OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT 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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT 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 verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Integrated 3Piece Vial Filling Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Integrated 3 Piece Vial Filling** Machine **(Make: ……..)** installed in the Vial **3 Piece Vial Filling & dropper fixing** Room.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of **Integrated 3 Piece Vial Filling Machine.**
- Successful completion of this Protocol will verify that **Integrated 3 Piece Vial Filling Machine** meet all acceptance criteria and ready for Performance Qualification.

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 operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol after Execution.
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Qualification Protocol cum Report after Execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Integrated 3 Piece Vial Filling & Dropper Fixing Machine
Equipment ID.	
Manufacturer's Name	Techline Industries
Supplier's Name	Techline Industries
Location of Installation	Vial Filling Room

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.

6 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.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Integrated 3 Piece Vial Filling & Dropper Fixing Machine.
- Draft SOP for Preventive Maintenance of Integrated 3 Piece Vial Filling & Dropper Fixing Machine.
- Electrical Circuits Diagram.
- Technical specification of equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	Executed DQ Protocol cum Report				
2.	Executed IQ Protocol cum Report				
3.	Draft SOP for Operation & Cleaning of Integrated 3 Piece Vial Filling & Dropper Fixing Machine				
4.	Draft SOP for Preventive Maintenance Integrated 3 Piece Vial Filling & Dropper Fixing Machine				

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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8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 Operational and Functional Checks:

Operate the Integrated 3 Piece Vial Filling & Dropper Fixing Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Speed	80-120VPM.		
Storage Capacity of Hopper	200-300 vials		
Feed Height of the Machine	Adjustable		
Compressed Air Required	0.5 Kg Pressure		
Switch **"ON"** the Power	**"ON"** Indication on Control panel.		
Digital Counter	RPM at vial Per Min.		
Start Push Button	Machine START		
Stop Push Button	Machine STOP		
Emergency Button	To Stop Machine Immediately		
Safety guard interlocking	To bypass or interlock safety guard		
Variable Frequency Drive functionality			
Check the functionality of Variable Frequency Drive.	Frequency of input current to motor in Hz		
1H.P AC MOTOR - I	ON/OFF /INCH (For Orientator)		
½ H.P AC MOTOR - I	ON/OFF/INCH (For Filling)		
1H.P AC MOTOR - III	ON/OFF/INCH (For Dropper Fixing)		
1H.P AC MOTOR - IV	ON/OFF/INCH (For Screw capping)		
I/R SENSOR -I	Intermittently sensing the flow of bottles and switching off the AC motor-I if any one bottle stays there for more than 2 seconds. (OR- Turn Table full)		

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ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
I/R SENSOR –II	Intermittently sensing the flow of bottles and switching off the AC motor-II if there is no flow of bottles for more than 2 seconds. (FL- No Bottle)		
/R SENSOR –III	Intermittently sensing the flow of bottles and switching off theAC motor-II any one bottle stays there for more than 2 seconds (FL-Turn Table full)		
I/R SENSOR –IV	Intermittently sensing the flow of bottles and switching off the AC motor-III if there is no flow of bottles for more than 2 seconds. (DF-No bottle)		
I/RSENSOR –V	Intermittently sensing the flow of dropper and switching off the A.C motor-III if there is no dropper in the chute for more than		
I/R SENSOR –VI	Intermittently sensing the flow of bottles and switching off the A.C motor-III if any one bottle stays there for more than 2 seconds		
I/RSENSOR –VII	Intermittently sensing the flow of caps and switching off the A.C motor-IV if there is no cap in the chute for more than 2 seconds and Alarm is also required.(Chute-No cap)		
I/RSENSOR –VIII	Intermittently sensing the dropper and switching off the. A.C motor-IV if there is no dropper on the bottle for more than 2 seconds (No Dropper on Bottle)		

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ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
I/RSENSOR –IX	Intermittently sensing the bottle and switching off the AC motor-IV. if there is no flow of bottles for more than 2 seconds. (SC- No bottle)		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the Emergency Stop Pressed in, Try to cause movement of an Operating function.	The Equipment will be inoperative.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

9.0 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of Draft SOP's.
- Any other Relevant Documents.

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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:

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
SOP	:	Standard Operating Procedure
MOC	:	Material of Construction
SS	:	Stain less Steel
ID	:	Inner Diameter
CQA	:	Corporate Quality Assurance
TFM	:	Three piece filling machine
No.	:	Number

17.0 PROTOCOL POST 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)			