



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT  
FOR  
BOTTLE TORQUE TESTER**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
BOTTLE TORQUE TESTER**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Packing Area, Three Piece Line</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES No.</b>	<b>NIL</b>



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**1.0 PROTOCOL PRE – APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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**2.0 OBJECTIVE:**

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Bottle Torque Tester Device and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

**3.0 SCOPE:**

- The scope of this operational qualification protocol cum report is limited to qualification Bottle Torque Tester Device installed in Packing Area, Three Piece Line
- This Protocol will define the methods and documentation used to perform OQ activity the Bottle Torque Tester Device.
- After Successful completion of Operational Qualification Activity, Performance Qualification Not Required Because Bottle Torque Tester in a Measuring Device. Concerned use as Per SOP
- Bottle Torque Tester is a Standalone Unit with plug in type electrical connections for operation, Hence may be use as per Requirement.



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Authorization and Compilation of the Operational Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Operational Qualification Activity.</li><li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li></ul>
<b>Warehouse</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in Check Weigher Machine Installation Qualification Activity.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Instrument Name</b>	Bottle Torque Tester
<b>Equipment</b>	
<b>Manufacturer's Name</b>	Vinsyst Technologies.
<b>Supplier Name</b>	Vinsyst Technologies.
<b>Serial No.</b>	
<b>Model</b>	VBT-20
<b>Location of Installation</b>	Packing Area, Three Piece Line

**6.0 SYSTEM DESCRIPTION:**

Bottle Torque Tester is Torque Measuring Device Specially designed to Work on Bottle 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 Appropriate amount of Torque . Even child Resistant Caps Requiring downward force during the opening Operation cab be tested.

Torque Tester Machine Consist of Following Components.

- LCD
- Indicating Lamp
- Function Keys
- Special Fixture
- Printer
- USB Interface
- Charging Socket
- Power Socket



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**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- DQ Protocol Cum Report
- IQ Protocol cum Report
- Draft SOP for operation & Cleaning of Bottle Torque Tester Devices

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum report.

**7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.



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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Verification of documents:**

The results of any tests should meet the limits and acceptance criteria specified in the test documents.  
Any deviations or issues should be rectified and documented prior to OQ commencing.

S. NO.	DOCUMENT NAME	DOCUMENT/SOP NO.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	Draft SOP for operating & Cleaning of Bottle Torque Tester Devices			

**Checked By**  
**Production**  
**Sign/Date: .....**

**Verified By**  
**Quality Assurance**  
**Sign/Date: .....**

**Inference:**

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**Reviewed By**  
**Manager QA**  
**Sign/Date: .....**





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**8.2 Operational and Functional Checks:**

**8.2.1 Operational Checks:**

Operate the Bottle Torque Tester Devices as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

<b>Parameter</b>	<b>Specifications</b>	<b>Satisfactory Yes / No</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Upper Limit Value Setting</b>	To Set the upper Limit Value , when Reaching the upper limit Value , Automatic Audible and Visual alarm the upper limit Value should be lower be lower than full Range		
<b>Lower Limit Value Setting</b>	To Set Lower Limit Value ,when Reaching the Lower Limit Value Automatic Audible and Visual Alarm ,the lower Limit Value Should be lower then set Upper Limit		
<b>Minimum Saved Value Setting</b>	To Set Minimum Saved Value According to storage needs ,the data Smaller than this valve will not Saved .		
<b>Minimum Peak Holding Value Setting</b>	Automatic Peak Value Measurement needs to set Freely ,the value ,the value Smaller then this Value Can Not Peak Saved.		
<b>Automatic Peak time Setting</b>	To the Condition of Measured Automatically peak Value to set from 1-99 Second Freely.		



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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<b>Automatic Set Down Time Setting</b>	In no operation Condition the Automatic Should Down setting times Can be set From 0 minute to 9 Minute Freely		
<b>Acceleration of Gravity Setting</b>	According to Area of Position to set the Acceleration value native Machine is Acquiesced as 9.794		
<b>Revert to original Setting</b>	Improper Operation and Change data many Times Will appear Confusion can through this Item Setting to Make the 1-7 Data Return to Factory Setting.		

**Checked By  
Production**

**Sign/Date:** .....

**Inference:**

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**Verified By**

**Quality Assurance**

**Sign/Date:** .....

**Reviewed By**

**Manager QA**

**Sign/Date:** .....



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**9.0 REFERENCES:**

- Validation Master Plan.
- Operational & Maintenance Manual

**10.0 DOCUMENTS TO BE ATTACHED:**

- Copy Of Draft SOPs
- Any Other Relevant Documents

**11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY ):**

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# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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### 14.0 CONCLUSION:

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### 15.0 RECOMMENDATION:

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**16.0 ABBREVIATIONS:**

AC	:	Alternative Current
cGMP	:	Current Good Manufacturing Practice
BTT	:	Bottle torque Tester
DC	:	Direct Current
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
Hz	:	Hertz
Ltd.	:	Limited
mm	:	Millimeter
No.	:	Number
QA	:	Quality Assurance
V	:	Volt



**PHARMA DEVILS**

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**17.0 PROTOCOL POST -APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			