CALIBRATION TOOLS

CONTROLLING HARDWARE VARIABLES

It is important to ensure the dissolution bath is working as intended, and giving precise and reproducible results. To do this it is important that the bath meets the USP or ASTM physical specification. The ASTM variables are tighter as they rely only on the physical measurement whereas the USP also requires a test using calibrator tablets.

KEY CONSIDERATIONS

The variables are:

Specification	ASTM	USP
Shaft Wobble	1.0mm Max.	No significant wobble
Shaft Verticality	Must be vertical, bubble within the lines	Not defined
Basket Wobble	1.0mm Max. at bottom rim	1.0mm Max. at bottom rim
Vessel Centering	1.0mm Max.	2.0mm Max.
Paddle/Basket Height	+/- 8% or +/- 2.0mm	+/- 2.0mm
Rotation	2% or +/- 2 rpm	+/- 4%
Temperature	+/- 0.5°C	+/- 0.5°C
Vibration	No significant vibration	No significant vibration
Vessel verticality	1° from vertical Max.	Not specified

QLA provides a comprehensive set of validation tools to measure these variables. All tools (except the verticality meter) are serialized and supplied with a traceable 1 year certificate of calibration.

Wobble Meter (WOBMET-UN) — The Wobble Meter uses a special vessel cover that fits securely inside the top of the vessel. The gauge is firmly attached to this cover then placed against the shaft or basket. The shaft is then rotated at a slow speed and the wobble (displacement) is displayed on the easy to read dial. The gauge works with all open dissolution baths (where you can access the vessel during the test).

Vibration Meter (VIBMET-UN) — This simple Vibration Meter allows you to quickly assess vibration levels and ensure that low levels are maintained when new equipment is introduced into the lab or after routine bath maintenance. It uses digital electronics but is equipped with an analog needle display. For this type of device, an analog display is better than a digital one because it gives a much better feel for the nature of the vibrations.

The meter uses an accelerometer probe that is calibrated to the meter as a matched set. The probe end has a custom mounting block that is compatible with most dissolution instruments.

Universal Level (LEVEL-UN) — The bath's vessel plate must be level to ensure the bath has been properly set up. Baths are equipped with adjustable feet which may be adjusted while observing the Universal Level to achieve vessel plate levelness. The certified level is a simple circular, bubble level that allows quick and easy verification of the vessel plate level in all directions at once.

Verticality Meter (VERTMET-MI) — This digital Verticality Meter is a highly precise device which permits accurate measurement of shaft and vessel verticality as required by the ASTM Specification. The meter is suitable for any open dissolution bath where vessels and shafts are accessible. The meter requires a simple user calibration at each time of use and for this reason is not supplied with a certificate of calibration (Available on request only).

Depth Setting Tools (DEPSET-25, DEPSET-25A, DEPSET-MI, DEPGAG-VK, ASTMBALL-25, DEPSET-45, DEPSET-PK, DEPSET-SB) — QLA offers multiple tools for setting the height of the basket/ paddle (use DDAPT-Plus to measure the height). See descriptions and pictures to identify which style will best suit the needs of your laboratory. To set the correct depth, simply place the gauge at the bottom of the vessel, lower the basket or paddle until it touches the

Depth Measuring Gauges, Digital Depth Gauge (DDAPT-Plus) — The new Digital Depth Gauge is an extremely precise instrument used to accurately measure the basket/paddle distance from the vessel spherical bottom. This allows basket or paddle height to be determined within .01mm. The DDAPT-Plus Digital Depth Gauge is made to fit most open access dissolution baths.

spacer and lock the shaft into position.

Optical Tachometer (TACHOM-UN) — The most accurate method of measuring the rotational speed is by using an Optical Tachometer. A reflective sticker is placed on the shaft or shaft drive, the Optical Tachometer shines an infrared light on to the shaft at this point. The reflection is then measured at every rotation, giving an accurate reading of the rotational speed. The tachometer can be used on all dissolution baths.

Centering Gauge (CNTGAG-MI) — The Centering Gauge comes with a 3/8" OD surrogate shaft that fits directly into the shaft drive. A 10mm OD surrogate shaft (EUROINDC-M) is also available separately. The gauge may be placed near the vessel top and bottom (beginning of the spherical radius). This allows the impact of vessel verticality on centering to be evaluated. The spindle is rotated slowly and the measuring arm follows the inside of the vessel perimeter. Deviation from the center position can be directly read from the dial, which always faces the operator.

The gauge works on most open access baths. For bathless systems where the shaft cannot be easily removed, the gauge fits directly onto the bottom of the shaft once the basket hub or paddle is removed.

Calibrated Thermometer (THERMD-LC) — The digital Calibrated Thermometer is an extremely accurate thermistor-based low cost thermometer. It is ideal for validating dissolution bath and media temperature as well as general lab use. A simple switch lets you set the digital display to show either Celsius or Fahrenheit readings. The thermometer is supplied with a certificate of calibration.

Validation Tool Kits (VALTOL-KT2 & VALTOL-ASTM) — Our Validation Tool Kits contain everything necessary to make a complete calibration of a dissolution bath.

- The VALTOL-KT2 standard tool kit contains a Centering Gauge, Precision Level, Wobble Meter, Go/No Go Gauge (this is used to verify that the height is more than 23mm but less than 27mm) and a 25mm Depth Set Tool.
- The VALTOL-ASTM Tool Kit is the same as the KT2 kit but also includes the verticality meter and manual verticality tools.

Both kits contain instruction manuals, together with individual certificates of calibration.



