



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning, Operation and Calibration of Digital Tablet Tester (Campbell)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

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1.0 OBJECTIVE:

To lay down a procedure for cleaning, operation and calibration of Electronic Tablet Tester (Campbell).

2.0 SCOPE:

This procedure is applicable to the cleaning, operation and calibration of Electronic Tablet Tester (Campbell) 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 Dedust 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 IPQA.

5.1.2 Clean the apparatus with dry lint free cloth followed by moist lint free cloth.

5.1.3 Cleaning should be done after performing each test.

5.2 MACHINE SETTING:

5.2.1 Switch ON the apparatus, the screen displays

5.2.2

CAMPBELL ELECTRONICS	
MODEL No	:
SERIAL No	:
S/W	:
PRESS ANY KEY TO CONTINUE _	



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5.2.3 Press the ENTER key, now screen displays

CAMPBELL ELECTRONICS	
USER NAME	:
PASSWORD	:
‘P’ : CHANGE PASSWORD	
‘C’ : CONTINUE	
‘ECS’ : EXIT	

Select ‘C’ and enter the user name, password as per there level (i.e. administrator, supervisor, operator/user level). To change the password press ‘P’.

5.2.4 If **Administrator level** login, then screen displays main menu.

CAMPBELL ELECTRONICS		Date
		Time
‘S’ : START TEST	LEVEL : ADMIN	
‘C’ : CALIBRATION / VERIFICATION		
‘U’ : CREATE USER		
‘R’ : CREATE RECIPE	‘P’ : REPORT	
‘V’ : VIEW RECIPE	‘T’ : SETTING	
‘E’ : EDIT RECIPE	‘L’ : LOG OFF	

* In Supervisor level ‘U’ Create User option doesn’t appears.

* And In User/Operator level ‘U’ Create User, ‘R’ Create Recipe, ‘E’ Edit Recipe, ‘P’ Report and ‘T’ Setting option doesn’t appears.

5.2.1 Create Recipe

5.2.1.1 To create the recipe press “R” in step no. 5.2.4. The screen displays

NEW RECIPE	
RECIPE No	:
PRODUCT NAME :	
PRESS ID	:

Here different recipe can be created. The recipe no. is auto generated.



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5.2.1.2 After entering the product name and ID press enter. The screen displays

NEW RECIPE	
RECIPE No : xy	

UNIT OF WEIGHT : [g]m/[m]g	
NOMINAL WEIGHT:	
TOLERANCE : [A]BS/[P]CENT	
+T1 : 0.00 -T1 : 0.00	
+T2 : 0.00 -T2 : 0.00	

Select the unit of weight by pressing the “g” for gram & “m” for milligram and press enter the cursor comes to the NOMINAL WEIGHT i.e. standard weight, enter this weight as per BMR and press enter.

The cursor comes to “+T1”, this is the upper limit of weight enter this then press enter the cursor comes to “-T1”, this is the lower limit of weight enter this then press enter the cursor comes to “+T2” this is the deviated upper limit of weight enter this then press enter the cursor comes to “-T2”, this is the deviated lower limit of weight then press enter this then press enter.

5.2.1.3 Now the screen displays

NEW RECIPE	
RECIPE No : xy	

UNIT WIDTH : [m]m/[I]nch	
NOMINAL WIDTH:	
TOLERANCE : [A]BS/[P]CENT	
+T1 : 0.00 -T1 : 0.00	
+T2 : 0.00 -T2 : 0.00	

Select the unit of width by pressing the “m” for mm & “I” for inches and press enter the cursor comes to the NOMINAL WIDTH i.e. standard width, enter this width as per BMR and press enter.

The cursor comes to “+T1”, this is the upper limit of width enter this then press enter the cursor comes to “-T1”, this is the lower limit of width enter this then press enter the cursor comes to “+T2” this is the deviated upper limit of width enter this then press enter the cursor comes to “-T2”, this is the deviated lower limit of width then press enter this then press enter.



