STANDARD OPERATING PROCEDURE

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

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```
                    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
```

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+T2: 0.00   -T2: 0.00

Create Recipe Menu Screen 2

4.2.3   Put the nominal/standard weight here. To select unit of weight as gram press 'G' and as milligram press 'M'. For tolerance press 'A' for Absolute or press 'P' for Percent.

4.2.4   After putting those parameters press ''ENTER'' and the screen appears as-

EDIT RECIPE

RECIPE NO: 2

UNIT OF WIDTH: [m]m/[I]inch

NOMINAL WIDTH: 0.00

TOLERANCE: [A]BS/[P]CENT

+T1: 0.00   -T1: 0.00

+T2: 0.00   -T2: 0.00

Create Recipe Menu Screen 3

4.2.5   Put the Nominal/Standard width here. To select unit of length as Millimeter press 'm' and as Inch press 'I'. For tolerance press 'A' for Absolute or press 'P' for Percent. Then press 'ENTER' and the screen appears as-

4.2.6   Put the Nominal/Standard thickness. To select unit of length as Millimeter press 'm' and as Inch press 'I'. For tolerance press 'A' for Absolute or press 'P' for Percent. Then press 'ENTER' and the screen appears as-

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EDIT RECIPE

RECIPE NO: 2

UNIT OF DIAMETER: [m]m/[I]inch

NOMINAL DIAMETER: 0.00

TOLERANCE: [A]BS/[P]CENT

+T1: 0.00   -T1: 0.00

+T2: 0.00   -T2: 0.00

Create Recipe Menu Screen 5

4.2.7   Enter the Nominal/Standard Hardness here. To select unit of Hardness as Kilopond press

'K', as Newton press 'N' as Strong Cubb press 'S'and for User Defined press 'U'. For

tolerance press 'A' for Absolute press 'P'.

4.3   View recipe:

4.3.1   By pressing 'V' key it will go into the View recipe menu. It shows different recipes which

have created. The screen appears as-

ENTER' RECIPE NO <1-100> _

View Recipe Menu Screen

4.3.2   Put the recipe no. then it will show the View recipe screen.

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4.4   Edit Recipe:

By pressing 'E' key it will go into edit recipe menu. Here different recipes can be edited which have been already created.

4.5   Initial Setting :

> CAMPBELL ELECTRONICS
>
> STARTING NEW TEST PREVIOUS TEST DATA WILL BE ERASED.
>
> 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 –

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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-

> 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

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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
```

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--------------------------------------

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```
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
```

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.

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```
                      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

                Start Test Menu Screen 11
```

4.7   Reports:

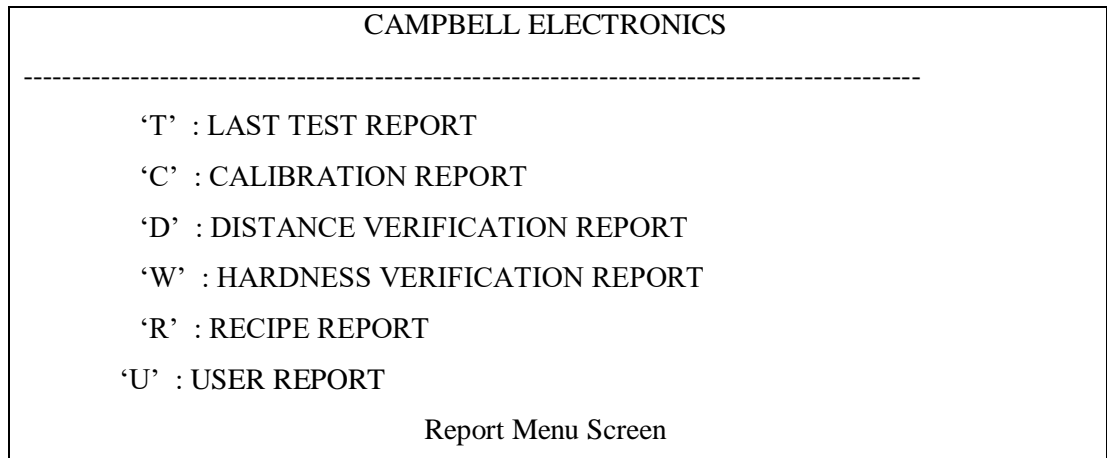4.7.1   In main menu by pressing the 'P' key ,then 'Report Menu' appears as –

