which will aid in the dissolution of the drug. The various dissolution apparatuses offer different hydrodynamics and these may be varied to allow for the best results.

Number of units to be tested. Dissolution tests designed to assess the quality of a batch of tablets are normally repeated for at least 6 units per batch or formulation, depending on test variability.

The design of suitable dissolution tests; QC versus predictive dissolution testing

QC dissolution methods are often easier to design; these make use of established compendial equipment, and the composition and volume of the dissolution medium is generally chosen according to the solubility of the drug. Devising a predictive dissolution test is more challenging as bio-relevant conditions need to be sought to mimic the physiological parameters which affect the dissolution of the drug in the GI tract. The major considerations in designing both types of dissolution test methods will be commented upon below.

Dissolution testing for quality control

QC methods are described in the monograph of the product in the various pharmacopoeias. As a general rule these methods are of simple execution, reliable, reproducible, yet sufficiently discriminatory to be able to detect small product deviations. From a QC point of view, an over-discriminatory method is sometimes preferred so as to detect any product changes before the performance in the gastrointestinal tract is affected. The other prime concern of a QC test is to use conditions under which at least 80% of the drug can be dissolved.

Compendial dissolution apparatuses

There are currently four dissolution apparatus described in the US and European Pharmacopoeias for the testing of oral solid drug products. These are the basket and paddle apparatus, the reciprocating cylinder and the flow through cell (Figures 35.4–35.7). The selection of a dissolution apparatus

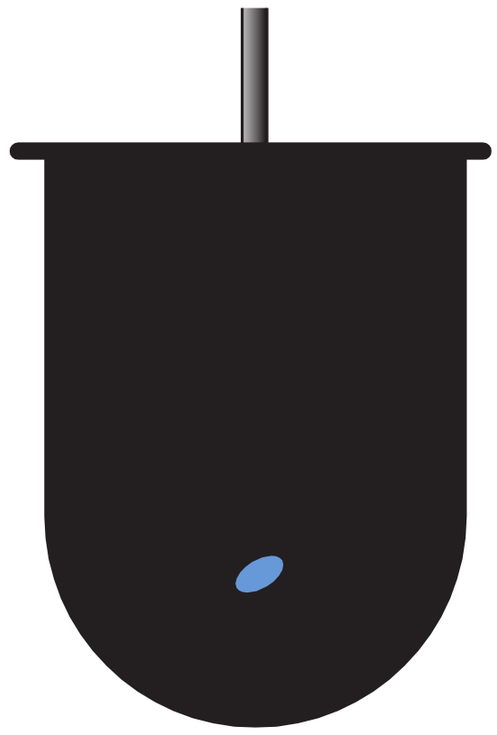

Fig. 35.4 • Basket apparatus (USP Apparatus 1).

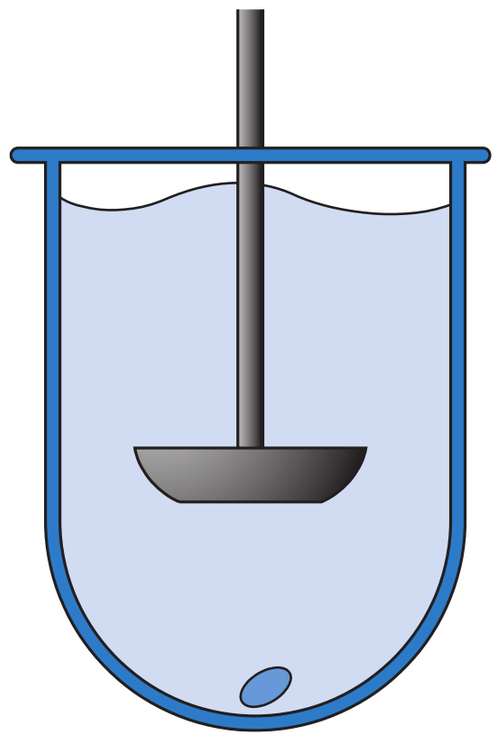

Fig. 35.5 • Paddle apparatus (USP Apparatus 2).

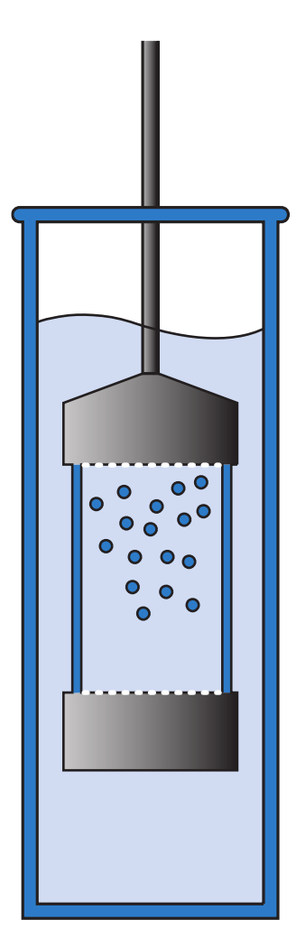

Fig. 35.6 • Reciprocating Cylinder (USP Apparatus 3).