

inserted into the vagina for local effects. They are prepared by compression and shaped to fit snugly on plastic inserter devices that accompany the product. They contain antibacterials for the treatment of nonspecific vaginitis caused by *Haemophilus vaginalis* or antifungals for the treatment of vulvovaginitis candidiasis caused by *Candida albicans* and related species.

COMPRESSED TABLETS

The physical features of compressed tablets are well known: round, oblong, or unique in shape; thick or thin; large or small in diameter; flat or convex; unscored or *scored* (Fig. 8.6) in halves, thirds, or quadrants; engraved or imprinted with an identifying symbol and/or code number; coated or uncoated; colored or uncolored; and one, two, or three layered.

Tablet diameters and shapes are determined by the die and punches used in compression. The less concave the punches, the flatter the tablets; conversely, the more concave the punches, the more convex the resulting tablets (Fig. 8.7). Punches with raised impressions produce recessed impressions on the tablets; punches with recessed etchings produce tablets with raised impressions or monograms. Monograms may be placed on one or on both sides of a tablet, depending on the punches.



FIGURE 8.6 Packages of a drug product of different tablet strengths.

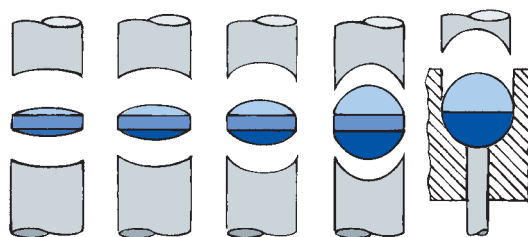


FIGURE 8.7 Contours of the punches determine the shape of the tablets. From left to right: flat face, shallow cup, standard cup, deep cup, and modified ball. (Courtesy of Cherry-Burrell Corporation.)

Quality Standards and Compendial Requirements

In addition to the apparent features of tablets, tablets must meet other physical specifications and quality standards. These include criteria for weight, weight variation, content uniformity, thickness, hardness, disintegration, and dissolution. These factors must be controlled during production (in-process controls) and verified after the production of each batch to ensure that established product quality standards are met (Fig. 8.8).



FIGURE 8.8 Quality control in the manufacturing of tablets. (Courtesy of Eli Lilly and Company.)