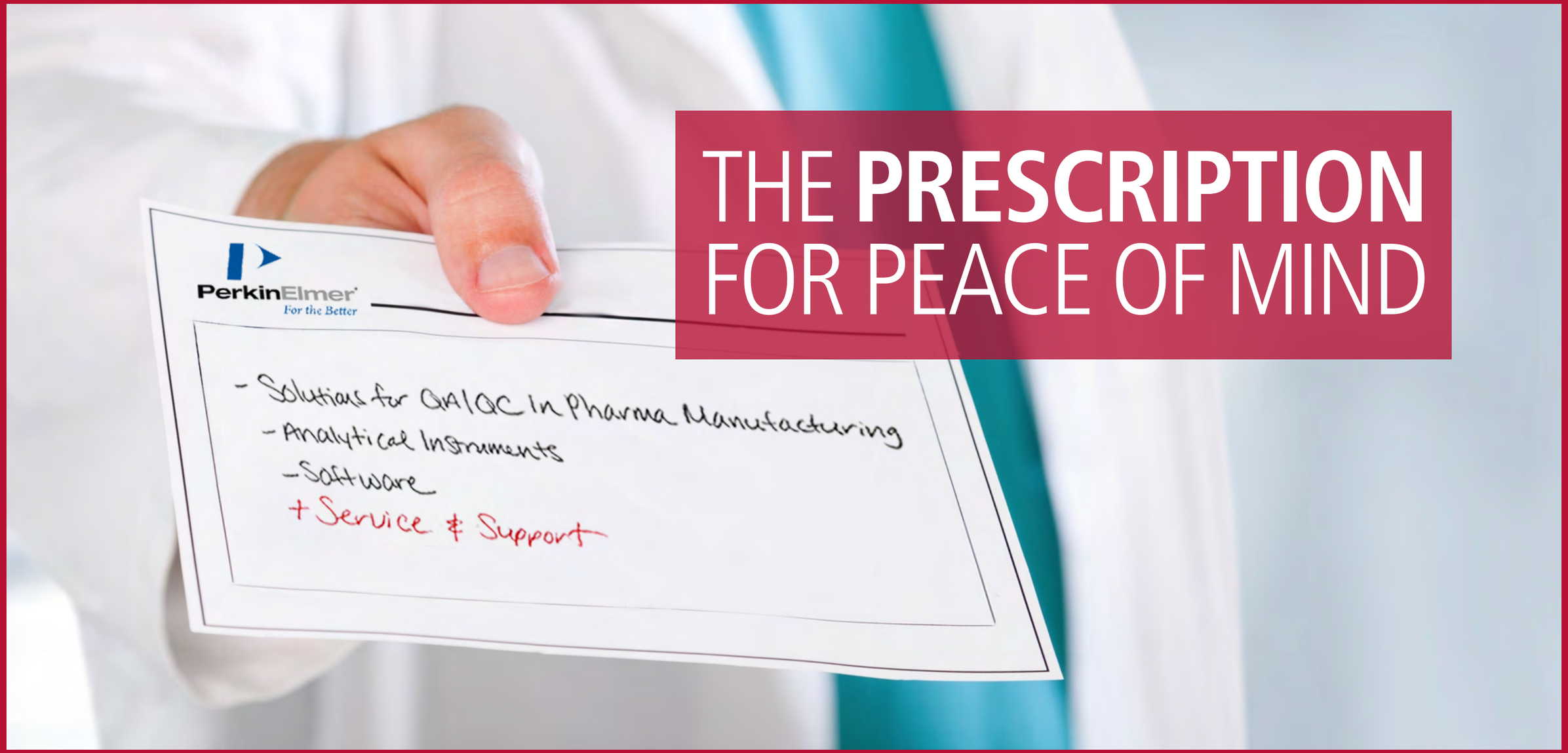

THE **PRESCRIPTION** FOR PEACE OF MIND

Choosing the Right Dissolution Testing Methods

PerkinElmer®
For the Better

Quality and Compliance
Where You Need Them Most

Pharmaceutical labs consider dissolution testing to be one of the critical steps in the drug development process. And it makes its impact at almost every step of the journey, from early product development to late-stage quality control.

