissolve, melt, or soften at body temperature.
5-6. **SHAPES AND WEIGHTS**

The shapes and weights of suppositories depend on the route of administration. See figure 5-1 for the various shapes that a suppository may take.

a. **Rectal Suppositories.** The most suitable shape for rectal suppositories is that of a bullet tapered on one or both ends with the base longer and more tapered than the head. This shape allows easy insertion and helps prevent accidental expulsion of the suppository before it has the time to melt. Rectal suppositories weigh about 2 grams. Suppositories for children should be smaller, longer, and narrower than adult suppositories.

b. **Vaginal Suppositories.** Vaginal suppositories should weigh about 5 grams.

![Figure 5-1. Identification of suppositories.](image-url)
5-7. ACTION

Suppositories have a local effect or a systemic effect (an effect on the entire body), depending upon the active ingredients in the suppository.

a. Local. Frequently, a local action is desirable for a rectal or vaginal inflammation or condition. In such cases, the local action of an emollient, local anesthetic, astringent, analgesic, or antibiotic is sought. Drugs that are not absorbed from the site to which they are introduced can exert only a local effect. Those that are absorbed may exert both a local and a systemic action. The concentration of the agent will have a bearing upon the systemic action, if the drug is absorbable.

b. Systemic. The systemic actions for which suppositories are used are limited only by the drug's solubility and absorbability. Thus, it is possible to administer antiemetics, antibiotics, analgesics, antipyretics, muscle relaxants, sedatives, hypnotics, and so on, in the form of suppositories.

5-8. USES OF SUPPOSITORIES

Suppositories are often used when the patient is unable to swallow medications. For example, a patient who is vomiting would probably be unable to swallow (and retain) a tablet or capsule. Suppositories can be used as vehicles for antiemetics (drugs which prevent nausea and vomiting) and sedatives. Further, suppositories can be used as vehicles to carry drugs that irritate or upset the stomach.

5-9. DOSES

Extensive testing and research have shown that, because of many variables, there is no accurate relationship of rectal to oral dose. That is, it cannot be said that half, twice, or four times the oral dose is necessary to elicit the same response rectally. In practice, however, the rectal dose prescribed is normally in the range between one-half and twice the oral dose. Factors entering this variable dose are: the nature of the base used, rapidity of release of the active principles, the nature of the active medication, and the solubility and absorbability of the drug. The inability to accurately calculate a rectal dose for medication is probably the biggest reason that more and more drugs are not routinely given by the rectal route.

5-10. SUPPOSITORY CASES

a. Theobroma Oil. Theobroma oil (cocoa butter) is a yellowish-white, greasy-to-the-touch, nonirritating, emollient substance with the characteristic odor of chocolate. It is solid at room temperature and begins to liquefy at about 30º C (94º Fahrenheit (F)). Thus, at body temperature (37º C/98.6º F), theobroma oil is a liquid.
(1) **Effect of excessive heat.** Cocoa butter has a crystalline structure which breaks down when overheated. If suppositories are made from overheated cocoa butter, they will liquefy at approximately 23º to 24º C (75º F) rather than the desired higher temperature of 30º C (94º F). Therefore, when making suppositories of theobroma oil, always be careful to use only enough heat to liquefy the material, NEVER enough to destroy the natural crystalline structure.

(2) **Raised or lowered melting point.** When substances such as chloral hydrate and liquefied phenol are added to theobroma oil, they cause the melting point of the finished suppository to be greatly lowered. They may become soft or even liquid at room temperature. In addition, unusually warm or cold climates make the melting point of cocoa butter suppositories unsatisfactory.

b. **Glycerinated Gelatin.**

(1) There are many different formulas for this substance. They involve varying amounts of glycerin, gelatin, and water. The following formula for making pure or medicated glycerinated gelatin suppositories has been recommended.

<table>
<thead>
<tr>
<th>Medicinal substance (prescribed quantity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purified water, a sufficient quantity to make .. ... 10 g</td>
</tr>
<tr>
<td>Gelatin, granular ................................. 20 g</td>
</tr>
<tr>
<td>Glycerin ............................................. 70 g</td>
</tr>
</tbody>
</table>

(2) Unlike cocoa butter suppositories, glycerinated gelatin suppositories do not melt at body temperature. Instead, they dissolve in body secretions or in contents of the cavity into which they are introduced. The time necessary for solution varies, depending upon the ratio of the ingredients, and the presence of peptizing agents or chemicals.

