

VALIDATION SERVICES

LET DISTEK HANDLE ALL YOUR VALIDATION NEEDS

Distek provides a large variety of service and validation offerings. All qualifications include cGMP documentation with evidence and verification according to the most recent USP/ASTM specifications. After execution of the applicable tests, Distek's validation engineer will prepare a comprehensive final report. All Distek field service engineers are industry professionals, thoroughly trained and certified with hands on experience. Distek has been an ISO 9001 certified since 2002.

SERVICES & CAPABILITIES

- Asset Management
- Calibration
- Multi-Vendor Services
- Preventive Maintenance
- Qualification (IQ/OQ/PQ/PVT)
- Repairs
- Setup & Installation
- Spare Parts Inventory
- Technical Support
- Validations
- and More

MARKETS SERVED

- Academia
- Agricultural Sciences
- Animal Health
- Bioprocessing
- Biosimilars
- Cannabis
- Food & Flavors
- Generics
- Government Agencies
- Nutraceuticals
- Pharmaceuticals
- and More



DISTEK

distekinc.com • info@distekinc.com



VALIDATION & QUALIFICATION SERVICES

DISTEK PROVIDES A LARGE VARIETY OF VALIDATION & QUALIFICATION SERVICES AND OFFERINGS

Installation Qualification (IQ)

- Provides documented evidence to verify that the system was received in good condition and meets manufacturer's specifications. The IQ certifies that the system is set up and installed correctly in an appropriate environment and properly prepared for the operational and performance qualifications. Installation Qualification should be performed at installation or after an instrument relocation.

Mechanical Qualification (MQ)

- Verifies that the mechanical performance of the dissolution system meets specifications, is functioning properly, and is available for further performance qualification, if applicable. Services include comprehensive testing of the instrument using specialized, certified validation tools to ensure that the equipment meets current Good Manufacturing Practices (cGMP) standards. The test is executed in accordance with the more rigorous ASTM E2503-13(2020) and/or USP Toolkit Procedure.

Performance Verification Test (PVT)

- Formerly referred to as the Prednisone "Calibrator Tablet" Performance Qualification (PQ), this test ensures that the apparatus meets system suitability test requirements per USP <711> guidelines. The PVT employs USP 10mg Prednisone tablets and reference standards. This process assures reliability of dissolution results that reflect the quality of the drug product.

Multi-Vendor Services

- Allows access to our expertise and qualification services for both Distek and non-Distek equipment. Eliminates the hassle of maintaining multiple vendors.

Preventative Maintenance (PM)

- Servicing of equipment to confirm continued proper operation per the manufacturer's specifications including the replacement of certain parts, inspections, adjustments, documenting all the critical steps performed and more. Annual or semi-annual preventative maintenance (PM) visits help ensure the accuracy of your analytical results and increases instrument uptime, all while reducing repair costs.

Operational Qualification/Performance Verification (OQ/PV)

- Verifies that the system is functioning correctly and that all critical operational parameters are within specifications. An OQ report makes certain your laboratory equipment performs within the manufacturer's operational guidelines and supplies the documented evidence needed to meet the requirements of regulatory agencies.

Training

- Ranges from basic familiarization to advanced user training which can be tailored to your specific needs. Our knowledgeable trainers and consultants use their firsthand experience to help you manage your team's requirements. We offer virtual and on-site, one-on-one or group training.

Validation Contracts

- Offer priority, pre-planned scheduling which eliminates worry and allows analysts to focus on analytical results, not the validation of the instruments. Prescheduled annual or semi-annual qualification and preventive maintenance services help avoid downtime and optimize performance.

Technical Support

- Our technical support staff is made up of highly experienced service engineers and validation experts that are on-call and ready to support your team with technical issues or questions over the phone, email, and LiveChat.

Setup & Installation

- Includes instrument unboxing and installation for your delivered product.

On-site or Depot Repair

- Factory trained specialists are available to provide instrument repairs onsite at your location or in our facility.

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INSTRUMENT TYPE	IQ	PM	OQ	PV	PVT	USP TOOLKIT MQ	ASTM-MQ
Content Uniformity	Yes	Yes	Yes	N/A	N/A	N/A	N/A
Disintegration	Yes	Yes	Yes	N/A	N/A	N/A	N/A
Dissolution							
Apparatus 1 and 2	Yes	Yes	N/A	N/A	Yes	Yes	Yes
Apparatus 3 and 7	Yes	Yes	N/A	N/A	N/A	N/A	N/A
Dissolution Autosampler	Yes	Yes	Yes	N/A	N/A	N/A	N/A
Dissolution Media Preparation	Yes	Yes	Yes	N/A	N/A	N/A	N/A
Dissolution Vessel Washer	Yes	Yes	Yes	N/A	N/A	N/A	N/A
Friability	Yes	Yes	Yes	N/A	N/A	N/A	N/A
Tapped Density	Yes	Yes	Yes	N/A	N/A	N/A	N/A
UV Fiber Optic Dissolution	Yes	Yes	Yes	N/A	N/A	N/A	N/A
UV/Vis Spectrophotometer	Yes	Yes	Yes	Yes	N/A	N/A	N/A

* Please contact your Distek representative for more information concerning your specific make and model.



888.2.DISTEK

distekinc.com • info@distekinc.com

121 North Center Drive • North Brunswick, NJ 08902