
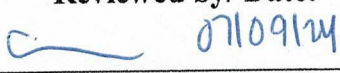
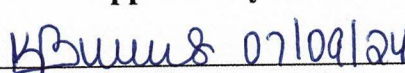
	Standard Operating Procedure Calibration and Operation of the Sotax MT-50 Hardness Tester		SOP Number G-209	Revision 0
			Effective Date 09/09/24	Page Page 1 of 6
Written by/ Date:  07/09/24		Reviewed by/ Date:  07/09/24		Approved by/ Date:  07/09/24
Title: Metrologist		Title: QC Laboratory Manager		Title: Quality Assurance Director

1.0 Purpose

The purpose of this procedure is to provide detailed guidelines for the calibration and operation of the Sotax MT-50 hardness tester using the 5 kg weight and gage blocks.

2.0 Scope

This procedure applies to the Sotax MT-50 hardness tester. This procedure provides comprehensive guidelines for the proper testing of tablet hardness as per USP <1217> Tablet Breaking Force.

3.0 Responsibility

- 3.1 It is the responsibility of the Metrologist or designee to keep this procedure aligned with current practices, and to calibrate the Sotax MT-50 hardness tester.
- 3.2 It is the responsibility of Production (Compression) personnel to follow this procedure.
- 3.3 It is the responsibility of Production 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
- 4.2 **USP** – United States Pharmacopeia

Standard Operating Procedure Calibration and Operation of the Sotax MT-50 Hardness Tester	SOP No G-209	Rev 0	Page 2 of 6
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5.0 References

- 5.1 G-201-F2, Form, Calibration Certificate
- 5.2 USP <1217> Tablet Breaking Force

6.0 Use Procedure

6.1 Location and General Setup

- 6.1.1 Set the Sotax MT-50 hardness tester on a level surface free of vibration.
- 6.1.2 Ensure the ambient temperature is between 4°C and 35°C, with a relative humidity between 10% and 75%, and no condensation.
- 6.1.3 Protect the unit from direct sunlight, dust, smoke, and corrosive fumes.

6.2 Preparation for Use

- 6.2.1 Ensure the hardness tester is connected to a power source on a level.
- 6.2.2 Turn on the unit and allow it to initialize. Allow unit to perform its automatic prestart check.
- 6.2.3 Verify that the pre-check was performed without issue.
- 6.2.4 Inspect the testing area and jaws for cleanliness; clean if necessary.

6.3 Hardness Testing

- 6.3.1 Use the menu buttons to navigate to test then select “Easy Test”.
- 6.3.2 Enter the number of samples to be tested next to the “H” field. Then press the green arrow.
- 6.3.3 Place a tablet in the test area according to product specifications.

Standard Operating Procedure Calibration and Operation of the Sotax MT-50 Hardness Tester	SOP No G-209	Rev 0	Page 3 of 6
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6.3.4 If no specifications are provided, follow these guidelines:

6.3.4.1 Tablets are placed face up.

6.3.4.2 Round tablets can be oriented any way.

6.3.4.3 Elongated tablets should have the longer axis parallel to the jaw.

6.3.5 Press the start arrow to initiate the test.

6.3.6 The left jaw will move to break the tablet, then retract, allowing for the next tablet to be placed.

6.3.7 Clean the test area as needed with a brush to remove debris.

6.3.8 Repeat the test for the specified number of tablets in the sample group.

6.3.9 Data recorded can be found in the list and statistic buttons at the top of the display.

6.4 Cleaning After Use

6.4.1 The hardness tester is a non-product contact surface.

6.4.2 Use a brush to remove broken tablets and clean the catch pan.

6.4.3 Clean the instrument carefully with a slightly dampened rag with all-purpose cleaner.

6.4.3.1 Ensure that no liquid enters the unit and wipe it off with a soft cloth.

6.4.3.2 Remove calcification by a suitable cleaning solvent.

6.4.3.3 Handle Plexiglas cover carefully and clean it with suitable cleaning solvent (no alcohol or acetone).

6.4.4 While cleaning, inspect the unit for wear and tear. Report any findings to the

Standard Operating Procedure Calibration and Operation of the Sotax MT-50 Hardness Tester	SOP No G-209	Rev 0	Page 4 of 6
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Metrologist or QC Laboratory Management.

7.0 Calibration Procedure

7.1 Setup for Calibration

7.1.1 Place the MT-50 hardness tester securely on a flat surface.

7.1.2 Connect the appropriate power cord and ensure the tester is powered on.

7.1.3 Navigate to Service, Calib.

7.1.4 Ensure appropriate calibration settings are selected via the Calib. Settings option.

7.1.5 Select Hardness then rotate unit onto its left side.

7.1.6 Attach the calibration kit as described:

7.1.6.1 Remove the fixed jaw by loosening the two screws, taking care not to drop the jaw.

7.1.6.2 Fix the guide block in place of the crushing jaw (ensure center hole is aligned).

7.1.6.3 Insert the calibration plate into the guide block, ensuring the shaft is fully inserted into the calibration cube.

7.2 Calibration

7.2.1 Press the “Run” button and place the 5 kg reference weight on the calibration plate. Ensure the weight is centered correctly.

7.2.2 Press the “Run” button again to begin the calibration process.

7.2.3 Wait for the message “Please wait...” to disappear and confirm the next

Standard Operating Procedure Calibration and Operation of the Sotax MT-50 Hardness Tester	SOP No G-209	Rev 0	Page 5 of 6
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calibration date displayed on the screen.

- 7.2.4 Press “Ok” to complete the calibration. Remove the reference weight and calibration kit.
- 7.2.5 Reinsert the fixed jaw and tighten both screws.
- 7.2.6 Return the MT-50 to its normal horizontal position.

8.0 Maintenance

- 8.1 Follow the preventive maintenance schedule as outlined in the Sotax MT-50 manual.
- 8.2 Ensure all maintenance activities are documented and any issues are reported to management.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/11/24	New procedure.	N/A	J. Nicholson