INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
BOTTLE TORQUE TESTER

INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

BOTTLE TORQUE TESTER

INSTRUMENT ID. No.	
LOCATION	**Packing Area, Three Piece Line**
DATE OF QUALIFICATION	
SUPERSEDES No.	**NIL**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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FOR
BOTTLE TORQUE TESTER

PROTOCOL CONTENTS

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR BOTTLE TORQUE TESTER

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 provide documented evidence for the Installation Qualification of Bottle Torque Tester Devices.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

The scope of this installation qualification protocol cum report is limited to qualification of Bottle Torque Tester Devices to be installed in Packing Area First Floor, Three Piece Line.

- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Bottle Torque Tester.

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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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review Authorization and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Bottle Torque Tester Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution.

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5.0 EQUIPMENT DETAILS:

Instrument Name	Bottle Torque Tester
Equipment	
Manufacturer's Name	Vinsyst Technologies.
Supplier Name	Vinsyst Technologies.
Serial No.	
Model	VBT-20
Location of Installation	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:

- Executed and approved design qualification document
- Technical specification of equipment

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 IQ 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 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Three Piece Line Packing Line 'I' Block		
Room Condition	General working condition		
Illumination in area	NLT 300 Lux		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

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 EQUIPMENT VERIFICATION:

8.2.1 TECHNICAL SPECIFICATIONS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Make	Vinsyst Technology VBT Series		
Serial Number	340080877		
Model	VBT-20		
Capacity	20 N.m		
Net Weight	12 kg		
Safe over Torque	120 % of Rated Capacity		
Fatigue Rating	1 millions Cycle		
Accuracy	Better than ± 0.5 % of full Scale		
Non- Linearity	± 0.15 % of Full Scale		
Hysteresis	± 0.05 % of Full Scale		
Non – Repeatability	± 0.1% of Full Scale		
Input Resistance	400 omh Nominal		
Sensitivity	2 m V/V, ± 10 %		
Calibration Unit	3 (Nm,lb in ,Kg cm)		
Display	12 mm High bright LED		
Calibration	Factory Calibrated to National Standard		
Peak Hold	yes		

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Temperature Range	5 to 55°C		
Clock wise / Anti Clock wise Torque	Indicated by (+) and (-) Sign		
Range	26 – 62.5 mm		
Sensor Type	Sensor Inside		
Power	8.4 V 1.2 V x 7 Ni –MH Battery Group		
Power Adapter	Input : AC 220 V 50 Hz Output DC 10 V 300 mA		
Charging Time	4-6 Hours		
Battery Life	300 Times		
Size	400 x 200 x200 mm		

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8.3 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING (SIGN/DATE)
No Sharp Edges	Rounded Corners		
Electrical & Electronic Guard	Safely enclosed control box and display unit.		
External Components	All external material used are of stainless steel 304 and Food grade		

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8.4 UTILITIES PROVIDED:

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED By (ENGINEERING) (SIGN/DATE)
Electricity	Voltage: Single phase AC220V (+10% / -15%), Frequency: 50Hz		

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9.0 REFERENCES:

- Validation Master Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.
- Party Documents

10.0 DOCUMENTS TO BE ATTACHED:

- Instruction Manual
- Dimension Drawing

11.0 DEVIATION FROM PRE-DEFINED 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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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
Hz	:	Hertz
Ltd.	:	Limited
mm	:	Millimeter
No.	:	Number
QA	:	Quality Assurance
V	:	Volt

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17.0 PROTOCOL POST -APPROVAL:

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