



**PERFORMANCE QUALIFICATION REPORT
FOR
BOTTLE TORQUE TESTER**

**PERFORMANCE QUALIFICATION
REPORT
FOR
BOTTLE TORQUE TESTER**

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



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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT
FOR
BOTTLE TORQUE TESTER**

1.0 REPORT 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 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 scope of this report is limited for qualification of Torque Tester Machine installed in **Packing Area, Three line.**
- This report provides all the relevant information of the performance qualification activity, In-process observations write in Report



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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	<ul style="list-style-type: none">• Preparation, review Authorization and Compilation of the Performance Qualification Report.• Co-ordination with Quality Control, Engineering and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Production	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Performance Qualification Activity.• Post Approval of Performance Qualification Report After Execution.
Engineering	<ul style="list-style-type: none">• Reviewing of qualification protocol for correctness, completeness and technical excellence• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.• Post Approval of Performance Qualification 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	
Location of Installation	Packing Area, Three Piece Line

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification document			
2.	Executed and approved Installation Qualification document			
3.	Executed and approved Operational Qualification document			
4.	Approved Performance Qualification Protocol			

Inference:

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Reviewed By
Manager QA
Sign/Date:



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7.0 TESTS AND CHECKS:

7.1 VERIFICATION OF TORQUE:

7.1.1 Start of the Batch:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Pack Size		Torque Lower Limit	
		Torque Upper Limit	
Vender Name		Block / Area	

Date	Vial No.	Minimum Speed of Capping Machine ()		Optimum Speed of Capping Machine ()		Maximum Speed of Capping Machine ()	
		Leak Test	Torque	Leak Test	Torque	Leak Test	Torque
	1.						
	2.						
	3.						
	4.						
	5.						
	6.						
	7.						
	8.						
	9.						
	10.						
	11.						
	12.						
	13.						
	14.						
	15.						

Acceptance Criteria : Leak Test Should be Performed before Torque Testing. Leak test Should be Passed & Torque Found with in limit.

Checked By
Production
Sign/Date:

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

Inference:

.....
.....

Reviewed By
Manager QA
Sign/Date:



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7.1.2 Middle of the Batch:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Pack Size		Torque Lower Limit	
		Torque Upper Limit	
Vender Name		Block / Area	

Date	Vial No.	Minimum Speed of Capping Machine ()		Optimum Speed of Capping Machine ()		Maximum Speed of Capping Machine ()	
		Leak Test	Torque	Leak Test	Torque	Leak Test	Torque
	1.						
	2.						
	3.						
	4.						
	5.						
	6.						
	7.						
	8.						
	9.						
	10.						
	11.						
	12.						
	13.						
	14.						
	15.						

Acceptance Criteria : Leak Test Should be Performed before Torque Testing. Leak test Should be Passed & Torque Found with in limit.

Checked By
Production
Sign/Date:

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

Inference:

.....
.....

Reviewed By
Manager QA
Sign/Date:



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7.1.3 End of the Batch:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Pack Size		Torque Lower Limit	
		Torque Upper Limit	
Vender Name		Block / Area	

Date	Vial No.	Minimum Speed of Capping Machine ()		Optimum Speed of Capping Machine ()		Maximum Speed of Capping Machine ()	
		Leak Test	Torque	Leak Test	Torque	Leak Test	Torque
	1.						
	2.						
	3.						
	4.						
	5.						
	6.						
	7.						
	8.						
	9.						
	10.						
	11.						
	12.						
	13.						
	14.						
	15.						

Acceptance Criteria : Leak Test Should be Performed before Torque Testing. Leak test Should be Passed & Torque Found with in limit.

Checked By
Production
Sign/Date:

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

Inference:

.....
.....

Reviewed By
Manager QA
Sign/Date:



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8.0 CHECKLIST OF ALL TESTS AND CHECKS:

This checklist is provided to ensure that all tests or checks required for this report have been executed.

TESTS OR CHECKS	EXECUTED [Y/N]	REMARK
Verification of Leak test & Torque for 5.0 ml at Minimum Speed		
Verification of Leak test & Torque for 5.0 ml at Optimum Speed		
Verification of Leak test & Torque for 5.0 ml at Maximum Speed		

Checked By
Production
Sign/Date:

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

Inference:

.....
.....
.....

Reviewed By
Manager QA
Sign/Date:



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9.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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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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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

BTT	:	Bottle Torque Tester
ID.	:	Identification Number
Ltd.	:	Limited
ml	:	Milliliter
No.	:	Number
PPQ	:	Performance Qualification Protocol
QA	:	Quality Assurance
RPQ	:	Performance Qualification Report
SOP	:	Standard Operating Procedure
Vol	:	Volume



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17.0 REPORT 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)			