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5.2.1.4 Now the screen displays

NEW RECIPE	
RECIPE No	: xy

UNIT THICKNESS	: [m]m / [I]nch
NOMINAL THICKNESS:	
TOLERANCE	: [A]BS / [P]CENT
+T1 : 0.00	-T1 : 0.00
+T2 : 0.00	- T2 : 0.00

Select the unit of thickness by pressing the “m” for mm & “I” for inches and press enter the cursor comes to the NOMINAL THICKNESS i.e. standard thickness, enter this width as per BMR and press enter.

The cursor comes to “+T1”, this is the upper limit of thickness enter this then press enter the cursor comes to “-T1”, this is the lower limit of thickness enter this then press enter the cursor comes to “+T2” this is the deviated upper limit of thickness enter this then press enter the cursor comes to “-T2”, this is the deviated lower limit of thickness then press enter this then press enter.

5.2.1.5 Now the screen displays

NEW RECIPE	
RECIPE No	: xy

UNIT OF DIAMETER	: [m]m / [I]nch
NOMINAL DIAMETER :	
TOLERANCE	: [A]BS / [P]CENT
+T1 : 0.00	-T1 : 0.00
+T2 : 0.00	- T2 : 0.00

Select the unit of diameter by pressing the “m” for mm & “I” for inches and press enter the cursor comes to the NOMINAL DIAMETER i.e. standard diameter, enter this width as per BMR and press enter.

The cursor comes to “+T1”, this is the upper limit of diameter enter this then press enter the cursor comes to “-T1”, this is the lower limit of diameter enter this then press enter the cursor comes to “+T2” this is the deviated upper limit of diameter enter this then press enter the cursor comes to “-T2”, this is the deviated lower limit of diameter then press enter this then press enter.



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5.2.1.6 Now the screen displays the hardness parameter.

Select the unit of hardness by pressing the [K]p for Kilopond & [N] for Newton, [S]c for Strong Cobb and [U]d user defined press enter the cursor comes to the NOMINAL HARDNESS i.e. standard diameter, enter this width as per BMR and press enter.

The cursor comes to "+T1", this is the upper limit of hardness enter this then press enter the cursor comes to "-T1", this is the lower limit of hardness enter this then press enter the cursor comes to "+T2" this is the deviated upper limit of hardness enter this then press enter the cursor comes to "-T2", this is the deviated lower limit of hardness then press enter this then press enter.

NEW RECIPE	
RECIPE No	: xy
UNIT OF HARDNESS : [K]p/[N]/[S]c/[U]d	
NOMINAL HARDNESS :	
TOLERANCE	: [A]BS/[P]CENT
+T1 : 0.00	-T1 : 0.00
+T2 : 0.00	-T2 : 0.00

5.2.1.7 After feeding all the 5 parameters i.e. weight, width, thickness, diameter, and hardness the screen displays the main menu as in step no. 5.2.4.

5.2.2 Edit Recipe

5.2.2.1 Press 'E' in main menu (5.2.4), the "Edit Recipe Menu" comes

ENTER RECIPE NO <1-50> :

Enter the recipe no (i.e. already added) what to be edit

5.2.2.2 Now follow the step 5.2.1.1 to 5.2.1.7, in these steps EDIT RECIPE will be come on top of screen instead of NEW RECIPE.

5.2.3 View Recipe

5.2.3.1 Press "V" in main menu (5.2.4), here the loaded recipe parameters can be viewed.

5.2.4 Clock / Reset Test No./Company Name/Printer Setting

5.2.4.1 To set the Clock / Reset Test No./Company Name/Printer press "T" in main menu (step 5.2.4).

5.2.4.2 After pressing "T" in main menu the new screen displays



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CAMPBELL ELECTRONICS

“C” : REAL TME CLOCK SETTING

“R” : RESET TEST NO

“N” : COMPANY NAME

“P” : PRINTER SET

“ECS” : EXIT

- 5.2.4.3 To set the TIME & DATE press “C” . Here the options comes to edit date,month,year,hours and minutes.
- 5.2.4.4 To reset the TEST SERIES No press “R”.
- 5.2.4.5 To change the company name press “N” and enter the company name.
- 5.2.4.6 To set the printer press “P” the option comes, Press “D” for Dot Matrix and “I” for Ink Jet/laser printer.

