Micro Intrinsic Dissolution Rate (IDR) System

Measure intrinsic dissolution while conserving precious API

Intrinsic dissolution rate (IDR) of the active pharmaceutical ingredient (API) is a fundamental parameter in drug development and is defined as the dissolution rate of pure substances under the condition of constant surface area (USP <1087>). Solid state properties such as particle size, polymorphism, and crystal structure, as well as manufacturing techniques affect the IDR of a particular API.

IDR Press Overview

Pion's IDR Press compresses powdered API (5-10mg) to produce tablets of consistent size (3mm diameter) and weight, to deliver reproducible data for intrinsic dissolution testing. A digital load cell indicator provides real-time compression readout to ensure tablet-to-tablet consistency. Pressed tablets that are placed within Pion's Teflon Stirring Disks are compatible with the microDISS Profiler™ system.

The system works in combination with Pion's Rainbow R6™ Concentration Monitor which is an *in-situ* Fiber Optic UV-VIS spectrometer, measuring real-time dissolution as fast as every 2 seconds. Equipped with up to eight independent fiber-optic channels, the Rainbow R6 uses the same amount of API for eight measurements as a single experiment using the traditional method (Wood's Apparatus), and doesn't require manual sample handling.

The Pion Advantage

Strong Correlation
To traditional IDR methods (e.g., Wood's Apparatus) and meets USP <1087> testing requirements.

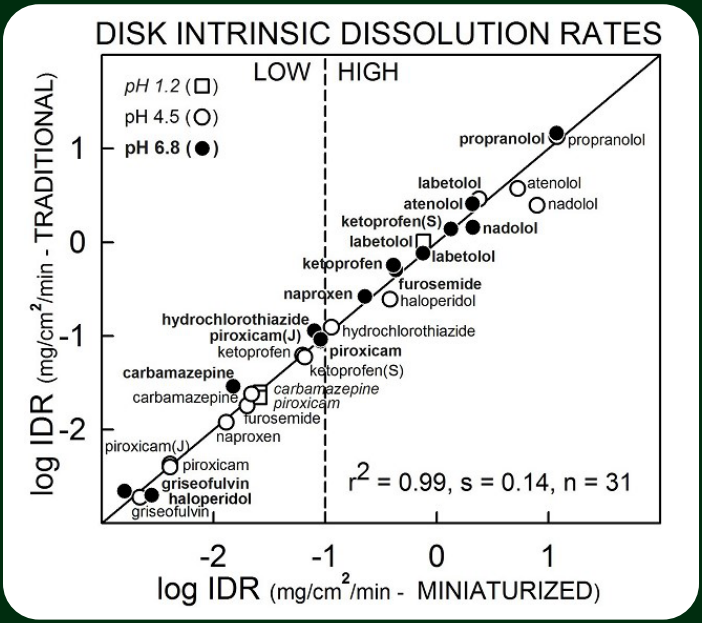
Low API
Material requirement (5-10mg) vs Wood's Apparatus (50-200mg)

High Throughput Testing
Ideal for screening and pre-formulation drug characterization

Small Volume Requirements
Leading to cost-savings on FaSSIF and FeSSIF media

Automated, Real-time Dissolution Measurements
In up to eight simultaneous experiments, when paired with Pion's microDISS™ dissolution system.

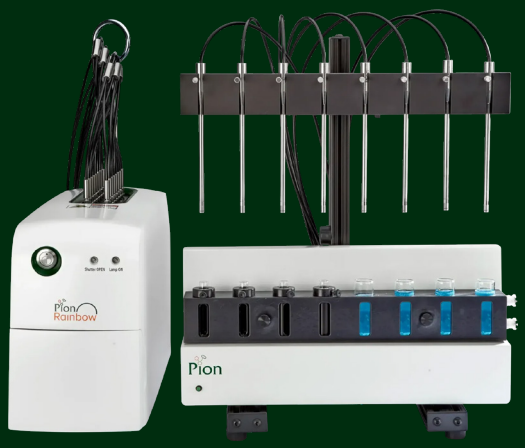
Correlation to Wood's Apparatus



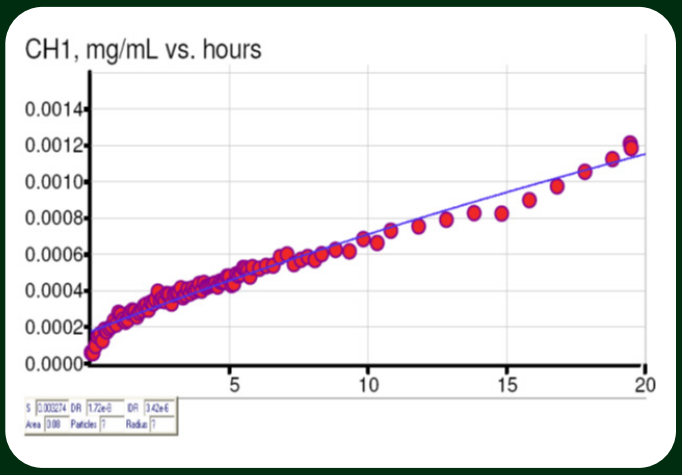
Test Procedure & Calculating IDR

Tablet discs securing the compressed API powder are suspended in temperature-controlled solution, enabling a known surface area of the drug tablet to be exposed to the solvent. Constant stirring within the vessel ensures sink conditions are maintained and air bubbles do not form on the surface of the drug.

IDR is calculated by plotting the cumulative amount of API dissolved from the exposed surface area versus time, until at least 10% of the API has dissolved. Linear regression is used to calculate dissolution rate (mass/time) which is then normalized by dividing by the known surface area of the tablet (mass/area/time e.g., mg/cm²/s).



Pion's microDISS Profiler system.



Technical Specifications

Battery operated:	2 x AA batteries are required
Dimensions:	335mm height x 210mm width/depth (rotating handle dimension)
Suggested bench space:	230mm x 230mm
Weight:	5.6 kg
Load Cell calibration:	Annually
Cleaning:	Use water or 50% ethanol or isopropyl alcohol DO NOT spray the instrument with liquids
Pressed tablets exposed surface area:	7.07mm²