



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

PERFORMANCE QUALIFICATION FOR TABLET HARDNESS TESTER

**PERFORMANCE QUALIFICATION
FOR
TABLET HARDNESS TESTER – 8M**



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1.0 Pre-Approval:

Signing of this Approval page of Performance Qualification Protocol No. VP/PQ/093 indicates agreement with the Performance Qualification approach described in this document. Should Modifications to the Performance Qualification become necessary, an addendum will be prepared and approved.

Written By	Signature	Date
Quality Assurance		

Checked By	Signature	Date
Production		
Quality Assurance		

Approved By	Signature	Date
Quality Assurance		
Plant Head		



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2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the performance attributes of the *Tablet Hardness Tester* critical to serve the intended purpose.
- To document the observations for future reference.
- To provide documented evidence that the *Tablet Hardness Tester* is operated and performed as per the Standard Operating Procedure.

2.2 Scope:

This protocol covers the performance qualification of *Tablet Hardness Tester*.

2.3 Responsibility:

The group comprising of representatives from each of the following departments shall be responsible for the overall compliance with this protocol:

- ◆ Production Department
- ◆ Quality Assurance Department

The Production and In Process Quality Control shall be responsible for Performing as well as the checking of the Performance Qualification along with the Quality Assurance and recording data as per the procedures outlined in this protocol.

Quality Assurance shall collect all the test data and shall compile the results to make the reports of qualification studies.

The Reports shall be checked by Quality Assurance.

The Quality Assurance and Plant Head shall finally approve the Qualification report.



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2.4 Requalification:

Performance Qualification to be repeated incase of

- ◆ Replacement of any major component.
- ◆ Major modification in the existing instrument.
- ◆ During monitoring if instrument is found to be malfunctioning.
- ◆ Shifting of the instrument from one location to another.

2.5 Instrument Identification

The subjected instrument is identified as *Tablet Hardness Tester.*

Model : **8M**

Serial No. :

In-house Instrument No. :

Name of the Supplier : *Dr. Schleuniger Pharmatron AG*

Purchase Order No. : _____ **Dated** _____

3.0 Performance Qualification

3.1 Performance Qualification Procedure

Perform the Qualification as per the following procedure.

- 3.1.1 Perform the calibration of the Hardness by using the calibrated 5.0 Kg standard weight and record the same in section 3.2.
- 3.1.2 Perform the calibration of the diameter by using the calibrated 10.0 mm gauze as standard and record the same in section 3.2.
- 3.1.3 Perform the Verification procedure for both, hardness and diameter, and record the same in section 3.2.
- 3.1.4 Report the deficiency from the specified function, if any in the section 3.3.



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3.2 Performance Qualification Test Data Sheet:

3.2.1 Calibration of the Instrument by 5.0 Kg Standard weight and 10 mm calibration gauze.

S.No	Test Particulars	Specified Function	Observations	Checked By
A)	CALIBRATION AND VERIFICATIONS OF DIAMETER			
1.	Move the cursor to the calibration menu and click the right arrow key.	The display shows Weight Thickness Diameter Hardness		
2.	Move the cursor to the Diameter and click right arrow key	The display shows Calibration Print last Accept. Range		
3.	Move the cursor to Acceptable range and click the right arrow key	The display shows Accept. range 0.20 mm		
4.	Press enter and move the cursor to the calibration menu and click the right arrow key	The display shows Start Calibration Press RUN		
5.	Press run or F10	The display shows References 0.00 mm Press run		
6.	Jaw will start moving and retract once it comes in contact with the opposite jaw	The display shows References 10.00 mm Press run		

Verified By:

Name: _____ Signature: _____ Date: _____



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S.No	Test Particulars	Specified Function	Observations	Checked By
7.	Keep the 10.00 mm gauge block in the jaw and press run or F10	The jaw moves and retracts back to its original position once it touches the gauge block The display shows Finished calibration OK Press stop		
		Display shows Next due date (DD.MM.YY) 09.2.23 Press Enter		
		Display shows Calibrations End Press < -		
8.	Move the cursor to the verifications menu and click right arrow key	The display shows WEIGHT THICKNESS DIAMETER HARDNESS		

Verified By:

Name: _____ Signature: _____ Date: _____



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S.No	Test Particulars	Specified Function	Observations	Checked By
9.	Move the cursor to the diameter menu and click right arrow key	The display shows Verify Print Last Accept. Range		
10.	Click the verify menu	The display shows Start Verification Values in [mm] Press RUN		
11.	Press run or F10	The display shows Enter Reference 0.00 mm Enter		
12.	Press Enter	Display shows Measure start Press run		

Verified By:

Name: _____ Signature: _____ Date: _____



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S.No	Test Particulars	Specified Function	Observations	Checked By
13.	Keep the references gauge block in the jaw and press run or F10. Jaw moves and retracts back to its original position once it touches the gauge block	The display shows Measure results Next : Press run End : Press stop		
14.	Press Stop	The display shows Next due date (DD.MM.YY) 17.02.03 Press Enter		
		The display shows Verification End Press < -		

Verified By:

Name: _____ Signature: _____ Date: _____



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S. No	Test Particulars	Specified Function	Observations	Checked By
B)	HARDNESS CALIBRATION AND VERIFICATION			
1.	Removing the pressing jaw by pulling to the left, that is the right – hand of the jaw	Jaw shall be removed		
2.	Place the instrument in the upright position, over the plaxiglass on the right side of the instrument	The instrument shall stand straight		
3.	Make sure that the instrument is steady	The instrument shall stand steady		
4.	Place the calibration arm over the load cell shaft	It should get properly fixed.		
5.	Move the cursor to the calibration menu and press the right arrow key.	The display shows Weight Thickness Diameter Hardness		
6.	Move the cursor to the hardness and press right arrow key	The display shows Calibrate Print last Accept. Range		

