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1.0 OBJECTIVE

To lay down a procedure for cleaning, operation and calibration of Tablet Hardness Tester (Pharmatron Dr. Schleuniger Model-MultiTest 50)

2.0 SCOPE

This procedure is applicable to the cleaning, operation and calibration of Tablet Hardness Tester (Pharmatron Dr. Schleuniger MultiTest 50) in production area.

3.0 RESPONSIBILITY

Technical Associate   : Cleaning and Operation

Officer and Executive : Calibration, Supervision

Head Production   : SOP compliance

4.0 DEFINITION (S)

NA

5.0 PROCEDURE

5.1 CLEANING

5.1.1 De-dust the tablet platform of apparatus with the help of brush and collect all the powder and crushed tablet in tablet collecting bowl. And finally dispose the tablets in disposal bin in respective area.
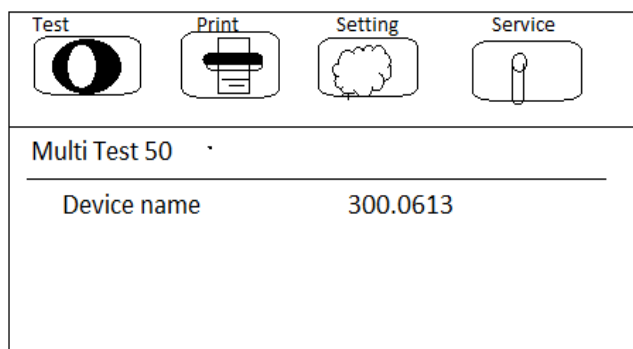
5.1.2 Clean the apparatus with dry lint free cloth followed by moist lint free cloth.

5.1.3 Clean the apparatus jaw with dry lint free cloth than moist lint free cloth followed by 70% v/v IPA

5.2. FOR TEST

5.2.1. Switch ON the apparatus, the screen displays as:-

5.2.2.

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5.2.3   Press the Test icon on, screen displays as:-
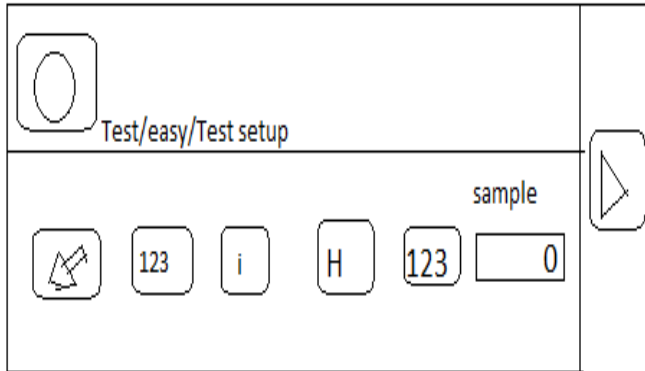
5.2.4   **FOR EXTENDED TEST SETUP** (i,e. details of product name batch No and operator name) press the i icon screen display as :-
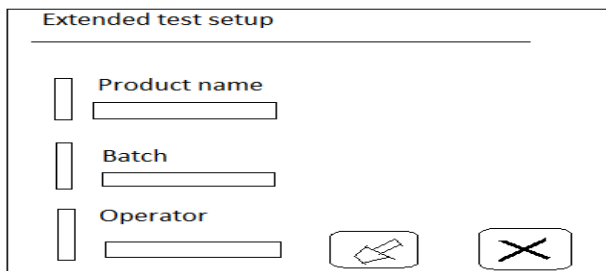
5.2.5   Press the erase icon and the erase previous data and update the new data of the batch details i.e. product name its batch number and operator's name. After updating all details press the X icon and come back to previous screen (fig. No-5.2.3)

5.2.6   For testing the sample quantity (as per requirement or as per the batch manufacturing record) press the 123 icon screen display as:-
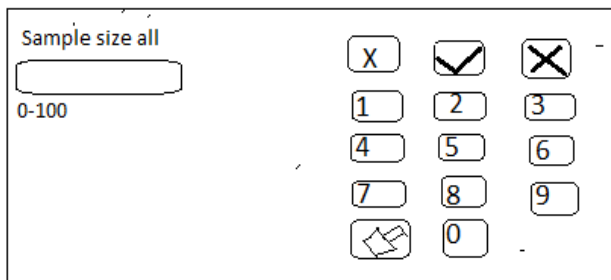
5.2.7   Press the erase icon and erase the previous data and update the new data (as per batch manufacturing record). After updating the sample quantity press the X icon on the screen and come back to previous screen fig. No-5.2.3

