

present to prompt emulsification when the suppository makes contact with the aqueous body fluids. These types of bases are arbitrarily placed in the third, or miscellaneous, group of bases.

Cocoa Butter, NF, is the 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. Chemically, it is a triglyceride (combination of glycerin and one or different fatty acids) primarily of oleopalmitostearin and oleodistearin. Because cocoa butter melts at 30°C to 36°C (86°F to 97°F), it is an ideal suppository base, melting just below body temperature and yet maintaining its solidity at usual room temperatures. However, because of its triglyceride content, cocoa butter exhibits marked *polymorphism* or existence in several crystalline forms. Because of this, when cocoa butter is hastily or carelessly melted at a temperature greatly exceeding the minimum required temperature 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. In fact, the melting point may be so low that the cocoa butter will not solidify at room temperature. 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. Consequently, if suppositories that have been prepared by melting cocoa butter for the base do not harden soon after molding, they will be useless to the patient and a loss of time, materials, and prestige to the pharmacist. 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.

Substances such as phenol and chloral hydrate have a tendency to lower the melting point of cocoa butter. If the melting point is low enough that it is not feasible to prepare a solid suppository using cocoa butter alone

as the base, solidifying agents like cetyl esters wax (about 20%) or beeswax (about 4%) may be melted with the cocoa butter to compensate for the softening effect of the added substance. However, the addition of hardening agents must not be so excessive as to prevent the base from melting in the body, nor must the waxy material interfere with the therapeutic agent in any way so as to alter the efficacy of the product.

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), the Wecobee bases (triglycerides derived from coconut oil), and 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 the 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.

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 if they are to maintain their shape and consistency. Also as a result of the hygroscopicity of the glycerin, the suppository 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.