



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the procedure for the Operation and Calibration of Tablet Tester.

2.0 SCOPE:

This procedure is applicable to the Operation and Calibration of Tablet Tester used in Quality Control department.

3.0 RESPONSIBILITY:

Executive, Officer - QC

Head - Quality Control

4.0 PROCEDURE :

4.1 Operation:

- 4.1.1 Check and ensure that all the systems of the machine are properly connected.
- 4.1.2 Check and ensure the cleanliness of the Tablet Tester.
- 4.1.3 Switch ON the instruments from the main switch on the rear panel of the instrument.
- 4.1.4 At power on initial screen appears as -

CAMPBELL ELECTRONICS

MODEL NO : WWTDH 550

SERIAL NO : 1505045

S/W : H550 3.0

PRESS 'ENTER' KEY TO CONTINUE _

- 4.1.5 After pressing 'ENTER' operator login screen appears as-
-



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

CAMPBELL ELECTRONICS

USER NAME :

PASSWORD :

‘P’: CHANGE PASSWORD

‘C’: CONTINUE

‘ESC’: EXIT_

4.1.6 Selects continue by pressing ‘C’ and put user name and password to login.

4.1.7 Selects change password option by pressing ‘P’ and put user name, old password, new password, confirm password in order to change the old password.

4.1.8 Selects exit by pressing ‘Esc’ key then control goes back to Main menu.

4.2 Create recipe:

4.2.1 By pressing ‘R’ key the screen will show Create recipe menu. Here different recipes can be created. It starts from recipe no. 1.If we trying to create new recipe then recipe will auto increment to 2

4.2.2 Put Product name and Press ID. Then press “ENTER” key

EDIT RECIPE

RECIPE NO: 2

UNIT OF WEIGHT: [G]M/[M]G

NOMINAL WEIGHT: 0.00

TOLERANCE: [A]BS/[P]CENT

+T1: 0.00

-T1: 0.00

+T2: 0.00

-T2: 0.00

Create Recipe Menu Screen 2



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

DO YOU WANT TO PRINT OUT?
'P' : CONTINUE WITH PRINT OUT
'C' : CONTINUE WITHOUT PRINT OUT _

Start Test Menu Screen 1

4.5.2 It is necessary for the end user to have print report of the last data conducted by pressing "P" key.

4.5.3 If continue without printing, and then go for "C". It appears as-

TEST NO :
RECIPE NO : _

Start Test Menu Screen 2

4.5.4 Put the recipe no. regarding the test tablet and press 'ENTER' key. Then next Start test menu appears as –

4.5.5 TEST NO :
RECIPE NO :

BATCH NO : _

Start Test Menu Screen 3

4.5.6 Press 'ENTER' Key after putting the Batch no. to view the next screen. It appears as-



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

TEST No:

RECIPE No:

VALID SAMPLES : 170

FOR WEIGHT : 50

FOR WIDTH : 50

FOR THICKNESS : 10

FOR DIAMETER : 50

FOR HARDNESS : 10

Start Test Menu Screen 4

Start Test Menu Screen 4

- 4.5.7 If 50 samples for weight, 50 samples for width, 10 samples for thickness, 50 samples for diameter and 10 samples for hardness check to be performed
- 4.5.8 Add the above value above the screen and press ““ENTER”” key to view the next screen of Auto and Manual mode screen.
- 4.6 Test in manual mode:**
- 4.6.1 After press ““ENTER”” key to Start test menu screen 4. Then next Start test menu appears, where unit ask about test mode whether Auto mode or Manual mode. It appears as-

TEST NO:

[A]UTO / [M]ANNUAL_

Start Test Menu Screen 5



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.6.2 For auto mode press 'A' key. For manual mode press 'M' key.

4.6.3 If manual mode selects ,the display appears as-

TEST NO:

[A]UTO / [M]ANNUAL_

'ENTER' BACK OF DISTANCE (2mm-15mm) : _

Start Test Menu Screen 6

4.6.4 After putting the back off distance screen displays as-

CAMPBELL ELECTRONICS

NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
	-----SAMPLE NO 1-----				
1					
	ESC: ABORT TEST_		'ENTER': CONTINUE		

Start Test Menu Screen 7

4.6.5 Place the tablet towards the load cell and press 'ENTER' key two times.

4.6.6 Place the tablet Horizontally to measure 'Width'. Jaw will start moving forward until tablet touches load cell without breaking tablet and goes back to home position.

