Welcome

From Discovery To Production.

Maximizing Lab Efficiency: The Advantages of Dissolution Automation.

Owain McKenzie

May 2025

DE44294.2044560185

Agilent

Trusted Answers

Agenda

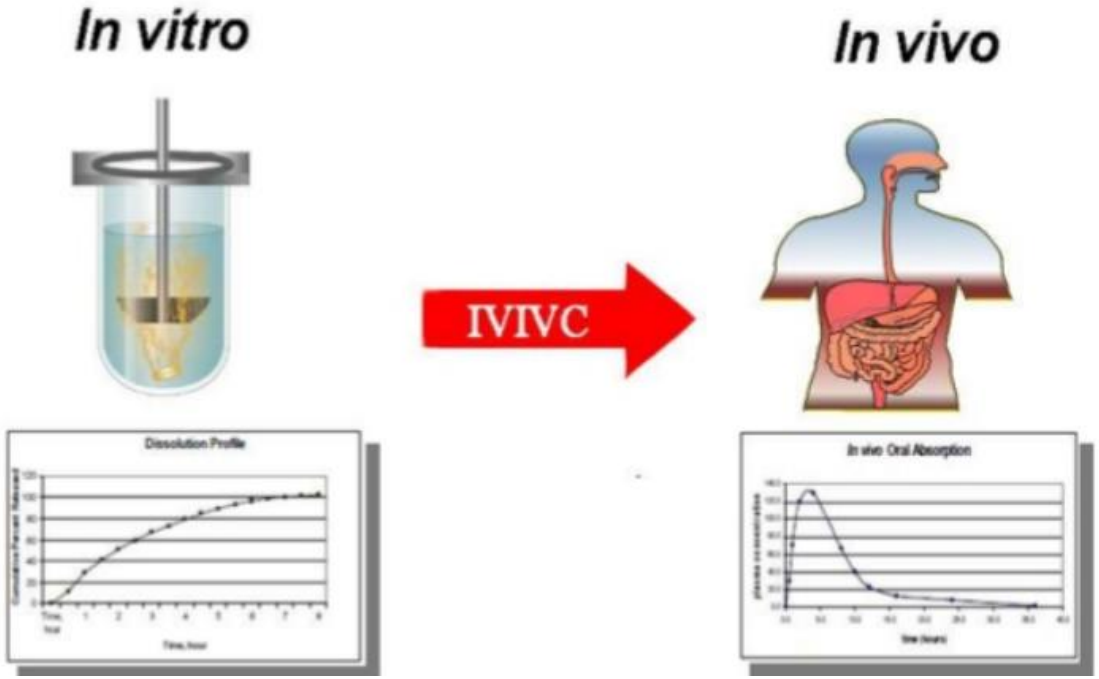
- Introduction To Dissolution Testing
- Overview of in vitro testing in drug development.
- Agilent’s Six workflow solutions
- Solution details and unique features
- Sources of further information.

Introduction and Overview of In Vitro Dissolution Testing.

Introduction to Dissolution

- The dissolution “in Vitro” test has evolved to become a definitive tool used to evaluate the performance characteristics of many types of pharmaceutical dosage forms.

- As dosage forms have become more varied over the last fifty years, dissolution apparatus have required continuous improvement and modification to provide suitable conditions for performance testing.



Introduction to dissolution?

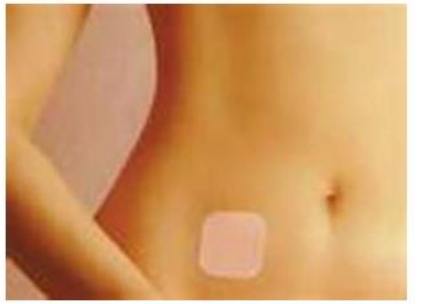
Dissolution is not just about orally ingested products. We test tablets, capsules, powders, ointments, creams, gels, osmotic pumps, transdermal patches, implants, medicated contact lens, stents, coated beads, catheters, wound care products, etc….

Tablets/capsules

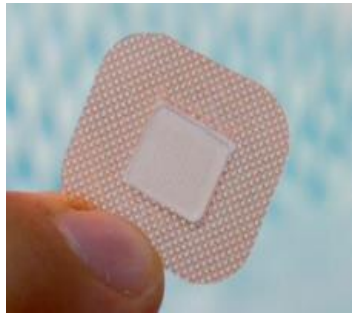
Suspensions

3D printed drugs

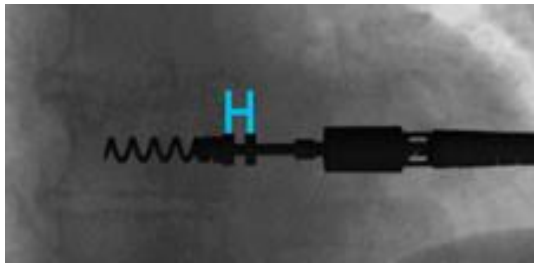
Ointments



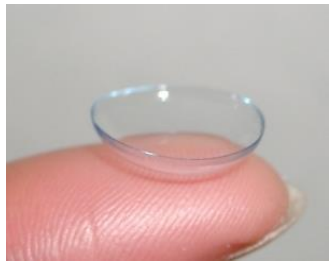
Transdermal patches



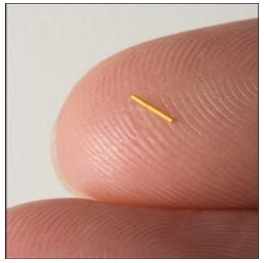
Microneedle patches



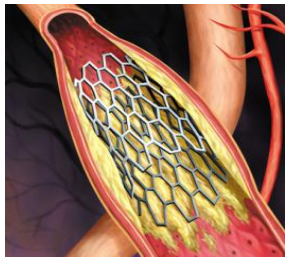
Pacemaker Lead



Contact Lens



Ophthalmic Implant



Drug Coated Stents

Drug Coated rings

Introduction to In Vitro Dissolution

In vitro dissolution is a key tool for characterizing the biopharmaceutical properties of a pharmaceutical product at different stages throughout its life cycle.

- Product Development
  - API characterisation, Formulation evaluation, Stability testing.
- Bioavailability
  - In Vitro / In Vivo Correlation, Bioequivalence.
- Quality Control
  - Pass / Fail product release.
- Scale-Up and Post-Approval Changes
  - Raw materials, Formulation, Process, Manufacturing site.

Introduction to Dissolution

Dissolution assesses the **performance** of drug products.

Dissolution testing is principally a **comparative** process.