Verified By:

Name: _____ Signature: _____ Date: _____



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S.No	Test Particulars	Specified Function	Observations	Checked By
7.	Move the cursor to Acceptable range and press the right arrow key	The display shows Accept. range 0.40 kg		
8.	Press Enter and move the cursor to the calibrate menu and press the right arrow key	The display shows Start Calibration Press RUN		
9.	Press run of F10	The display shows Reference 0.0 kg Press run		
		Display shows Reference 5.00 kg Press run		
11.	Keep the 5.00 kg weight on the calibration arm and press run or F10	The display shows Finished calibration OK Press Stop		

Verified By:

Name: _____ Signature: _____ Date: _____



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S.No	Test Particulars	Specified Function	Observations	Checked By
12.	Remove the 5.00 Kg weight from the calibration arm	The display shows Next due day (DD.MM.YY) 17.02.03 Press Enter		
		Display shows Calibration End Press < -		
13.	Return the instrument in the normal operating position	Remove the calibration arm and install back the right pressing jaw		
14.	Removing the pressing jaw	Pull to the left, that is the right – hand of the jaw		
15.	Place the instrument in the upright position, over the plaxiglass on the right side of the instrument	The instrument shall stand straight		
16.	Make sure that the instrument is steady	The instrument shall stand steady		

Verified By:

Name: _____ Signature: _____ Date: _____



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S.No	Test Particulars	Specified Function	Observations	Checked By
	Place the calibration arm over the load cell shaft	It should get properly fixed.		
17.	Move the cursor to the verifications menu and press the right arrow key	The display shows Weight Thickness Diameter Hardness		
18.	Move the cursor to the hardness and press right key	The display shows Verify Print last Accept. range		
19.	Move the cursor to acceptable range and press the right arrow key.	The display shows Accept. Range 0.40 Kg		
20.	Move the cursor to the verifications arm and press the right arrow key	The display shows Start Verifications Values in (kg) Press RUN		

Verified By:

Name: _____ Signature: _____ Date: _____



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S. No	Test Particulars	Specified Function	Observations	Checked By
21.	Press run or F10	The display shows Enter References 0.00 Kg Press Enter		
22.	Enter in the value of the references and keep the 5.00 Kg weight on the calibration arm and press run	The display shows Measure start Press run		
		The display shows Measure result Next : Press run End : Press stop		
23.	Remove the 5.00 Kg weight			
24	Press STOP	Display shows Next due day (DD.MM.YY) 17.02.03 Press Enter		
25	Press Enter	Display shows Verification End Press < -		
26	Press left arrow key for three times to come back to the original menu.	Display shows the original menu.		
27..	Return the instrument in the normal operating position	Remove the calibration arm and install back the right pressing jaw		
27.	Press the reset button on the front plate of the instrument	The display shows the original menu		

Verified By:

Name: _____ Signature: _____ Date: _____



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Record the details of calibration and Verifications in following table:

Type of Calibration	Details of the Weight and Plate	Observations	Checked By (Sign / Date)
Standard 5.0 Kg Weight			
10 mm gauge			

Type of Verification	Details of the Weight and Plate	Observations	Checked By (Sign / Date)
Standard 5.0 Kg Weight			
10 mm gauge			

Verified By:

Name : _____ Signature : _____ Date : _____



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3.3.1 Performance Check with Product Tablets:

Details of the Sample :

Batch No. :

S.No.	Observations		Done By
	Hardness	Diameter	
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
Mini mum			
Maxi mum			
Avera ge			
SD			
RSD			

Verified By :

Name : _____ Signature : _____ Date : _____



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3.4 Deficiency (if any) and Corrective Action Report

If there is no deficiency, then write NA.

Description of deficiency and date observed:

Person, responsible for corrective action and date assigned:

Corrective actions taken and date conducted:

Conducted By: _____ Approved By: _____

Date: _____ Date: _____

Comments (if any):

Verified By:

Name: _____ Signature: _____ Date: _____



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4.0 Acceptance Criteria:

Performance Qualification shall be considered acceptable when all the conditions specified in various data sheets under section 3.0 have been met.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the instrument / component.



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5.0 Summary:

Checks	Observations Yes / No	Remarks (if any)
Whether the acceptance criteria of the protocol and specific checkpoints are met.		
A] Calibration and Verification of Diameter		
B] Hardness Calibration and Verification		
C] Performance Trial using Tablets		

5.1 Conclusion:

The Tablet Hardness Tester (8M) bearing Instrument No....., **is / is not** qualifying the Performance Qualification tests as per the Protocol No. The Instrument **can / cannot** be used for the routine analysis.

5.2 Post-Approval:

Name	Signature	Date
Quality Assuranc		
Quality Assurance		
Plant Head		



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6.0 Appendix:

6.1 Abbreviations and Definitions

PQ	- Performance Qualification
mm	- Millimeter
Kg.	- Kilogram
cm	- Centimeter
N.A.	- Not Applicable
Sr.	- Senior
S. No.	- Serial Number
AC	- Alternate Current
DC	- Direct Current
g	- Gram
RH	- Relative Humidity

Acceptance criteria : The product, instrument., and / or process specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject.

Performance Qualification : The documented verification that all aspects of a facility, utility, or equipment that can affect product quality perform as intended meeting predetermined acceptance criteria.

Validation : Establishing documented evidence that a system does what it purports to do.

Revalidation : Repetition of the validation process or a specific portion of it