CAMPBELL ELECTRONICS

NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
	-----SAMPLE NO 1-----				
1		9.49			

Start Test Menu Screen 8



STANDARD OPERATING PROCEDURE

Department: Quality Control

SOP No.:

Title: Operation and Calibration of Tablet Tester

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

4.6.7 Place the tablet Vertically to measure 'Thickness'. Jaw will start moving forward until tablet touches load cell without breaking tablet and goes back to home position.

CAMPBELL ELECTRONICS					
NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
-----SAMPLE NO 1-----					
1		9.49	6.70	18.55	
Start Test Menu Screen 9					

4.6.8 Place the tablet Horizontally to measure 'Diameter'. Jaw will start moving forward until tablet touches load cell without breaking tablet and goes back to home position.

CAMPBELL ELECTRONICS					
NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
-----SAMPLE NO 1-----					
1		9.49	6.70	18.55	
Start Test Menu Screen 10					

4.6.9 Place the tablet Horizontally to measure 'Hardness'. Jaw will start moving forward until tablet breaks and goes back to home position.

CAMPBELL ELECTRONICS					
NO.	WEIGHT	WIDTH	THICK	DIAM	HARDNESS
	50	50	10	50	10 N
-----SAMPLE NO 1-----					
1		9.49	6.70	18.55	130.42



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Start Test Menu Screen 11

4.7 Reports:

4.7.1 In main menu by pressing the 'P' key ,then 'Report Menu' appears as –

CAMPBELL ELECTRONICS

'T' : LAST TEST REPORT
'C' : CALIBRATION REPORT
'D' : DISTANCE VERIFICATION REPORT
'W' : HARDNESS VERIFICATION REPORT
'R' : RECIPE REPORT
'U' : USER REPORT

Report Menu Screen

4.8 Calibration

4.8.1 Press the 'C' key in the Main Menu to open the Calibration/Verification Menu Screen appears as-

CAMPBELL ELECTRONICS

'V' :- DISTANCE VERIFICATION
'L' :- HARDNESS VERIFICATION
'C' :- DISTANCE CALIBRATION
'Q' :- HARDNESS CALIBRATION

'ESC' :- EXIT

Calibration/Verification Menu Screen

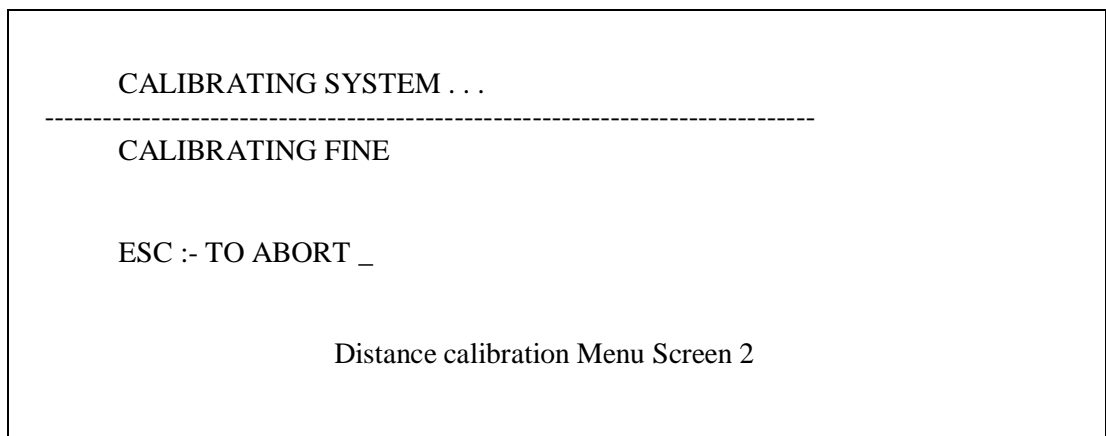
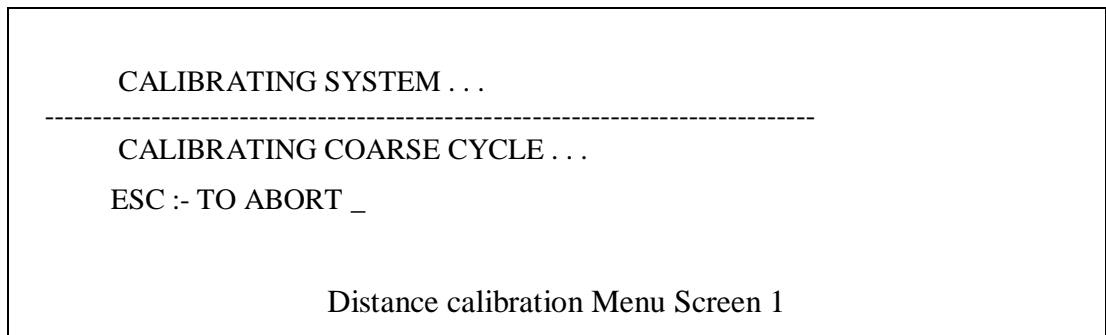


