

QUALITY ASSURANCE DEPARTMENT

### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

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



QUALITY ASSURANCE DEPARTMENT

# ${\bf PERFORMANCE\ QUALIFIC \underline{ATION\ REPORT\ FOR\ BOTTLE\ TORQUE\ TESTER}$

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### 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)			



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### 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 score 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, Inprocess observations write in Report



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### 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		
	Preparation, review Approval and Compilation of the Performance		
	Qualification Report.		
Quality Assurance	Co-ordination with Quality Control, Engineering and Engineering to		
Quanty Assurance	carryout Performance Qualification Activity.		
	Monitoring of Performance Qualification.		
	Post Approval of Performance Qualification Report After Execution.		
	Review of Performance Qualification Report.		
Production	To co-ordinate and support Performance Qualification Activity.		
	Post Approval of Performance Qualification Report After Execution.		
	Reviewing of qualification protocol for correctness, completeness and		
	technical excellence		
Engineering	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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### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

Instrument Name	Bottle Torque Tester
Equipment	
Manufacturer's Name	
Supplier Name	
Serial No.	
Model	
<b>Location of Installation</b>	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:	
	Reviewed By
	Manager QA
	Sign/Datas

# \*\*\*\*

## PHARMA DEVILS

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### 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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### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2	<b>VERIFICATION OF</b>	TORQUE:
-----	------------------------	---------

- 7.2.1 First Batch of 10 ml Pack Size:
- 7.2.1.1 Start of the Batch:

Date of	f test			<b>Equipment ID</b>	No.		
Produc	t Name			Batch No.			
Pack S	ize			<b>Torque Lower</b>	Torque Lower Limit		
				<b>Torque Upper</b>	Limit		
Vender	r Name						
Date	_		Optimum Spec Capping Mach		Maximum S		
	NU.	Capping Mac	hine ( )	Capping Maci	hine ( )	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.						
		ria: Leak Test Si with in limit.	hould be Perfo	ormed before Tore	que Testing. Lea	k test Should be	e Passed
Checked By Production Sign/Date:			Verified By Quality Assurance Sign/Date:				
Infere	nce:						

Reviewed By Manager QA

**Sign/Date:** .....



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Date of	f test				Equipm	ent ID No.		
	ct Name				Batch No.			
					Torque Lower Limit			
Pack S	Size					Upper Limit		
Vende	r Name							
Date	Vial No.			mum Speed of bing Machine ( )		Maximum Speed of Capping Machine ( )		
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
Accent		 ria: Leak Test S	hould be Perfo	ormed b	efore To	raue Testino L	eak test Should	he Passed
		vith in limit.		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			- In tost Should	
Produ						Qua	fied By lity Assurance /Date:	
Infere	ence:							
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							•••••	
						Mana	ewed By ager QA Date:	



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7.2.1.3	3 End of the	e Batch:						
Date of	f test				Equipm	ent ID No.		
Produc	ct Name				Batch N	0.		
Pack S	·				Torque	<b>Lower Limit</b>		
					Torque	Upper Limit		
Vende	r Name							
Date	Vial No.			mum Speed of bing Machine ( )		Maximum Capping Mac	_	
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
Accept	Lance Crite	ria: Leak Test S	⊥ hould be Perfo	ormed b	efore Tor	uue Testing. Le	L eak test Should b	e Passed
		with in limit.		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,01010 101	que resting. Le	vair test should t	or assect
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Produ						Qua	fied By lity Assurance /Date:	•••••
Infere	ence:							
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							ewed By ager QA	
							Date:	• • • • • • • •
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### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7	2	2	Second	Ratch	of 10 ml	Pack	Size.
7.	.4.	4	Second	Daten	OI IV III	rack	DIZE.

### 7.2.2.1 Start of the Batch:

Date of test	<b>Equipment ID No.</b>	
<b>Product Name</b>	Batch No.	
De al- Ci	<b>Torque Lower Limit</b>	
Pack Size	<b>Torque Upper Limit</b>	
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.						
	3.						
	4.						
	5.						
	6.						
	7.						
	8.						
	9.						
	10.						
	11.						
	12.						
	13.						
	14.						
	15.						

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By Manager QA Sign/Date:



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7.2.2.2	2 Middle of	the Batch:						
Date o	f test				Equipm	ent ID No.		
Produc	ct Name				Batch N	0.		
Pack S	Size				Torque Lower Limit			
Vanda	r Name				Torque	Upper Limit		
venue	1 Maine							
Date	Vial	al Minimum Speed of			mum Spe		Maximum	
	No.	Capping Mac	hine ( )	Capp	oing Macl	hine ( )	Capping M	lachine (
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							-
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
Accept	tance Crite	ria: Leak Test S	Should be Perfe	ormed	before To	orque Testing. L	eak test Should	be Passed
& Toro	que Found w	vith in limit.						
Chock	ked By					Vorif	ied By	
Produ							ity Assurance	
		•••••					Date:	•••••
Inference:								
						Revie	ewed By	
						Mana	ager QÅ Date:	•••••



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7.2.2.3 End of the Batch:		
7.2.2.5 End of the batch.		