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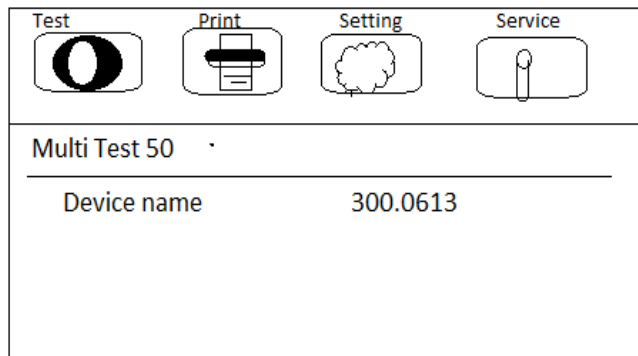| **STANDARD OPERATING PROCEDURE**	
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5.2.8   After updating all the batch details as sample quantity, product name batch No and operator's name on screen (fig. No-5.2.3) then press the RUN icon and perform the test.
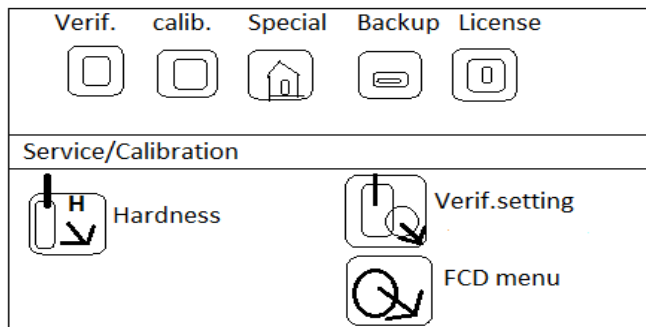
5.2.9   After completion of the test print will generate automatically and attach the print along with the batch record.

5.3   CALIBRATION SETTING/CALIBRATION OF HARDNESS TESTER

5.3.1   Switch ON the apparatus, the screen displays as:-

5.3.2   For calibration of apparatus press the service icon, screen display as:-

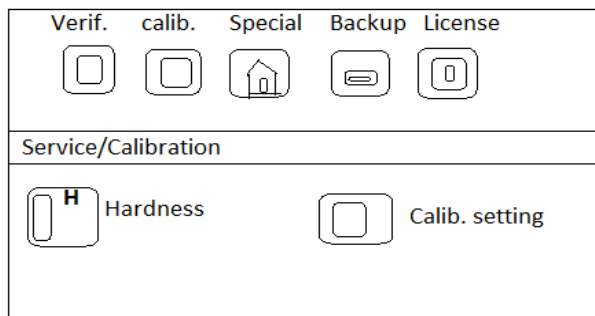
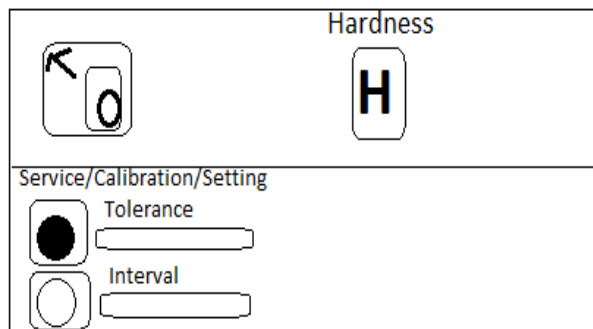**5.3.3   FOR CALIBRATION SETTING**

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5.3.3.1   Press the Calib. icon on the top of the screen then display show as:-

5.3.3.2   Press the Calib. Setting icon screen display as:-

5.3.3.3   Fill the tolerance limit and calibration interval on the screen.

5.3.3.4   After updating the tolerance limit and calibration interval come back on previous screen (Fig. No.5.3.3.1)

**5.4.   CALIBRATION OF HARDNESS TESTER:**

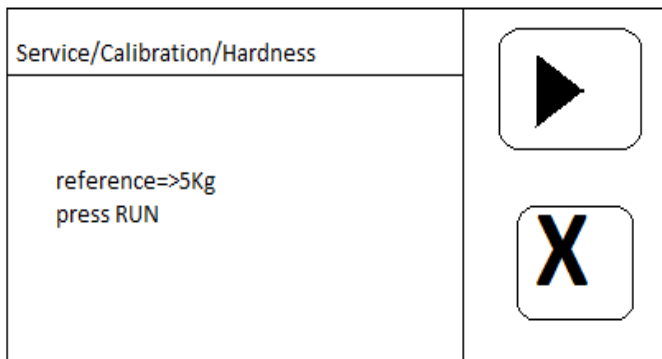|	PHARMA DEVILS	
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5.4.1   Press the Hardness icon, on the screen (Fig. No-5.3.3.1) display show as:-

Service/Calibration/Hardness

insert calibration adapter, press RUN.