- R & D - Formulation to formulation
- Stability Testing - Fresh product to stored product
- Manufacturing generics - Innovator to Generic
- Quality Control - Batch to batch
- Scale up - Old process to new process

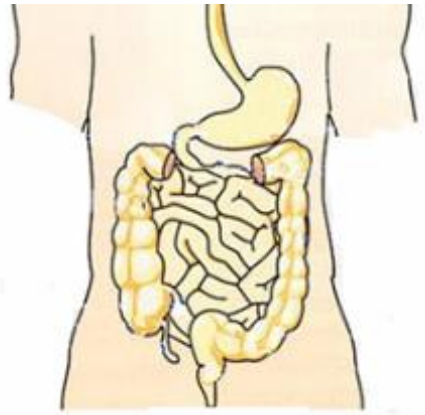
Introduction to Dissolution

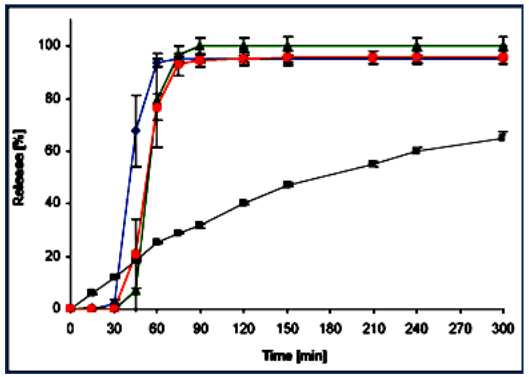
To be effective, dissolution tests apparatus must be:

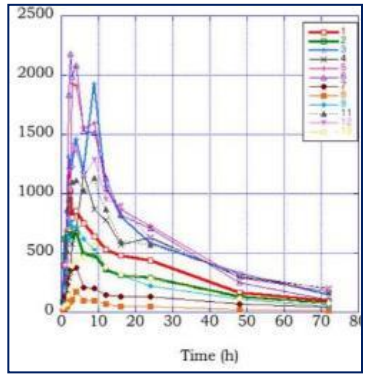
- Predictive
- Comparative
- Discriminatory
- **Reproducible**

- Dissolution is a ***quantitative*** analytical procedure.

- Agilent offer a large range of apparatus, and 6 workflows used throughout the development process, which provide complete **peace of mind.**







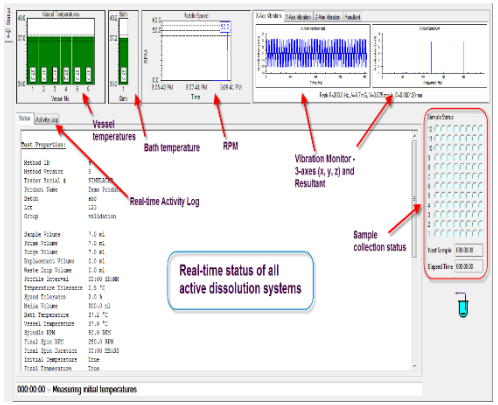
Agilent’s Portfolio and Workflow Solutions.

Dissolution Product Portfolio

Dissolution Apparatus 1,2,5,6

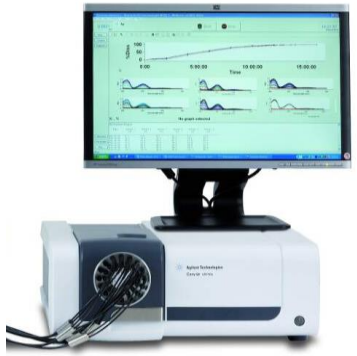
Dissolution Apparatus 3,7

Small volume Dissolution Apparatus 3,7



Software solutions for data integrity

Auto samplers



Flow through & Fibre Optic UV Systems

Qualification tools

The Concept of Dissolution Workflows.

- When performed manually these operations are technique dependent which cause inconsistencies in test results.
- Others are highly labour intensive.

Solution One
The LC Workflow

Dissolution Automation One – Used from Characterization To Production. The 850-DS LC or Off Line UV Workflow

Agilent 850-DS Autosampler

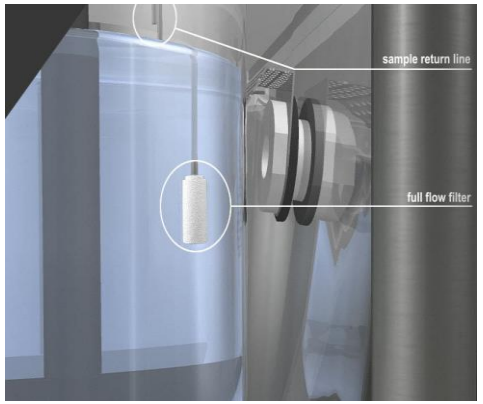
- **Fast**, sample as often as every 60 seconds.
- **Integrated,** with Filtration down to 0.2 micron, dilution and media replacement.
- **Versatile,** Test tube, standard LC Racks, well plates and Agilent LC plates
- **Compact** – completely integrated unit
- **Practical**, Self cleaning, multi user levels, large method storage.
- **Flexible** Can be used with any dissolution apparatus

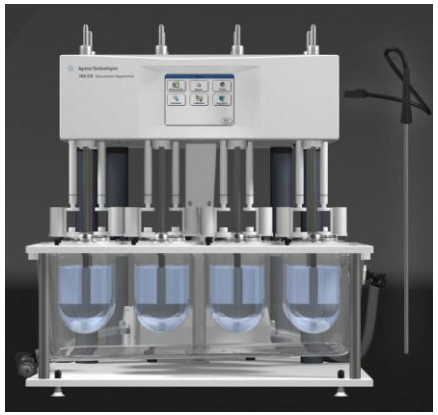
708-DS & 850-DS

Agilent Restricted
Agilent

Agilent 708-DS Overview

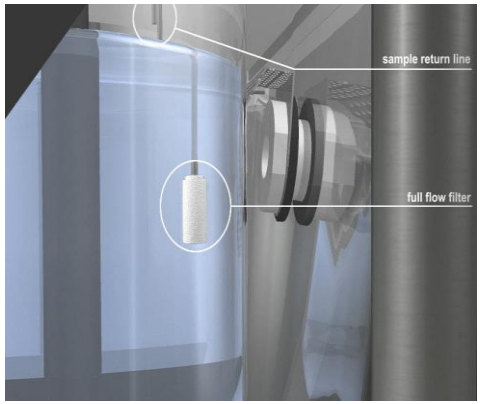
- **Flexibility**: Choose from a range of options for manual or automated dissolution testing
- **Verification**: The design allows simple measurement of physical parameters with completely automated MQ testing using the 280-DS
- **Simplicity**: Colour touch screen display allows direct and intuitive control over the apparatus

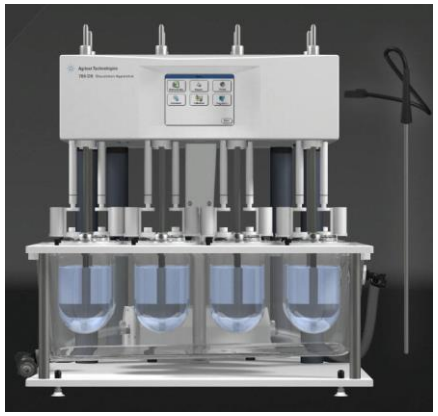




Agilent 708-DS

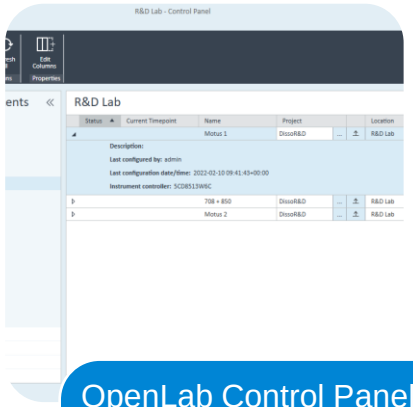
- **Guaranteed compliance** : Interchangeable verified components, molded vessels, automatic tablet introduction, automatic sampling at the correct position no matter what the volume with convenient bracket to remove samples and in vessel temperature monitoring all included, to make manual sampling 100% secure
- **Data integrity**: Methods and users protected by muti level log ins and passwords
- **Energy efficient:** Programable wake up and sleep functions mean the system only user power when in use.





