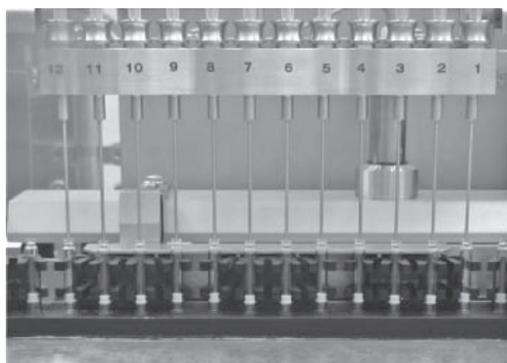


Nominal and exact dose filling



1.5–3.0mL volumes



12 (24) Two-stage filling



Time/pressure and Sensor Filling

Figure 19-5 Cartridge filling machine (Bausch & Strobel KFM-6024). *Source:* Courtesy of Baxter Healthcare Corporation.

SOLID FILLING

Sterile solids, such as antibiotics, are more difficult to subdivide evenly into containers than are liquids. The rate of flow of solid material is slow and often irregular. Even though a container with a larger diameter opening is used to facilitate filling, it is difficult to introduce the solid particles, and the risk of spillage is ever present. The accuracy of the quantity delivered cannot be controlled as well as with liquids. Because of these factors, the tolerances permitted for the content of such containers must be relatively large.

Powder filling also must control dose uniformity and accuracy that is a function both of the engineering of the powder filling machine and the particle size characteristics dictated by methods used to produce the solid product. Control of relative humidity during filling and minimizing foreign particle contamination also are challenges with powder filling. Primary vendors of powder filling machines are Perry and Chase-Logeman.

Some sterile solids are subdivided into containers by individual weighing. A scoop usually is provided to aid in approximating the quantity required, but the quantity filled into the container finally is weighed on a balance. This is a slow process. When the solid is obtainable in a granular form so that it will flow more freely, other methods of filling may be employed. In general, these involve the measurement and delivery of a volume of the granular material that has been calibrated in terms of the weight desired. An adjustable cavity in the rim of a wheel is filled by vacuum and the contents held by vacuum until the cavity is inverted over the container. The solid material then is discharged into the container by a puff of sterile air.

The Perry Accofil[®] system was developed as a solution to the problem encountered by the pharmaceutical industry with the introduction of penicillin many years ago. Until the availability of this machine, powders had to be manually weighed, causing lots of potential problems with sterility assurance and operator exposure to powder particles. The principle of