After all, in *in vitro/in vivo* correlation studies, dissolution testing can be used as valid stand-in and surrogate for studies on human subjects, according to the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other regulatory bodies – so the dissolution apparatus you depend on must provide the most accurate and reproducible results available.

At the same time, dissolution testing is routinely used to deliver critical *in vitro* drug-release information for QA/QC and batch-to-batch consistency of solid oral dosage forms. And it can even be used to predict *in vivo* drug product release profiles.

Keep Reading

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Results That Are Real, Reproducible, *Compliant*

Dissolution testing helps labs control key variables in the drug development process, enabling you to:

- Confirm immediate quality control
- Include stability testing within strict, well-defined criteria for each drug
- Validate the manufacturing process and confirm therapeutic equivalence
- Ensure that the drug is still pharmaceutically active throughout its shelf life

Noncompliance in any of these criteria can mean out-of-spec (OOS) test results, an FDA form 483 observation, or even a warning letter from the FDA. So to meet U.S. and E.U. compliance guidelines, you need confidence in your compliance regimen, up and down the workflow. And compliance is what our dissolution testing solutions deliver.

These solutions provide flexible, automated testing that's fully 21 CFR Part 11 compliant and compatible with a variety of multivendor dissolution baths – making it the platform of choice for pharma labs everywhere.

Back

Introduction
Regulatory
Services
Instruments
Software
Consumables
Contact Us

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Dissolution Testing That Meets GMP Standards – and Yours

All new drug applications (NDAs) to the FDA contain data from a variety of sources that characterize the quality and performance of the drug product, including:

- Bioavailability data
- *In vitro* dissolution data
- Chemistry, manufacturing, and controls data (CMC)

Acceptable bioequivalence data and comparable *in vitro* dissolution and CMC data are mandated for abbreviated NDAs, and *in vitro* specifications for generic drugs should also be based on a dissolution profile.

The International Conference on Harmonisation (ICH) goes even further. Its Q1A guideline, Stability Testing of New Drug Substances and Drug Products, recommends that three batches (two pilot and one smaller scale) should be stability tested. What's more, these batches can be used to set dissolution specifications when there's a three-way equivalency between them and the clinical trial batch and the product intended for public consumption.

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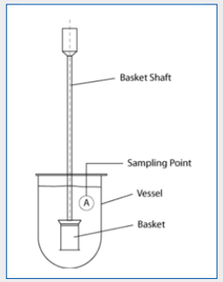
Choose the Dissolution Test Method That's Right for You

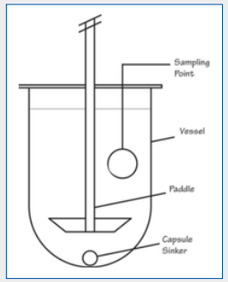
Dissolution testing is commonly performed using USP Apparatus 1 (basket) or USP Apparatus 2 (paddle). The dissolution test assembly consists of six or more individual vessel/stirring-element combinations with individual components that can be independently adjusted. The purpose of the dissolution test assembly is to simulate drug release from the dosage form in a reproducible manner. Our OneSource service teams are staffed with engineers and consultants who know the intricacies of dissolution testing, having contributed to the FDA/USP working group on vibration limit evaluations and settings. We offer both eMQ and PVT services that meet the very latest global regulatory guidelines.

Performance Verification Test (PVT)

Enhanced Mechanical Qualification (eMQ)



Basket



Paddle

Performance Verification Test (PVT)

Also known as chemical calibration, the USP PVT test asseses 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 enhanced mechanical calibration, which should be scheduled semi-annually.

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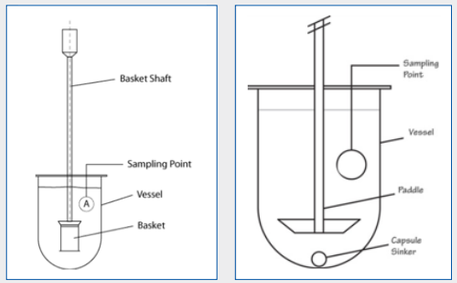
Enhanced Mechanical Qualification (eMQ)



Basket

Paddle

Enhanced 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.

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Great Science Is Built on Compliance

Dissolution testing mimics the behaviour of pharmaceuticals in the body and is an important part of quality control, determination as to whether drugs are performing to regulatory standards, and decisions around pharmaceutical excipients. And it's a key concern for the FDA and other regulatory bodies.

