1.0 Purpose

The purpose of this procedure is to provide general guidelines for the calibration and operation of the VK-200 hardness tester or equivalent.

2.0 Scope

This procedure applies to the VK-200 or equivalent hardness tester in use at Ion Labs, Inc. This procedure provides general guidelines. Specific instructions from sources such as BPRs and protocols are needed to properly test hardness. This procedure complies with USP <1217> Tablet Breaking Force.

3.0 Responsibility

3.1 It is the responsibility of the QC Laboratory Metrologist or designee to complete the calibration of the VK-200 hardness tester.

3.2 It is the responsibility of Production (Compression) Personnel to follow this procedure.

3.3 It is the responsibility of Production and QC Management to ensure that this procedure is being followed.

3.4 It is the responsibility of QC Laboratory Management to keep this procedure aligned with current practices.

4.0 Definitions

4.1 **QC** – Quality Control

5.0 References

5.1 G-201-F2, Form, Calibration Certificate

5.2 USP <1217> Tablet Breaking Force

6.0 Procedure

6.1 Location and General Setup

6.1.1 The VK-200 hardness tester should be set on a level surface free of vibration.

6.1.2 Allow the system to stabilize for five minutes after power up.

6.2 Setup for Calibration

6.2.1 Place the VK-200 hardness tester on the side and resting on a flat surface. Hold securely.

6.2.2 Secure the hardness tester to the calibration fixture with two locking screws by threading them through the fixture and into the bottom of the tester.

6.2.3 Ensure that the threaded end of the calibration weight hanger is straight. If not, replace the screw.

6.2.4 Thread the calibration weight hanger into the sensing jaw for approximately ten turns, or until gently snug.

6.2.5 Ensure that the weight hanger is tight and does not rotate.

6.2.6 Ensure that the weight hanger is hanging free and stable.

6.2.7 Verify the calibration of the unit using the process outlined in section 6.3 before continuing with calibration. If verification passes, the unit does not require further adjustment.

6.3 Calibration

6.3.1 Put the unit into calibration mode by toggling <initialize/print/calibrate> to the calibrate position.

6.3.1.1 When the system is ready, the hardness tester will display 0.00. A slight flicker of the final digit is acceptable.

6.3.2 Select a 10kg calibration weight and carefully place it on the weight hanger.

6.3.2.1 The force displayed should match the weight used.

6.3.3 Compare the hardness tester weight reading to the weight used.

6.3.3.1 If the reading does not match the weight used, adjust the calibration trip pot on the underside of the unit using the trim pot tool supplied in the accessory kit.

6.3.3.2 Turn the trip pot screw until the value displayed matches exactly the weight applied.

6.3.4 When the displayed value matches the applied weight, remove the weight and wait for the display to return to 0.00.

6.3.5 Repeat steps 6.3.1 through 6.3.4 at least once until the display matches the 10kg calibration weight and the display returns to exactly 0.00 after removing the calibration weight.

6.3.6 The calibration (verification) should be performed very six months.

6.4 Calibration Verification

6.4.1 During calibration and verification, ensure that the device has been thoroughly cleaned of any dust and debris that has gotten under the crushing jaw. A brush and air has proven to be great tools to remove this debris.

6.4.2 The hardness tester will be verified using 5kg, 10kg, and 20kg calibration weights.

6.4.3 The tolerance for each weight is +/- 0.2kg from the applied true weight.

6.4.4 If verification fails, recalibrate the unit by following section 6.3.

6.4.5 If verification fails multiple times, check the weights for cleanliness and clean as necessary.

6.4.6 If the weight does not conform, replace it. Verify that the weight certification is current.

6.4.7 If the cause for nonconformance cannot be determined, the hardness tester will be labeled as out-of-service until the unit is professionally inspected.

6.4.8 Once calibration is complete, document the results on Form G-201-G2 Calibration Certificate and place a calibration sticker on the hardness tester.

6.5 Preparation for Use

6.5.1 After verification is complete, toggle the <initialize/print/calibration> switch to operation mode.

6.5.2 Unscrew the hanger from the sensing jaw.

6.5.3 Unfasten the calibration fixture and carefully place the unit in the upright position.

6.5.4 The instrument is ready for use.

6.6 Hardness Testing

6.6.1 Place a tablet adjacent to the left jaw of the machine.

6.6.2 See product specifications for orientation of the tablet.

6.6.3 If no product specifications are found, follow these rules:

6.6.3.1 Tablets are to be placed face up on the tester.

6.6.3.2 Round tablets may be placed at any orientation relative to the jaws.

6.6.3.3 Elongated tablets are placed with the longer axis parallel to the jaw.

6.6.4 Initiate the test by pressing the <test> button.

6.6.5 The right jaw moves to the left, crushing the tablet. The jaw then retracts, allowing another tablet to be placed in the testing zone.

6.6.6 The surface will be cleaned as needed with a brush to ensure broken tablets and/or particles that may interfere with testing are removed.

6.6.7 Repeat the test with the number of tablets specified in the BPR, protocol, or other test record.

6.7 Cleaning

6.7.1 For cleaning purposes, the hardness tester is a non-product contact surface.

6.7.2 Broken tablets can be removed from the testing area with a brush and properly discarded.

6.7.3 The catch pan can be removed and cleaned.

6.7.4 The instrument can be cleaned with a damp rag or other standard all-purpose cleaner.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/09/10	New	-	-
1	01/24/12	Updated SOP	-	-
2	02/21/13	Formatted for easier readability	13-104	B. Johns
3	10/01/14	Changed format. Aligned calibration procedure with current practices.	14-0778	B. Johns
4	04/04/17	Added step to clean surface of tester as needed.	17-0340	K. Burris
5	04/15/20	Added calibration information, added responsibilities	CC-20-0294	J. Maignan
6	04/15/23	Scheduled review: changed responsibilities section. Updated logo and format.	CC-23-0201	K. Burris