

# ASTM Calibration Tools



## ASTM Validation Toolkit

For a diversity of dissolution systems and purposes different tools are available. Dissolution Accessories provides you with a broad range of tools used for quick reference, detailed mechanical qualification and requalification.

**For Mechanical Qualification different procedures are available. One of them is ASTM procedure E2503.**

ASTM International, American Society for Testing and Materials (ASTM), is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services.

Dissolution Accessories assembled an ASTM Validation Toolkit capable to perform mechanical qualification according ASTM or USP for a wide range dissolution systems.



### Among the systems supported are:

- Hanson
- Agilent
- Distek
- Erweka
- Sotax
- Pharmatest
- ElectroLab

### The Validation toolkit comes with a step by step user guide.

#### Features:

- Gauge with digital readout
- Digital Level
- Set gauge
- Height measurement adapter
- Centering measurement adapter
- Wobble adapter (incl. cover and brackets)
- Calibrated shaft (incl. retaining ring)
- Depth Gauge (for USP 1 and 2)
- Thermometer
- Tachometer

### The Dissolution Accessories toolkit provides you the tools to perform apparatus 1 & 2 ASTM measurements.

- System leveling measurements
- Shaft and Vessel verticality
- Vessel centering
- Wobble
- Depth measurement
- Temperature measurements
- Speed measurements

Part No.	Description
PSASTMKT-HDA	ASTM Validation Tool kit for Hanson, Distek, Agilent
PSASTMKT-EP	ASTM Validation Tool kit for Erweka, PharmaTest
PSASTMKT-ST	ASTM Validation Tool kit for Sotax
PSASTMKT-EL	ASTM Validation Tool kit for ElectroLab
PSASTMEX-EP	Expansion kit to make it "EP" compatible, incl. extra shafts
PSASTMEX-ST	Expansion kit to make it "ST" compatible, incl. shaft and adapter ring

# Calibration Tools



## TOOLS Verification/Calibration

Tools are standard Factory Calibrated. When additional certification is needed or re-certification, this is done according to NEN ISO 17025, certified by the RvA. RvA is member of the European Co-operation for Accreditation (EA) and is one of the signatories to the EA multilateral agreement and to the ILAC mutual recognition arrangements (MRA) for the mutual recognition of calibration certificates. Please order this service extra.

Part No.	Description
PSCAL-ASTMKTX	Calibration Service; ASTM kit Complete
PSCAL-CNTGAG	Calibration Service; Centring kit
PSCAL-DEPTH	Calibration Service; Digital Depth Gauge Kit
PSCAL-THERMO	Calibration Service; Thermometer, 2-points
PSCAL-VERTMET	Calibration Service; Digital Verticality meter
PSCAL-WOBMET	Calibration Service; Wobble meter kit
PSCALHTA6-UN	Calibration Service; Height Tool, Universal

Before analysis a reference/adjustment of paddle/basket height can be needed. Dissolution Accessories has several adjustment reference tools as Height spacers, ball gauges, and depth set gauges specific for dissolution system for USP (1, 2, 5 and 6) method. In order to overcome different depth tools a universal depth gauge is available.

Part No.	Description	OEM Ref
PSCALHTA5-35	Calibration Height Tool App 5, 35mm patch holders	Universal
PSCALHTA5-56	Calibration Height Tool App 5, 56mm patch holders	Universal
PSCALHTA5-80	Calibration Height Tool App 5, 80mm patch holders	Universal
PSCALHTA6-UN	Calibration Height Tool App 1, 2 & 6	Universal
PSDEPGAG-VK	Depth Gage for height setting	12-7300
PSDEPSET-MI	Ball Style Depth Set Gauge	Universal
PSDEPSET-SB	Stationary Basket Spacer, 1cm –	Universal
PSDPSPBK-HR	Basket Height Spacer, Hanson	72-800-501
PSDPSPPD-HR	Paddle Height Spacer, Hanson	72-800-502
PSDPSPBK-VK	Basket Height Spacer, Agilent	12-7210
PSDPSPPD-VK	Paddle Height Spacer, Agilent	12-7200
PSGNGDEP	Go no Go tool	–



PSDEPSET-SB



PSDPSPBK-VK



PSDPSPPD-VK



PSDEPGAG-VK



PSDEPSET-MI



PSCALHTA6-UN



PSCALHTA5-35



PSCALHTA5-50



PSCALHTA5-56



PSCALHTA5-80

# Calibration Tools

## Shaft Wobble

The ASTM standard tolerates a shaft wobble of  $\leq 1.0$  mm. For measurement, the shafts and stirring elements must be installed according to the dissolution bath manual. The measurement values are recorded by the digital gauge. According to FDA guidelines, shaft wobble is measured 2 cm above the paddle or basket rim.

Part No.	Description
PSWOBMET-MI	Wobble kit for open top baths
PSWOBMET-ST	Wobble kit for Sotax AT7

## Vessel Centering

According to ASTM the specification of the vessel position from the length axis of the stirrers is  $\leq 1.0$  mm. Vessel centering is determined by measurement in two positions inside the vessel.

Part No.	Description
PSCNTGAG-HDA	Vessel Centering kit for Agilent, Distek and Hanson
PSCNTGAG-MI	Vessel Centering kit for Erweka, Pharmatest and Sotax

## Paddle and Basket Height

According to ASTM, the stirring element height is specified  $25 \pm 2$  mm. The height is tested with empty and centered vessels.

Part No.	Description
PSDDAPT-MI	Height measurement Tool kit, multi-instrument

## Speed

According to ASTM standard, the rotational speed may deviate from set speed by a max of  $\pm 2$  rpm @ 50rpm.

Part No.	Description
PSTACHOM-UN	Tachometer, multi-instrument

## Temperature

Part No.	Description
PSTHERMD-LC	Calibrated Thermometer with temperature probe, multi-instrument

## Vibration

Part No.	Description
PSVIBMET-UN	Vibration meter, multi-instrument

## System leveling

Part No.	Description
PSVERTMET-MI	Digital, verticality and leveling meter



PSCNTGAG-HDA



PSDDAPT



THERMOMETER



TACHOMETER



DIGITAL VERTICALITY METER

# Calibration Tools



## Model SenseLine F410 pH/mV/°C Meter



- Clear display of measured values and settings
- Watertight and dustproof to IP67 specifications
- Continue indication of electrode and battery status
- Automatic endpoint and buffer recognition
- Automatic Temperature Compensation
- Data memory for 30 GLP data points
- 3-point calibration with predefined or user-defined buffers

Specifications				Ordering Information	
<b>F410</b>	<b>Measuring range</b>	<b>Resolution</b>	<b>Accuracy</b>	<b>F410</b>	Meter only option includes F410 pH portable meter, operation manual and four AA batteries
pH	0.00 ~ 14.00	0.01	± 0.01	<b>F410T</b>	Meter kit option includes F410 + 2 pH buffers + KCl solution + epoxy pH electrode with built-in ATC (IP67) and carrying case
mV	1999 ~ 1999	1	±1	<b>QP411T</b>	Epoxy pH-electrode with temperature compensator, 12x120mm, 0-14 pH, 0-80°C
Temperature	5.0 ~ 105 °C	0.1 °C	± 0.5 °C		
Sensor inputs	BNC (>10 <sup>12</sup> Ω); NTC 30 KΩ (both IP67)				
Power requirements	4AA batteries 1.5V or NiMH accumulators 1.3V				
Operation environment	0 ~ 40 °C, 5 ~ 85% rel. humidity (non-cond.)				
Size / Weight	220 x 90 x 45mm / 325g (without batteries)				