c. **Polyethylene Glycols.** These substances are solid at room temperature and very soluble in water. Suppositories made with polyethylene glycol bases must be prepared by the fusion method. They are popularly called Carbowaxes and the increasing solidity is identified by an increasing number in the name. Carbowax 300 is a viscid liquid; Carbowax 1540 is a solid. The Carbowaxes are becoming ever more popular as suppository bases and are excellent for water-soluble medicaments. Other water miscible formulations are surface active derivatives of polyethylene glycol and they are nonionic. An example is polyethylene glycol sorbitan monopalmitate (Tween 61).
5-11. DISPENSING

a. **Packaging.** Glycerin and glycerinated gelatin based suppositories are best dispensed in tightly closed, glass bottles with wide mouths. They are hygroscopic (readily absorb and retain moisture) and unless protected from the atmosphere will absorb water. Cocoa butter and Carbowax based suppositories may be dispensed in cardboard boxes containing partitions so that each suppository has its own compartment. If the suppository is wrapped individually in foil, the need for compartments is removed and such suppositories can be correctly dispensed in plain boxes. Suppositories containing volatile ingredients such as menthol and liquefied phenol should be dispensed in wide-mouthed, tightly closed, glass bottles.

b. **Labeling.** Directions on the label should specify use of the suppositories and their site of insertion. A "Keep in Cool Place" or "Refrigerate" label should be used. The patient should be instructed to remove the foil wrapping before insertion of the suppository.

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Continue with Exercises

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EXERCISES, LESSON 5

INSTRUCTIONS: Answer the following exercises by marking the lettered response that best answers the question or best completes the incomplete statement or by writing the answer in the space provided.

After you have completed all the exercises, turn to "Solutions to Exercises" at the end of the lesson and check your answers. For each exercise answered incorrectly, reread the material referenced with the solution.

1. From the group of definitions below, select the most correct definition of the term ointment.
   b. A semi-solid preparation that is thicker than a paste.
   c. A semi-solid preparation that can be sterilized by filtration.
   d. A semi-solid preparation intended for external application.

2. From the list below, select the type of substance that can be used as an ointment base.
   a. Adsorption.
   b. Lotion.
   c. Emulsion.
   d. Emollient.
3. When using the Fusion Method (melting base and active ingredients together), the different parts of the ointment should be melted separately. Select the statement that best describes the preparation procedure.

   a. The substance with the lowest melting point should be melted first.
   b. The substance with the highest melting point should be melted first.
   c. The substance with the highest melting point should be melted last.
   d. After all the ingredients have been melted, the liquid ingredients should be removed from the heat and placed in a refrigerator to cool. Do not stir the liquid.

4. From the list below, select the type of auxiliary label that should be placed on a container in which an ointment is dispensed.

   a. “Refrigerate--Do Not Freeze.”
   b. “Shake Well.”
   c. “For The Eye.”
   d. “For External Use Only.”

5. From the group of definitions below, select the most correct definition of the term suppository.

   a. Semi-solid bodies of various weights and shapes adapted for introduction into different orifices of the human body.
   b. Solid bodies of various weights and shapes adapted for oral use.
   c. Solid bodies of various weights and shapes adapted for introduction into different orifices of the human body.
   d. Semi-solid dosage forms intended for introduction into the rectum or vagina.
6. From the list of uses below, select a common use of suppositories.
   
a. As a vehicle for an emetic.

b. As a vehicle for an anti-emetic.

c. As a vehicle for an anti-diarrheal.

d. As a vehicle for an anthelmintic.

7. From the group of statements below, select the most correct statement pertaining to the relationship between the rectal and oral dose of a medication.
   
a. The oral dose of a medication should be approximately one-half of the rectal dose.

b. The rectal dose of a medication should be approximately twice that of the oral dose.

c. The rectal dose of a medication should be approximately three times that of the oral dose.

d. There is no known accurate relationship between the rectal and oral dose.

8. Select, from the list below, the auxiliary label that should be placed on a prescription bottle or box that contains suppositories.
   
a. “Keep in a Cool Place.”

b. “Shake Well Before Using.”

c. “Freeze Prior To Use.”

d. “Caution: This Medication May Be Habit-Forming.”

Check Your Answers on Next Page
SOLUTIONS TO EXERCISES, LESSON 5

1. d (para 5-1)
2. c (para 5-2)
3. b (para 5-3b)
4. d (para 5-4c)
5. c (para 5-5)
6. b (para 5-8)
7. d (para 5-9)
8. a (para 5-11b)

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