New Product
Agilent Dissolution Manager in OpenLab.

Dissolution Workflow Manager and Main Components



OpenLab Control Panel Plugin

- Dissolution Instrument Configuration
- Roles/Privileges
- Project Management
- Licensing
- E-Signatures
- Users/Groups

DWM

- Instrument Control
- Instrument Methods
- Method Run
- Activity Log

Data Analysis

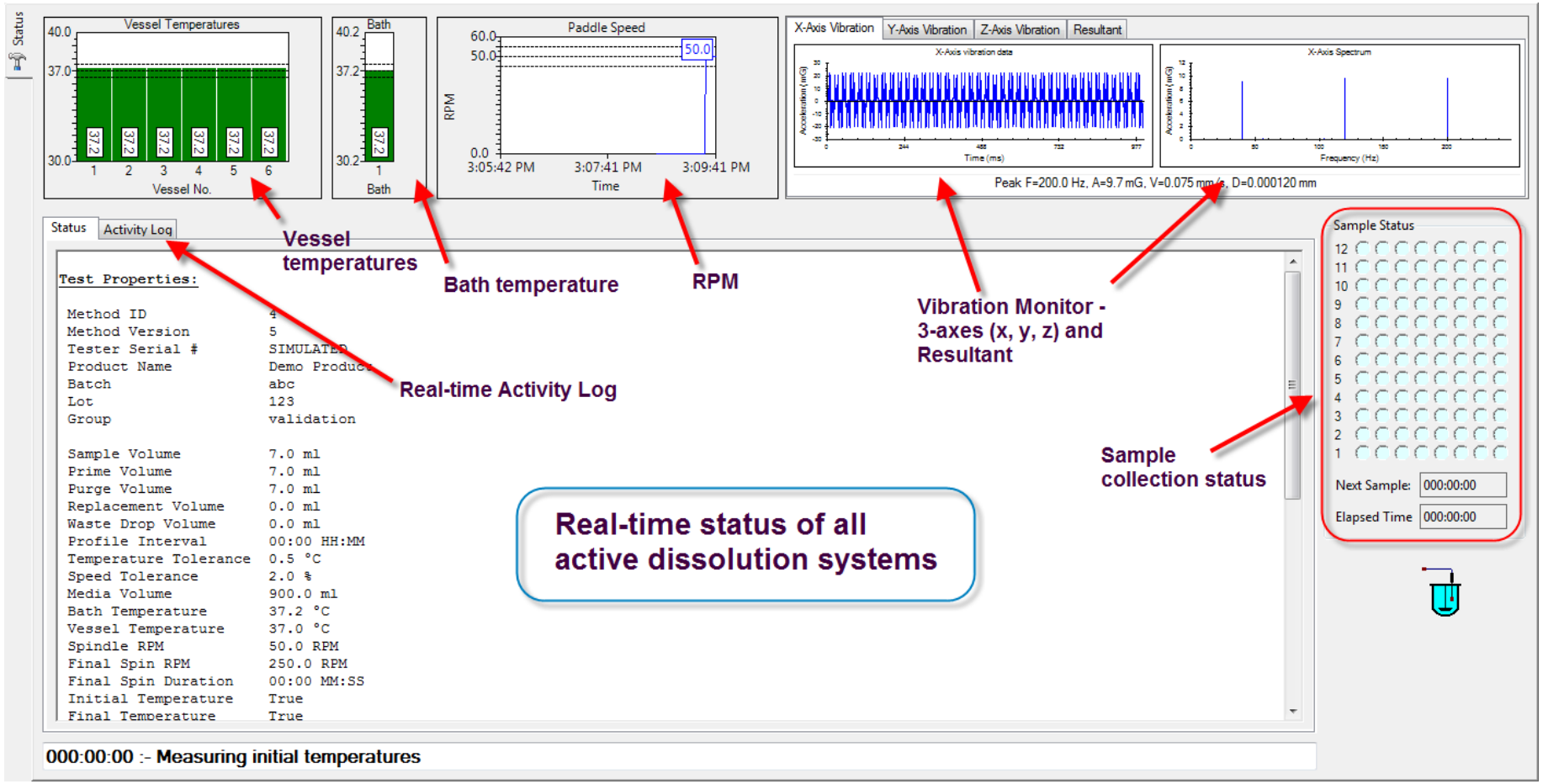
- Review Results
- E-Signatures
- Reporting

Configure

Control and Run

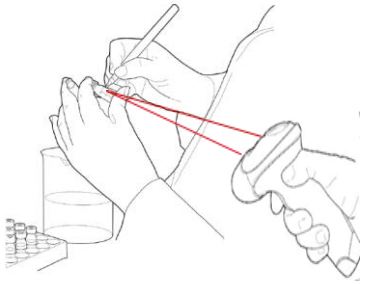
Review and Report

Dissolution Workflow Software
System Status

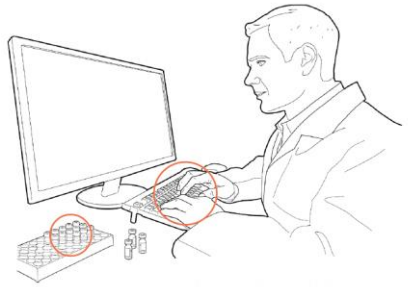


Sample ID Reader Infinity III – Dissolution Workflow

1 Use Barcode to build sequence



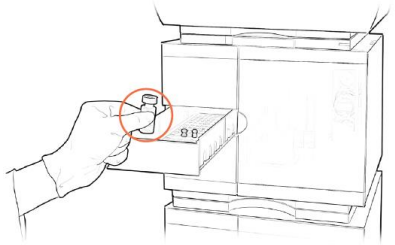
2 Prepare sequence



3 Prepare product according to SOP

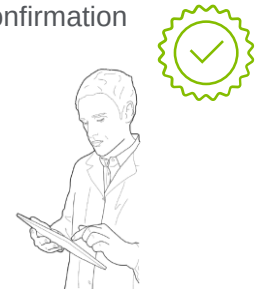
4 Receive Samples in the 850 DS vial rack

