OPERATIONAL QUALIFICATION

FOR

TABLET HARDNESS TESTER – 8M

PHARMA DEVILS	
QUALITY CONTROL DEPARTMENT	

OPERATIONAL QUALIFICATION FOR TABLET HARDNESS TESTER

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OPERATIONAL QUALIFICATION FOR TABLET HARDNESS TESTER

1.0   Pre-Approval:

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

Written By	Signature	Date
Quality Control		

Checked By	Signature	Date
Production		
Quality Assurance		

Approved By	Signature	Date
Quality Assurance		
Plant Head		

OPERATIONAL QUALIFICATION FOR TABLET HARDNESS TESTER

2.0   Overview:

2.1   Purpose:

The purpose of this protocol is:

- To verify the operational attributes of *Tablet Hardness Tester 8M,* critical to serve the intended purpose.
- To establish the suitability of the draft SOP prepared for the operation of System.
- To document the observations for future reference.

2.2   Scope:

This protocol covers the operational qualification of Tablet Hardness Tester 8M.

2.3   Responsibility:

The validation 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
♦ Engineering Department

The Production and -Engineering shall be responsible for checking the operations and recording data as per the procedures outlined in this protocol.

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

The Reports shall be checked by Production and Quality Assurance.

The post approval of the qualification shall be done by the Quality Assurance and plant Head.

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2.4   Requalification:

Operational 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 instrument is identified as ***Tablet Hardness Tester,***

Dr. Schleuniger Pharmatron AG

Model   : **8M**

Serial No.   :

In-house Instrument No.   :

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

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

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3.0   Operational Qualification Procedure

1) A draft SOP shall be prepared on the basis of manufacturer guide / instrument manual for operation before the Qualification testing.

2) Prior to the Qualification test, the Personnel shall be trained by the Engineer from the Manufacturer / supplier on the operational features of the instrument. This training shall be recorded in Section 3.1.

3) The trained personnel shall carry out the Operational Qualification along with the Service Engineer, following the Procedures mentioned under Section 3.2.1 for Key Functionality and Safety Features. Record the observations of Qualification Test in Test Data Sheet of Section 3.2.1. Checkpoints designed for the purpose of OQ are also aimed at verification of these draft SOPs.

4) Operate the instrument as per the draft SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.3.

5) Report the deficiency from the specified function, if any in the section 3.4

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3.1   **Training**   **Date:** _____

Title: Tablet Hardness Tester – 8M

Name of the Trainers: _____

S.No.	Name of the Trainee	Employee Number	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Signature of Trainer(s): _____

Date: ____ _____

3.2. **Key Functionality & Safety Features:**

A. **Purpose:**

The purpose of this procedure is to demonstrate that the control panel and other manual operations (if any) of Tablet hardness Tester – 8M function as specified by the manufacturer.

B. **Testing:**

1. Check all the displays on the panel are identified.
2. Turn on the power from the electrical panel.
3. Set the control(s) on the panel.
4. Verify functionality of each component on the panel as well as the keyboard against its Specified functions.
5. Observe and record the responses in the Test Data Sheet, under section 3.2.1.

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3.2.1   TEST DATA SHEET (Confirmation of Services Connection):

S.No.	Test Particulars	Specified Function	Observations	Checked By
A	**SETTINGS**			
1.	Switch ON the A/C power supply and the switch at the back of the instrument	The display shows TEST SETUP PRODUCT SETUP GLOBAL SETTINGS CALIBRATION		
2.	Move the curser down by using the down arrow key on the keyboard or the instrument	Display shows VERIFICATIONS PRINT SECURITY		
3.	Press the right arrow key	The display shows MODE PRINTOUT REPORT LIMITS		
4.	Press the right arrow key	The display shows MODE MANUAL		
5.	Select the mode either MANUAL or AUTOMATIC	Use the up and down key and press ENTER		

Verified By:

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S.No.	Test Particulars	Specified Function	Observations	Checked By
6.	Move the curser down to PRINTOUT and press the right arrow key	The display shows PRINTOUT GRAPH		
7.	Select the type of print out. Use up and down key and then press ENTER	Cursor should move as per movement		
8.	Move the cursor to REPORT and press the right arrow key	The display shows DATE GRAPH		
9.	Press the right arrow key	The display shows HEADER SETUP STATISTICS NOMINAL		
10.	Press the right arrow key	The display shows HEADER ON		
11.	Select the header. Use up and down key and press ENTER	Cursor should move as per movement		
12.	Move the cursor to setup and press right arrow key	The display shows SETUP ON		

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Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
13.	Select the SETUP. Use up and down key and press ENTER	Cursor should move as per movement		
14.	Move the cursor to STATISTICS and press the right arrow key	The display shows STATISTICS ON		
15.	Select the STATISTICS. Use up and down key and press ENTER	Cursor should move as per movement		
16.	Move the cursor to NOMINAL and press the right arrow key	The display shows NOMINAL ON		
17.	Move the cursor to the PLAUSIBILITY and press right arrow key	The display shows PLAUSIBILITY ON		
18.	Similarly put "ON" the T1 Limits, T2 Limits, Mean, Max, Min, Range, S Absolute, S Relative, T1 Violation, T2 Violation and Values. Use up and down key and press ENTER	Cursor should move as per movement		