STANDARD OPERATING PROCEDURE

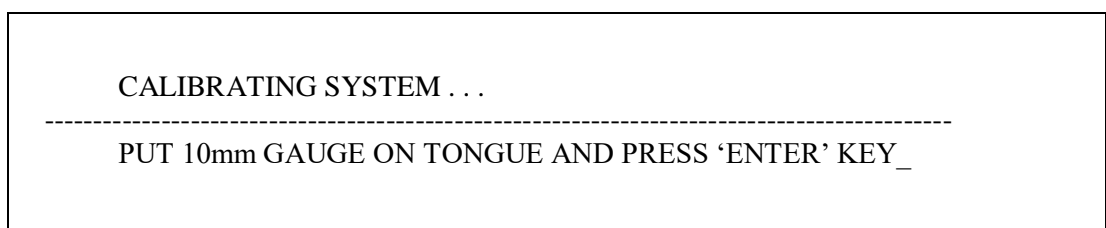
Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.8.2 Distance Calibration:

- 4.8.2.1 In the Calibration Menu, press 'C' key to enter into the Distance Calibration Menu Screen.
- 4.8.2.2 The unit will show Coarse Calibration first followed by Fine Calibration as shown below.
- 4.8.2.3 Here, tongue starts moving forward from home position, then tongue jaw touches the load cell and comes back to ensure the Zero position.



- 4.8.2.4 After ensuring the zero position the display appears as-





STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ESC :- TO ABORT

Distance calibration Menu Screen 3

- 4.8.2.5 To continue the calibration, put 10 mm gauge on tongue and press 'ENTER' key.
If the result is in acceptable limits the unit will complete the calibration and display
4.8.2.6 will return to main menu otherwise the display will prompt the following screen.

CALIBRATING SYSTEM . . .

GAUGE DIMENSION NOT IN ACCEPTANCE LIMIT
CALIBRATION ABORTED.

“ENTER” :- TO ABORT

Distance calibration Menu Screen 4

4.8.3 Hardness Calibration:

- 4.8.3.1 In the Calibration/Verification Menu Screen press the 'Q' key to 'ENTER' in to the
'Hardness Calibration Menu Screen' appears as-

CAMPBELL ELECTRONICS

HARDNESS CALIBRATION

DO YOU WANT TO CALIBRATE FOR HARDNESS?

