



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

**PERFORMANCE QUALIFICATION
REPORT
FOR
BOTTLE TORQUE TESTER**

EQUIPMENT ID. No.	
LOCATION	Packing Area
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

REPORT CONTENTS

S.No.	TITLE	PAGE No.
1.0	REPORT PRE-APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	EQUIPMENT DETAILS	6
6.0	PRE-QUALIFICATION REQUIREMENT	6
7.0	TESTS & CHECKS	7-25
8.0	CHECKLIST OF ALL TESTS AND CHECKS	26
9.0	DOCUMENTS TO BE ATTACHED	27
10.0	NON COMPLIANCE	27
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY	27
12.0	CHANGE CONTROL, IF ANY	27
13.0	REVIEW INCLUSIVE OF FOLLOW UP ACTION, IF ANY	27
14.0	CONCLUSION	28
15.0	RECOMMENDATIONS	28
16.0	ABBREVIATIONS	29
17.0	REPORT POST APPROVAL	30



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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



PERFORMANCE QUALIFICATION REPORT 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 scope of this Addendum report is limited for qualification of Torque Tester Machine by Using Close Nozzle Vial,
- Torque Tester Machine installed in **Packing Area**.
- This report provides all the relevant information of the performance qualification activity, In-process observations write in Report



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

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 Approval and Compilation of the Performance Qualification Report.• Co-ordination with Quality Control, Engineering and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.• Post Approval of Performance Qualification Report After Execution.
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.



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

5.0 EQUIPMENT DETAILS:

Instrument Name	Bottle Torque Tester
Equipment	
Manufacturer's Name	
Supplier Name	
Serial No.	
Model	
Location of Installation	Packing Area

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	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		

Inference:

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Reviewed By
Manager QA
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.0 TESTS AND CHECKS:

7.1 TEST OF TORQUE:

A) OBJECTIVE:

The objective Of Torque Tester is used for Exact Determination of Torque of Close Nozzle 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 16 Filled & Capped vials at Minimum (40 %), Optimum (70 %) & Maximum Speed(90 %). At Initial Middle and end of The Batch
- e) Set the Limit by Manually in Torque Tester Machine.
- f) Perform the test for 5.0 & 10 ml close Nozzle 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 Close Nozzle .
- h) Passed the Filled vials through Of Torque Tester
- i) Before Checking Torque Performed Leak Test
- j) Observation Recorded.

C) ACCEPTANCE CRITERIA:

Before Evaluation of Torque, Leak test of capped Vial Should be passed. Torque Value Found with in Limit as Per Given Table

Vendor	Pack Size	Maximum Torque	Minimum Torque
VGM	5 ml	- 625 NM	-315 NM
VGM	10 ml	- 756 NM	-310 NM



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7.2 VERIFICATION OF TORQUE:

7.2.1 First Batch of 10 ml Pack Size :

7.2.1.1 Start of the Batch:

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

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

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Manager QA
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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.1.2 Middle of the Batch:

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

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.						
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7.2.1.3 End of the Batch:

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

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.						
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Reviewed By
Manager QA
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.2 Second Batch of 10 ml Pack Size:

7.2.2.1 Start of the Batch:

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

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

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Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.2.2 Middle of the Batch:

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

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

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Reviewed By
Manager QA
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.2.3 End of the Batch:

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

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

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Reviewed By
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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.3 Third Batch of 10 ml Pack Size:

7.2.3.1 Start of the Batch:

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

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

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Reviewed By
Manager QA
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.3.2 Middle of the Batch:

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

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

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Reviewed By
Manager QA
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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.3.3 End of the Batch:

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

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

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Manager QA
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.4 First Batch of 5 ml Pack Size :

7.2.4.1 Start of the Batch:

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

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

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Quality Assurance
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Reviewed By
Manager QA
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.4.2 Middle of the Batch:

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

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

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Quality Assurance
Sign/Date:.....

Inference:
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Reviewed By
Manager QA
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.4.3 End of the Batch:

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

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

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Reviewed By
Manager QA
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.5 Second Batch of 5 ml Pack Size:

7.2.5.1 Start of the Batch:

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

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

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

Inference:

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Reviewed By
Manager QA
Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.5.2 Middle of the Batch:

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

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.						
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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.5.3 End of the Batch:

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

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.						
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Reviewed By
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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.6 Third Batch of 5 ml Pack Size:

7.2.6.1 Start of the Batch:

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

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.						
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Reviewed By
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Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.6.2 Middle of the Batch:

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

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.						
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7.2.6.3 End of the Batch:

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

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

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Reviewed By
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Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

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 5.0/10 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		

Verified By
Quality Assurance
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Reviewed By
Manager QA
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

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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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

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
NM	:	Newton Meter



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			