5 Load samples



6 Scan & analyze samples

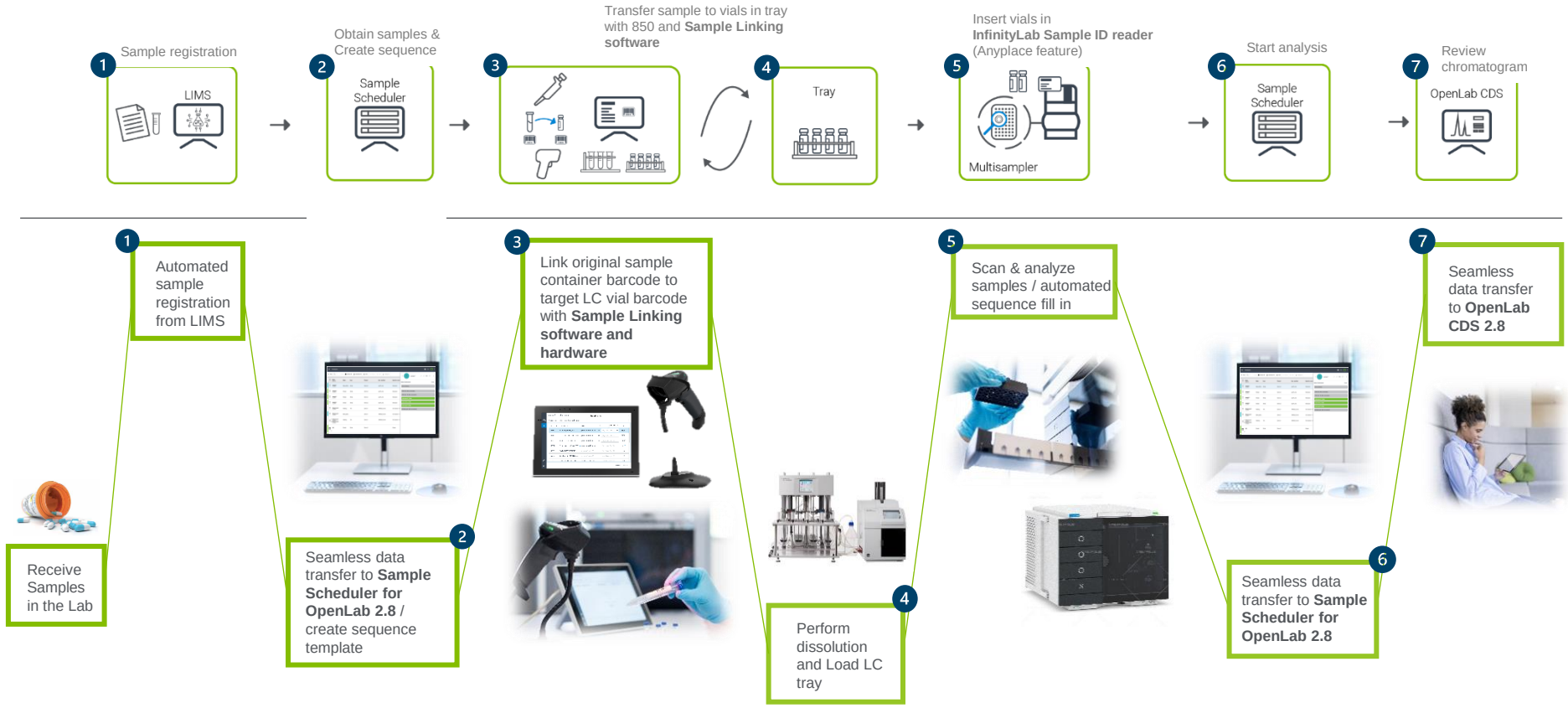
7 Confirmation



Anyplace feature available with OL 2.8

NEW Dissolution Solution: Advanced Sample Linking With OpenLab.

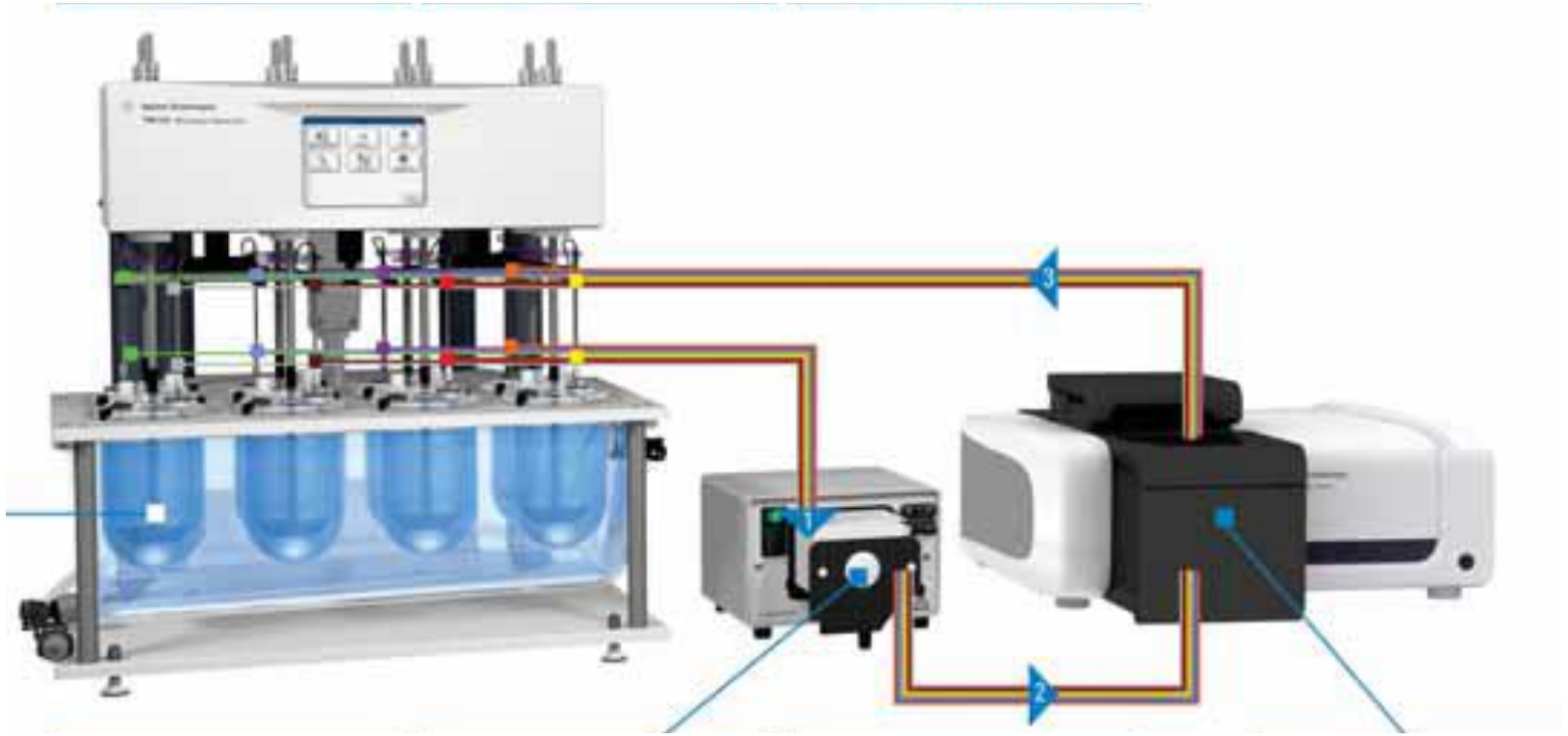
Automated sequences for reducing errors and saving time



