STANDARD OPERATING PROCEDURE

Title: Operation and Calibration of Cap Torque Tester

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 7	

1.0 OBJECTIVE:

To lay down a procedure for Operation of Cap Torque Tester.

2.0 SCOPE:

This SOP is applicable for the Operation of Cap Torque Tester used to check the adequate torque of capped vials in Three Piece line.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

%	Percentage
LCD	Liquid Crystal Display
LTD	Limited
No.	Number
PVT	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
USB	Universal Serial Bus

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 Ensure the battery of tester shall be charged before to start the operation.

6.1.2 Ensure the availability of printing paper with instrument.

6.1.3 In case, if cap torque tester machine of respective section is under breakdown/ malfunctioning then cap torque tester machine of other working production section I/Q (three piece) can be used and update the test record in respective operation log book or respective torque tester machine can be transferred to working production section of I/Q (three piece) considering the production planning along with respective logbook in case the machine kept at idle condition in any section.

6.2 OPERATION:

6.2.1 Bottle Cap Torque Tester is having the below features.

6.2.2 High precision, High Resolution, Quick sampling speed, full screen display.

6.2.3 Adopting high precision Torque sensor with direction display.

6.2.4 Upper and lower limit value setting, red and green indicating light and buzzer audible and visual alarm.

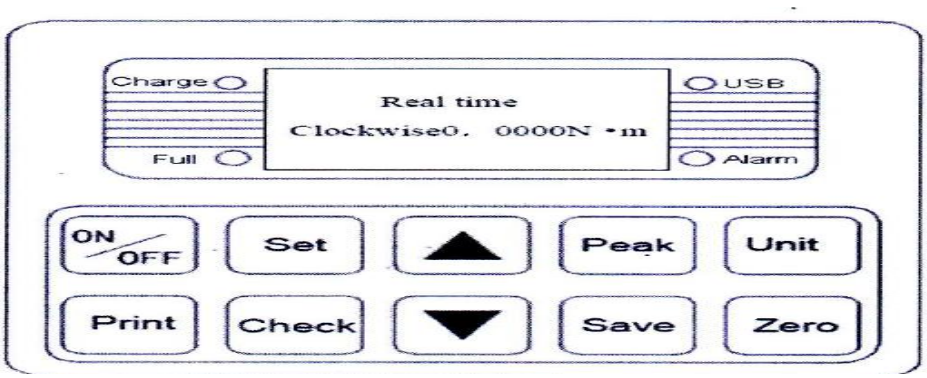
6.2.5 Measurement in three selectable units [Nm (Newton meter),kg/cm^2 (Kilogram/centimeter square, lb/in (Pound/inch^2)].

6.2.6 Real Time, Peak, Automatic peak option.

6.2.7 The tester can be connected with computer through USB interface communication and can save & print the data after doing all the analysis.

1. LCD
2. Indicating lamp
3. Function keys
4. Special fixture
5. Printer
6. USB interface
7. Charging socket
8. Power socket

6.2.8 Button Introductions:



6.2.8.1 ON/OFF Button: Use this button to start and shut down.

6.2.8.2 Printer Button: Use this button to take print the internal measured data of instrument.

6.2.8.3 Set Button: During measuring interface, user can enter into setting menu through this button.

6.2.8.4 Check Button: When in measuring interface, press this button to check the saved measuring data and on clicking again it return into measurement model.

6.2.8.5 Button: In users setting interface on pressing this button, it modifies the setting items upward. In parameter setting on clicking this button, it modifies data. In checking interface on pressing this button, it can check the latest data.

6.2.8.6 Button: In users setting interface on pressing this button, it modifies the setting items downward. In parameter setting on clicking this button, it moves the site to choose the modified digits. In checking interface on pressing this button, it can check the latest data.

6.2.8.7 Peak Button: Use this button to switch Rea-time, peak, Automatic peak three measure modes.

6.2.8.8 Save Button: Use to save the measurement data.

6.2.8.9 Unit Button: Use to switch [Nm (Newton meter), kg/cm2 (Kilogram/centimeter square, lb/in (Pound/inch^2)].

6.2.8.10 Zero Button:

6.2.8.10.1 When in real time measurement, on click this button it can correct zero.

6.2.8.10.2 When in peak and automatic peak, on clicking this button it can clear peak, revert to zero.

6.2.8.10.3 When in checking interface, clicking this key for three times can delete all records.

6.2.8.10.4 When in user setting interface, on clicking this button will not save the data and it will turn back to the upper interface.

6.2.9 Operating Procedure:

6.2.9.1 Fix the four plastic covered grips on the pan at the top of the system. These grips can be adjusted by turning a built in screw. The system should be used in vertical condition only to get the optimum performance.

6.2.9.2 Before using digital bottle lid torque meter, check the power to make sure enough power.

6.2.9.3 Use the attached M8 inner hexagon spanner to install the special fixture 94 Pcs) on the measuring panel.

6.2.9.4 Turn on the power switch if the display data is not zero, click the zero button to reset, reset the torque value to zero.

