PERFORMANCE QUALIFICATION REPORT FOR INTEGRATED 3 PIECE VIAL FILLING MACHINE CFL-120

EQUIPMENT ID. No.	
LOCATION	**FILLING ROOM**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

REPORT CONTENTS

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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 **Integrated 3 Piece Vial Filling Line with** Model No. **CFL-120** Machine installed in Vial Filling Room.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the execution of Performance Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Authorization, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification. • Post Approval of Performance Qualification Report after Execution.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Quality Control	• Review of Performance Qualification Report. • Analytical Support (Microbiological Testing/Analysis). • Post Approval of Performance Qualification Report after Execution.
Engineering	• 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 FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

5.0 EQUIPMENT DETAILS:

Equipment Name	Integrated 3 Piece Vial Filling Machine
Equipment	
Manufacturer's Name	
Model	cGMP Model
Supplier's Name	
Location of Installation	Vial Filling Room

6.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Integrated 3 Piece Vial Filling Machine.
- SOP for Preventive Maintenance Integrated 3 Piece Vial Filling Machine.

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

7.0 TESTS AND CHECKS:

7.1 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	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.	**PQ Protocol approved**				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

7.2 PERFORMANCE EVALUATION FOR MACHINE SPEED OPTIMIZATION

Date of Test		**Equipment ID**	
Total Vials taken for test		**Vial Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Vials without Dropper			
Vials without Caps			
Rejection	**……..(B1)**	**……..(B2)**	**……..(B3)**
Sample after …….(min)			
Machine jam			
Vials without Dropper			
Vials without Caps			
Rejection	**……..(B1)**	**……..(B2)**	**……..(B3)**
Sample after …….(min)			
Machine jam			
Vials without Dropper			
Vials without Caps			
Rejection	**……..(B1)**	**……..(B2)**	**……..(B3)**
Total rejection	**Σ B1=**	**Σ B2=**	**Σ B3=**

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

7.3 TEST FOR VOLUME VERIFICATION

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Std. Filled Volume		**Volume Variation Limit**	
Vial Size	**5 ml**	**Cycle -1**	

	Date	**Time**	**Filling volume in ml**						**Checked by (QA)**
			1	**2**	**3**	**4**	**5**	**6**	
Initial									
Middle									
End									

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

TEST FOR VOLUME VERIFICATION

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Std. Filled Volume		**Volume Variation Limit**	
Vial Size	**5 ml**	**Cycle -2**	

	Date	Time	Filling volume in ml						Checked by (QA)
			1	2	3	4	5	6	
Initial									
Middle									
End									

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

TEST FOR VOLUME VERIFICATION

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Std. Filled Volume		**Volume Variation Limit**	
Vial Size	**5 ml**	**Cycle -3**	

	Date	**Time**	**Filling volume in ml**						**Checked by (QA)**
			1	**2**	**3**	**4**	**5**	**6**	
Initial									
Middle									
End									

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

TEST FOR VOLUME VERIFICATION

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Std. Filled Volume		**Volume Variation Limit**	
Vial Size	**10 ml**	**Cycle -1**	

	Date	Time	Filling volume in ml						Checked by (QA)
			1	2	3	4	5	6	
Initial									
Middle									
End									

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

TEST FOR VOLUME VERIFICATION

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Std. Filled Volume		**Volume Variation Limit**	
Vial Size	**10 ml**	**Cycle -2**	

	Date	**Time**	**Filling volume in ml**						**Checked by (QA)**
			1	**2**	**3**	**4**	**5**	**6**	
Initial									
Middle									
End									

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

TEST FOR VOLUME VERIFICATION

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Std. Filled Volume		**Volume Variation Limit**	
Vial Size	**10 ml**	**Cycle -3**	

	Date	**Time**	**Filling volume in ml**						**Checked by (QA)**
			1	**2**	**3**	**4**	**5**	**6**	
Initial									
Middle									
End									

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

7.4 DROPPER FIXING QUALITY:

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**5 ml**
Cycle No.	**01**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**5 ml**
Cycle No.	**02**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**5 ml**
Cycle No.	**03**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
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Sign/Date: ……

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PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**10 ml**
Cycle No.	**01**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**10ml**
Cycle No.	**02**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**10ml**
Cycle No.	**03**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Dropper Fixing Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dropper Fixing Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

7.5 SCREW CAPPING QUALITY

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**5ml**
Cycle No.	**01**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

7.6 SCREW CAPPING QUALITY

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**5ml**
Cycle No.	**02**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

SCREW CAPPING QUALITY

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**5ml**
Cycle No.	**03**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

SCREW CAPPING QUALITY

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**10ml**
Cycle No.	**01**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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Sign/Date: ……

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

SCREW CAPPING QUALITY

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**10ml**
Cycle No.	**02**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

SCREW CAPPING QUALITY

Date of test		**Equipment ID**	
Product Name		**Block / Area**	
Total Vials taken for test		**Machine speed**	
Machine start time		**Vial size**	**10ml**
Cycle No.	**03**		

Initial										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
Middle										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										
End										
Vial No.	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**
Screw capping Quality (OK/ Not OK)										
Vial No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Screw capping Quality (OK/ Not OK)										

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

Checked By
(Production)
Sign/Date: ……

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(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

8.0 CHECKLIST OF ALL TESTS & CHECKS:

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

Tests or Checks	Executed (Yes/No)	Remarks
Verification of DQ, IQ & OQ & Other Documents		
Verification of Machine Performance		
Test for Volume Verification		
Tests for Dropper Fixing Quality		
Tests for Screw Capping Quality		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

9.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of SOP's.
- 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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PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

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:

cGMP	:	Current Good Manufacturing Practices
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
Sr.	:	Senior
SS	:	Stain less Steel
TFM	:	Three piece Filling Machine
WHO	:	World Health Organization
LTD.	:	Limited

PERFORMANCE QUALIFICATION REPORT FORINTEGRATED 3 PIECE VIAL FILLING MACHINE CFL- 120

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			