Solutions Two & Three
The UV Workflows

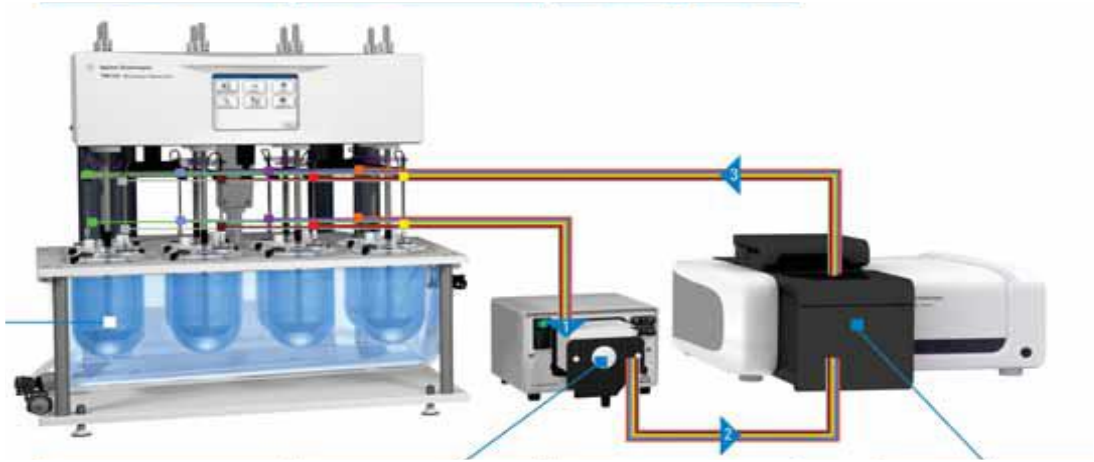
Dissolution Automation Two – Used from Discovery to Production.
The Fibre Optic UV Workflow

Dissolution Automation Three - Used from Characterization To Production. The Cary 60 Flow Through UV Workflow



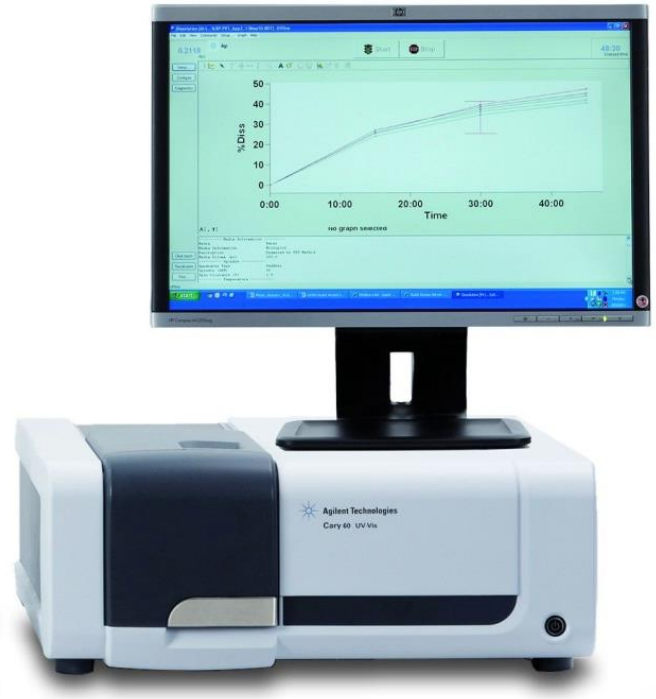
Dissolution UV Workflows.

- Used with and without dissolution apparatus.
- Fibre Optic Direct readings of finished products for QC.
- Solution withdrawn, filtered and returned
- Dedicated UV dissolution software
- Single vendor support unique to Agilent.