Date of test		Equipment ID No.						
Produc	ct Name				Batch N	<b>[0.</b>		
Pack S	Sizo				Torque	Lower Limit		
					Torque	<b>Upper Limit</b>		
Vende	r Name							
Date	Vial	Minimum S	Speed of	Onti	num Spe	ed of	Maximum S	Speed of
	No.	Capping Macl			ing Macl		Capping Mac	
		Leak Test	Torque		k Test	Torque	Leak Test	Torque
	1.		1			1		1
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
_		ria: Leak Test S	hould be Perfe	ormed l	pefore To	orque Testing. L	eak test Should	be Passed
& Toro	que Found v	vith in limit.						
Produ						Qual	ied By ity Assurance Date:	
Infere	ence:							
	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •					•••••
						Man	ewed By ager QA Date:	



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### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7	.2.3	Third	Ratch	of 10 ml	Pack Size:
,	4	, iiiiiu	Datti	VI IV IIII	I ack bize.

7	2 3	2 1	Star	t of t	ha R	otch.
1.	. Z	١. (	ı Sıar	I. ()  I.	ne B	aicn:

Date of test	<b>Equipment ID No.</b>	
<b>Product Name</b>	Batch No.	
Pack Size	<b>Torque Lower Limit</b>	
rack Size	<b>Torque Upper Limit</b>	
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.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By
	Manager QA
	Sign/Date:



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7.2.3.2	2 Middle of	the Batch:						
Date of	f test				Equipme	ent ID No.		
Produc	ct Name				Batch No.			
Pack S	ize				<b>Torque Lower Limit</b>			
Vender Name					Torque 1	Upper Limit		
					~			
Date	Vial No.				mum Spec oing Mach		Maximum Speed of Capping Machine (	
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
		ria: Leak Test Sl vith in limit.	hould be Perfo	rmed b	efore Toro	que Testing. Lea	k test Should b	e Passed
Check Produ Sign/L	ction	•••••					ed By ty Assurance Date:	
Infere	nce:							
	•••••			• • • • • • • • •				
						Mana	ewed By ager QA Date:	



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7.2.3.3 End of the Batch:		

Date of	f test				Equipm	ent ID No.		
Produc	ct Name				Batch N			
Pack S	Size					<b>Lower Limit</b>		
					Torque	<b>Upper Limit</b>		
Vende	r Name							
Date	Vial		Minimum Speed of Option		mum Spe		Maximum S	
	No.	Capping Mac	hine ( )		oing Mac	hine ( )	Capping Mac	hine ( )
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3. 4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
Accept	tance Crite	ria: Leak Test S	Should be Perfe	ormed l	before To	orque Testing. I	Leak test Should	be Passed
		vith in limit.						
Check Produ Sign/I	iction	•••••				Qua	ified By lity Assurance l/Date:	
Infere	ence:							
	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	•••••					
						Mar	iewed By nager QA /Date:	•••••



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# PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.4	Firet	Ratch	of 5 ml	Pack	Size	•
/ · <del>/</del> · <del>/</del>	THSU	Datti	or 2 mm	rack	SIZE	٠

_	A 4 -	• 0		O 41	ı m		
7.	Z.4.	1 5	tart.	OI I	ne B	Ratch	ı:

Date of test	<b>Equipment ID No.</b>	
<b>Product Name</b>	Batch No.	
Pack Size	<b>Torque Lower Limit</b>	
rack Size	<b>Torque Upper Limit</b>	
Vender Name		

Date	Vial No.	Minimum S Capping Macl		Optimum Spec Capping Mack		Maximum S Capping Mach	
		Leak Test	Torque	Leak Test	Torque	Leak Test	Torque
	1.						
	2.						
	3.						
	4.						
	5.						
	6.						
	7.						
	8.						
	9.						
	10.						
	11.						
	12.						
	13.						
	14.						
	15.						

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By
	Manager QA
	Sign/Date:



**Date of test** 

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**Equipment ID No.** 

7717	Middle of the	. Datah.
1 / 4 /	villine of the	, Dallali,

Product Name					Batch No.			
Pack S	ize					Lower Limit		
Vender	r Name				Torque	Upper Limit		
Date	Vial No.	Minimum S Capping Macl			num Speo ing Macl		Maximum S Capping Mach	
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
		ria: Leak Test Si vith in limit.	hould be Perfo	rmed b	efore Tor	que Testing. Le	ak test Should be	Passed
Check Produ Sign/D	ction					Qual	ied By ity Assurance Date:	
Infere	nce:							
						Man	wed By ager QA Date:	•••••



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7.2.4.3 End of the Batch:		

Date of	f test				Equipm	ent ID No.		
Produc	ct Name				Batch N	0.		
Dook C	Pack Size Torque Lower Limit							
Torque Upper Limit								
Vender	r Name							
Date	Vial	Minimum	Speed of	Onti	mum Spe	ed of	Maximum	Speed of
Date	No.	Capping Mac			ing Macl		Capping Mac	
		Leak Test	Torque		k Test	Torque	Leak Test	Torque
	1.		•			•		1
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
Accept	ance Crite	ria: Leak Test S	Should be Perfo	ormed l	pefore To	rque Testing. L	eak test Should	be Passed
		vith in limit.						
~.								
Check Produ							fied By	
		•••••					ity Assurance Date:	
oign, i	<i>,</i> , , , , , , , , , , , , , , , , , ,	•••••				Sign,	Dutci	•
Infere	nce:							
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							ewed By ager QA	
							ager QA Date:	



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### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7	2.5	Second	Ratch	of 5 ml	Pack	Size
, ,	4.0	occona	Datti	or 2 mm	1 ack	DIZE.

