

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**




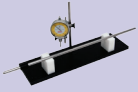



Saving valuable time and money, the validation services team will write your SOP's to qualify your instruments as well as train your staff to execute them.

- **VALIDATION CONTRACTS**

Eliminate worry while keeping costs down.



VALIDATION TOOLS

ALL DISTEK VALIDATION TOOLS COME READY TO USE WITH NIST TRACEABLE CALIBRATION CERTIFICATES	
	CenterChek (0500-0281) - [Accuracy ±0.2 mm] 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.
	Digital Level (0500-1046-CAL) - [Accuracy 0-10° = 0.1°, 11-79° = 0.2°, 80-90° = 0.1° w/Certificate] The Digital Level (Protractor) is a handheld, portable angle measuring instrument used for measuring the shaft verticality. Range: 360°, Resolution: 0.1° Requires Digital Level Sleeve (2800-0351-SN) for measuring vessel verticality.
	HeightChek (0500-0300) (1L) / (3500-0003-2L) (2L) - [Accuracy ±0.2 mm] 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.
	ShaftChek (0500-0301) - [Accuracy ±0.002 in] The ShaftChek is a calibrated NIST traceable precision measurement device for checking the straightness of a shaft.
	Tachometer (0500-1044) (Contact) / (0500-1047) (Optical) - [Accuracy ±1 RPM] Distek offers two tachometers to verify rotations per minute: a contact tachometer with a measurement range of 1.5 - 10,000 rpm and an optical tachometer which utilizes visible red light and has a measurement range of 30 - 50,000 rpm.
	TempChek (0500-0298) - [Accuracy ±0.02°C] The TempChek's high resolution (0.01°C), accuracy and portability make this precision instrument useful for dissolution vessel and general-purpose temperature measurements or as a NIST traceable reference thermometer.
	WobbleMeter (2821-0273) - [Accuracy ±0.002 in] The WobbleMeter features a light and versatile design, effective with all vessel positions on most all dissolution apparatus.
DISTEK OFFERS RECALIBRATION SERVICE FOR ALL OF OUR VALIDATION TOOLS.	

ADDITIONAL TOOLS

	PART NUMBER	DESCRIPTION
Digital Level Sleeve	3200-0350-SN	Vessel verticality measuring sleeve for Digital Level (Serialized) - [Accuracy ±0.1°]
TimeChek	8100-0014	3 Line Timer - NIST Traceable [Accuracy ±0.01%]
PrepEngine RPM Tool	TS-05-000317	RPM Tool for PrepEngine. Requires Distek Optical Tachometer
VibraChek	8100-0315	Used to validate benchtop and instrument vibration
Mini HeightChek	2800-0296	Height Adjustment Fixture (10 mm) for Distek Mini Paddles and Baskets (Serialized)

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	8100-0005	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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