

rather than the maximum size possible. Several factors that need to be considered in determining batch sizes are the following:

1. Market demand predictions
2. Available production capacity
3. Cost of the batch
4. Stability of the finished product
5. Analytical testing efficiency

The manufacturing process and operating parameters utilized in smaller batch manufacturing are to be considered in the scale-up plan. The technology and equipment used in the development process often impose several constraints during scale-up work. Because pharmaceutical products are usually manufactured using several discrete batch processes, it would be appropriate to discuss the scale-up of each of these unit operation processes. The following are some of the most common pharmaceutical unit processes used in the manufacture of solid dosage forms:

1. Dry blending
2. Wet granulation
3. Roller compaction
4. Milling
5. Drying
6. Extrusion/spheronization
7. Compression
8. Encapsulation
9. Coating
10. Fluid-bed processing

Dry Blending

Dry blending is often the most common unit operation in the pharmaceutical industry due to its simplicity and use of less complicated equipment. However, several factors are to be considered while scaling up a dry blending process [30]. Equipment considerations such as blender type and design, blender load, mixing speed, use of auxiliary dispersion equipment such as intensifier bars and choppers, and the dynamics of mixing action produced within the mixer need careful evaluation. Formulation variables that influence a mixing operation are particle shape and size distribution and cohesiveness of major components, their bulk densities, and the order of addition of various components into the blend. Mixer selection should be based on the assessment of cohesive nature and the flowability of the ingredients to be mixed. Low shear tumble blenders, such as bin blenders (Bohle, TOTE Blenders), V-blender (Patterson–Kelley) and double cone blender (Gemco), are well suited for mixing free-flowing and slightly cohesive powders. V-blenders are widely used in handling potent drugs due to their ability to mix by geometric dilution and ease for containment. However, improper load (too high or too low), and wide difference in ingredient particle size and shape, may lead to segregation. Intermediate shear