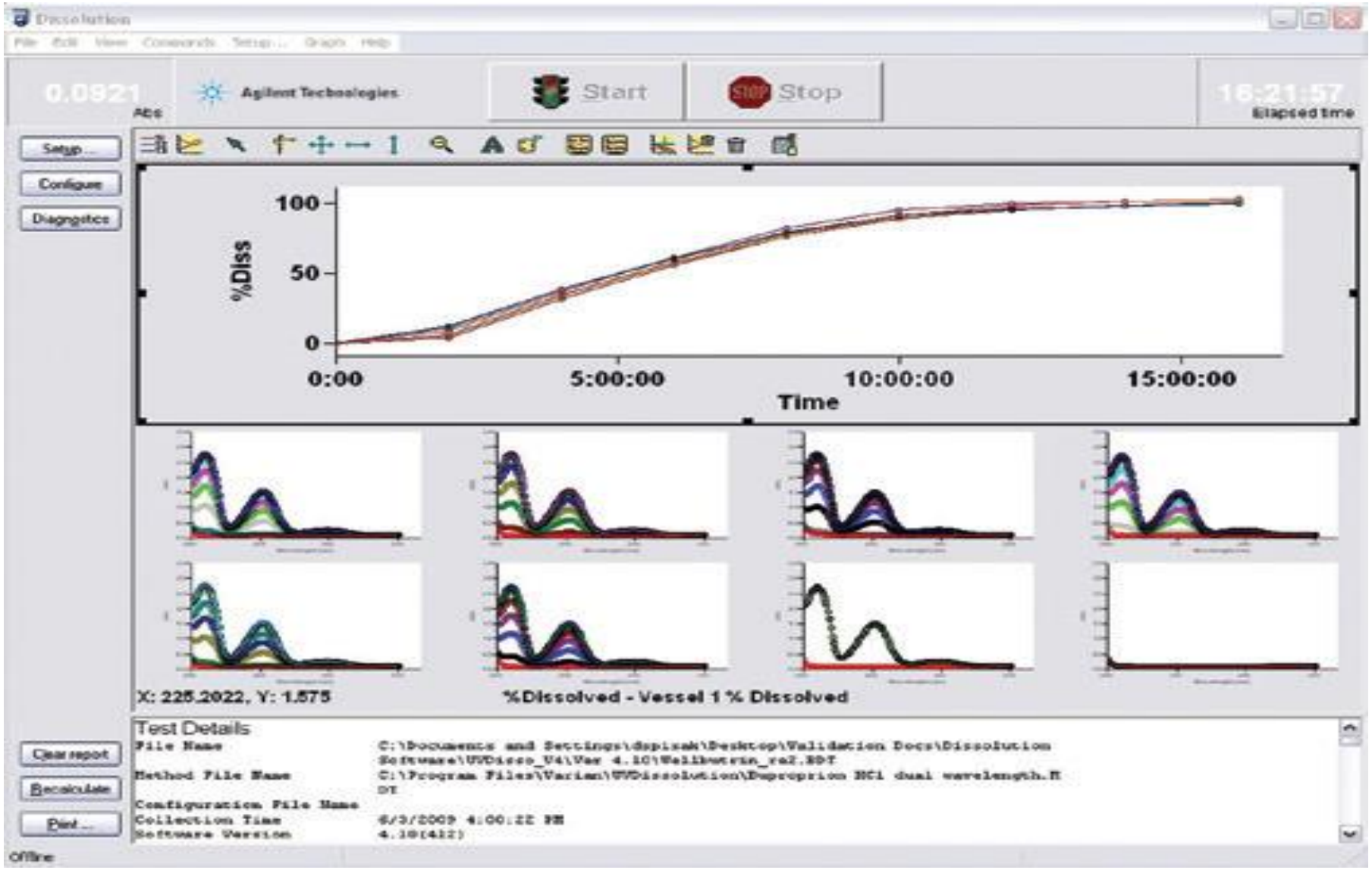


Agilent's Unique Technology – UV, Cary 60

- **Powerful**, Linear over 4 absorbance units, high intensity Xenon flash lamp
- **Practical**, Room light immune.
- **Stable**, Split beam dual Si diode detectors.
- **Fast**, 80 readings a second, scanning speed up to 24,000 nm/min



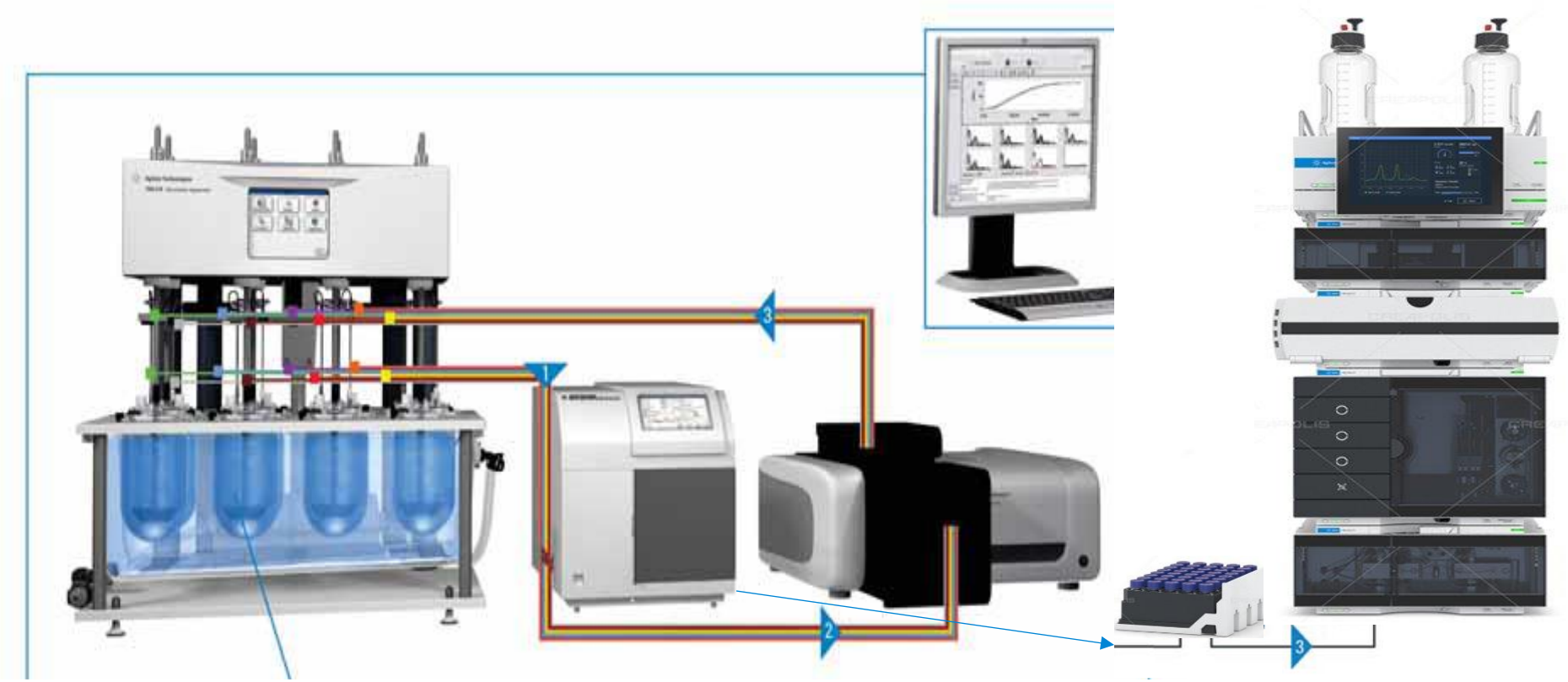
UV Dissolution – See everything at a glance.



Confidentiality Label
May 22, 2025

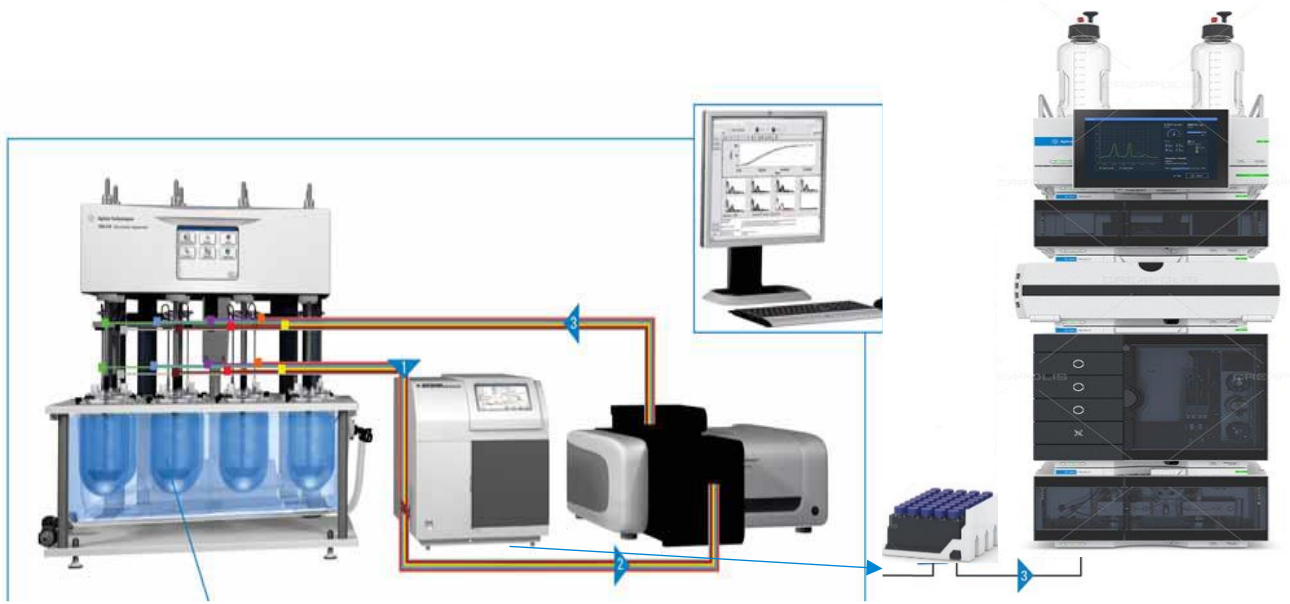
Solutions Four
The LC/UV Total Solution Workflows

