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OPERATIONAL QUALIFICATION	
Equipment Name: Automatic Injectable Powder Filling With Rubber Stopping Machine	**Equipment No.:**

Protocol Reference No.	Report No.	Page No.
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1.0	PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the operational qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		QUALITY ASSURANCE		
REVIEWED BY		ENGINEERING		
REVIEWED BY		PRODUCTION		
APPROVED BY		QUALITY ASSURANCE		

2.0	**OVERVIEW:**

2.1	**OBJECTIVE:**
	The objective of developing and executing this protocol is to collect sufficient data pertaining to Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 and define the qualification requirements and acceptance criteria for the machine. The objective of the operational qualification is to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document.
2.2	**PURPOSE:**
	The purpose of this protocol is to establish documentary evidence to ensure that the installed Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 will operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specifications and to demonstrate that the control panel and other manual operation of Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 provides the proper functionality as specified in the design qualification.

2.3	**SCOPE:**
	The Scope of this protocol is limited to the operational qualification of Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 in XYZ Pharmaceuticals. The objective of developing and executing this protocol is to collect sufficient data pertaining to the Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 and define the qualification requirements and acceptance criteria for the machine. This protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 operates and performs as intended in accordance with the design qualification.

2.4	**RESPONSIBILITY:**
	The following shall be responsible; Quality assurance officer/Executive – For Preparation of Protocol /Execution Projects / Engineering Head – For execution Production Head – For execution support Quality Assurance Head – For adequacy and final approval

2.5	EXECUTION TEAM:
	The satisfactory operation of the Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 is operational and is satisfactorily working. Execution team is responsible for the execution of operation of Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125. All executors involved with this protocol shall sign within the prescribed format given below:

DEPARTMENT	DESIGNATION	NAME	SIGNATURE	DATE
PROJECTS/ENGINEERING				
PRODUCTION				
QUALITY ASSURANCE				

3.0	ACCEPTANCE CRITERIA:
3.1	The equipment shall be operational as per its specified operating instructions.
3.2	All SOPs for the equipment shall be verified and checked.
3.3	All material of constructions of the contact parts to be checked as per the specifications.
3.4	All the functionality of equipment components to be checked.
3.5	All the safety features of the equipment shall be verified and utilities shall be available near the equipment.
3.6	The validity of the calibration of tests instruments shall be checked and all the required calibration of the components of the equipment shall be performed.

4.0	REVALIDATION CRITERIA:
	The machine has to be revalidated if
	• There are any major changes, which affect the performance of the equipment. • After major breakdown maintenance is carried out. • As per revalidation date and schedule

5.0	OPERATIONAL QUALIFICATION PROCEDURE :
5.1	EQUIPMENT DESCRIPTION

Equipment Name	:	Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125
Supplier / Manufacturer	:	Enter Supplier Name.
Overall Dimension (LXW)	:	1525(W) x 2340(H) x 3960(L) mm
Out put	:	120 Vials/Min
Model	:	ATPF-125
Service it offers	:	Filling and Rubber stoppering of vials
Location	:	XYZ

5.2	INSTRUCTION FOR FILLING THE CHECKLIST
5.2.1	In case of the compliance of the test use the word ‘Complies’ otherwise use‘ Does not comply ‘ to indicate non-compliance.
5.2.2	For identification of the components of the equipment and utilities use the word ‘’yes’’ to show its presence and use ‘No’ to indicate the absence of the identity
5.2.3	Give the detailed information in the summary and conclusion part of the Operational Qualification report.
5.2.4	Whichever column is blank or not used ‘NA’ shall be used.

5.3	CALIBRATION OF PROCESS CONTROL INSTRUMENTS:

Objective	:	To verify that the process control instruments identified during the installation of the automatic injectable powder filling with rubber stoppering machine are calibrated.
Test Procedure	:	Verify the calibration certificate and calibration status label on the instrument and ensure that the same are calibrated and record the details in the table below. Also record the details of the instruments used for the calibration in the table below.
Acceptance criteria	:	All the critical process control instruments should be calibrated.

Instrument Details				Calibration Details			
Name	**Location**	**Id. No.**	**Range**	**Done On**	**Next Due**	**SOP No.**	**Certificate No.**

REFERENCE INSTRUMENTS DETIALS:

Instrument Details		Calibration Details			Checked By/date
Name	**Range**	**Done On**	**Next Due**	**Certificate No**	

Comments:

Reviewed By/Date:

5.4	VERIFICATION OF FUNCTIONAL KEYS:

Objective	:	To check and identify the individual functional keys and verify that the function of individual key is as per the manufacturers specifications.
Test Procedure	:	Identify each functional key listed below, operate and verify its function against the specified function and record the observations.
Acceptance criteria	:	Each functional key should perform the specified function when activated.

Functional Key / Procedure	Specified Function	Observation	Discrepancy Yes/No	Checked By/Date
Main ON / OFF key switch	To connect / disconnect the power supply to the control panel / machine.			
Emergency Stop Switch	To stop the machine in case of emergency			
Start Button	To start the machine			
Stop Button	To stop the machine			

Comments:

Reviewed By/Date:

5.5	**VERIFICATION OF DESIGN PARAMETERS:**

Objective	:	To measure and verify that the automatic injectable powder filling with rubber stoppering machine supplied is as per the standard / design parameters.
Test Procedure	:	Verify the automatic injectable powder filling with rubber stoppering machine by verifying the filling time by physically checking the No. Of vials filled and record the actual results in the table below. A minimum of three observations to be made.
Acceptance criteria	:	The observations made for different parameters should be same as the specification.

