# PERFORMANCE QUALIFICATION

# PROTOCOL

# FOR

# BOTTLE TORQUE TESTER

| | |
|---|---|
| **EQUIPMENT ID. No.** | |
| **LOCATION** | **Packing Area, Three Piece Line** |
| **DATE OF QUALIFICATION** | |
| **SUPERSEDES PROTOCOL No.** | **NIL** |

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

# PERFORMANCE QUALIFICATION PROTOCOL FOR BOTTLE TORQUE TESTER

## PROTOCOL CONTENTS

# PERFORMANCE QUALIFICATION PROTOCOL FOR BOTTLE TORQUE TESTER

## 1.0 PROTOCOL 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) | | | |

# PERFORMANCE QUALIFICATION PROTOCOL FOR BOTTLE TORQUE TESTER

## 2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

## 3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Bottle Torque Tester installed in **Packing Area, Three Piece Line.**
- This Protocol will define the methods and documentation used to qualify the Check Weigher Machine for PQ.

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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 Performance Qualification.<br>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.<br>• Monitoring of Performance Qualification. |
| **Production** | • Review of Performance Qualification Protocol.<br>• To co-ordinate and support Performance Qualification Activity. |
| **Engineering** | • Reviewing of Performance Qualification protocol for correctness, completeness and technical excellence<br>• Responsible for trouble shooting (if occurred during execution).<br>• Maintenance & preventive maintenance as per schedule. |

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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** | |
| **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

.

# PERFORMANCE QUALIFICATION PROTOCOL FOR BOTTLE TORQUE TESTER

## 7.0 REASON FOR QUALIFICATION:

- New equipment in Packing Area, Three Piece Line.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

## 8.0 SITE OF STUDY:

Packing Area, Three Piece.

## 9.0 FREQUENCY OF QUALIFICATION:

- Once in 2 year
- After any major breakdown or after major modification.
- After Change of Location.

# PERFORMANCE QUALIFICATION PROTOCOL FOR BOTTLE TORQUE TESTER

## 10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

### 10.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

| S. No. | Document Name | Document / SOP No. | Completed (Yes/No) | Checked By (Engineering) Sign/Date |
|---|---|---|---|---|
| 1. | Executed and approved Design Qualification document | | | |
| 2. | Executed and approved Installation Qualification document | | | |
| 3. | Executed and approved Operational Qualification document | | | |
| 4. | SOP for operating & Cleaning Of Torque Tester | | | |
| 5. | SOP for Preventive Maintenance Of Torque Tester | | | |

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

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

**Inference:**

……

……

……

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

# PERFORMANCE QUALIFICATION PROTOCOL FOR BOTTLE TORQUE TESTER

## 11.0 TESTS AND CHECKS:

## 11.1 TEST OF TORQUE:

**A) OBJECTIVE:**

The objective Of Torque Tester is used for Exact Determination of Torque of vials after Capping

**B) METHOD APPLIED:**

**a)** The test should be carried out Each Vender each pack size of vial.

**b)** Switch "ON" the machine & Operate as per SOP.

**c)** Capping Machine Should be Operate at Full Torque

**d)** Collect 15 Filled & Capped vials at Minimum (40 %), Optimum (70 %) & Maximum Speed (90 %). At Initial Middle and of The Batch

**e)** Set the Limit by Manually in Torque Tester Machine.

**f)** Perform the test for 5.0 & 10 ml pack size vials.

**g)** For Evaluation of Torque range, Capping Run at minimum, Optimum & Maximum Speed, at Full Torque Range from Capping Machine, & Take 3 Batch of Each Pack Size.

**h)** Passed the Filled vials through Of Torque Tester

**i)** Before Checking Torque Performed Leak Test

**j)** Observation Record in Performance Qualification Report.

**C) ACCEPTANCE CRITERIA:** before Evaluation of Torque, Leak test of capped Vial Should be passed.

| Vendor | Maximum Torque | Minimum Torque |
|---|---|---|
| BP Rex-10 ml vial | -0.800 Nm | -0.311 Nm |
| Dr.Pack –10 ml vial | -0.733 Nm | -0.303 Nm |
| Dr.Pack –5 ml vial | -0.924 Nm | -0.281 Nm |
| BP Rex-5 ml vial | -0.867 Nm | -0.300 Nm |
| Rexam -10 ml vial | -0.602 Nm | -0.310 Nm |
| Rexam – 5 ml Vial | -0.992 Nm | -0.302 Nm |

**D) RESULT RECORDING:**

Record the results in the performance Qualification report

## 12.0 CHECKLIST OF ALL TESTS AND CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol to be executed and consisting of following tests.

| Tests or checks | Executed [Y/N] | Remark |
|---|---|---|
| Verification of Leak test & Torque for 5.0, 10 ml at Minimum Speed | | |
| Verification of Leak test & Torque for 5.0, 10 ml at Optimum Speed | | |
| Verification of Leak test & Torque for 5.0,10 ml at Maximum Speed | | |

**PERFORMANCE QUALIFICATION PROTOCOL**
**FOR**
**BOTTLE TORQUE TESTER**

## 13.0 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.

## 14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

## 15.0 NON COMPLIANCE:

- If any discrepancies or Non-compliance observed during Performance Qualification, it shall be immediate report to User Department Head & QA head.
- Note down the Non-Compliance with proper justification and mentioned simultaneously in Performance Qualification Report also.

## 16.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

## 17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

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## 18.0 ABBREVIATIONS:

| | | |
|---|---|---|
| cGMP | : | Current Good Manufacturing Practices |
| BTT | : | Bottle Torque Tester |
| ID. | : | Identification Number |
| Ltd. | : | Limited |
| No. | : | Number |
| PPQ | : | Performance Qualification Protocol |
| QA | : | Quality Assurance |
| SOP | : | Standard Operating Procedure |