▶

X
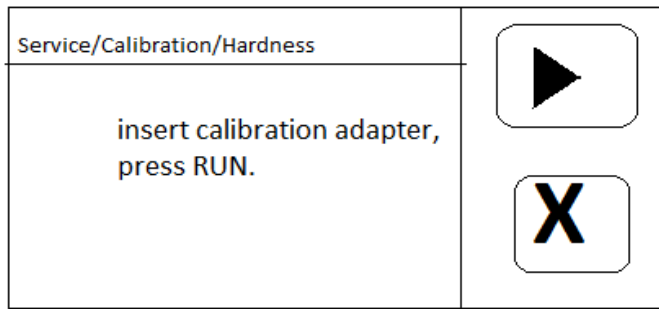
5.4.2   Place the machine in vertical position, and insert the adapter on the jaw and press RUN icon screen display as:-

Service/Calibration/Hardness

reference=>5Kg
press RUN

▶

X

5.4.3   Then place 5 kg certified weight on the platform genteelly. then press RUN key and calibration will started.

5.4.4   After completion of the calibration press OK icon, as in below figure.

Service/Calibration/Hardness

Due DD.MM.YYYY
PRESS OK

✓

X

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5.4.5   After pressing OK screen display as:-
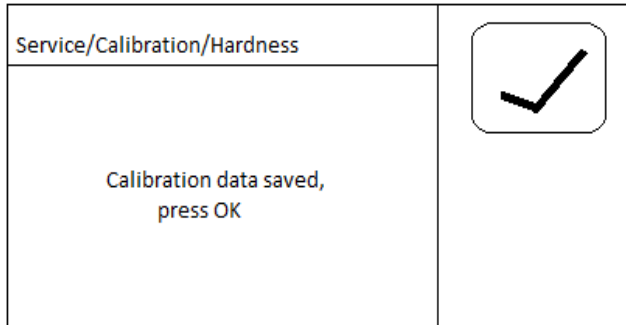
5.4.6   And press OK icon and remove the adepter.

5.5.   VERIFICATION OF HARDNESS TESTER

5.5.1   On home screen fig. No-5.2.2 press service icon, screen display as:

5.5.2   Press the verif. setting icon screen display as:

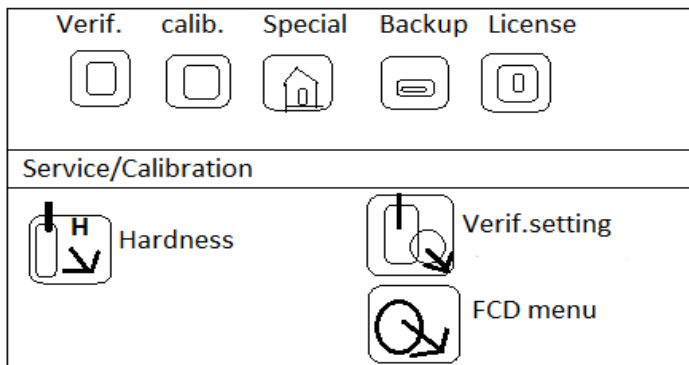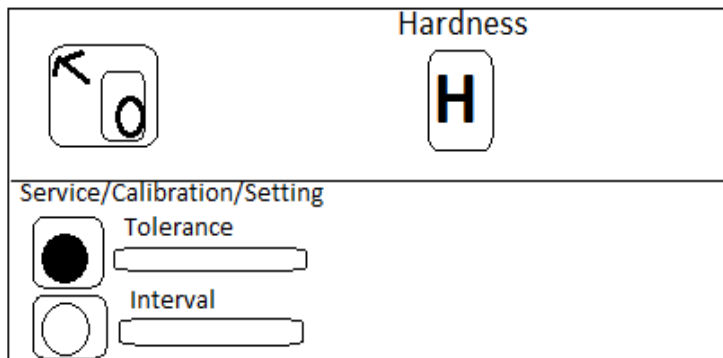|	PHARMA DEVILS	
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5.5.3   Update the tolerance limit and verification interval on the screen and come back on previous screen as fig. No-5.5.1 and press Hardness icon, screen display as:

5.5.4

Press the RUN icon screen display as:-

5.5.5   Fill the reference weight and press RUN icon and verification will start.

5.5.6   After completion of the verification following screen will be show and press OK icon.

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5.6 **PRINT OPTION DURING CALIBRATION/VERIFICATION:**

5.6.1 After performing calibration or verification print will be generated on the main HOME screen by pressing the Print icon as in Fig. No-5.3.1

