

INTRINSIC DISSOLUTION FOR "EASYDISS"

This short instruction is no replacement for the guidelines in any Pharmacopeia and is just for the operation with the Intrinsic Kit for the "easyDISS".

INTRINSIC DISSOLUTION

Intrinsic dissolution may be defined as the dissolution rate of a substance under constant surface area conditions.

It is normally measured in terms of *mg per minute per square centimetre*.

It differs from the more conventional dissolution methods in that **only one 7 mm diameter surface is exposed to the solvent** (dissolution media).

The kit for intrinsic dissolution studies is based on the same principles as the **Rotating Disk** apparatus described in USP Chapter <1087> Apparent Intrinsic Dissolution - Dissolution Procedures for Rotating Disk and Stationary Disk.

Both Rotating and Stationary Disk methods share the same characteristics, namely:

- Both rely on compression of the test compound into a compact prior to testing
- Both use a tablet die to hold that compact
- The die is located in a fixed position within the vessel in order to maintain the same hydrodynamic conditions

The Intrinsic Dissolution Kit normally consists of six or eight 7 mm diameter punch and die set kits together with a hand operated press specifically designed to allow the compression of the material into a compact.

The punch and die set kits can be purchased singularly if required.

The compaction process is relatively simple:

- 1) Place the die on to the lower punch (compaction plate).
- 2) Fill the die cavity (the hole in the centre of the die) with sufficient powdered drug to reach the top.
- 3) Use a flat blade or spatula to level off the powder such that the top of the powder is flush with the top of the die.
- 4) Now place the upper punch on to the top of the die locating the punch tip over the sample, and using light pressure from the hand, compact the powder mixture into the hole.
- 5) Then place the entire assembly into the hand operated press, and with the force transmitted to the top of the punch, apply the appropriate pressure (approx. 2 tons) to compact the powder.

6) Now release the assembly from the press, remove the die containing the compact and locate it into the three pronged spring holder as shown in the photographs below.

7) Finally, screw the assembly on to the dissolution shaft and adjust the shaft such that when in the fully lowered position the surface of the compact is not less than 1 cm from the bottom of the vessel.

8) Repeat the exercise for the other assemblies (where applicable).

Rotate the shafts at 200 rpm - the dissolution rate depends on the rotation speed used.



Drive Shaft, Intrinsic Dissolution Assembly and Top Punch