

DATA SHEET

Intrinsic Dissolution Apparatus

The Intrinsic Dissolution Apparatus provides a convenient and precise way to measure intrinsic dissolution rates by exposing pure active pharmaceutical ingredient (API) to a constant surface area of dissolution medium.



Key Benefits

- ▶ **Durable.** Components are made from stainless steel to provide inert material for testing and hardened steel to provide strong components capable of withstanding pressures required for compact formation.
- ▶ **Active drug characterization.** Provides vital dissolution rate constant data for pure drug substances (API), which is useful for optimizing formulations and predicting potential bioavailability issues, and providing valuable information for Quality by Design (QbD).
- ▶ **Adaptable.** Can be used with a variety of dissolution apparatus.
- ▶ **Compliant.** Be confident knowing your intrinsic apparatus is fully compliant with the rotating disk apparatus contained in USP General Information Chapter <1087> Apparent Intrinsic Dissolution.



Intrinsic Dissolution

In the analytical R&D lab, intrinsic dissolution rates are used to compare different physicochemical states of the API from various manufacturing processes or sources to ensure batch-to-batch consistency. R&D scientists also use intrinsic dissolution data during the pre-formulation phases of product development to gain understanding of the API dissolution rate constant and ultimately to control the performance of the finished product formulation.

The USP-compliant apparatus helps determine the dissolution rates per unit area of pure compounds by immersing a fixed amount of material in 37 °C dissolution medium. Periodic sampling of the resulting solution provides data to calculate the material's intrinsic dissolution rate, which is determined by plotting the cumulative amount of API dissolved from the exposed surface area with respect to time.

Features

- Based on the modified Woods apparatus design, the threaded rings on the inside of the die cavity prevent the compacted API from falling out of the die cavity during analysis.
- The stainless steel die cavity, along with a punch, are used to compress the API into a pellet with the aid of a suitable laboratory press equipped with a pressure gauge.
- The shaft/holder and gasket ring securely affix the die containing the compacted API to the dissolution apparatus, allowing it to be lowered into the vessel containing preheated dissolution medium.

Ordering Information

Product Description	Part Number
Intrinsic Dissolution Apparatus, 0.5 cm ² exposed surface area, with shaft and holder, for use with 7000/7010*	12-4100
Intrinsic Dissolution Apparatus, 0.5 cm ² exposed surface area, with shaft and holder, for use with 7000/7010, 708-DS, 705-DS*	12-4101
Intrinsic Dissolution Apparatus, 0.5 cm ² exposed surface area, for use with 7025	12-4105
Intrinsic Dissolution Apparatus, 0.125 cm ² exposed surface area	12-4110
Intrinsic die, 0.5 cm ² exposed surface area	12-4120
Surface plate	12-4130
Punch	12-4140
Shaft and holder	12-4150

*Surface plate sold separately. Only one plate required for testing.

Note: The Intrinsic Dissolution Apparatus is not recommended for use with DVH models, including the 7030 and the 709-DS.

To learn more about Dissolution Testing,
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