6.2.9.5 Before the test set all the value for this click the set button to enter into user setting interface, the screen shows as below.

1. Upper limit value setting
2. Lower limit value setting
3. The min. saved value
4. The min. peak holding value
5. Automatic peak time
6. Automatic shutdown time

6.2.9.6 Upper limit value setting: Set this value according to the requirement. When reaching the upper limit value, automatic audible and visual alarm, the upper limit value should be lower than full range.

6.2.9.7 Lower limit value setting: Set this value according to the requirement. When reaching the lower limit value, automatic audible and visual alarm, the lower limit value should be lower than the set upper limit value.

6.2.9.8 Min. saved value setting: users set the min. saved value according to storage needs, the data smaller than this value will not be saved.

6.2.9.9 Min. peak holding value setting: users according to peak value, automatic peak value measurement needs to be set freely, the value smaller than this value cannot be peak saved.

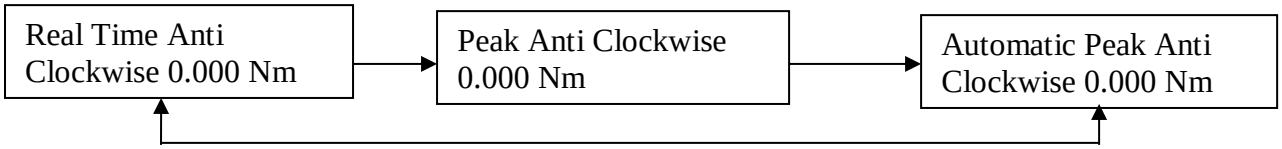
6.2.9.10 Automatic peak time setting: users according to the condition of measured automatically peal value to set from 1-99 seconds freely.

6.2.9.11 Automatic shutdown time setting: In no operating condition, the automatic shutdown time can be set from 0 minute to 9 minutes freely.

6.2.9.12 Acceleration of gravity setting: users can according to area of the position to set the acceleration value, native machine is acquiesced as 9.794.

6.2.9.13 Revert to original setting: users improper operation or change data many times will appear confusion, can through this item setting to make the 1≈7,1=16 data return to factory setting.

6.2.9.14 Before the test choose the measurement model. In the house holder interface of real time measurement model. when the first time to click the peak button to enter the peak measurement model, the second time to click the peak button to enter automatic peak measurement model, then the third time to click the peak button will back to real time measurement model, as shown below:



6.2.9.15 In the measurement model, the first time click the unit button will show Nm unit and enter into kg/cm^2 unit displaying the second time click unit button will enter into lb/in unit display.

6.2.9.16 In testing click the save button will save the measured data.

6.2.9.17 Use the above procedure for vials having open nozzle only.

6.2.9.18 After using click the On/OFF button to turn off the power and put the instrument in box.

6.2.9.19 **Frequency of Leak Test and Torque Test:** During initial setting, after everyone hour by Production and QA alternatively.

6.2.9.20 After completion of the operation take the print out and attach in the BMR.

6.2.9.21 Record the operation details in "Operation Log Book for Bottle Cap Torque Tester" as per Annexure-I and "Recording log book for observed torque" as per Annexure-II.

Note: During the testing process when the measurement value exceeds the upper limit value the communication indication lamp would become red and the buzzer would give out alarm. When the measurement value exceeds 120% of the peak load the transducer would probably be damaged. When the measurement value exceeds 150%of the peak load the system would surely be damaged. When the warning reminder of the serious overload appears the machine would automatically be shut down and enter into the status of automatic protection. At this time machine shall be start up again.

6.3 CALIBRATION:

6.3.1 Calibration of instrument shall be done by outside Party.
Frequency: Annually

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Operation Log Book for Bottle Cap Torque Tester	
Annexure – II	Torque Limit For Different Types Of Vials	

ENCLOSERS: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Instrument manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE-I
OPERATION LOG BOOK FOR CAP TORQUE TESTER

Equipment Name: **ID No.:**
Area: **Block:**

S.No.	Date	Product Name	Batch No.	Time		Observation	Done By Sign & Date	Remarks
				Start	End			

ANNEXURE-II
TORQUE LIMIT FOR DIFFERENT TYPES OF VIALS

Pack Size	Vendor Name	Limit as Per PQ Protocol	
		Lower Limit	Upper Limit
5 ml	Rexam	-0.302 Nm	-0.992Nm
10 ml	Rexam	-0.310Nm	-0.602Nm
5 ml	Dr. Pack	-0.281 Nm	-0.924Nm
10 ml	Dr. Pack	-0.303 Nm	-0.733 Nm
5 ml	BP. Rex	-0.300Nm	-0.867Nm
10 ml	BP Rex	-0.311Nm	-0.800Nm