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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
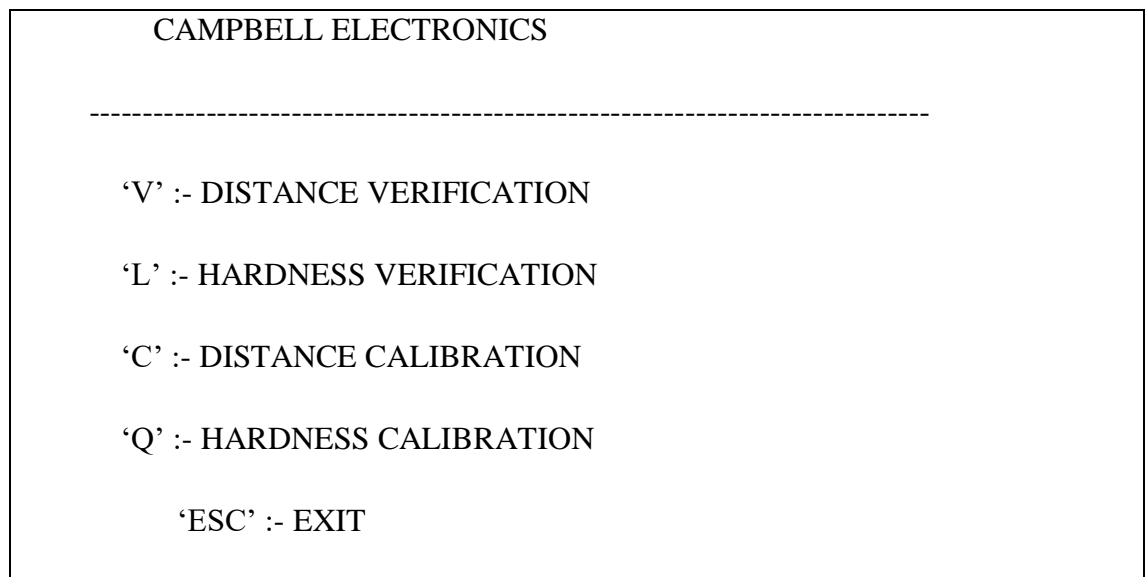
Calibration/Verification Menu Screen

4.8.2 Distance Calibration:

4.8.2.1 In the Calibration Menu, press 'C' key to enter into the Distance Calibration Menu

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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.

CALIBRATING SYSTEM . . .

CALIBRATING COARSE CYCLE . . .

ESC :- TO ABORT _

Distance calibration Menu Screen 1

CALIBRATING SYSTEM . . .

CALIBRATING FINE

ESC :- TO ABORT _

Distance calibration Menu Screen 2

4.8.2.4   After ensuring the zero position the display appears as-

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```
        CALIBRATING SYSTEM . . .
        -----------------------------------------------------------------------------------------
        PUT 10mm GAUGE ON TONGUE AND PRESS 'ENTER' KEY_



        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

    ---------------------------------------------------------------------------------------------
```

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```
HARDNESS CALIBRATION

DO YOU WANT TO CALIBRATE FOR HARDNESS?



'ENTER' : CONTINUE                ESC : EXIT_

        Hardness Calibration Menu Screen 1
```

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

```
CAMPBELL ELECTRONICS

--------------------------------------------------------------------------------

    SLIDE OUT LOADCELL COVER AND ARRANGE SET UP FOR

    CALIBRATION / VERIFICATION.

    REFER OPERATING MANUAL.


'ENTER' : CONTINUE                        ESC : EXIT_
            Hardness Calibration Menu Screen 2
```

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-

```
CAMPBELL ELECTRONICS

----------------------------------------------------------------------------------------

CALIBRATION FOR ZERO REFERENCE…..


            Hardness Calibration Menu Screen 3
```

