



◆ Suppositories and Inserts

Objectives

After reading this topic, the student will be able to :

Compare and contrast various suppository and insert, in terms of physical appearance, size and shape

Describe the advantages of suppositories and inserts .

Identify and explain physiologic factors that influence the drug absorption from rectal suppository administration

Identify and explain the physicochemical factors of the drug and suppository/insert base as these influence absorption

Compare and contrast the various classes of suppository bases

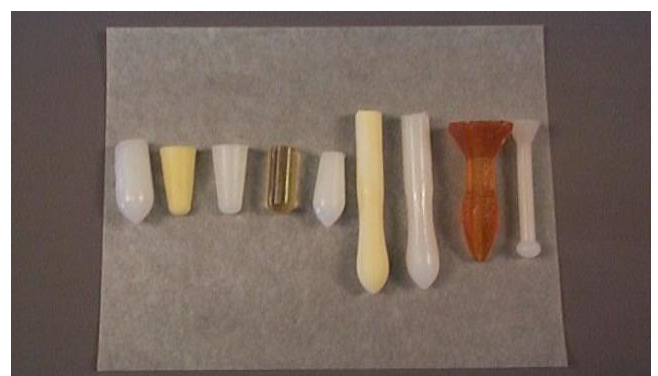
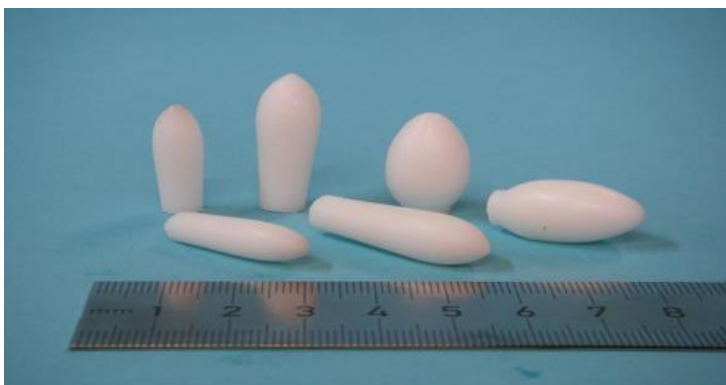
Describe the three methods of suppository preparation

◆ Suppositories

Suppositories are solid dosage forms intended for insertion into body orifices where they melt, soften, or dissolve and exert local or systemic effects .

Suppositories are commonly used rectally, vaginally, and occasionally urethrally

-They are used to deliver both systemically and locally acting medications



◆ Suppositories Shapes

-Suppositories have various shapes and weights .



-The shape and size of a suppository must be such that it can be easily inserted into the intended orifice without causing undue distension, and once inserted, it must be retained for the appropriate period.

-Rectal suppositories are inserted with the fingers, but certain vaginal suppositories, particularly the inserts, or tablets prepared by compression, may be inserted high in the tract with the aid of an appliance .

◆ Rectal suppositories

-Rectal suppositories are usually about 32 mm (1.5 in.) long, are cylindrical, and have one or both ends tapered. Some rectal suppositories are shaped like a bullet, a torpedo, or the little finger .

-Depending on the density of the base and the medicaments in the suppository, the weight may vary .

-Adult rectal suppositories weigh about 2 g when cocoa butter (theobroma oil) is employed as the base .

-Rectal suppositories for use by infants and children are about half the weight and size of the adult suppositories and assume a more pencil-like shape .

◆ Vaginal suppositories

Vaginal suppositories, also called (in past) **pessaries**, are usually globular, oviform, or cone-shaped and weigh about 5 g when cocoa butter is the base .

However, depending on the base and the manufacturer's product, the weights of vaginal suppositories may vary widely .

◆ Urethral suppositories

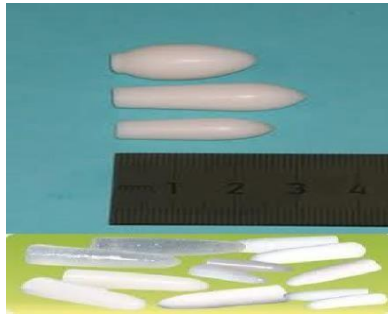
-Urethral suppositories, also called **bougies**, are slender, pencil-shaped suppositories intended for insertion into the male or female urethra .

