Operating Instructions

Quality Lab Accessories LLC

Wobble Meter

For use with USP Apparatus #1 & #2

Part Number MANWOBMET-MI, Rev. A, 6-15-2010

Table of Contents

1. General Information

1.1 Introduction

Thank you for purchasing the QLA Wobble Meter. This meter is a unique measuring tool that provides an accurate reading of paddle, basket shaft and basket wobble 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 gage is maintenance free, easy to use and should be returned to QLA once a year for recalibration.

1.2 Product Specifications

Parameter	Specification
Model #	WOBMET-MI
Range	0.0 -10.0 mm
Accuracy	+ / - .02mm

2. Unpacking

The meter is shipped in a foam padded storage case to minimize damage during transport. The case can also be used to return the gage to QLA for recalibration.

Unpack the meter carefully. After unpacking, check the meter for possible damage. Report any damage to the forwarding shipper immediately and inform QLA or your local representative.

3. Product Description

3.1 Diagram of Wobble Meter

Item #	Description	Part Number
1	Wobble Bracket Assembly	970-05-23
2	Dial Indicator Assembly	970-05-24
3	Indicator Shaft	10001006
4	Indicator Shaft Tool	970-05-26
5	Indicator Bracket	970-05-25
6	Storage Case	807-40
7	Foam Insert	950-05-34

4. Installation

4.1 For Hanson and Distek Testers

Assemble the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure #1. The indicator shaft tool can be used to secure the indicator shaft to the wobble bracket assembly by inserting the indicator shaft tool midway through the hole in the indicator shaft and rotating clockwise.

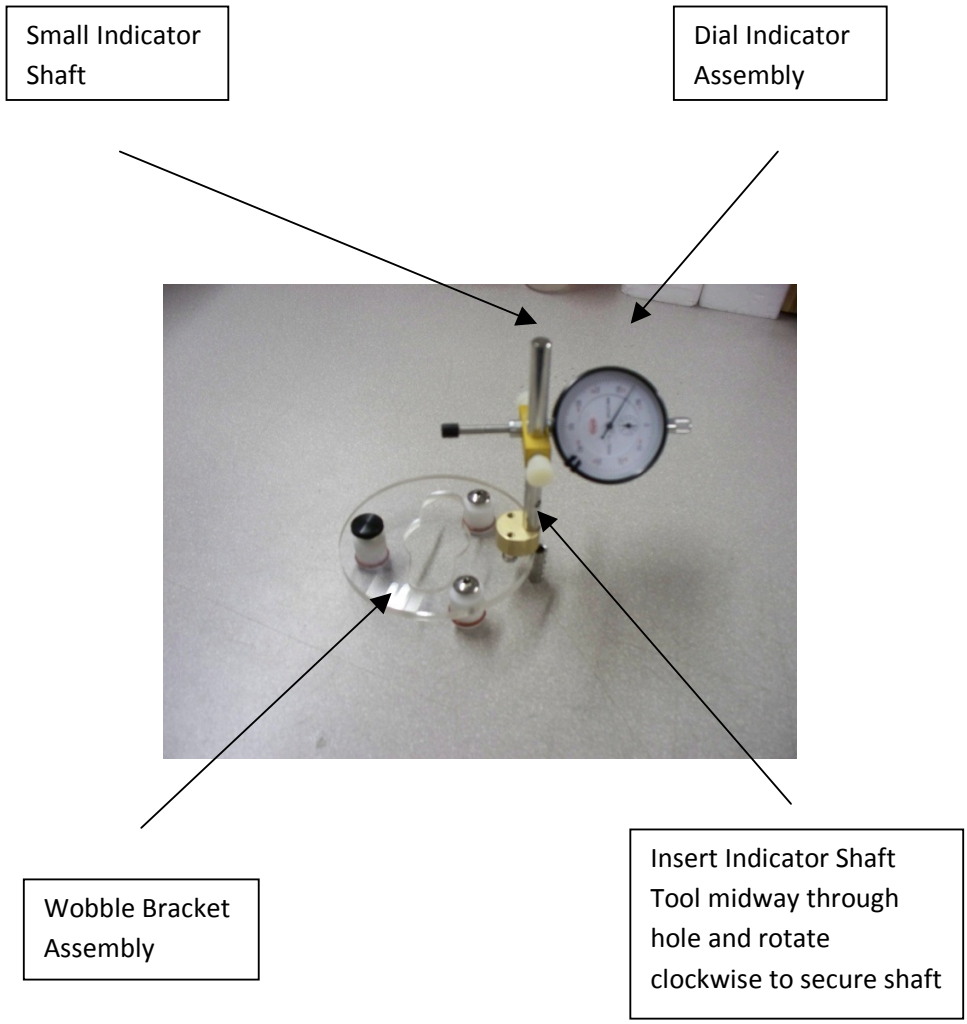

Figure #1

4.2 For VanKel / Varian Testers

Remove the indicator clamp and assemble the dial indicator to the indicator bracket as shown in figure #2.

