

# VALIDATION SERVICES

*Distek is committed to providing its customers with the most consistent, traceable results needed to satisfy regulatory requirements. Much like our philosophy for designing quality instruments, Distek's Validation Service Group utilizes highly skilled chemists and technicians that undergo comprehensive training and certification in all aspects of validation services. Our product is our people, each of which has an unparalleled commitment to both customer service and assuring that your instrument is performing according to industry specifications.*

- **INSTALLATION QUALIFICATION (IQ)**

Assuring that your system is received in good condition, IQ will verify the system meets specifications as well as certifies the system is set up and installed correctly, in the right environment and ready for operational qualifications and performance qualifications.

- **MECHANICAL QUALIFICATION (MQ)**

Certification that the mechanical performance of the system is satisfactory and that the system is available for further performance qualification.

- **PERFORMANCE VERIFICATION TEST (PVT)**

Ensures the system is working properly and both verifies and certifies the instrument meets system suitability test requirements per USP <711> guidelines using USP calibrator tablets and reference standards.

- **MULTI-VENDOR SERVICES**

Provides expertise and qualification services for Distek and non-Distek equipment. Contact Distek for specific instrument services.

- **PREVENTATIVE MAINTENANCE (PM)**

Servicing of equipment to confirm continued proper operation per the manufacturer's specifications including the replacement of parts, inspection and replacement of electronic components, connections, switches, motors and more.

- **OPERATIONAL QUALIFICATION / PERFORMANCE VERIFICATION (OQ / PV)**

Verifies the system is functioning and that all critical operational parameters are within specifications while supplying the evidence needed to meet the requirements of regulatory agencies and makes certain your laboratory equipment performs within specified guidelines.

- **SOP WRITING**



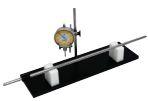



Saving valuable time and money, the validation services team will write your SOP's to qualify your instruments as well as train your staff to execute them.

- **VALIDATION CONTRACTS**

Eliminate worry while keeping costs down.



## VALIDATION TOOLS

ALL DISTEK VALIDATION TOOLS COME READY TO USE WITH NIST TRACEABLE CALIBRATION CERTIFICATES	
	<p><b>CenterChek™ (0500-0281)</b> The CenterChek allows users of all dissolution test systems to accurately verify paddle or basket shaft centering closer to the dosage form inside the vessel.</p>
	<p><b>HeightChek™ (0500-0300) (1L) / (3500-0003-2L) (2L)</b> The HeightChek is a novel gauge that can accurately set the paddle or basket height prior to a test, or it can be used as a precision tool to validate the height of each stirring element.</p>
	<p><b>ShaftChek™ (0500-0301)</b> The ShaftChek is a calibrated NIST traceable precision measurement device for checking and straightening paddle and basket shafts. Additionally, distorted baskets can be re-shaped and paddle blades can be verified for adherence to USP specifications.</p>
	<p><b>Tachometer (0500-1047) (Optical) / (0500-1044) (Contact)</b> The ShaftChek is a calibrated NIST traceable precision measurement device for checking and straightening paddle and basket shafts. Additionally, distorted baskets can be re-shaped and paddle blades can be verified for adherence to USP specifications.</p>
	<p><b>TempChek™ (0500-0298)</b> The TempChek's high resolution (0.01°C), accuracy (<math>\pm 0.02^\circ\text{C}</math>) and portability make this precision instrument useful for dissolution vessel and general-purpose temperature measurements or as a NIST traceable reference thermometer.</p>
	<p><b>WobbleMeter (2821-0273)</b> The WobbleMeter features a light and versatile design, effective with all vessel positions on any dissolution apparatus. The base of this measurement device can be easily attached to the vessel plate with the use of a common C-clamp, insuring faster setup and improved accuracy.</p>
DISTEK OFFERS RECALIBRATION SERVICE FOR ALL OF OUR VALIDATION TOOLS.	

## ADDITIONAL TOOLS

PART NUMBER	DESCRIPTION
Digital Level	0500-1046 360°, Resolution:0.1° Accuracy:0-10°=0.1°,11-79°=0.2°.80-90°=0.1° w/Certificate
Digital Level Sleeve	3200-0350-SN Vessel verticality measuring sleeve for Digital Level (Serialized)
VesselChek™	0500-0299 Used to verify the conformity of a vessel
VibraChek™	8100-0315 Used to validate benchtop vibration
TimeChek™	8100-0014 3 Line Timer - NIST Traceable

## KITS

PART NUMBER	DESCRIPTION
Kit #1	8100-0001 Includes CenterChek, HeightChek, WobbleMeter, and Contact Tachometer
Kit #2	8100-0002 Includes CenterChek, HeightChek, WobbleMeter, and Optical Tachometer
Kit #3	8100-0002 ASTM - Includes Two CenterChek, One each HeightChek, WobbleMeter, Digital Level, and Contact Tachometer
Kit #4	8100-0006 ASTM - Includes Two CenterChek, One each HeightChek, WobbleMeter, Digital Level, and Optical Tachometer



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