-Male urethral suppositories may be 3 to 6 mm in diameter and approximately 140 mm long.

-Female urethral suppositories are about half the length and weight of the male urethral suppository, being about 70 mm long and weighing about 2 g when made of cocoa butter .



-Urethral suppositories may be: antibacterial or a local anesthetic preparative for a urethral examination .



◆ Fate of the suppository

Once inserted, the suppository base melts, softens, or dissolves, distributing its medicaments to the tissues of the region .

-These medicaments may be intended for retention within the cavity for local effects, or they may be intended to be absorbed for systemic effects .

-They may exhibit the effect immediately or sustain the release of the drug such as Long-acting or slow-release suppositories are also prepared .

-Morphine sulfate in slow-release suppositories is prepared by compounding pharmacists. The base includes a material such as alginic acid, which will prolong the release of the drug over several hours .

◆ Local rectal suppositories

Rectal suppositories intended for local action are most frequently used to relieve

1. Constipation

A popular laxative, glycerin suppositories promote laxation by local irritation of the mucous membranes, probably by the dehydrating effect of the glycerin on those membranes .

2- The pain, irritation, itching, and inflammation associated with hemorrhoids or other anoctal conditions .

Anti-hemorrhoidal suppositories frequently contain a number of components, including local anesthetics, vasoconstrictors, astringents, analgesics, soothing emollients, and protective agents .





◆ Local vaginal suppositories

Vaginal suppositories or inserts intended for local effects are employed mainly as:

- 1-Contraceptives, the drugs used are nonoxynol-9
- 2-Antiseptics in feminine hygiene, trichomonacides to combat vaginitis caused by *Trichomonas vaginalis*
- 3-Specific agents to combat an invading pathogen. Most commonly, antifungals to treat *Candida (Monilia) albicans*, and anti-infectives/antibiotics directed at other microorganism



◆ Systemic effect of rectal suppositories

- For systemic effects, the mucous membranes of the rectum and vagina permit the absorption of many soluble drugs. However, **vaginal route is not frequently used for systemic purpose.**

The advantages of the rectal route (for systemic effects) over oral therapy are:

- a-Drugs destroyed or inactivated by the pH or enzymatic activity of the stomach or intestines need not be exposed to these destructive environment
- b-Drugs irritating to the stomach may be given without causing such irritation .
- c-Drugs destroyed by portal circulation may bypass the liver (partially) after rectal administration .
- d-The route is convenient for administration of drugs to patients who are unable or unwilling to swallow medication.
- e-It is an effective route in the treatment of patients with vomiting .

◆ Examples of drugs administered rectally for systemic effect

Prochlorperazine for the relief of nausea and vomiting, indomethacin (NSAIDs) and ondansetron for the relief of nausea and vomiting



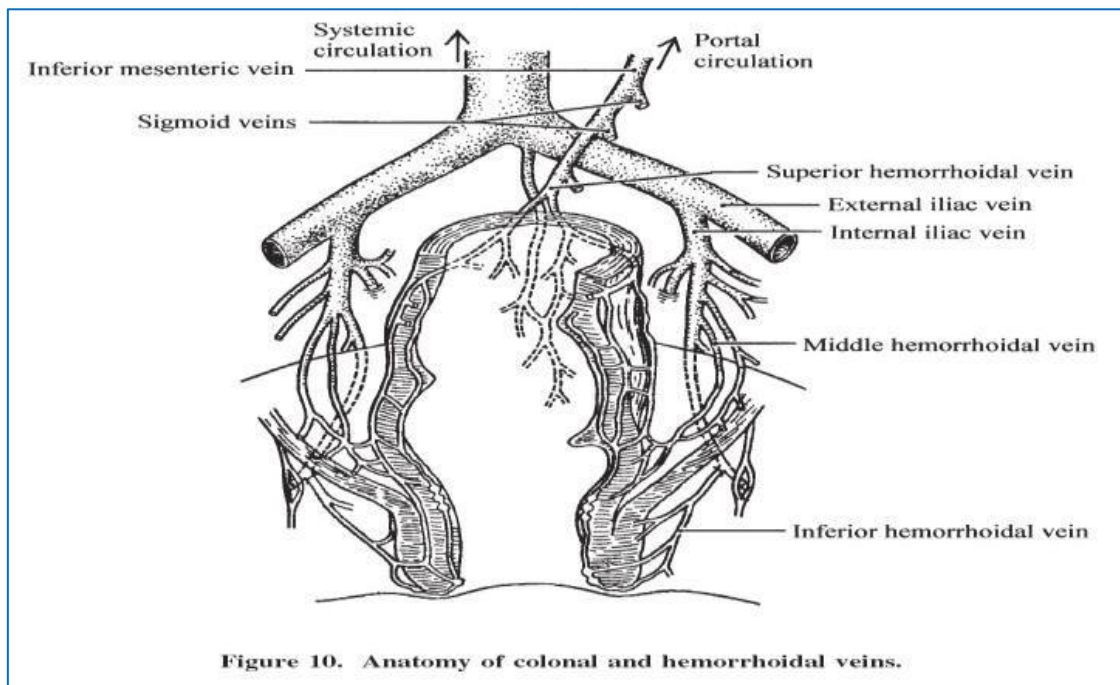
Some factors affecting on drug absorption from rectal suppositories The dose of a drug administered rectally may be greater than or less than the dose of the same drug given orally, depending on such factors as:

