



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation & Calibration of Tablet Hardness Tester	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down the procedure for the operation & calibration of Tablet Hardness tester.

2.0 SCOPE:

This SOP is applicable to the tablet hardness testers in Quality Control Department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department.

Head – Quality Control Department.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Operation:

Make: Monsanto , Model: Tab

- 5.1.1 Check and ensure the hardness tester is clean & free from dust.
 - 5.1.2 Hold the tablet between the fixed and moving jaw in edgewise position.
 - 5.1.3 Turn the screw knob in clockwise direction slowly until the tablet breaks.
 - 5.1.4 Note down the reading on the scale.
 - 5.1.5 Record the result of hardness in the kilogram per square centimeter.
 - 5.1.6 Release the screw knob in anti clockwise direction.
 - 5.1.7 Ensure that holding jaw is free of tablet powder before placing the tablet for testing.
- #### 5.2 Calibration:
- 5.2.1 Calibration of tablet hardness tester is done by External Approved Laboratory.
 - 5.2.2 Calibration Frequency: Once in one year.
 - 5.2.3 If instrument is out of calibration, affix “UNDER MAINTENANCE” label and call



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for service engineer.

5.2.4 Note calibration activity in the Instrument log book.

5.3 Cleaning:

5.3.1 Clean the hardness tester by wiping with a clean dry cloth followed by wiping with a clean cloth soaked with potable water and wipe it dry with a clean dry cloth.

6.0 ABBREVIATION(S):

QCD – Quality Control Department

SOP – Standard Operating Procedure

NA – Not Applicable

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

NA

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION