

A typical aqueous film-coating formulation contains the following (19):

1. *Film-forming polymer* (7% to 18%). Examples: cellulose ether polymers such as hydroxypropyl methylcellulose, hydroxypropylcellulose, and methylcellulose
2. *Plasticizer* (0.5% to 2.0%). Examples: glycerin, propylene glycol, polyethylene glycol, diethyl phthalate, and dibutyl subacetate
3. *Colorant and opacifier* (2.5% to 8%). Examples: FD&C or D&C lakes and iron oxide pigments
4. *Vehicle* (water, to make 100%)

There are some problems attendant on aqueous film coating, including the appearance of small amounts (*picking*) or larger amounts (*peeling*) of film fragments flaking from the tablet surface, roughness of the tablet surface due to failure of spray droplets to coalesce (*orange peel effect*), an uneven distribution of color on the tablet surface (*mottling*), filling-in of the score line or indented logo on the tablet by the film (*bridging*), and disfiguration of the core tablet when subjected for too long to the coating solution (*tablet erosion*). The cause of each of these problems can be determined and the problem rectified through appropriate changes in formulation, equipment, technique, or process.

## Enteric Coating

Enteric-coated solid dosage forms are intended to pass through the stomach intact to disintegrate and release their drug content for absorption along the intestines. The design of an enteric coating may be based on the transit time required for passage to the intestines and may be accomplished through coatings of sufficient thickness. However, usually an enteric coating is based on factors of pH, resisting dissolution in the highly acid environment of the stomach but yielding to the less acid environment of the intestine. Some enteric coatings are designed to dissolve at pH 4.8 and greater.

Enteric-coating materials may be applied either to whole compressed tablets or to drug particles or granules used in the fabrication of tablets or capsules. The coatings may be applied in multiple portions to build a thick coating or as a thin film coat. The

coating system may be aqueous or organic solvent based and effective so long as the coating material resists breakdown in the gastric fluid. Among the materials used in enteric coatings are pharmaceutical shellac, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, diethyl phthalate, and cellulose acetate phthalate.

## Fluid Bed or Air Suspension Coating

Fluid bed coating, which uses equipment of the type shown in Figure 8.35, is spray coating of powders, granules, beads, pellets, or



**FIGURE 8.35** Vector/Freund Flo-Coater production system. A fluid bed system used to apply coatings to beads, granules, powders, and tablets. Capacity of models ranges from 5 to 700 kg. (Courtesy of Vector Corporation.)