

1000 mL beaker at the downstroke. The open-ended glass tubes are 17.75 ± 0.25 cm long and have an inside diameter of 21.5 cm. The glass thickness is 0.2 cm.

Each tube is provided with a disk 95 mm thick and 20.7 mm in diameter, made of plastic of a specific gravity between 1.18 and 1.20 g/cm^3 . There are five 2 mm holes in the cylinder (one of them in the axis). The disk also has notches in it and serves to keep the tablet within the tube and submerged during the stroke of the assembly.

To operate the apparatus, one tablet is placed in each of the six tubes, disks are added, and the apparatus is operated at 37°C in the immersion fluid. For quality control release purposes as well as for investigational purposes the time is noted when all tablets have disintegrated completely, and if not all tablets have disintegrated at the end of the specification limit, then the basket is removed and the tablets observed. If one or two tablets have failed, then 12 more tablets are tested, and these must all disintegrate within the limit. However, in stability testing it is important to note the time that each individual tablet disintegrates.

It should be pointed out that complete disintegration is defined as "that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus is a soft mass having no palpably firm core." There are apparatuses on the market that have a sensor attached to the disk and can determine this state automatically and record the time at which it occurred. Such an attachment is strongly recommended for stability studies, since it provides an easy means of recording the time of disintegration of each tablet.

There are relatively few articles in the pharmaceutical literature that deal with the subject of the change in disintegration and dissolution upon storage, yet these qualities are as important as the retention of potency of the active compound. If a product falls short of specifications during its shelf life, it becomes unsatisfactory, regardless of the particular parameter that is shortfailing.

One fairly systematic study of this is the work by Chowhan (1979). Here disintegration and dissolution times of e.g. dicalcium phosphate based tablets were studied for prolonged times at 25 and 37°C . The pattern is a sigma minus type of pattern as shown in Fig. 23.

Carstensen et al. (1980a, 1980b) have shown that there often is a correlation between dissolution and disintegration, and Carstensen et al. (1978a, 1978b) have shown the theoretical basis for this. Figure 24 shows such a correlation of dissolution and disintegration times in a U.S.P. apparatus.

Couvreur (1975) has shown that the disintegration of a tablet is a function of several factors. If the tablet disintegrates by virtue of a disintegrant which expands, once it is wetted, then the most important attribute is the rate at which the disintegrating liquid penetrates the tablet, and hence the contact angle between the solid and the liquid is of importance.

8.4. Porosity of Tablets

Cruaud et al (1980) showed that there was a direct correlation between dissolution and porosity in a case where the correlation between disintegration and dissolution was not apparent.

There is one well documented case (Gucluyildiz et al., 1977) where the porosity was shown to change in a tablet as a function of time. What this indicates is that if