- The physicochemical nature of the drug
- Its ability to traverse the physiologic barriers to absorption
- The nature of the suppository vehicle and its capacity to release the drug and make it available for absorption .

◆ Rectal absorption

The factors that affect rectal absorption of a drug may be divided into two main groups:

- a-Physiological factors
- b-Physicochemical factors of the drug and the base



◆ Physiological factors

The human rectum is approximately 15 to 20 cm long .

- When empty of fecal material, the rectum contains only 2 to 3 mL of inert mucous fluid. (Low volume of fluid available)
- In the resting state, the rectum is not motile; there are no villi or microvilli on the rectal mucosa .



-However, there is abundant vascularization of the submucosal region of the rectum wall with blood and lymphatic vessels .

-Among the physiologic factors that affect drug absorption from the rectum are the colonic contents, and the pH and lack of buffering capacity of the rectal fluids .

◆ Colonic Content

When systemic effects are desired, greater absorption may be expected from a rectum that is void than from one that is distended with fecal matter .

- A drug will obviously have greater opportunity to make contact with the absorbing surface of the rectum and colon in an empty rectum .

-Therefore, when deemed desirable, an evacuation enema may be administered and allowed to act before the administration of a suppository of a drug to be absorbed .

-Other conditions, such as diarrhea, colonic obstruction due to tumorous growths, and tissue dehydration can all influence the rate and degree of drug absorption from the rectum .

◆ Circulation Route

Drugs absorbed rectally, unlike those absorbed after oral administration, bypass the portal circulation during their first pass into the general circulation, thereby enabling drugs otherwise destroyed in the liver to exert systemic effects .

-The lower hemorrhoidal veins surrounding the colon receive the absorbed drug and initiate its circulation throughout the body, bypassing the liver .

-Lymphatic circulation also assists in the absorption of rectally administered drugs

◆ pH and Lack of Buffering Capacity of the Rectal Fluids

Because rectal fluids are essentially neutral in pH (pH 7) and have no effective buffer capacity, the form in which the drug is administered will not generally be chemically changed by the environment .

-The suppository base has a marked influence on the release of active constituents. While cocoa butter melts rapidly at body temperature, because of its immiscibility with fluids, it fails to release fat-soluble drugs readily .



Physicochemical factors of the drug and suppository base Physicochemical factors of the drug include such properties as:

- 1-The relative solubility of the drug in lipid and in water and
- 2-The particle size of a dispersed drug, and surface properties
- 3-Amount of drug
- 4-pKa of the drug

Physicochemical factors of the base include:

- 1-Its ability to melt, soften, or dissolve at body temperature
- 2-Its ability to release the drug substance
- 3-Its hydrophilic or hydrophobic character (composition of the base) 4. Rheological properties .

◆ Lipid-Water Solubility of drug

The lipid-water partition coefficient of a drug is an important consideration in the selection of the suppository base and in anticipating drug release from that base.

-A lipophilic drug that is distributed in a fatty suppository base in low concentration has less tendency to escape to the surrounding aqueous fluids than a hydrophilic substance in a fatty base.

