



Operating Instructions Validation Tool Kit, KT2 For use with USP Apparatus #1 & #2

P/N VALTOL-KT2
Revision 2.0
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Revision History

Rev.	Description	Revised By	Revised On	Approved By	Approved On
A	Initial Release	RM	6/15/10	RM	6/15/10
2.0	Formatting	DMC	10/7/14	RM	10/8/14



1.0 General Information

1.1 Introduction

Thank you for purchasing the QLA Validation Tool Kit, KT2. This kit contains a variety of unique measuring tools and gages that provide an accurate reading of vessel plate levelness, paddle or basket shaft wobble, basket wobble, paddle or basket height and vessel centering anywhere within the dissolution vessel. With the purchase of the optional 80mm Standard (For Vankel / Varian Testers) and/or 80mm Spacer and Shaft Collar (For Hanson and Distek Testers), the centering gage can also be used to determine vessel verticality as described in the new FDA specifications outlining the use of an Enhanced Mechanical Calibration procedure as an alternate approach to current Apparatus Suitability procedure for Dissolution Apparatus 1 and 2 as described in the USP General Chapter <711> Dissolution. The KT2 kit is maintenance free, easy to use and should be returned to QLA once a year for recalibration.

1.2 Product Specifications

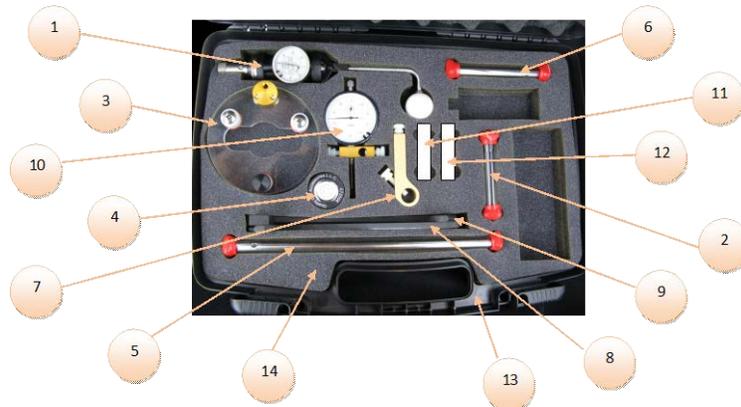
See individual Certificates of Calibration and Traceability.

2.0 Unpacking

The plastic storage box has been designed to minimize any damage that may occur during transport and can also be used to ship the KT2 Kit back to QLA for recalibration. Check the shipping container for any damage during transport. Unpack the individual parts carefully. After unpacking, check the parts for possible damage. Report any damage to the forwarding shipper immediately and inform QLA or your local representative.

3.0 Product Description

3.1 Diagram of Validation Tool Kit, KT2



Item #	Description	Part Number
1	Vessel Centering and Verticality Alignment Gage	970-05-21
2	Anti-Rotation Handle	Included with Gage
3	Wobble Bracket Assembly	970-05-23
4	Universal Level	LEVEL-UN
5	Indicator Shaft (Long)	10001006
6	Indicator Shaft (Short)	10001015
7	Indicator Bracket Assembly	97-05-25
8	Go, No-Go Gage	GNGDEP
9	Depth Set Gage	DEPSET-25
10	Dial Indicator Assembly	970-05-24
11	Spin Shaft Adapter for Hanson	ADPT-HR
12	Spin Shaft Adapter for VanKel / Varian	ADPT-VK
13	Plastic Storage Case	6785TC
14	Foam Insert	Current Version

4.0 Installation/Operating Instructions

4.1 Checking Vessel Plate Levelness

- 4.1.1 Place the Universal Level at the approximate center of the dissolution tester vessel plate and observe the location of the bubble.
- 4.1.2 The tester is considered adequately leveled when the bubble remains completely within the outer ring of the level and does not touch the lines.
- 4.1.3 Adjustments to the tester can be made by raising or lowering the adjustable feet located on the base of the tester. (Please refer to the dissolution testers operation manual for their recommended procedure)

4.2 Setting Paddle / Basket Height

- 4.2.1 The paddle or basket height can be set by placing the 25mm depth gage, (Part Number DEPSET-25) onto the paddle or rotating basket assembly by clamping the support arm onto the drive shaft and making sure the top of the gage is touching the bottom of the paddle blade or rotating basket as shown in Figure 1.

