



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: Operation and Cleaning of Torque Tester</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Torque Tester.

### 2.0 SCOPE:

This SOP is applicable to Procedure for Operation and Cleaning of Torque Tester in Three Piece Packing Area .....

### 3.0 RESPONSIBILITY:

**QA (Officer/Executive):** Preparation, Distribution (to Respective Department), Revision, Retrieval and Destruction of this SOP.

**QA Manager:** Review, Approval, Training and effective implementation of this SOP in all the applicable areas.

### 4.0 ACCOUNTABILITY:

**Head QA:** Authorization of this SOP & ensure Training and effective Implementation of SOP.

### 5.0 DEFINITION:

#### 5.1 TORQUE TESTER:

Torque Testers are a Torque-Measuring Device specially designed to work on Bottle/Vial Caps. The exact determination, especially of the opening torque, is a Quality-Defining Factor and provides Reliable Assurance and Documentation that bottle caps have been closed with the appropriate amount of Torque.

### 6.0 PROCEDURE:

#### 6.1 OPERATION OF TORQUE TESTER:

#### 6.2 FUNCTIONAL KEYS OF TORQUE TESTER:

**6.2.1 On/Off:** For start and stop the Torque Tester.

**6.2.2 Set:** For Setting of following contents:

- Upper limit
- Lower limit



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- Min save value
- Min peak value
- Auto peak time
- Auto off time
- Gravity set
- Reset factory
- Calibration
- High frequency peak
- Version

**6.2.3 Print:** For print the result.

**6.2.4 Check:** For check the recorded save torque value.

**6.2.5 Peak:** For maximum value measurement select the following:

- Peak
- Auto Peak
- Real time

**6.2.6 Unit:** Measurement unit choice:

- Kgf. cm
- Lbf. in
- N. m

**6.2.7 Save:** Save the result to the memory, after measurements – results exposure.

**6.2.8 Zero:** For zeroing is done by pressing zero key.



**FIGURE – TORQUE TESTER**



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- 6.3** Take required quantity if LDPE Vials from each capping head.
- 6.4** Connect the power plug in power supply board and ON the switch.
- 6.5** Press ON/OFF button for start the Torque Tester.
- 6.6** Put the vial in 4 tie grip on the tie rail and tightening the knob in clockwise direction.
- 6.7** Press the Peak button for maximum value measurement.
- 6.8** Break the seal of LDPE vial by rotate the cap in anticlockwise direction.
- 6.9** Press the save button for save the torque reading (Saving actual force indication to memory is done by pressing save key).
- 6.10** Press the check button for check the recorded torque value.
- 6.11** Press the print button for print generation by torque tester.
- 6.12** Acceptance Limit of Torque: Lower Limit = 0.200 N. m and Upper Limit = 0.900 N. m
- 6.13 CLEANING OF TORQUE TESTER:**
- 6.13.1** Press ON/OFF button for stop the Torque Tester.
- 6.13.2** Switch OFF the power supply and disconnect the power plug from power supply board.
- 6.13.3** Torque tester mope with lint free cloth.

### 7.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
Pvt.	:	Private
Ltd.	:	Limited
LDPE	:	Low Density Poly Ethylene
Kgf. cm	:	Kilogram force Centimeter
Lbf. In	:	Pound force inch
Lbf. In	:	Pound force inch
N. m	:	Newton Meter



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### 8.0 ANNEXURES:

ANNEXURE No.	ANNEXURE TITLE	FORMAT No.
Annexure-I	Torque Tester Apparatus Log Book	

### 9.0 DISTRIBUTION:

- Controlled Copy No. 01                      Head Quality Assurance
- Master Copy                                      Quality Assurance Department

### 10.0 REFERENCES:

- In House

### 11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