-Water soluble bases—for example, polyethylene glycols—that dissolve in the anorectal fluids release for absorption water-soluble and oil-soluble drugs .

◆ Drug solubility and suppository formulation

Solubility of drug in		
Fat	Water	Choice of base
Low	High	Fatty base
High	Low	Aqueous base
Low	Low	Intermediate

Amount of drug

Naturally, the more drug a base contains, the more drug will be available for absorption. However, if the concentration of a drug in the intestinal lumen is above a particular amount, which varies with the drug, the rate of absorption is not changed by a further increase in the concentration of the drug .



Particle Size

For un-dissolved drugs in a suppository (suspension), the size of the drug particle will influence its rate of dissolution and its availability for absorption .

-The smaller the particle, the greater the surface area, the more readily the dissolution of the particle and the greater the chance for rapid absorption.

Nature of the Base

The base must be capable of melting, softening, or dissolving to release its drug for absorption. If the base interacts with the drug to inhibit its release, drug absorption will be impaired or even prevented .

-Also, if the base irritates the mucous membranes of the rectum, it may initiate a colonic response and prompt a bowel movement, eliminating the prospect of complete drug release and absorption .

•Because of the possibility of chemical and/or physical interactions between the medicinal agent and the suppository base, which may affect the stability and/or bioavailability of the drug, the absence of any drug interaction between the two agents should be ascertained before or during formulation .

◆ Properties of the ideal suppository base خصائص قاعدة التحميلة المثالية

1-Non-toxic, non- irritating to sensitive and inflamed tissues .
2-Inert and compatible with medicaments .
3-Not deteriorated or contaminating the drug during storage .
4-Easily manufactured by compression or molding .
5-Dissolve or disintegrate in mucous secretions or melt quickly at body temperature to allow the release of medicament .
6-Remain molten for a sufficient period of time to allow pouring into molds .
7-Solidify rapidly to minimize sedimentation of dispersed solids.
8-Contract on cooling to allow easy withdrawal of the suppository from the mold .
9-Has wetting and emulsifying properties.
10-Stable on storage, keeps its shape during storage or handle (does not change color, odor and drug release pattern).



◆ Suppository bases

Requisites for a suppository base is that it should remain solid at room temperature but soften, melt, or dissolve readily at body temperature so that the drug is fully available soon after insertion .

Main types of suppository bases:

1-Fatty bases or oleaginous bases, Cocoa butter (theobroma oil) melts quickly at body temperature, but is immiscible with body fluids as for fat-soluble drugs tend to remain in the oil and have little tendency to enter the aqueous physiologic fluids .

For water- soluble drugs in cocoa butter, the reverse is usually true and good release results. Also, when irritation or inflammation is to be relieved, as in the treatment of anorectal disorders, cocoa butter appears to be the superior base because of its emollient or soothing, spreading action

2-Water soluble or water miscible bases, glycerinated gelatin or polyethylene glycol, Fat-soluble drugs seem to be released more readily from these bases, but both of which dissolve slowly in body fluids .

3-Miscellaneous bases, generally combinations of lipophilic and hydrophilic substances.

TABLE 12.5. Melting Ranges of some Suppository Bases

Base	Composition	Melting Range (°C)
Cocoa butter	Mixed triglycerides of oleic, palmitic, and stearic acids	34–35
Fattibase	Triglycerides from palm, palm kernel, and coconut oils with self-emulsifying glyceryl monostearate and polyoxyl stearate	35.5–37
Polybase	A homogeneous blend of PEGs and polysorbate 80	60–71
Suppocire OSI	Eutectic mixtures of mono-, di-, and triglycerides derived from natural vegetable oils, each type having slightly different properties	33–35
Wecobee W	Triglycerides derived from coconut oil	31.7–32.8
Witepsol H15	Triglycerides of saturated fatty acids C12–C18 with varied portions of the corresponding partial glycerides	33–35

◆ Fatty or Oleaginous Bases

1-Cocoa butter

2-Hydrogenated fatty acids of vegetable oils, such as palm kernel oil and cotton seed oil.

3-Fat-based compounds, esters of glycerin with the higher-molecularweight fatty acids, such as palmitic and stearic acids, such as glyceryl monostearate and glyceryl monopalmitate .