### 7.2.5.1 Start of the Batch:

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

Date	Vial No.	Minimum Speed of Capping Machine ( )		Optimum Spe Capping Macl		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.						
	16.						

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By Manager QA Sign/Date:



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# PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7.2.	52	Mi	441	മ പ്	the?	Rat	ch.
1.4.	J.4		uu	IC VI	LHC	Dat	L.II.

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

Date	Vial No.	Minimum Speed of Capping Machine ( )		Optimum Spe Capping Mac		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.						
	16.						

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By Manager QA Sign/Date:



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7.2.5.3 End of the Batch:		

Date o	f test	Equipme		ent ID No.				
Produ	ct Name	Batch No		0.				
Pack S	Size	Torque Lower Limit						
					Torque	Upper Limit		
Vende	r Name							
Date	Vial	Minimum S	Speed of	Opti	mum Spe	ed of	Maximum S	Speed of
	No.	Capping Macl	hine ( )	Capp	oing Macl	hine ( )	Capping Mac	hine ( )
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
Accept	Lance Crite	ria: Leak Test S	<u>l</u> Should be Perfo	ormed i	before To	ll praue Testing, I	eak test Should	be Passed
		with in limit.		)11110 Ca		rque resting. r	Jour Cost Silouid	oc i assoc
	-							
	ked By						fied By	
Produ							lity Assurance	
Sign/i	Jale:	•••••				Sign	/Date:	• • • • • • • • • • • • • • • • • • • •
Infere	ence:							
•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •			• • • • • • • • • • • • •	•••••		• • • • • • • • • • • • • • • • • • • •
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							ewed By	
							ager QA	
						Sign	/Date:	•••••



QUALITY ASSURANCE DEPARTMENT

### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

7 2 6	Third	Ratch	of 5 ml	Pack	Size
/ • <del>/</del> • U	IIIII U	Datti	$\mathbf{m} > \mathbf{m}$	Iach	DIZE.

### 7.2.6.1 Start of the Batch:

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

Date	Vial No.	Minimum Speed of Capping Machine ( )		Optimum Spec Capping Mach		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.						
	16.						

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By
	Manager QA



QUALITY ASSURANCE DEPARTMENT

### PERFORMANCE QUALIFICATION REPORT FOR BOTTLE TORQUE TESTER

Date of		the Batch:			Fauinm	ent ID No.		
	ct Name				Batch N			
						Lower Limit		
Pack S	size							
Vende	r Name				1 orque	Upper Limit		
Date	Vial	Minimum S	Speed of	Opti	num Spe	ed of	Maximum S	peed of
	No.	Capping Mac			ing Macl		<b>Capping Mach</b>	
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
		ria: Leak Test S vith in limit.	Should be Perfo	ormed l	pefore To	rque Testing. l	Leak test Should	be Passed
Produ	Oate:	••••••				Qua	ified By llity Assurance n/Date:	
			•••••		• • • • • • • • • • • • • • • • • • • •			• • • • • • • • • • • • • • • • • • • •
							iewed By nager QA	

Sign/Date: .....



7.2.6.3 End of the Batch:

# PHARMA DEVILS

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Date of test					Equipm	ent ID No.		
<b>Product Name</b>					Batch N	0.		
Pack S	izo				Torque	Lower Limit		
					Torque	<b>Upper Limit</b>		
Vender	r Name							
Date	Vial No.	Minimum S Capping Mac			num Speoing Macl		Maximum Capping Mac	
		Leak Test	Torque	Lea	k Test	Torque	Leak Test	Torque
	1.							
	2.							
	3.							
	4.							
	5.							
	6.							
	7.							
	8.							
	9.							
	10.							
	11.							
	12.							
	13.							
	14.							
	15.							
	16.							
Accept	ance Crite	ria: Leak Test S	hould be Perfo	ormed b	efore Tor	ue Testing. Le	eak test Should b	e Passed
_		vith in limit.						
Check Produ Sign/E	ction	••••••				Qua	fied By lity Assurance /Date:	••••••
Infere	nce:							
•••••				•••••				
			• • • • • • • • • • • • • • • • • • • •					
						• • • • • • • • • • • • • • • • • • • •		
						Man	iewed By nager QA /Date:	



QUALITY ASSURANCE DEPARTMENT

### 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

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



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9.0	DOCUMENTS TO BE ATTACHED:
	Any Other Relevant Documents.
10.0	NON COMPLIANCE:
11.0	DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:
12.0	CHANGE CONTROL, IF ANY:
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY ):



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14.0	CONCLUSION:
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

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### 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)			