



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

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

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL CUM REPORT No.	NIL



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FOR
BOTTLE TORQUE TESTER DESIGN**

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	PROTOCOL PRE-APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	PROJECT REQUIRMENTS	4
5.0	RESPONSIBILITY	5
6.0	BRIEF INSTRUMENT DESCRIPTION	6
7.0	EQUIPMENT SPECIFICATION	7
8.0	CRITICAL VARIABLES TO BE MET	7
8.1	PROCESS/PRODUCT PARAMETERS	7
8.2	UTILITY REQUIREMENT/LOCATION SUITABILITY	7
8.3	TECHNICAL SPECIFICATION/KEY DESIGN FEATURES	8
8.4	SAFETY	8
8.5	VENDOR SELECTION	9
9.0	DOCUMENT TO BE ATTACHED	10
10.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	10
11.0	ANY CHANGE MADE AGAINST THE FORMALLY AGREED PARAMETER	10
12.0	RECOMMENDATION	10
13.0	ABBREVIATIONS	11
14.0	REVIEWED BY	12



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

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 (QUALITY ASSURANCE)			

AUTHORIZED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



**QUALIFICATION PROTOCOL CUM REPORT
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BOTTLE TORQUE TESTER DESIGN**

2.0 OBJECTIVE:

- To prepare the Design Qualification of Bottle Torque Tester Devices on the basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Equipment / Product Requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Bottle Torque Devices procured from (**Make: Vinsyst Technology**).
- The equipment shall operate under the controlled environment and conditions as per the cGMP Requirements.

4.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and/or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

The holding Vessel, its associated components and stirrer are designed to process pharmaceutical products in accordance with cGMP principles.



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BOTTLE TORQUE TESTER DESIGN**

5.0 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	<ul style="list-style-type: none">• Preparation, Review and Authorization of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification activity.• Review of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.• Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.• GA Drawing• Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.• Details of utilities• Identification of components for calibration• Material of construction of all components• Brief Equipment Description• Safety Features and Alarms• Review of Design Qualification Protocol cum Report after Execution.



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6.0 BRIEF INSTRUMENT 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

7.0 EQUIPMENT SPECIFICATION:

- Equipment Specification is a document provided to manufacturer for engineering equipment as per the specifications.



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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Model	VBT-P20	Design Requirement
Capacity	20N.m	Design Requirement
Range	26 to 62.5 mm	Design Requirement
Accuracy	± 0.5 %	Design Requirement
Sensor Type	Sensor Inside	Design Requirement
Power	8.4 V 1.2 V x 7 Ni-MH Battery Group	Design Requirement
Charging Time	4-6 Hours	Design Requirement
Battery	Continuous Using time of about 10 Hours	Design Requirement
Battery Life	300 Times	Design Requirement
Power Adaptor	Input ;AC 220 V 50 Hz Output DC 10 V 300 mA	Design Requirement

8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electricity Supply with proper Earthing	Voltage: Single phase AC220V (+10% / - 15%), Frequency: 50Hz	Design Requirement



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8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

8.3.1 TECHNICAL SPECIFICATION :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Make	Vinsyst Technology VBT Series	Design Requirement
Serial Number	340080877	Design Requirement
Model	VBT-20	Design Requirement
Capacity	20 N.m	Design Requirement
Net Weight	12 kg	Design Requirement
Safe over Torque	120 % of Rated Capacity	Design Requirement
Fatigue Rating	1 millions Cycle	Design Requirement
Accuracy	Better than ± 0.5 % of full Scale	Design Requirement
Non- Linearity	± 0.15 % of Full Scale	Design Requirement
Hysteresis	± 0.05 % of Full Scale	Design Requirement
Non – Repeatability	$\pm 0.1\%$ of Full Scale	Design Requirement
Input Resistance	400 ohm Nominal	Design Requirement
Sensitivity	2 m V/V, ± 10 %	Design Requirement
Calibration Unit	3 (Nm,lb in ,Kg cm)	Design Requirement
Display	12 mm High bright LED	Design Requirement
Calibration	Factory Calibrated to National Standard	Design Requirement
Peak Hold	yes	Design Requirement
Temperature Range	5 to 55°C	Design Requirement
Clock wise / Anti Clock wise Torque	Indicated by (+) and (-) Sign	Design Requirement

8.4 SAFETY FEATURE :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
No Sharp Edges	Rounded Corners	Safety Requirement
Electrical & Electronic Guard	Safely enclosed control box and display unit.	Safety Requirement



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8.5 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Bottle Torque Tester	Selection of Vendor is done on the basis of review of vendor. Criteria for review include Vendor Background (General / Financial), Technical Know How, Quality Standards, Inspection of Site, Costing, and Feed Back from Market etc.).	cGMP Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement as specified in PO.
(2) Operating and service manual for Bottle Torque Tester shall be provided at the time of delivery of the equipment.

Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:
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.....
.....

Reviewed By
Manager QA
Sign/Date:



**QUALIFICATION PROTOCOL CUM REPORT
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9.0 DOCUMENTS TO BE ATTACHED:

- Instruction Manual
- Dimension Drawing
- Purchase Order Copy

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

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11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

AC	:	Alternative Current
cGMP	:	Current Good Manufacturing Practice
BTT	:	Bottle torque Tester
DC	:	Direct Current
DQ	:	Design Qualification
Gm	:	Gram
Hz	:	Hertz
Ltd.	:	Limited
mm	:	Millimeter
No.	:	Number
PO	:	Purchase Order
QA	:	Quality Assurance
URS	:	User Requirement Specification
V	:	Volt



PHARMA DEVILS
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FOR
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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			