'ENTER' : CONTINUE

ESC : EXIT_

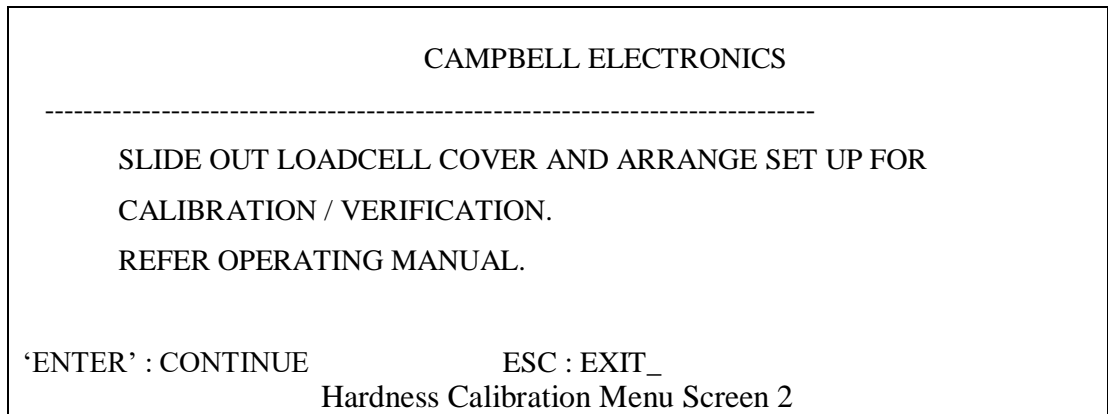


STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

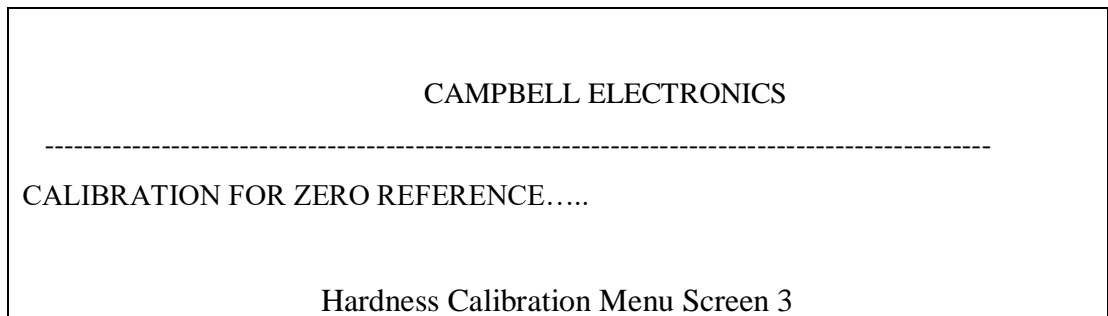
Hardness Calibration Menu Screen 1

4.8.3.2 After pressing “ENTER” in above menu screen the display appears as-

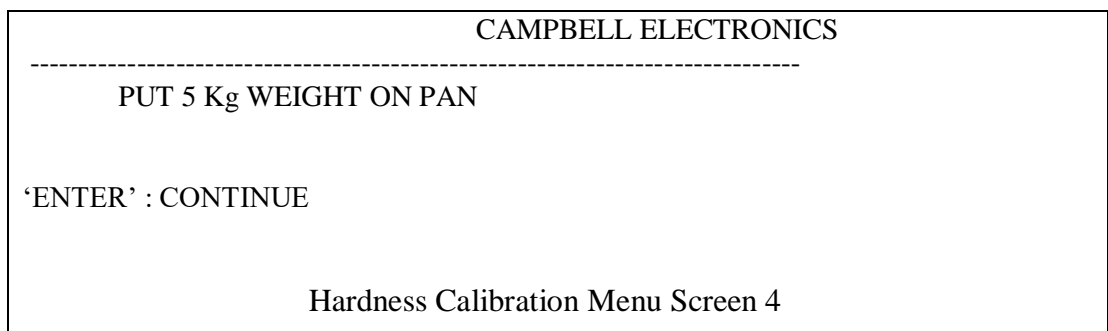


4.8.3.3 Remove the Load Cell Window Cover with the help of a screw driver.

4.8.3.4 Then remove the Allen screw by 4.0 mm Allen key and remove the Load Cell carefully and place over calibration plate and fix the weight holder over the load cell and Press “ENTER” key tester display appears as-



