PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning, Operation and Calibration of Digital Cap Torque Tester	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Vernacular SOP: No

1.0 OBJECTIVE:

1.1. To lay down a procedure for Cleaning, Operation and Calibration of Digital Cap Torque Tester.

2.0 SCOPE:

2.1. The procedure is applicable for the Cleaning, Operation and Calibration of Digital Cap Torque Tester in General Block.

3.0 RESPONSIBILITY:

3.1. Officer, Executive Production: Performing the calibration.

3.2. IPQA: Verification.

3.3. Operator: Operation and Cleaning.

3.4. Head Production: Ensure compliance and implementation of the SOP.

4.0 DEFINITION (S):

4.1. NA

5.0 PROCEDURE:

5.1. **Cleaning**

5.1.1. Switch ‘OFF’ the apparatus from the back side and from the mains.

5.1.2. Clean the rubber clamps with help of wet lint free cloth followed by dry lint free cloth.

5.1.3. Clean the SS bottle platform with clean wet lint free cloth followed by clean dry lint free cloth.

5.1.4. Clean the main body of the balance with a clean dry lint free cloth.

5.2. **Operation**

5.2.1. Attach one end of the power cable of the apparatus with the main plug and the other end to the apparatus, switch ‘ON’ from the main and switch provided back side of the apparatus. Red colour & Green colour light will ‘ON’ on the apparatus. If paper (for print) is not present in the apparatus then green light will blink, place the paper roll inside the apparatus. Switch ‘ON’ the apparatus by pressing ‘ON/OFF’ functional button situated on panel of apparatus. Fix the SS bottle platform on apparatus and tighten with Allen key(if required)

5.2.2. Take 8 bottles from the filling and sealing machine and mark them with number as per machine sealing head numbering.

5.2.3. Put the bottle (mark as no.1) between the rubber clamps and tighten the rod plate with rotating the knob to clockwise direction.

5.2.4. Rotate the ROPP cap on the bottle with hand to anticlockwise direction, as the torque is applied on bottle, cap seal will break and torque value will be shown on the screen.

5.2.5. As the torque value is in between the upper limit and lower limit, the 'OK' green light (pilot lamp) will glow.

5.2.6. Press the MEM function button (as the torque value shows on screen press MEM button to memorize the value), value will save in the memory and '√' mark on number grid 1 is shown on the screen. Use this bottle for further in process such as volume test as per reference SOP ("In Process Checks and Failure Handling During Manufacturing, Filling and Packing Operation").

5.2.7. Remove the open bottle from the rubber clamp with help of knob and place next numbered bottle (bottle having numbered 2) on the bottle platform. Press 'ZERO' function button so that the previous value will be zero, then rotate the ROPP cap on the bottle with hand to anticlockwise direction, as the torque apply on bottle, cap seal will break and torque value will be shown on the screen. As the torque value is in between the upper limit and lower limit , the 'OK' green light(pilot lamp) will glow. Use this bottle for further in process such as volume test as per reference SOP ("In Process Checks and Failure Handling During Manufacturing, Filling and Packing Operation").

5.2.8. Press the MEM function button (as the torque value shows on screen press MEM button within 10 seconds to memorize the value) on screen the value will save in the memory and '√' mark on number grid 2 is shown on the screen.

5.2.9. Repeat the process on next 6 bottles similarly (bottles having numbered from 3 to 8) and follow step no. 5.2.4 to 5.2.7. After completion of process on all 8 bottles, press 'PRINT' function button to take the print of all the value and attach it with the respective BPR.

5.2.10. On print out paper all the torque value is print with 'OK' along with the Upper limit value, lower limit value, Le.set value, Maximum value, minimum value and average value. After performing torque test clear the values by pressing CLR button.

5.2.11. If any value is below or above the lower or upper limit the torque value will print as: value '-' and value '+'.

5.2.12. Torque value in '-' or '+' means that torque value are not within the limit. Re perform the test on the bottles by adjusting the filling & sealing machine.

5.2.13. After completion of the torque take the print out and attach with the respective BPR.

5.2.14. After completions of batch clear all the values by pressing function button 'CLR' and switch 'OFF' the apparatus from the ON/OFF button and from the back side of the apparatus and from the mains.

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5.3. **SET UP**

5.3.1. Attach one end of the power cable of the apparatus with the main plug and other end to the apparatus, switch 'ON' from the mains and the switch provided back side. Red colour & Green colour light will 'ON' on the apparatus. If paper (for print) is not present in the apparatus then green light will blink, place the paper roll inside the apparatus. Switch 'ON' the apparatus by pressing 'ON/OFF' functional button situated on panel of apparatus.

5.3.2. Place the bottle platform on the apparatus and tighten it with Allen key (if required).

5.3.3. Rotate the SS knob of the bottle platform to anticlockwise direction to open the rod plates and fix the rubber clamps into the space provided into the rod plate with the help of Allen key as per requirement of bottle size.

5.3.3.1. Functional buttons on the apparatus :

- **ON/OFF button** to switch 'ON' & 'OFF' the apparatus.
- **ZERO button** to clean the peak value.
- **UNIT button** - Three units are shown on screen when this button is being pressed. (N.m , Kgf.cm, lbf.in)
- **CLR button** use to clear the value which is save in the memory.
- **PEAK button,** on pressing this button 'PEAK', 'AUTO PEAK' options are shown on screen. Operation to be performs on 'PEAK'.
- **PRINT button** use to print the value which is save in the memory.
- **SET button** - Press this button HIDT is displayed (Upper value) using the button '▲' & '▼' set the value as per requirement. Press set button again LODT is displayed (Lower value), using the button '▲' & '▼' set the value as per requirement. Press again set button, the LE.SET is displayed (it is the data showed in min. memory data), using the button '▲' & '▼' set the value as per requirement. Press the set button again 'P.OFF' is displayed, it is the time of auto power off of the apparatus (set the time of power off as per requirement). In case of power off, switch 'ON' the apparatus from the ON/OFF switch for further operation. Press again set button, A.PE is display it is time of auto clean peak (value). Again press set button rS 232 displayed and shows print, again press set button, all the setting will be kept save.