-The bases in many commercial products employ varied combinations of these types of materials to achieve the desired hardness under conditions of shipment and storage and the desired quality of submitting to the temperature of the body to release their medicaments .



Cocoa Butter, NF

-Are fat obtained from the roasted seed of Theobroma cacao.

-At room temperature, it is a yellowish-white solid having a faint, agreeable chocolate-like odor (naturally occurring comp.)

-Chemically, the main constituent of cocoa butter is the triglyceride derived from palmitic acid, stearic acid, and oleic acid, primarily of oleopalmito-stearin and oleo-distearin

-Cocoa butter melts at 30°C to 36°C, it is an ideal suppository base, melting just below body temperature and yet maintain in its solidity at usual room temperature.

-However, because of its triglyceride content, cocoa butter exhibits marked polymorphism, or existence in several crystalline forms

Cocoa Butter polymorphism

-When cocoa butter is carelessly melted at a temperature greatly exceeding the minimum required temperature (about 35°C) and is then quickly chilled, the result is a metastable crystalline form (alpha crystals) with a melting point much lower than that of the original cocoa butter (melts at 22°C) .

-However, because the crystalline form is a metastable condition, there is a slow transition to the more stable beta form of crystals having the greater stability and a higher melting point. This transition may require several days .

-Cocoa butter must be slowly and evenly melted, preferably over a bath of warm water, to avoid formation of the unstable crystalline form and ensure retention in the liquid of the more stable beta crystals that will constitute nuclei upon which the congealing may occur during chilling of the liquid .

Disadvantages of theobroma oil:

1-Polymorphism: when melt &solidify it form different crystal form depending on the temperature. if its melt at low temp, not exceed 36 °C it will form β -polymorph form which is stable form, if melted suddenly and quickly at high temperature then freezing or cooling it will form unstable γ form that melt at 15 °C.

2-Adherence to the mold, this can be solved by using lubricant agent that is immiscible with the base .

3-Low m.p, this can be solved by added medication, adding white bees wax.



- 4-Low water absorbance (poor water-absorbing capacity), this can be solved by adding surface-active agent .
- 5-Stability problem (slow deterioration during storage, chemical instability) .
- 6-Not suitable for warm countries .
7. Relatively high cost.

◆ Other fatty bases

Other bases in this category include commercial products such as:

- Fattibase** (triglycerides from palm, palm kernel, and coconut oils with self-emulsifying glyceryl monostearate and polyoxyl stearate) ,
- Wecobee bases** (triglycerides derived from coconut oil)
- Witepsol bases** (triglycerides of saturated fatty acids C12-C18 with varied portions of the corresponding partial glycerides) .

Water-Soluble and Water-Miscible Bases

The main members of this group are glycerinated gelatin and polyethylene glycols .

Glycerinated gelatin suppositories may be prepared by dissolving granular gelatin (20%) in glycerin (70%) and adding water or a solution or suspension of the medication (10%).

-A glycerinated gelatin base is most frequently used in preparation of vaginal suppositories, with which prolonged local action of the medicinal agent is usually desired. The glycerinated gelatin base is slower to soften and mix with the physiologic fluids than is cocoa butter and therefore provides a slower release .

Glycerinated gelatin suppositories disadvantages

A-Because glycerinated gelatin-based suppositories have a tendency to absorb moisture as a result of the hygroscopic nature of glycerin, they must be protected from atmospheric moisture to maintain their shape and consistency.

B-Due to hygroscopic nature, they may have a dehydrating effect and irritate the tissues upon insertion. The water in the formula for the suppositories minimizes this action; however, if necessary, the suppositories may be moistened with water prior to insertion to



reduce the initial tendency of the base to draw water from the mucous membranes and irritate the tissues .

◇ Polyethylene glycols (PEG)

Polyethylene glycols are polymers of ethylene oxide and water prepared to various chain lengths, molecular weights, and physical states, the most commonly used being polyethylene glycol 300, 400, 600, 1,000, 1,500, 1,540, 3,350, 4,000, 6,000, and 8,000. The numeric designations refer to the average molecular weight of each of the polymers .

