

harmonization of these standards most pharmacopoeial specifications are extremely similar. In the interests of brevity this chapter will refer to the United State Pharmacopeia (USP) specifications. All major pharmacopoeias are very similar but in others, even if the detail varies, the principle of operation and interpretation of results is the same.

### Basket apparatus (USP Apparatus 1)

The basket apparatus was the first official dissolution tester to be described in the USP in 1970 and remains one of the most commonly used methods for testing the dissolution of capsules and tablets.

In this apparatus, the dosage form is placed inside a rotating basket made of a stainless steel wire mesh and immersed in dissolution medium which has been pre-warmed at 37°C. An outline of the apparatus is shown in Figure 35.4 with a more detailed diagram shown in Figure 30.20. During the test, the basket rotates at a constant speed, typically set between 50 and 100 rpm. The dissolution medium is contained in a glass cylindrical vessel with a spherical bottom and with a nominal capacity of no less than 1 L. The dissolution medium volume used with this method is normally 0.9 L, although lower (0.5 L) and higher (4 L) volumes may also be employed. The composition and/or pH of the medium may be changed by manually replacing it or by adding media of different composition. At pre-determined times, samples of dissolution medium are removed and analysed for drug content.

### Paddle apparatus (USP Apparatus 2)

Following its introduction in the USP in 1978, the paddle apparatus became the most widely used dissolution tester. It utilizes the same dissolution vessels as the basket apparatus but here the dosage form is positioned at the centre bottom of the vessel. An outline of the apparatus is shown in Figure 35.5 with a more detailed diagram shown in Figure 30.21. Agitation is provided by a metallic paddle which rotates at speeds between 50 and 150 rpm (most often 50 to 75 rpm). To prevent dosage forms from floating (this normally occurs with capsules), the use of sinkers is recommended. Sinkers are a wire helix made of non-reactive material wherein the dosage form is placed. Changes of dissolution medium during the test are done manually as described for the basket apparatus.

### Reciprocating cylinder (USP Apparatus 3)

In 1991, driven by the need to provide a controlled and automated pH and volume change of the dissolution medium during the test, the USP introduced the reciprocating cylinder apparatus. Current designs of this equipment allow for up to 6 automated medium changes per test, as well as changes to the agitation speed. This feature makes it particularly suited to estimate the drug release profile in different parts of the gastrointestinal tract as needed in the case of modified-release formulations, such as extended-release or gastro-resistant coated products. It also represents a step closer to bio-relevant conditions and to developing in vitro/in vivo correlations (IVIVCs).

The apparatus (shown in Fig. 35.6) comprises two cylinders: an inner cylinder containing the dosage form and an outer cylinder vessel, which holds around 200 to 300 mL of dissolution medium. During the test, the inner cylinder is dipped vertically into the dissolution medium several times, creating convective forces for dissolution. It is generally considered that 5 dips per minute (dpm) are equivalent to 50 rpm in the paddle apparatus. The inner cylinder is fitted with a mesh screen at the bottom and top which allows the medium to circulate freely inside it, yet prevents losses of finely disintegrated material.

### Flow through cell (USP Apparatus 4)

The flow through cell was adopted by the USP in 1995, primarily for the testing of modified-release products. In this apparatus, the dosage form is positioned in a small-volume cell, on a glass bead bed or on a clip holder. The sample under test is subjected to a continuous flow of media in an upward direction. The medium is pumped from a reservoir at a flow rate which may vary from 5 to 20 mL/minute. The pulsating movement of the pump creates gentler hydrodynamics compared to other compendial apparatus (arguably more similar to the movement that would be experienced by a dosage form in the gut). The dissolution medium can be changed during the test by exchanging the media reservoirs.

This apparatus (shown in Fig. 35.7) can be configured to use a fixed volume (closed system) or unlimited volumes of dissolution medium (open system). In the latter set-up, fresh dissolution medium is delivered continuously by the pump and collected for analysis after passing through the sample