Dissolution Automation Five - Used from Characterization To Production. The “Total Solution” 850-DS LC & Cary 60 UV Workflow



Dissolution Automation Four The “Total Solution”

- Links together solutions two and three into a total UV/LC on and off line workflow solution.
- Independent dual system set up.
- Single vendor for all components
- Complete **peace of mind** for every method.

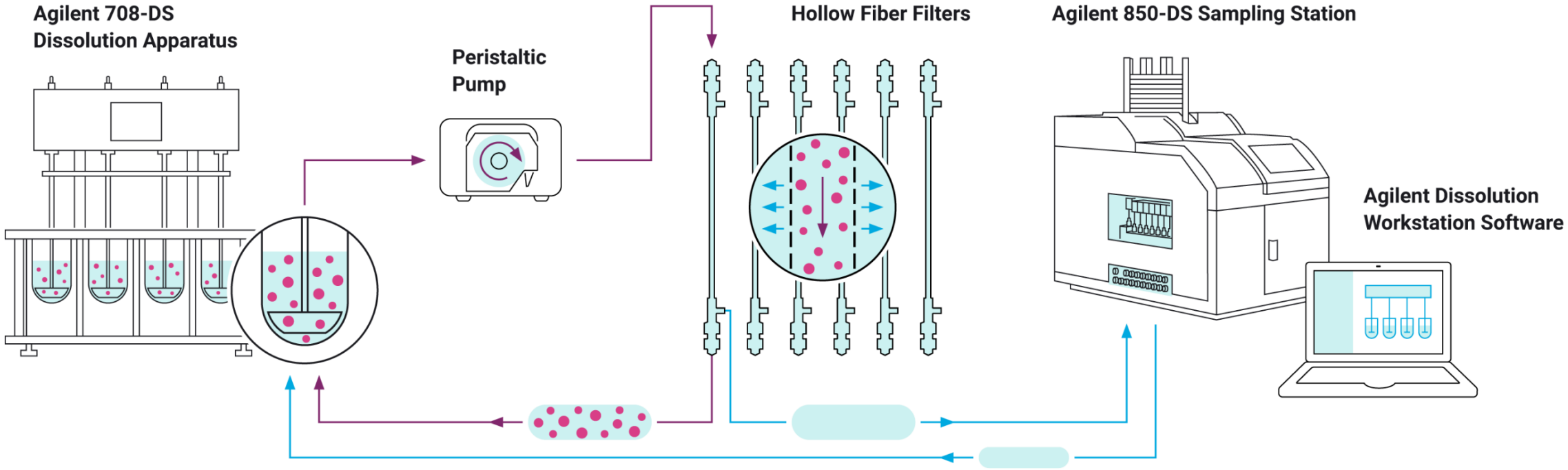


Solutions Five & Six
The Nano and Micro Workflows

Dissolution Automation Five – Used From Characterization To Production. The Nano-Dis LC Workflow

The NanoDis System – what is it?

A workflow that ensures *in vitro* dissolution of nanoparticle API – Used from discovery to production.



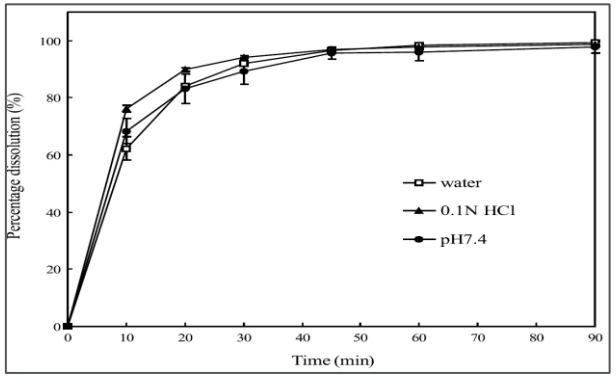
Cross Flow Filtration

Used for manufacturing for purification and solvent removal.

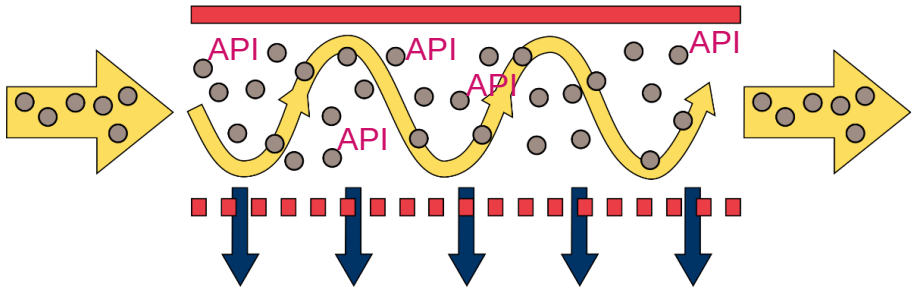
No filter cake.

No blockage of the filters.

True dissolution Results



Dissolution Media with Dispersed API loaded Nanoparticles + Dissolved (free) API



ONLY Dissolved API goes to 850-DS

API API API API

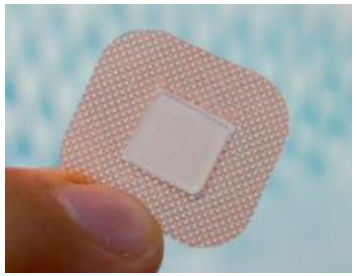
Dissolution Media with Dispersed API loaded Nanoparticles

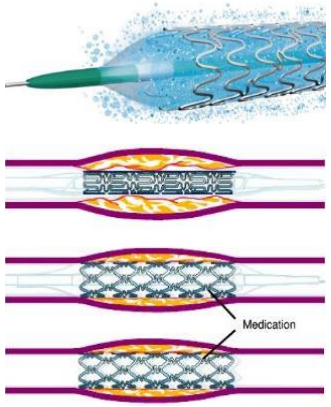
Dissolution Automation Six – Used From Drug Development To Production.
The USP VII 400-DS Small and Large Molecule Micro-Dis LC & LCMS Workflow

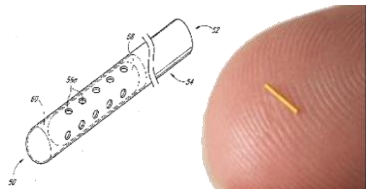
Novel Dose Development.