5.3 MACHINE OPERATION

- 5.3.1 To start the operation press “S” in the main menu (step 5.2.4).
- 5.3.2 The 2 option comes on screen “P” and “C”.
- Press “P” if want the print out of previous performed test.
- Press “C” if do not want the print out of previous performed test.
- 5.3.3 The screen displays

TEST NO : xy
RECIPE No : zx

The test no comes automatically with increment with last test.

Load the recipe no regarding the test tablet.

- 5.3.4 After loading the recipe no the BATCH NO displays. Enter the batch no and press enter the screen displays.

- 5.3.5

TEST NO : 1
RECIPE No : XY
VALID SAMPLES :
FOR WEIGHT :
FOR THICKNESS :
FOR DIAMETER :
FOR HARDNESS :

Here Put the total numbers of tablets to be tested, for “Valid Sample”/“For Weight”/“For Weight”/ “For Thickness”/ “For Diameter”/ “For Hardness”.



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5.3.6 After feeding above parameters press enter key, the screen displays

TEST NO : 1
[A]UTO / [M]ANUAL

For "Auto Mode" press "A" key and for "Manual Mode" press "M" key.

* In auto mode tests can be conducted one by one automatically till test set test are not over. As we select the auto mode the system asks for delay time (sec.) i.e. delay time each test parameter measurement. After entering delay time the system asks to enter the Back-Off Distance, as we enter the Back-Off distance the system adjusts the jaw position for specified jaw distance [2-15mm].

* And in manual mode before every test unit the "Enter" key to be pressed. As we select the manual mode the system asks to enter the Back-Off Distance, as we enter the Back-Off distance the system adjusts the jaw position for specified jaw distance [2-15mm].

5.3.7 Now put the tablet sample to be tested horizontally for measure width, diameter and hardness. And vertically to measure thickness.

5.4 CALIBRATION OF HARDNESS

5.4.1 To start the calibration press "C" in the main menu (step 5.2.4).

5.4.2 The screen displays

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

5.4.3 Press "Q" and message prompt on screen "DO YOU WANT TO CALIBRATION FOR HARDNESS?" Press "ENTER" key to continue.

5.4.4 Message prompt on screen to remove the load cell assembly cover by sliding it out.

5.4.5 Now remove the load cell from holder by removing allen bolt by using allen key.

5.4.6 Take out the load cell and affix it into the groove of load cell holder in vertical position. (Ensure the cables while taking out the load cell). Press "ENTER" key to continue.

5.4.7 Now affix the weight holder on the load cell.

5.4.8 When the message displays on "PUT 5 Kg WEIGHT ON PAN" then place 5 kg certified weight on the pan gently. And then press "ENTER" key.



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5.4.9 The calibration is over and message displays on screen “CALIBRATION FOR 5 Kg WEIGHT CALIBRATION DONE SUCESSFULLY”. And press “ENTER” key.

5.4.10 The message displays

CAMPBELL ELECTRONICS
CALIBRATION DUE DATE
1. AFTER 3 MONTH
2. AFTER 6 MONTH
3. AFTER 1 YEAR

Select the due date calibration period by selecting option 1,2 and 3. And pree “ENTER” key.

5.4.11 The “CLIBRATIN DATE” and “CALIBRATION DUE DATE” will display and press “ENTER” key. The calibration report get printed automatically. (If printer is attached)

5.5 VARIFICATION OF HARDNESS

5.5.1 Follow the step no. 5.4.1 to 5.4.2. And press “L” for hardness verification.

5.5.2 The message prompt on screen

CAMPBELL ELECTRONICS
HARDNESS VERIFICATION
DO YOU WANT TO VARIFICATION FOR HARDNE SS?
ENTER : CONTINUE ECS: EXIT

Press “ENTER” key to continue.

