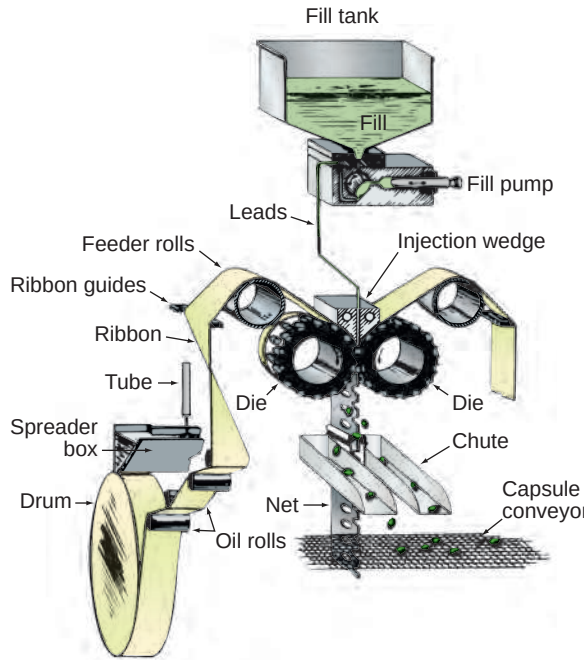

FIGURE 7.17 Rotary die process. (Courtesy of R.P. Scherer Corporation.)

are individually weighed, and the net weight of the contents is calculated by subtraction. From the results of an assay performed as directed in the individual monograph, the content of the active ingredient in each of the capsules is determined.

Soft Capsules

The gross weight of 10 intact capsules is determined individually. Then each capsule is cut open, and the contents are removed by washing with a suitable solvent. The solvent is allowed to evaporate at room temperature over about 30 minutes, with precautions to avoid uptake or loss of moisture. The individual shells are weighed and the net contents calculated. From the results of the assay directed in the individual monograph, the content of the active ingredient in each of the capsules is determined.

Content Uniformity

Unless otherwise stated in the USP monograph for an individual capsule, the amount of active ingredient, determined by assay, is within the range of 85% to 115% of the label claim for 9 of 10 dosage units assayed, with no unit outside the range of 70% to 125% of the label claim. Additional tests are prescribed when two or three dosage units are outside of the desired range but within the stated extremes.

Content Labeling Requirement

All official capsules must be labeled to express the quantity of each active ingredient in each dosage unit.

Stability Testing

Stability testing of capsules is performed as described in Chapter 4 to determine the intrinsic stability of the active drug molecule and the influence of environmental factors such as temperature, humidity, light, formulative components, and the container and closure system. The battery of stress testing, long-term stability, and accelerated stability tests help determine the appropriate conditions for storage and the product's anticipated shelf life.

Moisture Permeation Test

The USP requires determination of the moisture permeation characteristics of single-unit and unit-dose containers to ensure their suitability