As the availability of standard small molecule formulation drops. Many new formulations and large molecules now need to delivered in novel ways.

- Microneedle patches
- Implants.
- Pacemaker leads.
- Drug-eluting stents
- Medicated contact lenses
- Wound care products
- Chewing gums, etc….







Automated Workflow for Small Volume Drug Release.

- Small volume: 3ml – infinite.
- Can test over many weeks and months.
- Bio-inert and compatible with 100% organic solvent media.
- Automated sampling and media replacement
- Full LC and LCMS workflows

Qualification Tools

Agilent 280-DS – Peace of Mind.

- Fully Automated laser controlled Measurement Tool for Critical Physical Parameters of Dissolution Testing required for OQ and ASTM / FDA MQ tests.

Agilent Restricted
The Pharmaceutical Value Chain

Agilent 280-DS

- RPM,
- Shaft Wobble,
- Basket Rim Wobble,
- Shaft Verticality,
- Vessel Verticality,
- Vessel Table Level,
- Vibration
- Temperature,
- Vessel Centering
- Paddle/Basket Depth

All tested in under minute per position.

Agilent Restricted
The Pharmaceutical Value Chain

Optimising The Benefits of Dissolution Automation for Your Laboratory

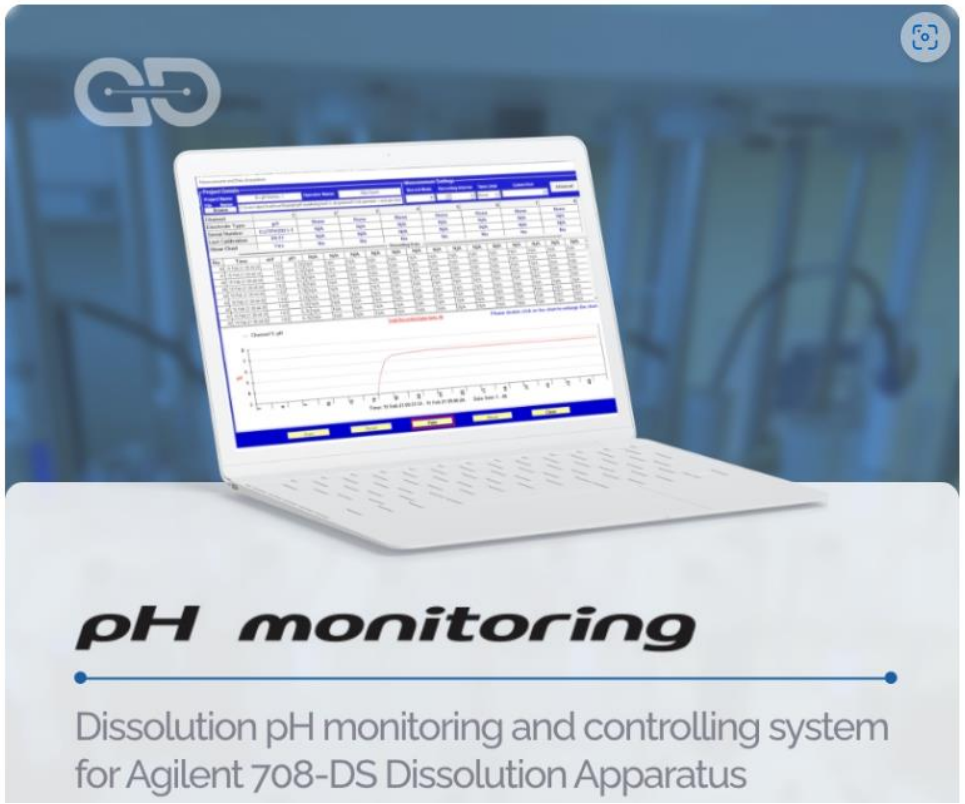
The Agilent Partnership To Enhance The Concept of automation

- When performed manually these operations can be technique dependent which may cause inconsistencies in test results.
- Others may be labour intensive or require action outside of the normal work schedule.

Products To Aid Automation Workflows

Automated Degassing

Automated pH monitoring



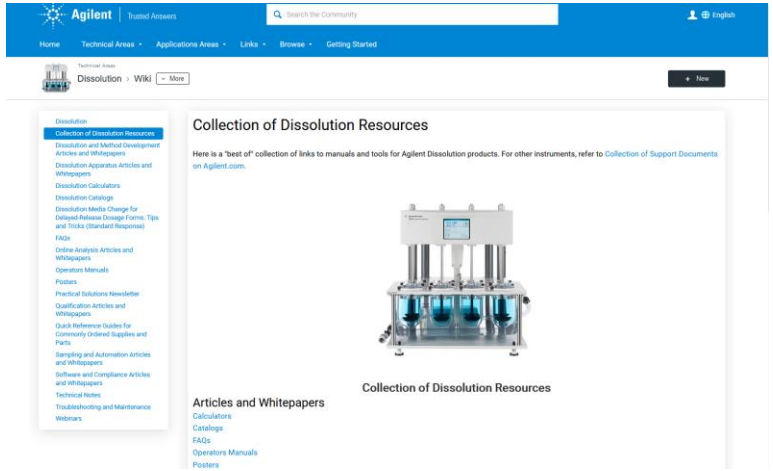
Products To Aid Automation Workflows

Automated Dispensing and Clean Up

Automated QC testing.

Further Information…

- Visit the **Agilent Community** for links to recorded webinars, FAQs, etc. (search "*Agilent community*" in Google)



- Sign-up for Practical Solutions Newsletter

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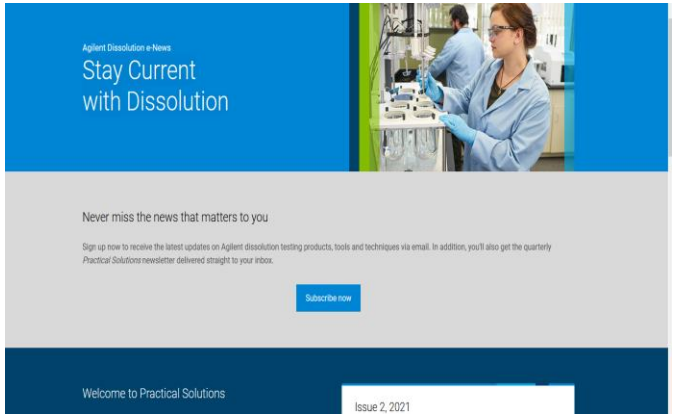

QUESTIONS?

owain.mckenzie@agilent.com

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Trusted Answers

May 22, 2025

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