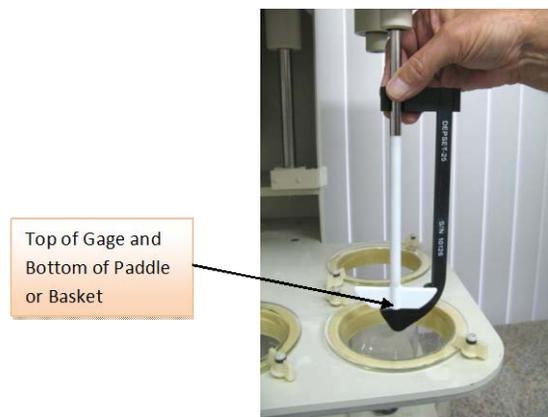


Figure 1

- 4.2.2 The paddle or basket assembly is lowered until the bottom of gage touches the inside bottom of the vessel as shown in Figure 2.

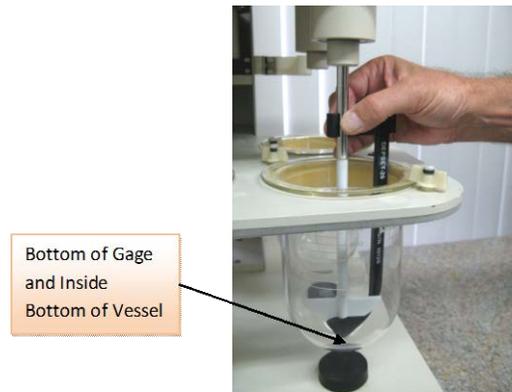


Figure 2

4.2.3 Once set, secure the paddle or basket shaft in place as recommended by the appropriate dissolution tester manufacturer. Then raise the dissolution drive head and carefully remove the gage.

4.3 Checking Paddle / Basket Height

4.3.1 After setting the paddle or basket height. The height can be checked by using the Go / No-Go Gage as outlined below.

4.3.2 With the dissolution drive head lowered to its normal operating position, the smaller knob labeled “GO” must fit in between the bottom of the paddle or rotating basket and the bottom of the vessel. While the larger knob labeled “NO-GO” must not.

4.3.3 If the “GO” knob does not fit or the “NO-GO” knob does, the height needs to be adjusted. (See Sections 4.2.1 -4.2.3)

4.4 Measuring Paddle Wobble

4.4.1 For Hanson and Distek Tester

4.4.1.1 The paddle wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure 3.



Figure 3

4.4.1.2 Place the wobble gage onto the top of the dissolution vessel and move the adjustable foot in or out until the assembly is secured to the inside of the vessel as shown in Figure 3.

4.4.1.3 With the paddle shaft secured, lower and position the dissolution drive head so that the dial indicator probe is located about 2cm above the top of the paddle blade and adjust the location of the indicator assembly to establish a pre-load of at least one revolution of the indicator dial. Tighten the thumb screws to lock the gage in place. See Figure 4.

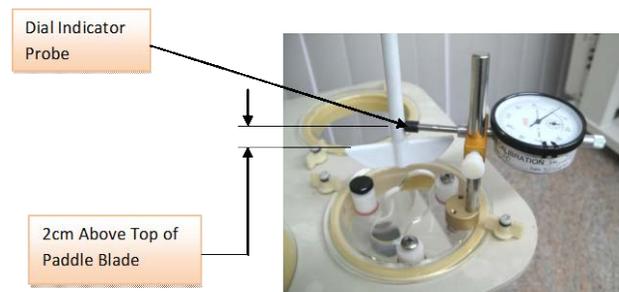


Figure 4

4.4.1.4 Set the dissolution tester to 25 RPMs. Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with "0" on the indicator. As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading (T.I.R.) or wobble. Each division on the dial indicator is equal to .01mm.

4.4.2 For VanKel / Varian Testers

4.4.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in Figure 5.