4.8.3.5 After completing Calibration for Zero Reference, the display will appears as

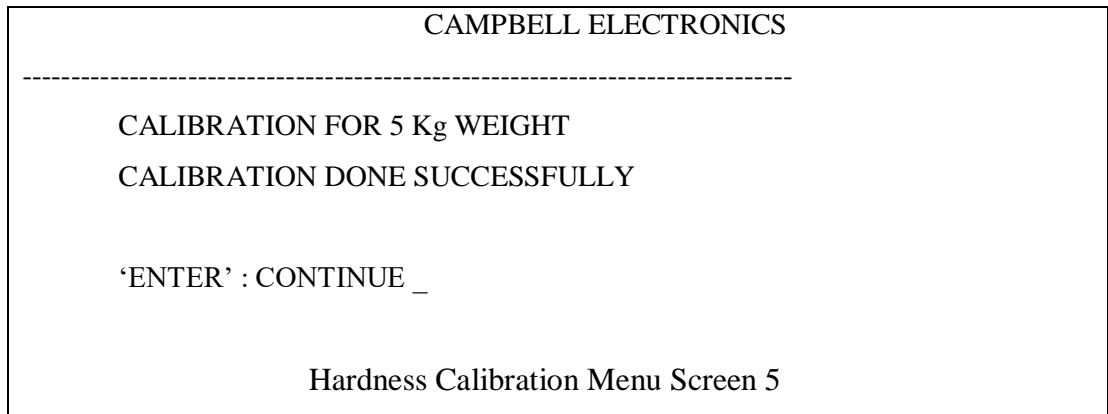




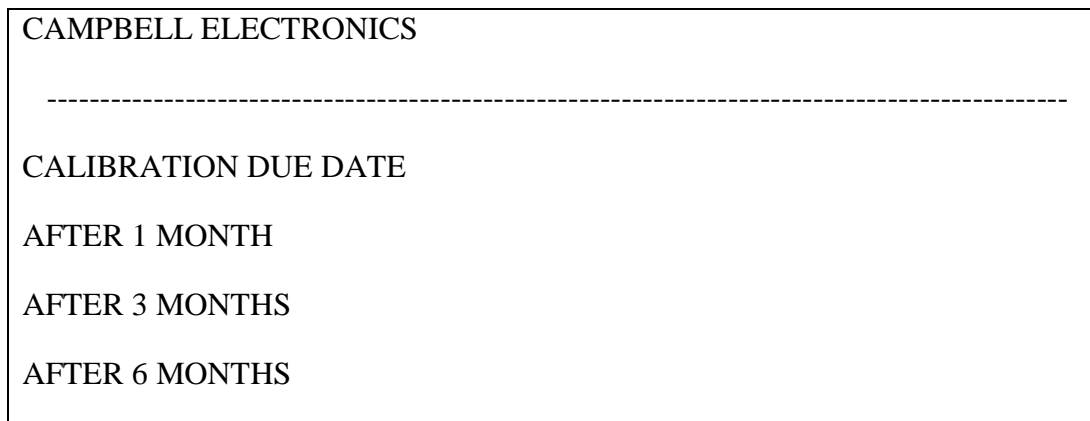
STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.8.3.6 Then load the 5.0 Kg weight on the Weight Holder and press 'ENTER' key to continue the Calibration. Then the display will show the below screen.



4.8.3.7 Select any of duration by pressing the appropriate Numerical key. Then the display will show the below screen.



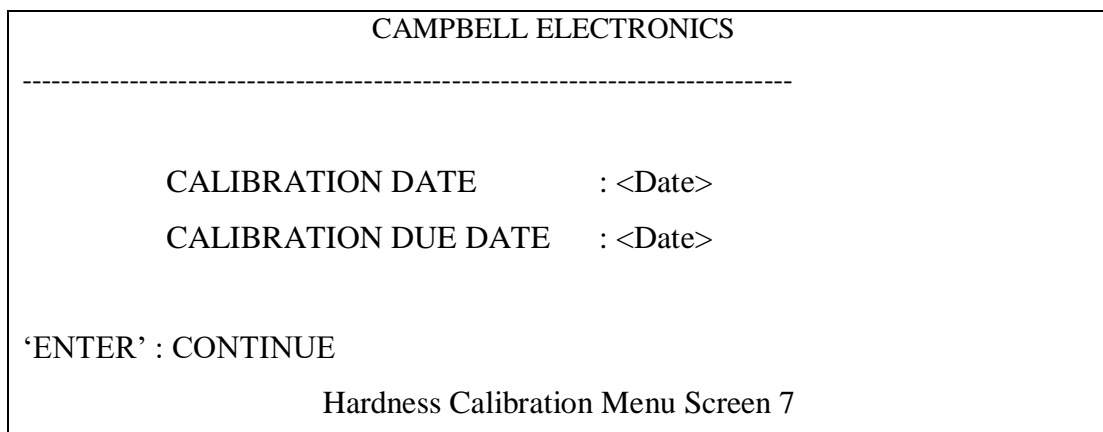
4.8.3.8 Select any of duration by pressing the appropriate Numerical key. Then the display will show the below screen.