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S.No.	Test Particulars	Specified Function	Observations	Checked By
19.	Press Left arrow key	The display shows DATA GRAPH		
20.	Move the cursor to the GRAPH and press the right arrow key	The display shows HEADER LINE GRAPH HISTOGRAM PLOT BREAK		
21.	Press the right arrow key	The display shows HEADER ON		
22.	Press ENTER	The display shows HEADER LINE GRAPH HISTOGRAM PLOT BREAK		
23.	Similarly move the cursor to each item	Individual item should be in "ON" position		
24.	Press the right arrow key	The display shows DATA GRAPH		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
25.	Again Press the Left arrow key	The display shows MODE PRINTOUT REPORT LIMITS		
26.	Move the cursor to the LIMITS and click the right arrow key	The display shows PLAUSIBILITY T1, T2		
27.	Press on the right arrow key	The display shows *PLAUSIBILITY abs		
28.	Press ENTER key	The display shows PLAUSIBILITY T1, T2		
29.	Move the cursor to the T1, T2 and click right arrow key	The display shows *T1, T2 abs		
30.	Press twice on the left arrow key	The display shows TEST SETUP PRODUCT SETUP GLOBAL SETTING CALIBRATION		

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S.No.	Test Particulars	Specified Function	Observations	Checked By
31.	Move the cursor to the PRODUCT SETUP and Press right arrow key	The display shows SELECT PROD # VIEW EDIT DELETE		
32.	Press the right arrow key	The display shows SELECT PROD # 0		
33.	Select the product number. Use Up and Down arrow key and press ENTER	Cursor should move as per key movement		
34.	Move the cursor to EDIT and Press right arrow key	The display shows PRODUCT # NAME NUMBER BATCH ID		
35.	Enter the Name, Number , Batch ID ,Press ID, Container Number, Operator and Comment id applicable. Use the letter keys and the Number keys of the key board	Should display the respective number and letters		
36.	Move the cursor to the sample size and press 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
37.	Press on the right arrow key	The display shows WEIGHT 0		
38.	Press ENTER	The display shows WEIGHT THICKNESS DIAMETER HARDNESS		
39.	Move the cursor to each of the parameter and enter the No. of tests to be carried out for each parameters and then Press left arrow key	The display shows SAMPLE SIZE PARAMETER BACKOFF DELAY		
40.	Move the cursor to the parameter and Press the 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
41.	Press the right arrow key	The display shows UNIT NOMINAL + PL % - PL % + PL abs - PL abs + T2 % - T2 % + T1 % - T1 % +T2 abs - T2 abs +T1 abs - T1 abs		
42.	Make all the above item zero. Use up and down key	Should display zero		
43.	Press the left arrow key	The display shows WEIGHT THICKNESS DIAMETER HARDNESS		

Verified By:

