

Combining these two equations gives

$$t_N = \frac{(N/q)^2}{\beta \cdot d} \quad (10.43)$$

Hence, the following hold for the disintegration time, t_N :

1. It is the larger the more disintegrating particles must swell to make the tablet disintegrate.
2. It is the longer the finer the pore (the smaller d is).
3. It is the smaller the larger the disintegrant concentration, q .
4. It is the smaller the larger the value of β (the smaller the contact angle and interfacial tension).

Of these, N may change, e.g., if the disintegrant becomes wetter, and partly expanded as a result of moisture uptake, this will affect the disintegration adversely. For instance, the Joel Davis test (40°C, 75% RH for three months) has an adverse effect on disintegration for this reason, although it is only true if the relative humidity of the testing station is above a certain critical moisture content (Grimm and Shepky, 1980a). This is demonstrated in Fig. 24.

8.5. Dissolution

The dissolution apparatuses used are usually USP Method I (basket apparatus) or USP Method II (paddle apparatus). Carstensen et al. (1976a,b) have pointed out that the hydrodynamics of the basket method is poor and results in highly different liquid velocities in different parts of the apparatus, and also causes a phenomenon known as coning: powder accumulates at the bottom of the dissolution vessel, where it is fairly stagnant and hence dissolves slowly. Most tests nowadays are therefore carried out with the paddle apparatus.

The assembly is described in USP XX p. 959 and is basically as shown in Fig. 25. The original apparatus could be operated at 50, 100, or 150 RPM, but the more up-to-date apparatus has a variable speed rheostat. In almost all instances the

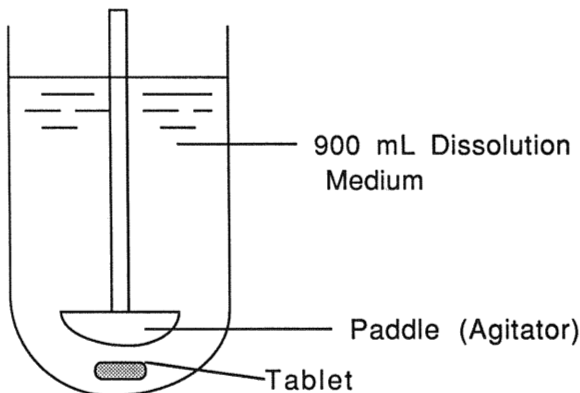


Fig. 25 USP dissolution apparatus.