-Various combinations of these polyethylene glycols may be combined by fusion, using two or more of the various types to achieve a suppository base of the desired consistency and characteristics.

PEG	Melting range	PEG	Melting range
300	- 15°C	3350	54°C -58°C
400	4°C -8°C	4600	57°C -61°C
600	20°C -25°C	6000	56°C -63°C
1000	37°C -40°C	8000	60°C -63°C
1450	43°C -46°C		

◇ Polyethylene glycol suppositories

PEG suppositories do not melt at body temperature but rather dissolve slowly in the body's fluids. Therefore, the base need not be formulated to melt at body temperature .

-It is possible to prepare suppositories from PEG mixtures having melting points considerably higher than body temperature .

This property permits a slower release of the medication from the base once the suppository has been inserted, and permits convenient storage of these suppositories without need for refrigeration and without danger of their softening excessively in warm weather .

-Further, their solid nature permits slow insertion without fear that they will melt in the fingertips (as cocoa butter suppositories sometimes do) .

-Because they do not melt at body temperature but mix with mucous secretions upon dissolution, PEG-based suppositories do not leak from the orifice, as many cocoa butter-based suppositories .



-PEG suppositories that do not contain at least 20% water should be dipped in water just before use to avoid irritation of the mucous membranes after insertion. This procedure prevents moisture being drawn from the tissues after insertion and the stinging sensation

◆ Miscellaneous Bases

The miscellaneous group of bases are mixtures of oleaginous and watersoluble or water-miscible materials. These materials may be chemical or physical mixtures .

1-Polyoxyl 40 stearate, a surface-active agent that is employed in a number of commercial suppository bases. Polyoxyl 40 stearate is a mixture of the monostearate and distearate esters of mixed polyoxyethylene diols and the free glycols, the average polymer length being equivalent to about 40 oxyethylene units.

The substance is a white to light tan waxy solid that is water soluble. Its melting point is generally 39°C to 45°C .

2-Other surface-active agents useful in the preparation of suppository bases also fall into this broad grouping. Mixtures of many fatty bases (including cocoa butter) with emulsifying agents capable of forming water-in-oil emulsions have been prepared. These bases hold water or aqueous solutions.

◆ Preparation of suppositories

Suppositories are prepared by three methods:

A-Molding from a melt
B-Compression
(C) Hand rolling and shaping .

-The method most frequently employed both on a small scale and on an industrial scale is molding.

Preparation by molding The steps in molding include:

a-Melting the base ,
b-Incorporating any required medicaments,
c-Pouring the melt into molds ,
d-Allowing the melt to cool and congeal into suppositories ,
e- Removing the formed suppositories from the mold.

Cocoa butter, glycerinated gelatin, polyethylene glycol, and most other bases are suitable for preparation by molding .

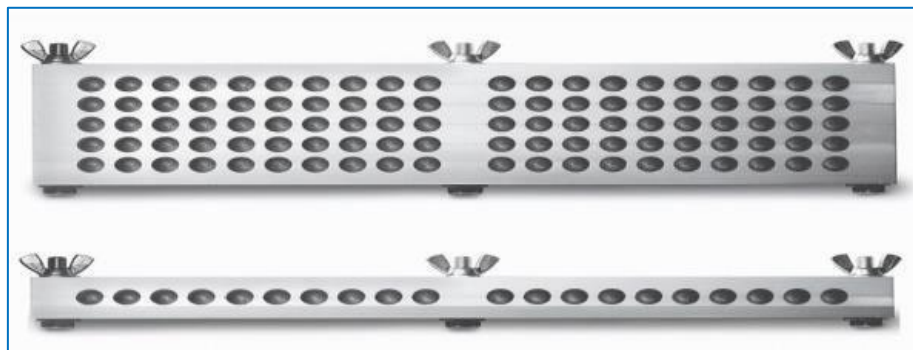


◆ Suppository Molds

Molds in common use today are made from stainless steel, aluminum, brass, or plastic .

The molds, which separate into sections, generally longitudinally, are opened for cleaning before and after preparation of a batch of suppositories, closed when the melt is poured, and opened again to remove the cold molded suppositories.