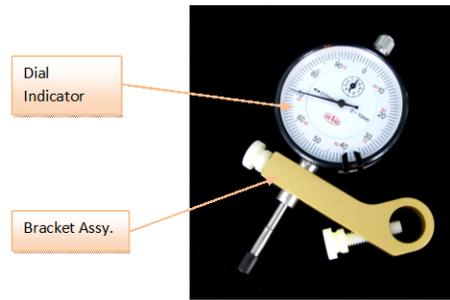


Figure 5

4.4.2.2 Place the indicator assembly onto the centering ring guide post as shown in Figure 6.

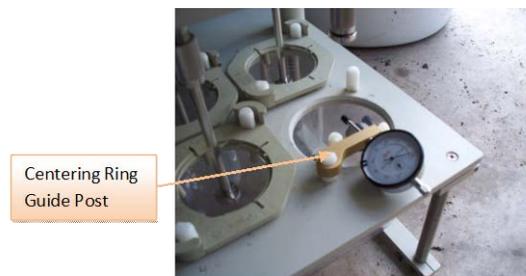


Figure 6

4.4.2.3 Repeat sections 4.4.1.3 & 4.4.1.4

4.5 Measuring Basket Shaft Wobble

4.5.1 For Hanson and Distek Testers

4.5.1.1 The basket shaft wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure 3.

4.5.1.2 Place the wobble gage onto the top of the dissolution vessel and move the adjustable foot in or out until the assembly is secured to the inside of the vessel as shown in Figure 3.

4.5.1.3 With the basket shaft secured, lower and position the dissolution drive head so that the dial indicator probe is located about 2cm above the top of the shaft hub and adjust the location of the indicator assembly to establish a pre-load of at least one revolution of the indicator dial. Tighten the thumb screws to lock the gage in place. See Figure 7.

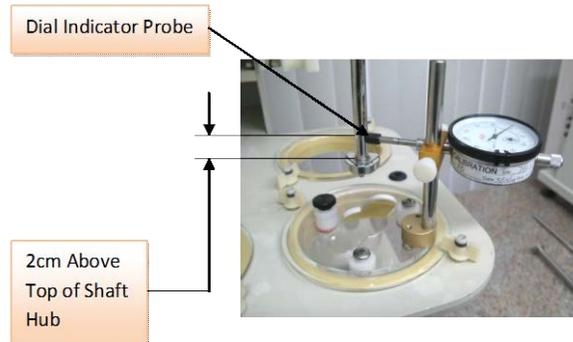


Figure 7

4.5.1.4 Set the dissolution tester to 25 RPMs. Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with "0" on the indicator. As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading (T.I.R.) or wobble. Each division on the dial indicator is equal to .01mm.

4.5.2 For VanKel / Varian Testers

4.5.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in Figure 5.

4.5.2.2 Place the indicator assembly onto the centering ring guide post as shown in Figure 6.

4.5.2.3 Repeat sections 4.5.1.3 & 4.5.1.4

4.6 Measuring Basket Wobble

4.6.1 For Hanson and Distek Testers

4.6.1.1 The basket wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure 3.

4.6.1.2 Place the wobble gage onto the top of the dissolution vessel and move the adjustable foot in or out until the assembly is secured to the inside of the vessel as shown in Figure 3.

4.6.1.3 With the basket secured to the shaft, lower and position the dissolution drive head so that the dial indicator probe is touching the bottom rim of the basket and adjust the location of the indicator assembly to establish a pre-load of at least one revolution of the indicator dial. Tighten the thumb screws to lock the gage in place. See Figure 8.

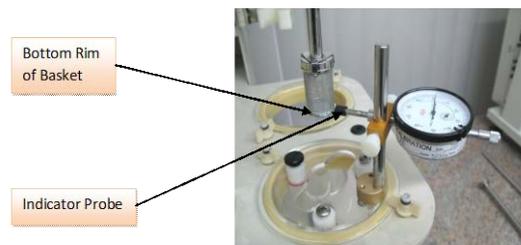


Figure 8

4.6.1.4 Set the dissolution tester to 25 RPMs. Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with "0" on the indicator. As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading (T.I.R.) or wobble. Each division on the dial indicator is equal to .01mm.

4.6.2 For VanKel / Varian Testers

4.6.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in Figure 5.

