Introduction

The scientific aspects of powders and powder technology have been discussed in Part 2 of this book. This chapter discusses the application of powders and granulated products in pharmaceutical dosage forms. Powders and granules are used as dosage forms in their own right, but by far the greatest use of granules in pharmaceutical manufacturing is as an intermediate during the manufacture of compressed tablets.

The term 'powder', when used in the context of a dosage form, describes a formulation in which a drug powder has normally been mixed with other powdered excipients to produce a final product. The function of the added excipients depends upon the intended use of the product. Colouring, flavouring and sweetening agents, for example, may be added to powders for oral use.

Granules that are used as a dosage form comprise powder particles that have been aggregated to form larger particles sufficiently robust to withstand handling.

Granulation is the process in which dry *primary powder particles* (i.e. single, discrete powder particles) are processed to adhere to form larger multi-particle entities called *granules*. Pharmaceutical granules typically have a size range between 0.2 and 4.0 mm, depending on the subsequent use of the granules. In the majority of cases, when granules will be made as an intermediate product, they have a size range towards the lower end of this spectrum – typical between 0.2 and 0.5 mm. When prepared for use as a dosage form in their own right, they are usually much larger (typically 1–4 mm).

After granulation, the granules will either be packaged (when used as a dosage form) or they may be mixed with other excipients prior to tablet compaction or capsule filling.

Reasons for granulation

The reasons why granulation is often necessary are as follows:

To prevent segregation of the constituents of the powder mix

Segregation (or demixing, discussed in Chapter 11) occurs primarily due to differences in the size and/or density of the components of the mix; the smaller particles and/or denser particles concentrate at the base of a container with the large particles and/or less dense above them. An ideal granulation will contain all the constituents of the mix in the correct proportion in each granule, and if this is achieved segregation of individual ingredients will not occur (Fig. 28.1).

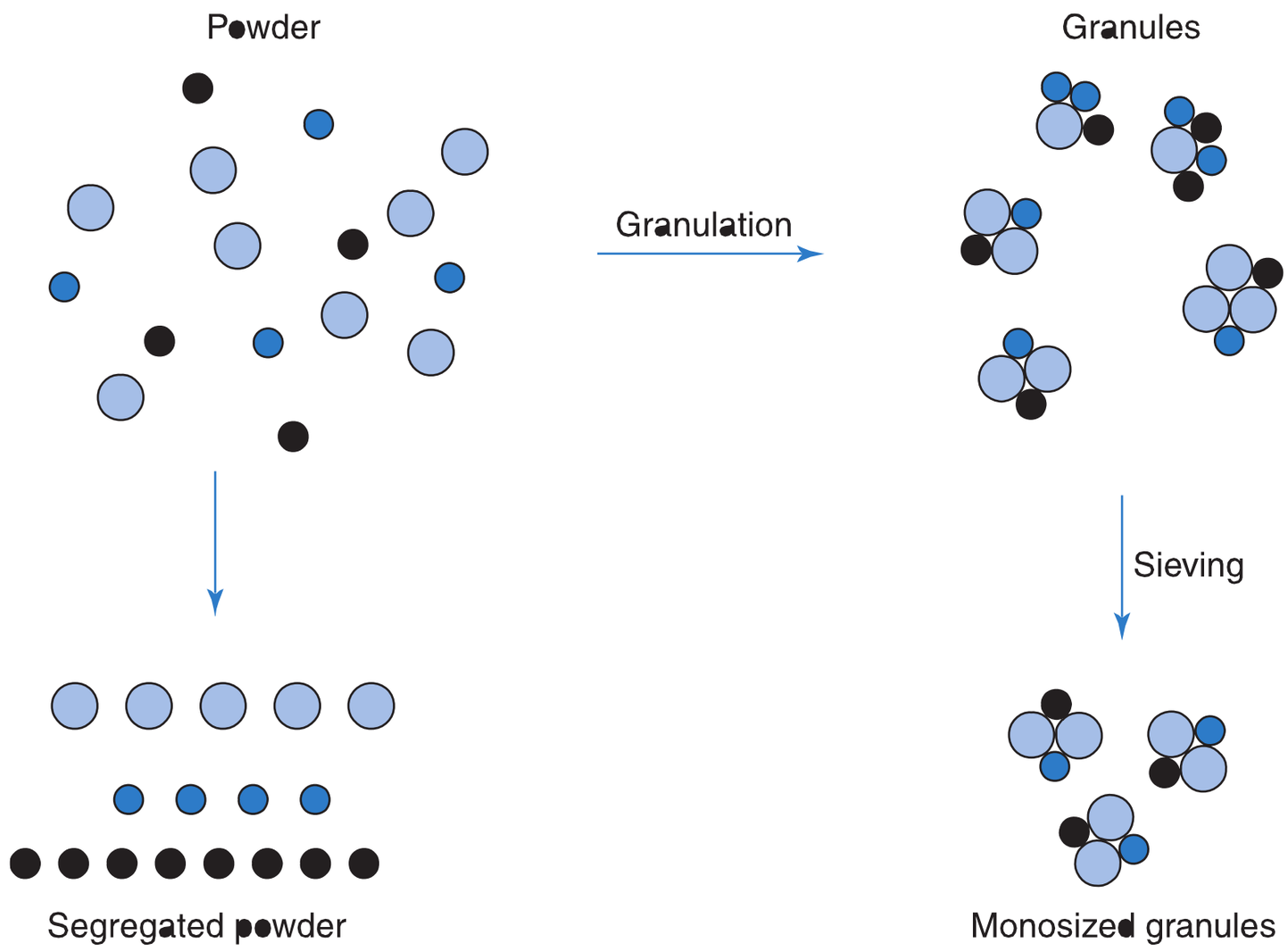

Fig. 28.1 • Schematic diagram to illustrate how granulation can prevent powder segregation.