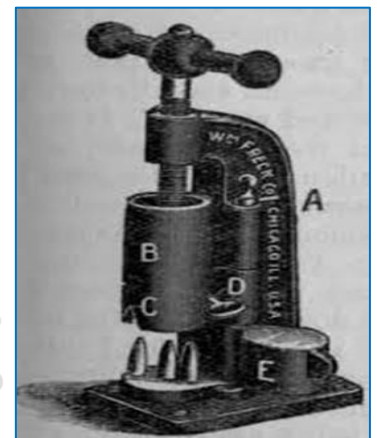
Care must be exercised in cleaning the molds, as any scratches on the molding surfaces will take away from the desired smoothness of the suppositories. Plastic molds are especially prone to scratching .



◆ Preparation by compression

-Suppositories may be prepared by forcing the mixed mass of the base and the medicaments into special molds using suppository-making machines. In preparation for compression into the molds, the base and the other formula ingredients are combined by thorough mixing, the friction of the process softening the base into a paste-like consistency .

-On a small scale, a mortar and pestle may be used. Heating the mortar in warm water (then drying it) greatly facilitates the softening of the base and the mixing.



-On a large scale, a similar process may be used, employing mechanical kneading mixers and a warm mixing vessel compression

◆ Preparation by hand rolling and shaping

It is the oldest and simplest method of supp. preparation

-With ready availability of suppository molds of accommodating shapes and sizes, there is little requirement for today's pharmacist to shape suppositories by hand.



-Hand rolling and shaping is a historic part of the art of the pharmacist (it requires considerable practice and skill) .

◆ Determination of the Amount of Base Required

-Generally, in preparing suppositories, the pharmacist calculates the amounts of materials needed for the preparation of **one or two more suppositories than the number prescribed** to compensate for the inevitable loss of some material and to ensure having enough material.

-In determining the amount of base to be incorporated with the medicaments, the pharmacist must be certain that the required amount of drug is provided in each suppository.

-Because the volume of the mold is known (from the determined volume of the melted suppositories formed from the base), the volume of the drug substances subtracted from the total volume of the mold will give the volume of base required.

-Because the bases are solid at room temperature, the volume of base may be converted to weight from the density of the material .

◆ Medicated suppositories

If the added amounts of medicaments are slight, they may be considered to be negligible, and no deduction from the total volume of base may be deemed necessary.

In preparation of suppositories, it is generally assumed that if the quantity of active drug is less than 100 mg/ 2-g suppository weight then the volume occupied by the powder is insignificant and need not be considered

-Obviously, if a suppository mold of less than 2 g is used, the powder volume may need to be considered .

-However, if considerable quantities of other substances are to be used, the volumes of these materials are important and should be used to calculate the amount of base actually required to fill the mold .

Example

If 12 mL of cocoa butter is required to fill a suppository mold and if the medicaments in the formula have a collective volume of 2.8 mL, 9.2 mL of cocoa butter will be required. By multiplying 9.2 mL times the density of cocoa butter 0.86 g/ mL, it may be calculated that 7.9 g of cocoa butter will be required.



After adjusting for the preparation of an extra suppository or two, the calculated amount is weighed .

◆ Density (Dose Replacement) Calculations for Suppositories

The density factors of various bases and drugs need to be known to determine the proper weights of the ingredients to be used. Density factors relative to cocoa butter have been determined. If the density factor of a base is not known, it is simply calculated as the ratio of the blank weight of the base and cocoa butter

-The three methods of calculating the quantity of base that the active medication will occupy and the quantities of ingredients required are:

a-Dosage replacement factor
b-Density factor
c-Occupied volume method

◆ Displacement value (D.V)

Displacement value is defined as the quantity of drug that displaces one part of the base (eg. hydrocortisone has a displacement value of 1.5) Means 1.5g hydrocortisone displaces 1g the suppository base.

-If the density of the drug equals the density of the base. The drug will displace the same amount of base

-If the density of the drug is more than the density of the base the drug will displace low amount of base

-If the density of the drug is less than the density of the base the drug will displace high amount of base

-DV. for liquids equals 1

◆ Calculations using displacement values

Prepare 8 codeine phosphate suppositories (D.V=1.1) using mold of 1g size each suppository containing 60mg of codeine phosphate

-Prepare 10 suppositories to compensate for any loss



$60 \times 10 = 600\text{mg} = 0.6\text{g}$ of codeine phosphate

- Supp. Base $1\text{g} \times 10 = 10\text{g}$ total weight of pure base
- Drug base
- $\frac{1.1 \text{ displace } 1\text{g}}{0.6 \quad ?}$ base displaced $= (1\text{g} \times 0.6) / 1.1 = 0.55 \text{ g}$
- Amount of base needed is $10\text{g} - 0.55 = 9.45 \text{ g}$

Example: Calculate the quantities required to make 8 theobroma oil supp.

