Ensure You Have the Trusted Consumables and Services for Dissolution Testing Systems

What is a Dissolution Analysis?

A dissolution analysis is performed by the pharmaceutical industry for drug development, research, quality control and stability testing. UV/Visible spectrometers are widely used as the quantification technique for dissolution testing.

The US Pharmacopoeia (USP) has several different methodologies (e.g. paddles or baskets) in place but they basically involve the continuous sampling of six or more dissolution tanks. A tablet is introduced in each and then the change in absorbance (and from that the % dissolved) data is collected.

Two analysis procedures are commonly in use today – off-line and on-line bath analysis. Both provide the benefits of automation, saving laboratories time and lowering operating costs.

What Consumables Do You Need for Dissolution Testing?

Ensure your lab is equipped to handle any quality control, stability testing, and validation for your samples with our solution. Whether a configuration is needed for on-line or off-line dissolution testing, we have you covered. With a full suite of sampling devices, manifolds, flow cells, and various tubing, you can relax knowing you have the best consumables to meet your laboratory needs.

Confidently Select Your Consumables by Browsing Our Offerings Below:

Dissolution Testing Consumables	
B0631087	1 cm Quartz Flow Cell 160 µL
B0631085	1 mm Quartz Flow Cell 62 µL
N4104018	8-Cell Changer with Manifold for Dissolution
N4104001	8-Cell Changer
B2000049	Inside Tubing connects the Flow Cells to the Manifold
5361	Tubing Kit, 7 Bundle Close Loop Peristaltic ID 1mm
50883	Flow Cuvettes for Dissolution, Quartz Z15
B2000515	Outside Tubing connects the Manifold to the Pump
N4104020	16-cell changer

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For the Better

GREAT SCIENCE IS BUILT ON COMPLIANCE

Taking the Strain out of Dissolution Testing

Our OneSource Laboratory Services teams are staffed with engineers and consultants who know the ins and outs of dissolution testing. We offer mechanical qualification and chemical validation services that meet the very latest U.S. and E.U. guidelines and deliver technologies that produce the clearest, most useful, and fully integrated reports available. And we work with lab managers to find the optimum testing level and frequency to fit your lab's compliance needs.

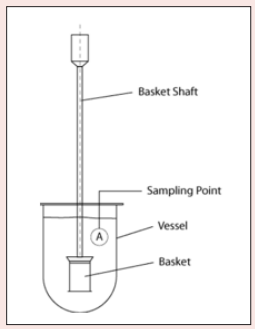
Preventive Verification Test (PVT)

Also known as chemical validation, the USP PVT test assess the performance of equipment used in dissolution testing, helping ensure that the results you get reflect drug qualities rather than the condition of the test equipment. The test is an important part of dissolution instrument qualification as outlined in the USP General Chapter <711>. It tests the entire apparatus using standardized materials and procedures, so your lab can compare results with other labs worldwide. Per USP <711> guidelines, USP PVT should be performed once per year, in conjunction with mechanical calibration, which should be scheduled semi-annually.

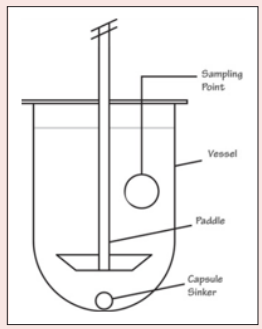
Mechanical Qualification

Recent studies performed in FDA and USP laboratories have identified several sources of variation within Apparatus 1 and 2 that can be minimized by employing an enhanced mechanical calibration procedure. The use of this procedure to satisfy the CGMP calibration requirement (§ 211.160(b)(4)) was endorsed by the FDA's Advisory Committee on Pharmaceutical Science (ACPS). The USP posted a toolkit to provide a mechanical calibration procedure, aligning with mechanical tolerances in USP <711> for dissolution apparatus assemblies. However, neither the mechanical tolerances specified in USP <711> nor the procedure described in the USP toolkit are as comprehensive or as stringent as those in the enhanced mechanical calibration procedure from the FDA.

There are two methods for calibrating your testing apparatus, and we provide service offerings for each:



Basket



Paddle

OneSource® Laboratory Services

Part Number	Description
LMXQUALDISSMET	LM OQ DISS- MC 1 SET PAD or BSKT
LMXQUALDISSMET2	LM OQ DISS- MC 2 SET PAD and/or BSKT
LMXQUALDISSUSP	LM OQ DISS- PVT + MC 2 SET PAD and/or BSKT
LMXQUALDISSMET2	LM OQ DISS- PVT + MC 2 SET PAD and/or BSKT

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