Figure #2

5. Operation

5.1 Measuring Paddle Wobble

5.1.1 For Hanson and Distek Testers

5.1.1.1 Place the wobble meter 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.

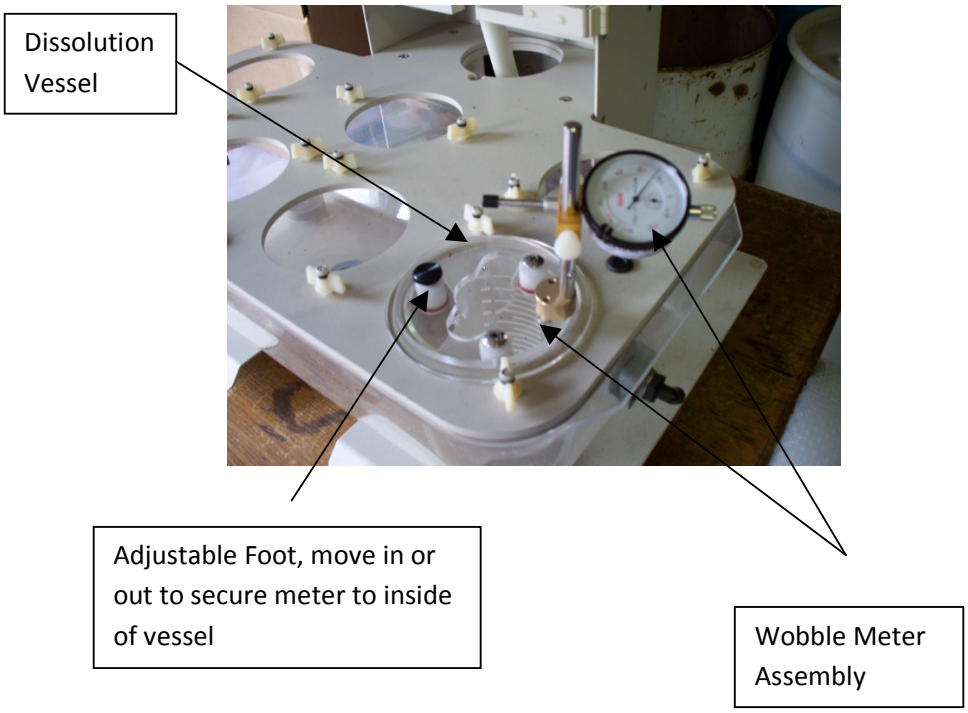

Figure #3

5.1.1.2 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.

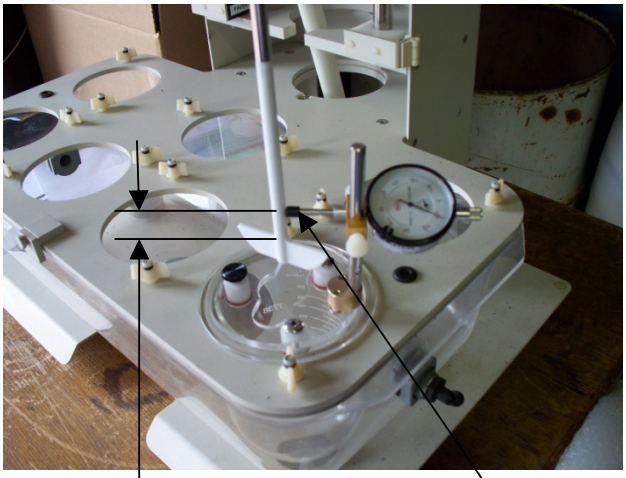

Figure #4

5.1.1.3 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.

5.1.2 For VanKel / Varian Testers

5.1.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in figure #2.

5.1.2.2 Place the indicator assembly onto the centering ring guide post as shown in figure #5.

Figure #5

5.1.2.3 Repeat sections 5.1.1.2 & 5.1.1.3

5.2 Measuring Basket Shaft Wobble

5.2.1 For Hanson and Distek Testers

5.2.1.1 The basket shaft wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure #1.

5.2.1.2 Place the wobble meter 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.

5.2.1.3 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 #6.

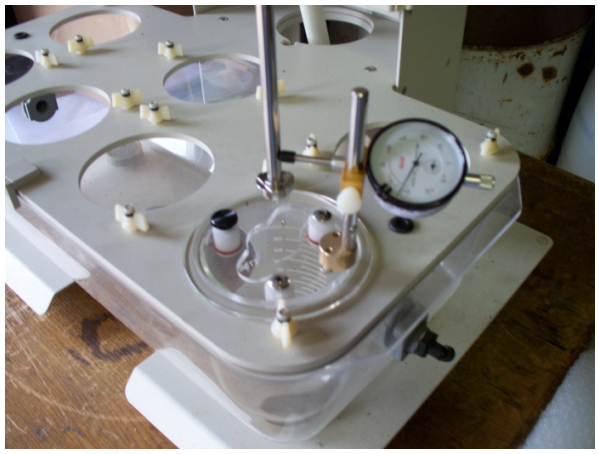

Figure #6

5.2.1.4 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.

5.2.2 For VanKel / Varian Testers

5.2.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in figure #2.

5.2.2.2 Place the indicator assembly onto the centering ring guide post as shown in figure #5.

5.2.2.3 Repeat sections 5.2.1.3 & 5.2.1.4

5.3 Measuring Basket Wobble

5.3.1 For Hanson and Distek Testers

5.3.1.1 The basket wobble can be measured by assembling the dial indicator assembly, small indicator shaft and wobble bracket assembly as shown in Figure #1.

5.3.1.2 Place the wobble meter 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.

5.3.1.3 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 #7.

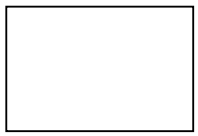

Figure #7

5.3.1.4 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.

5.3.2 For VanKel / Varian Testers

5.3.2.1 Remove the centering ring, dissolution vessel and assemble the dial indicator to the bracket assembly as shown in figure #2.

5.3.2.2 Place the indicator assembly onto the centering ring guide post as shown in figure #5.

5.3.2.3 Repeat sections 5.3.1.3 & 5.3.1.4

6. Qualification and Validation

Prior to shipment, the Wobble Meter is calibrated and includes a Certificate of Calibration. The meter should be returned to QLA for recalibration once a year.

7. Maintenance

The meter is maintenance free and does not require any daily service

8. Warranty

This meter is 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.