



*Pharmaceutical Technology for  
3rd year students  
2<sup>nd</sup> Course, Lec. 5*

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- ✓ Urethral suppositories may be prepared from a glycerinated gelatin base. They are much more easily inserted than those with a cocoa butter base.
- ✓ *Polyethylene glycols PEGs*; are polymers of ethylene oxide and water prepared to various chain lengths, molecular weights, and physical states. They are available in a number of molecular weight ranges, PEG300, 400, 600, 1,000, 1,500, 1,540, 3,350, 4,000, 6,000, and 8,000.

- ✓ Polyethylene glycols having average molecular weights of 300, 400, and 600 are clear, colorless liquids.
- ✓ While, those having average molecular weights of greater than 1,000 are wax-like white solids whose hardness increases with an increase in the molecular weight.

- Various combinations of these PEGS may be combined by fusion to achieve a suppository base of the desired consistency and characteristics.

- ✓ Polyethylene glycol 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.

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

- ✓ Poly-ethylene glycol suppositories that do not contain at least 20% water should be dipped in water just before use.
- ✓ 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.

## ✓ Miscellaneous Bases

- ✓ They are mixtures of oleaginous and water-soluble or water-miscible materials.
- ✓ These materials may be chemical or physical mixtures.
- ✓ Some are preformed emulsions, generally of the water-in-oil type, or they may be capable of dispersing in aqueous fluids.



- ✓ 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-45°C (102°F to 113°F).

✓ Suppositories are prepared by three methods:

(a) Molding from a melt,

(b) compression, and

(c) hand rolling and shaping.

**TABLE 12.1 EXAMPLES OF RECTAL SUPPOSITORIES**

SUPPOSITORY	COMMERCIAL PRODUCT	ACTIVE CONSTITUENT	TYPE OF EFFECT	CATEGORY AND COMMENTS
Bisacodyl	Dulcolax (Boehringer-Ingelheim)	10 mg	Local	Cathartic. Base: hydrogenated vegetable oil
Chlorpromazine	Thorazine (GlaxoSmith Kline)	100 mg	Systemic	Antiemetic; tranquilizer. Base: glycerin, glyceryl monopalmitate, glyceryl monostearate, hydrogenated fatty acids of coconut and palm kernel oils
Hydrocortisone	Anusol-HC (Salix)	25 mg	Local	Pruritus ani, inflamed hemorrhoids, other inflammatory conditions of the anorectum. Base: hydrogenated glycerides
Hydromorphone	Dilaudid (Abbott)	3 mg	Systemic	Analgesic. Base: cocoa butter with silicon dioxide
Indomethacin	Indocin	50 mg	Systemic	Anti-inflammatory: Base: polyethylene glycols
Mesalamine	Canasa (Axcen Scandipharm)	500 mg	Local	Anti-inflammatory. Base: hard fat
Oxymorphone	Numorphan (Endo)	5 mg	Systemic	Analgesic. Base: polyethylene glycols 1000 and 3350
Prochlorperazine	Compazine (SmithKline Beecham)	2.5, 5, 25 mg	Systemic	Antiemetic. Base: glycerin, monopalmitate, glyceryl monostearate, hydrogenated fatty acids of coconut and palm kernel oils
Promethazine HCl	Phenergan (Wyeth)	12.5, 25 mg	Systemic	Antihistamine, antiemetic, sedative: used to manage allergic conditions; preoperative or postoperative sedation or nausea and vomiting; motion sickness. Base: cocoa butter, white wax

**TABLE 12.2 EXAMPLES OF VAGINAL SUPPOSITORIES AND TABLETS**

PRODUCT (MANUFACTURER)	ACTIVE CONSTITUENTS	CATEGORY AND COMMENTS
Cleocin suppositories (Pfizer)	Clindamycin phosphate 100 mg	Bacterial vaginosis
Monistat 7 suppositories (Personal products)	Miconazole nitrate 100 mg	Antifungal for local vulvovaginal Candidiasis (moniliasis)
Mycelex-G vaginal tablets (Bayer)	Clotrimazole 500 mg	Vulvovaginal yeast ( <i>Candida</i> ) infections
Semicaid vaginal contraceptive inserts (Whitehall-Robins)	Nonoxynol-9 100 mg	Nonsystemic reversible birth control
Encare contraceptive inserts (Blairer)	Nonoxynol-9 100 mg	Nonsystemic reversible birth control

- ✓ Urethral Glycerinated gelatin suppositories
- ✓ Urethral suppositories may be prepared from a glycerinated gelatin base of a formula somewhat different from the one indicated earlier.
- ✓ For urethral suppositories, the gelatin constitutes about 60% of the weight of the formula, the glycerin about 20%, and the medicated aqueous portion about 20%.

# PREPARATION OF SUPPOSITORIES

Suppositories are prepared by three methods:

- (a) molding from a melt (fusion)
- (b) compression, and
- (c) hand rolling and shaping.

## ✓ PREPARATION BY MOLDING

The steps in molding include

- (1) melting the base,
- (2) incorporating any required medicaments,
- (3) pouring the melt into molds,

(4) allowing the melt to cool and congeal into suppositories,

(5) removing the formed suppositories from the mold.

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