- **MEM button** - On pressing this button the value (test performed value) will be save in the memory.
- ▲ & ▼ button, to increase and decrease the parameters.

5.3.4. After complete set up, perform the torque test as per respective BPR.

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5.4. **Calibration**

5.4.1. Frequency: Every three months.

5.4.2. Remove the bottle platform from the apparatus.

5.4.3. Attach one end of the power cable of the apparatus with the main plug and other end to the apparatus, switch 'ON' from the mains and the button provided back side. Switch 'ON' the apparatus by pressing 'ON/OFF' functional button. Red colour & Green colour light will 'ON' on the apparatus. If paper (for print) is not present in the apparatus then green light will blink, place the paper roll inside the apparatus.

5.4.4. Attach the calibration arm in the slot of the apparatus in such way that the wire of the calibration arm is on upper side. Place the apparatus vertically.

5.4.5. Select UNIT in Kgf.cm, PEAK, and set the HIDT value (51.00 kgf.cm) and LODT value (9.80 kgf.cm).

5.4.6. Calibration to be done on both side of the arm, hang rod on both side of the wire of the calibration arm.

5.4.7. Take the standard weights (0.500 kg, 1.0 kg, 2.0 kg) from the designated place.

5.4.8. Weight to be put on the rod for calibration are 1.0 kg , 1.5 kg, 2.0 kg, 2.5 kg, 3.0 kg, 3.5 kg, 4.0 kg, 4.5 kg & 5.0 kg . These weights are put in sequence.

5.4.9. Put weight one by one on the rod on one side of the arm. The value which is shown on the display is derived as: Weight put on the rod to be multiply with the distance (10 cm) from the center of the calibration arm to the right or left corner of the arm .

5.4.10. On print out paper all the torque value is print with 'OK' along with the Upper limit value, lower limit value, Le.set value, Maximum value, minimum value and average value. After performing torque test clear the values by pressing CLR button.

5.4.11. Clear all the values by pressing CLR button to carry out the calibration on other side.

5.4.12. Again done the same procedure on other side of the rod on the calibration arm (Follow step no. 5.4.10).After calibration clear all the values by pressing CLR button.

5.4.13. After completion of calibration remove the standard weights, calibration arm and calibration rod and clean them with dry lint free cloth and kept them in designated place.

5.4.14. If the calibration is satisfactory, affix the calibration label to the apparatus as per reference SOP No. ("Status labeling"). If the calibration is out of limit (any side left or right) affix "OUT OF CALIBRATION" tag and inform to head of department and intimate to engineering through breakdown maintenance intimation request for necessary action and after rectification re-perform the calibration.

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Note: - (i) Torque operation to be performed in N.m unit & Calibration to be perform in Kgf.cm unit.

(ii) Wear hand gloves during operation and calibration of digital cap torque tester.

(iii) Frequency of performance of torque test is as per respective BPR.

6.0 ABBREVIATION (S):

6.1. N.m : Newton tester

6.2. Kgf.cm : Kilogram force centimeter

6.3. Lbf.in : Pound force inch

6.4. MEM : Memory

6.5. BPR : Batch packaging record

6.6. CLR : Clear

6.7. ROPP : Roll on pilfer proof

7.0 REFERENCE (S):

7.1. SOP: Status labeling

7.2. SOP: In process checks in liquid oral manufacturing, filling & packing line

8.0 ANNEXURE (S):

Annexure No.	Tittle of Annexure	Format No.	Mode of Execution
Annexure - I	Calibration Record of Digital Cap Torque Tester		Format

9.0 DISTRIBUTION:

9.1. **Master copy** **:** Quality Assurance.

9.2. **Controlled copy (s)** **:** Production department (01), Quality Assurance (01).

9.3. **Reference copy (s)** **:** Production Department (01).

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (S) for revision	Details of Revision	Effective Date

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ANNEXURE I

Calibration Record of Digital Cap Torque Tester

Torque tester ID.:---------- **Location:----------**

Calibration done on:---------- **Next Calibration due On:----------**

S.No.	Target (kgf.cm)	Allowed tolerance	Deviation (kgf.cm)
1.	10	± 2.0%	9.80 - 10.20
2.	15	± 2.0%	14.70 - 15.30
3.	20	± 2.0%	19.60 - 20.40
4.	25	± 2.0%	24.50 - 25.50
5.	30	± 2.0%	29.40 - 30.60
6.	35	± 2.0%	34.30 - 35.70
7.	40	± 2.0%	39.20 - 40.80
8.	45	± 2.0%	44.10 - 45.90
9.	50	± 2.0%	49.00 - 51.00

Right side Calibration

S.No.	Weights in kg	Target (Kgf.cm) Distance (10cm) X Weight	Weight observed in kgf.cm	Tolerance limit (NMT ± 2.0%)	Remarks

Left side Calibration

S.No.	Weights in kg	Target (Kgf.cm) Distance (10cm) X Weight	Weight observed in kgf.cm	Tolerance limit (NMT ± 2.0%)	Remarks

Calibration status:

Calibration Done By: **Checked By:**