5.6.2 By pressing the print icon screen display as:-
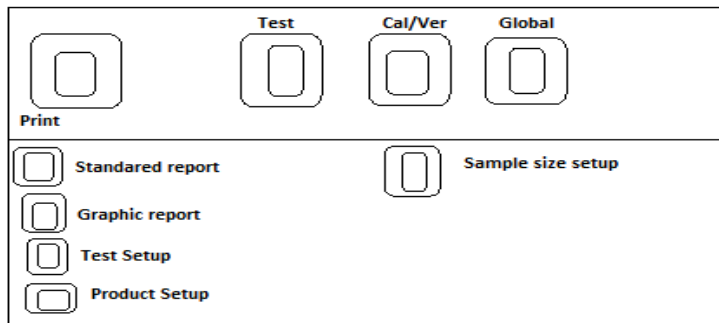
5.6.3 Then press the Cal/Ver icon screen display as:-
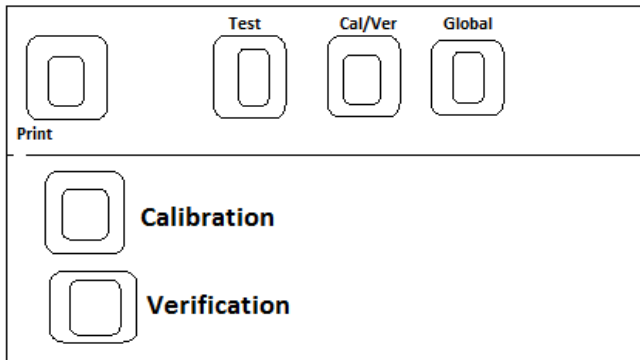
5.6.4 For calibration or verification print press the respective icon of calibration/verification

5.7. **CALIBRATION AND VARIFICATION FREQUENCY**

* The Calibration for Hardness should be done half yearly (i.e. once In six month).

* The Verification for Hardness should be done once in Month.

6.0 **ABBREVIATION (S)**

N : Newton

Kg : kilogram

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7.0   **RERERENCE (S):**

Nil

8.0   **ANNEXURE (S):**

Annexure I: Calibration & Verification Record of Hardness Tester (Multi-Test 50)
Annexure II: Incident Report Register
Annexure III: In-process Failure Report (Hardness Test)
Annexure IV: Time/ Date Synchronization

9.0   **DISTRIBUTION:**

Master Copy   : Quality Assurance

Controlled copy (S) : Production department, Quality Assurance

Reference copy (S)   : Production department

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ANNEXURE I

CALIBRATION & VERIFICATION RECORD OF HARDNESS TESTER (MULTI-TEST 50)

Equipment Id.		Area	
Equipment Serial No.		Standard weight used for calibration / verification	5.0kg
Standard weight Id.		Standard weight calibration due date	

CALIBRATION OF HARDNESS TESTER (Frequency 1st Week of Every 3 Month)

Standard weight used for calibration:	
Calibration Status: @	OK / NOT OK

Calibration done on:		Calibration Due on:	
Calibration Done by:		Calibration checked by:	

VERIFICATION OF HARDNESS TESTER (Frequency 1st Week of Every Month)

Standard weight used for Verification	

Verification status: @	OK / NOT OK	Deviation against reference:	
Verification done on:		Verification Due on:	
Verification Done By		Verification checked by:	

Note: **Strike out the calibration / verification table which is not applicable.**
    @ Mark "OK" if acceptance calibration / verification is "YES".

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ANNEXURE II
INCIDENT REPORT REGISTER

S.No.	Date	Incident No	Incident Details	Area/ Section	Issued By	Issued To	Nature of incident	Document no if raise with date	Sign /date with Remarks any

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ANNEXURE III
In-process Failure Report (Hardness Test)

Date of the incident observed:-	Incident No:
Time of the incident observed:-	
Product Name:-	
Batch No:-	
Market:-	
Instrument Name:-	
Instrument ID:-	
Calibration Status:-	

Brief Description of Incident:-	
Initiator Sign:	Date:

Primary Investigation and Comments(HOD/Shift In-charge):-	
Sign:	Date:

Evaluation by IPQA:-		
Nature of Incident: (Tick the option)	Related to Product	
	Related to Human Intervention	
	Related to Equipment	
Sign:	Date:	

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Incident No:
Comments By HOD/Designee (if Required):-

Sign:	Date:

Comment by Head QA/Designee:-
NA / Deviation / Change control / CAPA / Others:_____ **(Encircle which is applicable)**
Sign & Date (QA):-
Closure:-

Document No:-_____	Date of initiation_____
Sign/Date(User HOD):	Sign/Date(Head QA):

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ANNEXURE IV
Time/ Date Synchronization

Instrument ID:_____

Frequency for time/ Date synchronization checking is every first week of the month. Observation shall be recorded after the time/ date synchronization.

Date	Hardness Tester Time/ Date	Main Server Time/ Date	Computer Time/ Date	Time/ Date Synchronization OK/ Not OK	Done By Sign/ Date