









Quality Solutions for the Testing of Pharmaceuticals

2016 EDITION





DISSOLUTION



Apparatus 2 (Paddle)

COPLEY TABLET DISSOLUTION TESTERS

In the majority of cases, the effectiveness of tablets or capsules administered orally relies on the drug dissolving in the fluids of the gastrointestinal tract, prior to absorption through the walls of the gastrointestinal tract into the systemic circulation.

For this reason, the rate at which a tablet or capsule dissolves is critical to its therapeutic efficiency and is a key factor in both the formulation process and final quality control.

The most common apparatus used to measure the dissolution rate of solid dose forms are the basket and paddle.

Both use the same basic configuration, are simple and robust, and can be used to test a variety of different products.

The basic apparatus consists of a covered cylindrical vessel having a hemispherical bottom and capable of holding approx. 1000 mL of simulated gastric juice.

The vessel is partially immersed in a suitable water bath capable of maintaining the temperature of the vessel contents at 37 degrees C.

In the case of the basket method, the tablet or capsule is constrained in a cylindrical basket constructed of sieve mesh of defined proportions.

The basket is attached to a metal drive shaft by a 3-pronged retention spring and the shaft positioned in such a manner that the bottom of the basket is 25 mm from the bottom of the vessel.

In the case of the paddle method, the basket is replaced by a paddle and the sample to be tested is allowed to sink to the bottom of the vessel.

During the test, a motor is used to rotate the drive shaft at the speed (normally 50, 75 or 100 rpm) specified in the Pharmacopoeias.

Speeds outside the range 50 to 150 rpm are usually inappropriate because of hydrodynamic inconsistencies and problems with turbulence.

A sample of the dissolution

using a UV/Vis Spectrophotometer or High Pressure Liquid Chromatograph (HPLC).

All Copley Dissolution Testers feature:

- Sturdy, robust construction specifically designed to reduce clutter and maximise visibility and access in the critical sampling area above the water bath
- Simple, easy to use operation ensuring that the number of actions required to perform a test are kept to a minimum
- Full supporting documentation (including full IQ/OQ/MQ/PQ qualification documentation if required)



Dissolution Tester Model DIS 8000

COPLEY

predefined time

dissolved drug

present - this is



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