S.No.	**Description**	**Specification**	**Observation / Output**			**Discrepancy Yes/No**	**Checked By/Date**
			Trial 1	**Trial 2**	**Trial 3**		
	Vial filled per minute						
	Vial size						
	Acquired speed						

Comments:

Reviewed By/Date:

5.6	VERIFICATION OF SAFETY FEATURES:

Objective	:	To verify the safety features present in the automatic injectable powder filling with rubber stoppering machine are performing as per the specification when activated.
Test Procedure	:	Verify response of each safety feature listed below against the specified function by activating the same as per the procedure given. Record the observations.
Acceptance criteria	:	The safety features when activated should produce desired results.

Alarm / Interlock	Specified Function	Activation Procedure	Observation	Discrepancy Yes/No	Checked By/Date
No Vial No Filling Sensor	No vial no filling system is provided to avoid the wastage of costly powder, while machine is running in ideal condition and vial is not present below the powder wheel.	Try to run the machine keep minimum vials then see when the vials are over the dosing is still in operation or not.			
Vial Separator Proximity Switch	If during production any vial comes with the over diameter or over height then any of the three clutches will get operated and	Try to put some vials, which are of over diameter and see the results.			

	through that signal machine will get OFF.				

Alarm / Interlock	Specified Function	Activation Procedure	Observation	Discrepancy Yes/No	Checked By/Date
No stopper in chute machine stop sensor.	This sensor is used to sense the presence of rubber stopper in the chute. In case during the production time if there is no rubber stopper present in the chute then it will stop the machine.	Try to run the machine with minimum amount of rubber stoppers in the chute. You will see that once the rubber stoppers are over in the chute, the sensors indicates and stops the machine.			

Comments:

Reviewed By/Date:

5.7	VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective performance of Automatic four head vial sealing machine operation.

Sr. No.	SOP TITLE	SOP NUMBER	VERIFIED BY	DATE
1.				
2.				
3.				
4.				

5.8	TRAINING RECORD OF PERSONNEL (S) :

Sr. No.	Name of Personnel	Designation	Sign.& Date	Trained By	Remark
1.					
2.					
3.					
4.					
5.					

5.9	VERIFICATION OF SEQUENTIAL OPERATION OF THE EQUIPMENT:

Objective	:	To demonstrate that the automatic injectable powder filling with rubber stoppering machine is capable of achieving the desired results when operated as per the set parameters.
Test Procedure	:	Operate the automatic injectable powder filling with rubber stoppering machine as per the SOP. Verify that the machine is operating in safe and normal conditions; record the results and discrepancies observed if any.
Acceptance criteria	:	The automatic injectable powder filling with rubber stoppering machine should produce the expected results when operated as per the procedure.

Procedure / Parameter	**Expected Result**	**Observation / Results**		
		Trial – 1	**Trial – 2**	**Trial - 3**
Switch ON the machine by pressing the ON / OFF switch.	The machine is ready for operation.			
Operated By Name				
Signature and Date				

Comments:

Reviewed By/Date:

5.10	**VERIFICATION OF EFFECT OF POWER FAILURE ON THE EQUIPMENT:**

Objective	:	To verify that the automatic four head vial sealing machine reverts to failsafe condition in event of power failure, and that it returns to specified state when power is restored and can be restarted.
Test Procedure	:	Start the operation of the machine in auto mode as per the SOP for set time duration of 10 minutes. Approximately midway through the set operation time (4-6 minutes), switch OFF the total power supply to the equipment for 3 minutes. Restore the power supply and restart the machine by pressing the start button (the equipment should not be reset) record whether the equipment starts normally. Measure the total operational in the table below.
Acceptance criteria	:	The machine stops in safe and secure conditions in event of power failure. When power supply is restored the machine should not start till the operator intervenes and restarts the equipment. The machine should restart normally, without any problems. The total elapsed time (total run time + power failure duration) should br equal to the total time duration on the stopwatch. The timer should start operating from the time just before the power failure.

Parameter	**Observation / Results**		
	Trial – 1	**Trial – 2**	**Trial – 3**
Set time duration			
Elapsed time values Initial (a)			
At power failure (b)			
Run time (c= a-b)			
After power failure (d)			
Final (e)			
Run time (f = e-d)			
Total run time (g=c+f)			
Power failure duration (h)			
Total time duration On stop watch			
Actual (g+h)			

Parameter	**Observation / Results**		
	Trial – 1	**Trial – 2**	**Trial – 3**
Observations when power failure occurs			
Equipment stops in safe and secure condition (Yes/No)			
Observations when power supply is restored			
Operator intervention required to restart the equipment (Yes/No)			
Equipment restarts in normal condition (Yes/No)			
Operated By Name			
Signature and Date			

Comments:

Reviewed By/Date:

5.11	DEFICIENCY AND CORRECTIVE ACTION(S) REPORT(S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.
Description of deficiency:
Corrective action(s) taken :

Reviewed By:
Date

6.0	OPERATIONAL QUALIFICATION FINAL REPORT:

6.1	SUMMARY :
6.2	CONCLUSION :

6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signature in the block below indicate that all items in this qualification report of Automatic Single Head Injectable Powder Filling with Rubber stoppering Machine Model ATPF-125 has been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		ENGINEERING		
		PRODUCTION		
		QUALITY ASSURANCE		