(2g mold) each containing 400 mg of zinc oxide (DV= 4.7) .

1. Calculate the total weight of zinc oxide required. $0.4 \times 10 = 4\text{g}$
2. Calculate what weight of base would be required to prepare 10 unmedicated supp. $2\text{g} \times 10 = 20 \text{ g}$
- 3-Determine what weight of base would be displaced by the medicament. Replaced base = wt. of drug/ D.V $= 4 / 4.7 = 0.85$
- 4-Calculate, therefore, the weight of base required to prepare the medicated supps.
 $20 - 0.85 = 19.15 \text{ g}$ wt. of base required

• **Glycero-gelatin base has a density 1.2 times greater than theobroma oil.** Therefore, a 1 g supp. mold will produce a 1 g theobroma oil supp., but a 1.2 g glycero-gelatin supp. This factor must be taken into account in displacement value calculations.

Example:

Calculate the quantities required to make **six** glycero gelatin supp. (4 g mold), each containing 100 mg aminophylline (Displacement value = 1.3)

Drug $6 \times 100 = 0.6 \text{ g}$

Glycerin gelatin Base $6 \times 4\text{g} \times 1.2 = 28.8 \text{ g}$

Glycerin gelatin Base replaced $= 0.6 / 1.3 = 0.46$ (by theobroma oil base)

$0.46 \times 1.2 = 0.55 \text{ g}$ base displaced by the base (glycero gelatin)

Base required $28.8 - 0.55 = 28.25\text{g}$ of the base required



◆ Vaginal suppositories

The most commonly used base for vaginal suppositories consists of combinations of the various molecular weight polyethylene glycols. To this base is frequently added surfactants and preservative agents, commonly the parabens.

Many vaginal suppositories and other types of vaginal dosage forms are buffered to an acid pH usually about 4.5, consistent with the normal vagina. This acidity discourages pathogenic organisms and provides a favorable environment for eventual recolonization by the acidproducing bacilli normally found in the vagina .

Rx	
Progesterone, micronized powder	q.s.
Polyethylene glycol 400	60%
Polyethylene glycol 8000	40%

◆ Vaginal inserts

Vaginal tablets are more widely used nowadays than are commercial vaginal supps; but compounded vaginal supps are very widely used. The tablets are easier to manufacture, more stable, and less messy.

Vaginal tablets, frequently referred as vaginal inserts, are usually ovoid and are accompanied in their packaging with a plastic inserter, a device for easy placement of the tablet within the vagina. Vaginal tablets contain the same types of anti-infective and hormonal substances as vaginal supps.

They are prepared by tablet compression and are commonly formulated to contain lactose as the base or filler, a disintegrating agent such as starch, a dispersing agent such as polyvinylpyrrolidone, and a tablet lubricant such as magnesium stearate. The tablets are intended to disintegrate within the vagina, releasing their medication.

Some vaginal inserts are capsules of gelatin containing medication to be released intravaginally.

◆ Packaging and storage

Most commercial supps are individually wrapped in either foil or plastic. Some are packaged in a continuous strip, separated by tearing along perforations or otherwise separated in compartmented boxes to prevent contact and adhesion.



Suppositories containing light-sensitive drugs are individually wrapped in an opaque material such as a metallic foil. Because supps. are adversely affected by heat, it is necessary to maintain them in a cool place .

Cocoa butter supps. must be stored below 30°C and preferably in a refrigerator (2°C to 8°C).

Glycerinated gelatin supps. can be stored at controlled room temperature (20°C to 25°C) .

Supps. made from a base of PEG may be stored at usual room temperatures. Supps. stored in high humidity may absorb moisture and tend to become spongy, whereas supps. stored in places of extreme dryness may lose moisture and become brittle .



Pharmacy Drug