4.8.3.5   After completing Calibration for Zero Reference, the display will appears as
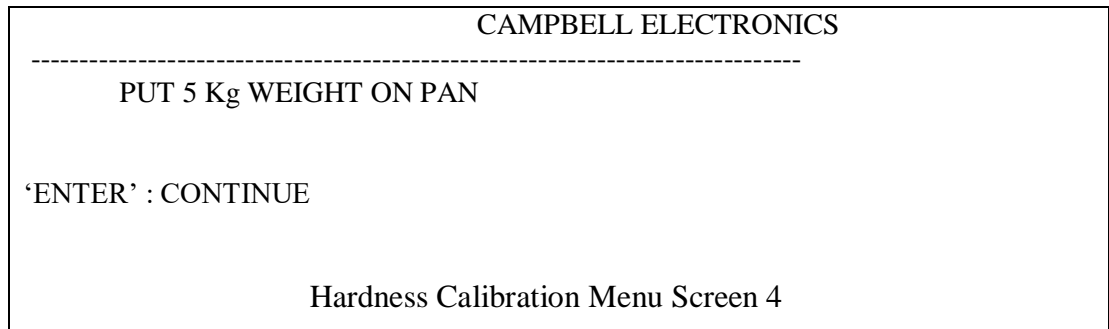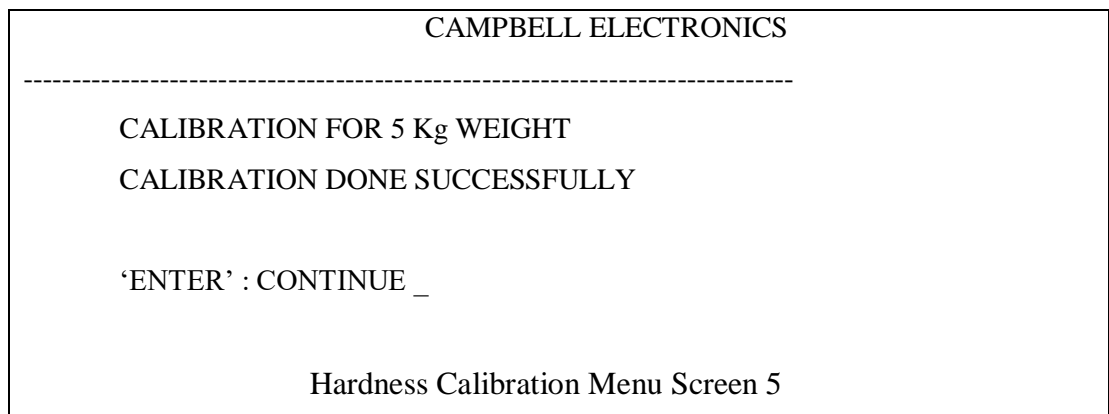
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```
                        CAMPBELL ELECTRONICS
     ----------------------------------------------------------------
            PUT 5 Kg WEIGHT ON PAN


     'ENTER' : CONTINUE



                    Hardness Calibration Menu Screen 4
```

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.

```
                        CAMPBELL ELECTRONICS
     ----------------------------------------------------------------
            CALIBRATION FOR 5 Kg WEIGHT
            CALIBRATION DONE SUCCESSFULLY


            'ENTER' : CONTINUE _



                    Hardness Calibration Menu Screen 5
```

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

```
     CAMPBELL ELECTRONICS

       -----------------------------------------------------------------------------------------

     CALIBRATION DUE DATE

     AFTER 1 MONTH

     AFTER 3 MONTHS

     AFTER 6 MONTHS
```
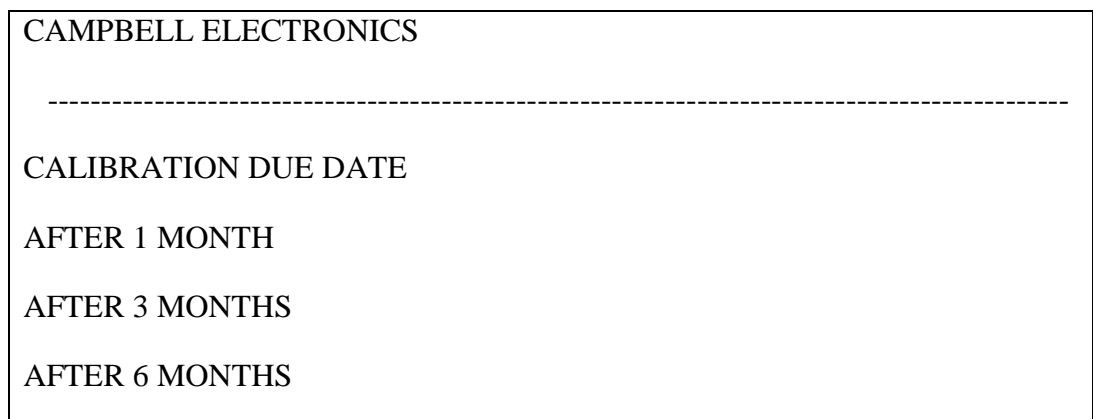
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Hardness Calibration Menu Screen 6

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

```
                    CAMPBELL ELECTRONICS

    ----------------------------------------------------------------


        CALIBRATION DATE          : <Date>
        CALIBRATION DUE DATE      : <Date>



    'ENTER' : CONTINUE
```

Hardness Calibration Menu Screen 7

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.

```
                    CAMPBELL ELECTRONICS

    -------------------------------------------------------------------

        PRINTING……..




        PRINTER ERROR        'ENTER' : RETRY        ESC : EXIT
```

Hardness Calibration Menu Screen 8

4.8.4   Frequency:

Frequency: Quarterly

4.8.5   Cleaning:

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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.

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	----

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ANNEXURE I

TABLET TESTER CALIBRATION RECORD

TABLET TESTER CALIBRATION RECORD			
			Reference SOP No.: ………
Location		**Page No.**	17 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 : **Date:**	**Checked By :** **Date:**	**Approved By :** **Date:**