fill material from the holes to rest upon the punches for drying.

The base for molded tablets is generally a mixture of finely powdered lactose with or without a portion of powdered sucrose (5% to 20%). The addition of sucrose results in less brittle tablets. In preparing the fill, the drug is mixed uniformly with the base by geometric dilution when potent drugs are used. The powder mixture is wetted with a 50% mixture of water and alcohol sufficient only to dampen the powder so that it may be compacted. The solvent action of the water on a portion of the lactose or lactose–sucrose base binds the powder mixture upon drying. The alcohol portion hastens drying.

The upper mold is placed on a clean flat glass surface and the damp mass added by a rubbing motion. When each opening is filled completely and smoothed, top and bottom, the mold is fitted on the punch portion of the mold and pressed down, leaving the tablets raised on the pegs to dry.

Before use, the mold should be calibrated for the fill material used since the densities of different formulas result in tablets of different weights. This may be done by preparing a test batch of the formula and weighing and recording the weight of the dry tablets. This weight is used in calculations for production quantities.

Molded tablets are intended to dissolve rapidly in the mouth. They do not contain disintegrants, lubricants, or coatings to slow their rate of dissolution. (A more complete discussion of the preparation of molded tablets and the standardization of laboratory molds may be found on this book's companion Web site.)

TABLET COATING

Tablets are coated for a number of reasons, including to protect the medicinal agent against destructive exposure to air and/or humidity, to mask the taste of the drug, to provide special characteristics of drug release (e.g., enteric coatings), and to provide aesthetics or distinction to the product.

In a limited number of instances, tablets are coated to prevent inadvertent contact with the drug substance and the effects of drug absorption. For example, Proscar tablets (finasteride, Merck) are coated for just this reason. The drug is used by men in the treatment of benign prostatic hyperplasia. The labeling instructions warn that women who are pregnant or who may become pregnant should not come into contact with it. Drug contact can occur through handling broken tablets. If finasteride is absorbed by a woman who is pregnant with a male baby, the drug has the potential to adversely affect the developing male fetus.

The general methods involved in coating tablets are as follows.

Sugarcoating Tablets

The sugarcoating of tablets may be divided into the following steps: (*a*) waterproofing and sealing if needed, (*b*) subcoating, (*c*) smoothing and final rounding, (*d*) finishing and coloring if desired, and (*e*) polishing. The entire coating process is conducted in a series of mechanically operated acorn-shaped coating pans of galvanized iron, stainless steel, or copper. The pans, which are partially open in the front, have diameters ranging from about 1 to 4 feet and various capacities (Figs. 8.30 and 8.31). The smaller pans are used for experimental, developmental, and pilot plant operations and the larger pans for industrial production. The pans operate at about a 40-degree angle to contain the tablets while allowing the operator visual and manual

FIGURE 8.30 Tablet coating, an old-style coating pan, showing the warm air supply and the exhaust. (Courtesy of Wyeth Laboratories.)