4.6.2.2 Place the indicator assembly onto the centering ring guide post as shown in Figure 6.

4.6.2.3 Repeat sections 4.6.1.3 & 4.6.1.4

4.7 Measuring Vessel Centering

4.7.1 For Testers with One-Piece Shafts

4.7.1.1 Raise the dissolution tester to its highest position. Remove any existing paddle or basket shafts and replace it with the Indicator Shaft with Gage as shown in Figure 9.



Figure 9

- 4.7.1.2 Insert the indicator shaft into the spindle such that the hole on the shaft protrudes about 1 inch below the spindle assembly.
- 4.7.1.3 Attach the top of the gage to the bottom of the indicator shaft by turning the knurled knob clockwise until snug. Use the anti-rotation handle to insert thru the indicator shaft. Hold the gage handle in place and then fully tighten the knurled knob. Raise the assembled gage into the spindle assembly and then fully tighten the Chuck Assembly. (Chuck assemblies are not used on Distek Dissolution Testers).
- 4.7.1.4 While gently pressing back on the gage shaft to avoid hitting the vessel rim or centering ring as shown in Figure 10. Lower the dissolution drive head so that the indicator ball is positioned about 2mm above the top of the vessels spherical radius. (This approximates the normal paddle or basket position)



Figure 10

- 4.7.1.5 Set the dissolution tester speed to 25 RPMs and place one finger in front of the anti-rotation handle as shown in Figure 4. (Some Distek 5100 series instruments may be equipped with a drive head position limit switch that prevents spindle rotation. These instruments require manual rotation.)

4.7.1.6 Start the spindle rotation and observe the dial indicator travel. Rotate the dial face so that the minimum counter clockwise pointer position coincides with 40 on the indicator.

4.7.1.7 As the shaft rotates, the pointer will move clockwise to a maximum value. This distance is the total indicated reading or T.I.R.. Each division on the dial indicator is equal to .05mm.

4.7.1.8 Stop the spindle rotation and raise the drive head so that the indicator ball is near the top of the vessel just below the rim and repeat Sections 4.7.1.5 to 4.7.1.7

4.7.2 For Testers with Two-Piece, Spin-Off Shafts

4.7.2.1 Follow the instructions in Section 4.7.1 with the following exceptions. Remove only the lower portion of the paddle or basket shaft assembly and replace it with one of the following Spin-Shaft adapters as shown in Figure 11. (Distek Testers do not require the use of an adapter.)

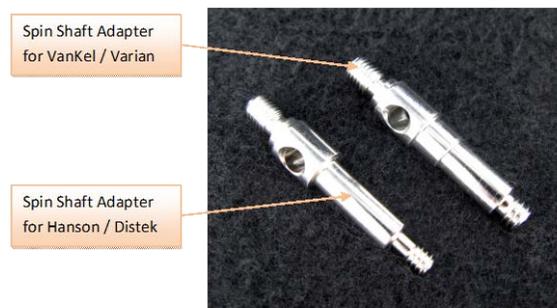


Figure 11

4.8 Calculating Vessel Centering

4.8.1 The actual vessel centering or spindle to vessel misalignment is calculated by dividing the total indicated reading or T.I.R. by two.

Example: The dial indicator moved clockwise from 40 to 15. The total indicated reading is 1.5mm. Thus, 1.5mm divided by two equals .75mm.

Example: The dial indicator moved clockwise from 40 to 25. The total indicated reading is 2.5mm. Thus, 2.5mm divided by two equals 1.25mm.

5.0 Qualification and Validation

Prior to shipment, the kit is calibrated and includes Certificates of Calibration and Traceability. The complete kit should be returned to QLA for recalibration once a year.



6.0 Maintenance

Although the measuring tools and gages contained in this kit are maintenance free and do not require any daily service, it is recommended that after each use, the gages and tools are returned to the plastic protective case for storage.

7.0 Warranty

This parts contained in this kit are warranted to be free from defects in materials and workmanship under normal installation, use and service for a period of (1) year from the date of purchase as shown on the purchase order receipt. The obligation of QLA under this warranty shall be limited to repair or replacement (at our option) during the warranty period, provided the product is returned to QLA with transportation charges prepaid. This warranty shall be invalid if the product is damaged as a result of defacement, misuse, accident, destruction or alteration of the serial numbers, repair alteration or maintenance by any person or party other than our own service facility or authorized QLA service technician.