5.5.3 Follow the step no 5.4.4 to 5.4.7.

5.5.4 The message prompt on screen “VARIFICATION FOR ZERO REFERENCE” “PUT KNOWN WEIGHT ON THE PAN” then put the known weight rather then used for calibration (1- 50 kg) and press “ENTER” key to continue.

5.5.4 The message displays on screen

CAMPBELL ELECTRONICS
ENTER WEIGHT :

Enter the standard weight value on screen.



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5.5.5 The message prompt on screen

CAMPBELL ELECTRONICS
VALIDATION RESULT : 00.00
DO YOU WANT TO VALIDATE
AGAIN
ENTER : VALIDATE ECS: EXIT

If the validation result is closer to standard weight used press “ECS” or if not closer the press “ENTER” to re-validate.

5.6 CALIBRATION OF DISTANCE

5.6.1 Follow step no. 5.4.1 to 5.4.2.

5.6.2 Press “C”, the message prompt on screen and the jaw moves towards load cell for zero reference by performing coarse cycle.

CALIBRATING SYSTEM...
CLIBRATING COARSE CYCLE
ECS :- TO ABORT

After calibrating coarse cycle the unit starts to do fine calibration with message displayed on screen “CALIBRATION FINE”, Here the tongue starts moving forward from home position, then tongue jaw touches the load cell and come back to ensure zero position. And screen displays.

CALIBRATING SYSTEM...
PUT 10 mm GAUGE ON TONGUE AND
PRESS ENTER KEY
ECS :- TO ABORT

Now put standard 10 mm gauge and press “ENTER” key. The jaw start moving to measure the gauge.

If the calibration result is in acceptance limits, the display returns to main menu otherwise display prompts the following screen

CALIBRATING SYSTEM
GAUGE DIMENSION NOT IN ACCEPTANCE
LIMIT
CALIBRATION ABORTED
‘ECS’ :- TO ABORT

If gauge dimension is not in acceptance limit press” ENTER” and put the known value of gauge to be measured, after pressing “ENTER” key screen goes back to main menu.

5.7 VARIFICATION OF DISTANCE



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5.7.1 Follow the step no. 5.4.1 to 5.4.2 and press “V” for distance verification. The screen displays.

DISTANCE VERIFICATION
PUT ANY KNOWN VALUE GAUGE ON JAW
ENTER VALUE OF GAUGE :-
ENTER :START

Put 10 mm standard gauge block and enter the value 10 mm. Press “ENTER” key to start the verifying the dimension.

The jaw moves forward and measures the dimension of gauge block and come back to home position. The screen displays.

DISTANCE VERIFICATION
BLOCK SIZE (mm) :
VARIFICATION RESULT (mm) :
DEVIATION (mm) :
ENTER : VARIFY AGAIN
‘ECS’ : EXIT

5.8 CALIBRATION AND VARIFICATION REPORT

5.8.1 Press ‘P’ for reports in main menu (step no 5.2.4), the screen displays

CAMPBELL ELECTRONICS
‘T’ : LAST TEST REPORT
‘C’ : CALIBRATION REPORT
‘D’ : DISTANCE VARIFICATION REPORT
‘W’ : HARDNESS VARIFICATION REPORT
‘R’ : RECIPE REPORT
‘U’ : USER REPORT

Press the alphanatical option in key board to take the print out of desired report.

5.9 CALIBRATION AND VARIFICATION FREQUENCY

*The Calibration for Hardness and Distance should be done Quarterly (i.e. once in three month).

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

6.0 ABBREVIATION (S):

Nil



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7.0 RERERENCE (S):

Nil

8.0 ANNEXURE (S):

Annexure –I: Hardness/Distance Calibration & Verification Record

9.0 DISTRIBUTION:

Master Copy : Quality Assurance

Controlled copy (S) : Production department, Quality Assurance

Reference copy (S) : Production department