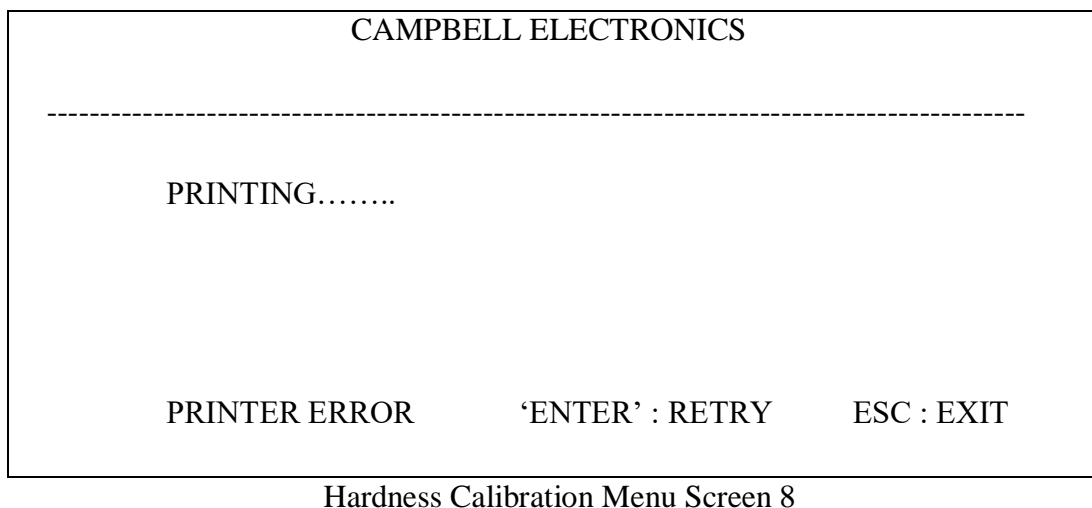
PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



4.8.3.9 Then press the 'ENTER' key to print the calibration data and after printing is over the displays shows the Main Menu Screen. Remove the weight from the Weight Holder.



4.8.4 Frequency:
Frequency: Quarterly

4.8.5 Cleaning:

4.8.5.1 Clean the Platform, area between jaws, load cell, moving Jaws, Tablet Debris Collection Box and Outer Side of the Tablet Tester with the help of dry Lint free cloth followed by lint free cloth dipped in 70% V/V IPA once daily before starting of activity and no powder is adhered to the jaws before further testing.



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.8.5.2 Clean the platform, area between jaws and load cell & moving jaws with help of dry lint free cloth and nylon brush after every test.

4.8.6 Precaution:

4.8.6.1 Never keep the hardness tester jaws under tension, when not in use.

4.8.6.2 Do not perform operation without putting Tablet between the moving Jaws.

5.0 ANNEXURE (S):

Annexure-I: Tablet Tester Calibration Record.

6.0 REFERENCE (S) :

SOP for Preparation, approval, Distribution control, Revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S) :

V/V : Volume /Volume

kg : Kilogram

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	----



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Calibration of Tablet Tester	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

TABLET TESTER CALIBRATION RECORD

TABLET TESTER CALIBRATION RECORD			
			Reference SOP No.:
Location		Page No.	16 of 1
Manufactured By		Model No.	
Date of calibration		Instrument ID	
Next Calibration Due on		Frequency	

1) Hardness Calibration:

S.No.	Standard Weights (kg)	Calibration Status OK/NOT OK
1.	5.00	

2) Distance Calibration:

S.No.	Reference block gauge (mm)	Calibration Status OK/NOT OK
1.	10.00	

Remarks: The Instrument Calibration is **OK / Not OK**

Calibrated By :	Checked By :	Approved By :
Date:	Date:	Date: