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

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

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PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR INTEGRATED 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)			

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2.0 OBJECTIVE:

To carry out the Performance Qualification of **Integrated 3 Piece Vial Filling Line with** Model No. **CFL-120** being used for filling, dropper fixing & screw capping of LDPE Vials

To Provide Documented Verification that the Equipment as connected with ancillary system is suitable for indented purpose and produced product as per pre defined Acceptance Criteria

3.0 SCOPE:

The scope of this qualification protocol is limited to qualification of **Integrated 3 Piece Vial Filling** Machine **(Make: ……..)** installed in the Vial **3 Piece Vial Filling & dropper fixing** Room.

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, Approval and Compilation of the Performance Qualification Protocol. • Protocol Training. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review & Approval of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing / Analysis).
Engineering	• Review & Approval of Protocol. • Co-ordination, Execution and technical support in HVAC Qualification activity. • Calibration of Process Instruments. • Responsible for Trouble shooting (if occurs during execution).

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5.0 EQUIPMENT DETAILS:

Equipment Name	Integrated 3 Piece Vial Filling & Dropper Fixing Machine
Equipment ID.	
Model	CFL-20
Manufacturer's Name	
Supplier's Name	
Location of Installation	Vial Filling Room

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6.0 EQUIPEMENT DESCRIPTION:

The Line consists of four parts / machines

1. Bottle Orienting & Feeding Machine
2. 6 Head Filling Machine
3. Dropper Fixing
4. Screw Capping Machine

Bottle Orienting & Feeding Machine:

Orientator is a simple mechanical feeding system for plastic vials. The machine is equipped with multi-pocket Pick-up Star wheel. This star wheel picks up and feeds vials one by one into the feeder star wheel through a chute. A mechanical inverter is used to invert the vials which are coming upside down. And a feeder star wheel transfers vials from the Orientator to the Turn table. Another star wheel is used to transfer vials from Turn table to Filling station. Two IR sensors are used in between Orientator and Filling station to maintain trouble free running of the machine.

Head Filling Machine:

Filling machine consists of syringe less “Pressure and Time Setting” Filling System with the Pre and Post Nitrogen Flushing attachment. This machine consists of 18 head filling station in which 6 heads re used for filling and remaining 12 heads are used for pre and post Nitrogen flushing. An indexing mechanism is used for transferring vials from Orientator to filling station with the help of a intermediate turn table. Filling volumes can be adjusted independently on PLC screen while the machine is running.

Dropper Fixing & Screw Capping Machine:

It is a eight head rotary screw capping machine. It works on rotary basis in which screw capping is done in a continuous running system. The whole machine is driven on a single motor. A vibrator is used for feeding caps and cap dispenser is used for placing caps. Screwing cap is done by most advanced Bush type capping head. This machine is provided with 8 heads to achieve required output. Vial transfer from inlet conveyor to outlet conveyor is achieved by means of star wheel. Enough height adjustment is given on the capping head to suit different size of vials.

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7.0 REASON FOR QUALIFICATION:

- New equipment installed in filling room.
- 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:

Integrated 3 Piece Vial Filling & Dropper Fixing Machine **installed in filling room.**

9.0 FREQUENCY OF QUALIFICATION

- Yearly as per Validation Master Plan.
- After any major breakdown or after major modification

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10.0 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.

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	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification cum report				
2.	Executed and approved Installation Qualification cum report				
3.	Executed and approved Operational Qualification cum report				
4.	PQ Protocol approved				
5.	SOP for Operation & Cleaning of Integrated 3 Piece Vial Filling Machine				
6.	SOP for Preventive Maintenance Integrated 3 Piece Vial Filling Machine				

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……..

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

10.2 Training Record of Validation Team:

- All the persons involved in the execution of qualification activity must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working.
- Verify the training records and record the details in table mentioned in performance qualification report.

10.3 Calibration of Test Instruments:

- Calibration of all the instruments used for qualification should be mentioned along with Calibration Certificates.

11.0 TESTS AND CHECKS:

The following performance test have been carried out in order to demonstrate the Performance in Conformance.

11.1 PERFORMANCE EVALUATION FOR MACHINE SPEED OPTIMIZATION

A) OBJECTIVE:

To establish machine speed optimization by the different sets of Filling Needles on different volumes..

B) EQUIPMENT / INSTRUMENT USED:

Measuring Cylinder

C) METHOD APPLIED:

- The test should be carried out on each size of vial.
- Load the Liquid filling & Dropper Fixing Machine with the vials.
- Switch “ON” the machine & Operate as per **SOP.**
- Set the machine speed through HMI at 50 %, 80 % & 100 %.
- Start the machine with individual speed & count the vials via in built counter after 5 minute.
- Final machine output shall be decided & verified after performing the test.

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11.2 TEST FOR VOLUME VERIFICATION:

A) OBJECTIVE:

To establish that the filling volume variation in the vials filled by the different sets of Filling Needles.

B) EQUIPMENT / INSTRUMENT USED:

Measuring Cylinder

C) METHOD APPLIED:

- The test should be carried out in triplicate for each size of vial.
- Load the Liquid filling & Dropper Fixing Machine with the vials.
- Switch "ON" the machine & Operate as per SOP on operation of three piece vial filling machine
- Collect Filled vials from the machine at initial middle and End Measure Filled Volume through calibrated measuring cylinder.
- Perform the test for 5 ml, & 10 ml size Vials.
- Perform the test by filling WFI.

D) ACCEPTANCE CRITERIA:

Filling Machine should deliver the solution in each vial as per required Qty. or standard filled volume. Variation in volume from different nozzle should not be more than 10 % of standard volume

E) RESULT RECORDING:

Record the results in Performance Qualification Report.

11.3 TESTS FOR DROPPER FIXING QUALITY:

A) OBJECTIVE:

To establish maximum operational speed for Dropper Fixing machine for different pack size.

B) METHOD APPLIED:

- The test should be carried out in triplicate for each size of vial.
- Load the Liquid filling with Dropper fixing Machine with the vials.
- Switch "ON" the machine & Operate as per **SOP.**
- Collect Filled & Dropper fixing vials from the machine and check Dropper fixing vials quality.
- Perform the test for 5 ml, & 10 ml vial size.

C) ACCEPTANCE CRITERIA:

Vial Dropper Fixing Should be proper. Rejected should not be more than 1 %

D) RESULT RECORDING:

Record the results in the Performance Qualification Report.

11.4 TESTS FOR SCREW CAPPING QUALITY:

A) OBJECTIVE:

To establish Maximum operational speed for Screw Capping machine for different pack size.

B) METHOD APPLIED:

a. The test should be carried out in triplicate for each size of vial.

b. Load the Liquid filling with screw capping Machine with the vials.

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

d. Collect Filled & screw capping vials from the machine and check screw capping pressing quality.

e. Check the screw capping & dropper fixing quality through leak testing.

f. Perform the test for 5ml, &10ml vial size.

C) ACCEPTANCE CRITERIA:

Vial screw capping should be Proper. Rejection should not be more than 1 %.

D) RESULT RECORDING:

Record the results in the 3 of Performance Qualification Report.

12.0 CHECKLIST OF ALL TESTS & CHECKS

S.No.	Name of Test or Check	Execution (Yes/No.)	Remark	Verified By (Sign & Date)
1.	Test For Volume Verification			
2.	Performance Evaluation For Machine Speed Optimization			
3	Tests For Dropper Fixing Quality			
4	Tests For Screw Capping Quality			

13.0 REFERENCES:

The Principle Reference is the following:

- 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:

- Operation and Maintenance Manual.
- Any other Relevant Documents.

15.0 NON COMPLIANCE:

- In case of any Non compliance observed during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of Non compliance. If Non compliance is acceptable and it does not have an impact on performance of the Qualification, prepare final conclusion.

16.0 DEVIATION FROM PRE-DEFINED 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 performance of the Qualification, prepare final conclusion & 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 performance of the Qualification, prepare final conclusion & prepare final conclusion.

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18.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
TFM	:	Three piece filling machine
PVT	:	Private
LTD.	:	Limited
ID.	:	Identification
No.	:	Number
PPQ	:	Performance qualification protocol
%	:	Percentage