Our OneSource service teams are staffed with engineers and consultants who know the ins and outs of dissolution testing. Our teams have contributed to the FDA/USP working group on vibration limit evaluations and settings. 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. Plus, we work with your lab managers to find the optimum testing level and frequency to fit your lab's compliance needs and budget. Services include:

- Basic preventative maintenance
- Enhanced mechanical qualification
- Corrective maintenance
- Performance verification test

In addition, we can evaluate your testing regimen and advise on best practices for minimizing everyday operational problems.

OneSource® Laboratory Services

PerkinElmer® *For the Better*

Benchtop UV/VIS Made for Dissolution Testing

The pharmaceutical industry performs dissolution analysis for drug development, research, quality control, and stability testing, often using UV/Vis technology. Our LAMBDA™ 365 and LAMBDA 465 systems deliver state-of-the-art UV/Vis performance that meets the needs of pharmaceuticals and manufacturing QA/QC analysts everywhere. And with 21 CFR Part 11 software available, these systems also support applications requiring regulatory compliance.

Two dissolution-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. We offer flexible ways to automate dissolution testing, which can be used with a variety of high-quality dissolution baths made by third-party vendors.

For other applications of our LAMBDA 365 and LAMBDA 465 and their wide range of accessories, click here.

Introduction
Regulatory
Services
Instruments
Software
Consumables
Contact Us

LAMBDA 365
Compact, versatile, easy-to-use double-beam UV/Vis

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LAMBDA 465
Ultrafast, high-performance, reliable photodiode array single-beam UV/Vis

Learn More

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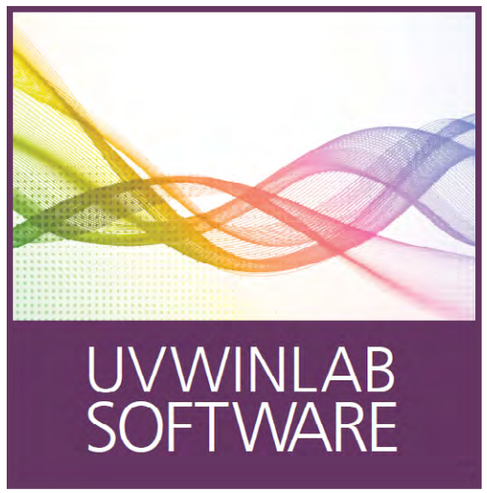

Learn More

Advanced Software That Works the Way You Work

UV WinLab software mirrors the way you work, guiding you through method development, analysis, reporting, and results in simple steps. With advanced software capabilities such as macros and sample tables, it's easy to personalize all stages of your analysis.

With a single click, UV WinLab software archives results and methods into a secure database, transforming data from a collection of individual results into valuable knowledge to help you make faster decisions. Intelligent querying options allow you to instantly answer questions from customers and auditors and identify potential problems. The Enhanced Security (ES) version of UV WinLab software integrates 21 CFR Part 11 compliance and eliminates compliance loopholes without compromising productivity or data integrity. It includes:

- Multilevel user permissions, including administrator, method developer, analyst, and reviewer
- Password-protected access control, including password aging and expiry
- Method-lock facility, ensuring methods can't be overwritten and revisions are saved in a single location
- Fully configurable e-signature points, allowing you to remain paperless securely

Introduction
Regulatory
Services
Instruments
Software
Consumables
Contact Us

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Consumables Make the Solution

To make the most of your dissolution testing, you need the right consumables and supplies. Whether it's QA/QC, stability testing, or validation for samples, offline or on line, we have you covered with a full suite of sampling devices, manifolds, flow cells, tubing, and more.

Learn More

LAMBDA Accessories for Sample Control

Our UV/Vis consumables and accessories are the perfect fit for your LAMBDA 365 and 465 systems, engineered for high lab productivity and flexibility.

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A Column for Every Application

Packed with rugged, high-purity silica in 3-µm and 5-µm, 80 Å pore-size particles, our super-reliable Pecosphere columns are capable of very fast analysis and exceptional performance, with standard end-capping for acidic or neutral analytes.

Learn More

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To learn more about our dissolution testing solutions, click here.

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For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs

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