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S.No.	Test Particulars	Specified Function	Observations	Checked By
44.	Move the cursor to the THICKNESS and click the right arrow key	The display shows UNIT NOMINAL + PL % - PL % + PL abs - PL abs + T2 % - T2 % + T1 % - T1 % +T2 abs - T2 abs +T1 abs - T1 abs		
45.	Similarly Move the cursor to the DIAMETER and HARDNESS	The display shows UNIT NOMINAL + PL % - PL % + PL abs - PL abs + T2 % - T2 % + T1 % - T1 % +T2 abs - T2 abs +T1 abs - T1 abs		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
46.	Press the left arrow key	The display shows SAMPLE SIZE PARAMETERS BACKOFF DELAY		
47.	Move the cursor to BACK OFF and press the right arrow key and enter the back off distance depending on the size of the tablet. Use the numerical or up and down keys of the key board	Cursor should move to back off distance set		
48.	Similarly enter the delay time only if the test to be carried out in the AUTO mode. Use the numerical or up and down keys of the key board	The numerical values should be displayed as per respective key.		
49.	Move the cursor to UD factor and enter in the factor if you are using any other unit than N, kp, or Sc. Use the numerical or up and down keys of the key board	The numerical values should be displayed as per respective key.		
50.	press twice the left arrow key	The display shows TEST SETUP PRODUCT SETUP GLOBAL SETTING CALIBRATION		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
51.	Move the cursor to GLOBAL SETTING and press right arrow key	The display shows LANGUAGE DEFAULT DATE FORMAT DAT E TIME COMMUNICATIO N BALANCE AUDIBLE SIGNAL FACTORY DEFAULTS FEED RATE PRIMARY HEADER CAL. INTERVAL VER. INTERVAL CHR / DEFAULTS PAPER FORMAT PRINTER TYPE TEST STAMP TECHNICAL MODE		
52.	Choose the language, date format, date, time, type of balance, printer type, paper format. Press the left arrow key	The display shows TEST SETUP PRODUCT SETUP GLOBAL SETUP CALIBRATION		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Specified Function	Observations	Checked By
B)	**OPERATION**			
1.	Switch the instrument "ON"	The beep sound is produced and display shows 8M – 400 N 01921 – DH – 01921 Version 1.35 Press any key		
2	Keep the instrument in MANUAL mode. Move the cursor to TEST SETUP and select MANUAL mode	Instrument should be in MNAUAL Mode.		
3	Keep the first tablet in the jaw and press the "RUN" button on the frontplate or F10 key on the keyboard	Instrument will display that the tester is in manual mode and both the date and time of test		
4	Press again the "RUN" or F10.	the slide will move forward at full speed		
5.	When the slide contacts that tablet, it will retract the backoff distance set during the configuration and stop	The display will show 0D : 0.00 mm 0H : 0.00 kp or any other unit set		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Specified Function	Observations	Checked By
6.	Press " RUN " or F10.	The jaw will move and on contact with the tablet, will give a beeps sound and The display shows 1D : X mm or any other specific value 0H : 0.00 kp or any other unit set		
7.	The jaw automatically moves and break the tablet.	The display shows 1D : X mm or any other specific value 1H : Y kp or any other unit set		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Specified Function	Observations	Checked By
08.	After the completion of the specific test.	it will show the specific parameter with the tick mark.		
09.	Stopping of test in middle	Use the "STOP" key on front plate or F11 key on the keyboard		
C)	**OPERATION OF THE INSTRUMENT WITHOUT SOFTWARE IN AUTO MODE**			
1.	Switch the instrument "ON"	The beep sound is produced and display shows 8M – 400 N 01921 – DH – 01921 Version 1.35 Press any key		
2.	Set the number of measurment to be carried out by going in the sample size and keping the weight paraneters to zero. This can be done by going in the sample size and keeping the weight parameters to zero	Number of measurements can be set		
3.	Keep the instrument in AUTO mode and set the delay time as requires	Move the cursor to TEST SETUP and select AUTO mode		
4.	Keep the first tablet in the jaw and press the "RUN" button on the frontplate or F10 key on the key board	Instrument will display that the tester is in AUTO mode and both the date and time of the test started		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Specified Function	Observations	Checked By
5.	Press again the "RUN" or F10.	The slide will move forward at full speed		
6.	When the slide contacts the tablet, it will react the back off distance set during the cinfuguration and stop.	The display shows 0D : 0.00 mm 0H : 0.00 kp or any other unit set		
7.	Jaw will move automatically and on contact with the tablet, will give a beep sound.	The display shows 1D : X mm or any specific value 0H : 0.00 kp or any other unit set		
8.	Jaw will automatically move and break the tablet	The display shows 1D : X mm or any specific value 1H : Y kp or any other unit set		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATIONAL QUALIFICATION FOR TABLET HARDNESS TESTER

S.No	Test Particulars	Specified Function	Observations	Checked By
09.	The jaw will start moving automatically again	After the set delay time for testing the next tablet		
10.	Once the specific test is over	It will show that parameters with tick mark.		
11.	Stopping of test in middle	Use the "STOP" key on front plate or F11 key on the keyboard		

Verified By:

Name: _____ Signature: _____ Date: _____

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3.3   SOP Verification:

Draft SOP No.   : SAP/0

Title   : Operation, Calibration and cleaning of Tablet Hardness
                                    Tester (8M)

Operate the instrument. as per the draft SOP and record the details given below:

Operated By :   ……………………

Checked By :   …………………...

The operating personnel understand and follow the SOP description (Yes/No) : YES

Changes required in draft SOP (If any) : _____

_____

_____

SOP to be revised (Yes/No) :

If yes, Review No. _____

Remarks: SOP Confirmed / Not Confirmed

Verified By:

Name : _____ Signature : _____ Date : _____

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3.2   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: _____

4.0   Acceptance Criteria:

Operational 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 for each of the following		
A] Setting		
B] Operation in Manual Mode		
C] Operation in Auto mode		

5.1   Conclusion:

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

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5.2 Post-Approval:

Name	Signature	Date
Quality Control		
Quality Assurance		
Plant Head		

6.0 Appendix:

6.1 Abbreviations and Definitions

OQ	- Operation Qualification
mm	- Millimeter
Min	- Minutes
V	- Volt
Hz	- Hertz
cm	- Centimeter
N.A.	- Not Applicable
S. No.	- Serial Number
Sr.	- Senior
mV	- milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
DC	- Direct Current
g	- Gram
RH	- Relative Humidity
USP	- United States Pharmacopoeia
SOP	- Standard Operating Procedure

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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.
Operational qualification	The documented verification that all aspects of a facility, utility, or equipment that can affect product quality operate as intended throughout all anticipated ranges.
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