OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD AUTOMATIC POWDER FILLING MACHINE

EQUIPMENT ID. No.	
LOCATION	**OINTMENT SECTION**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD AUTOMATIC POWDER FILLING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD AUTOMATIC POWDER FILLING MACHINE	PROTOCOL No.:

1.0 PROTOCOL 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)			

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 Single Head Automatic Powder 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 Single Head Automatic Powder Filling Machine (**Make:** …...) installed.
- This Protocol Cum Report will define the methods and documentation used to perform Operational Qualification activity of Single Head Automatic Powder Filling Machine.
- Successful completion of this Protocol Cum Report will verify that Single Head Automatic Powder 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, and Approval, 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 Operational Qualification Protocol cum Report after Execution.
Production	• Review & Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Operational Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Single Head Automatic Powder Filling Machine
ID. Number	
Capacity	270 Kg.
Gross Capacity	550 Kg.
Manufacturer's Name	D.M. Engineering Co.
Model	NA
Supplier's Name	D.M. Engineering Co.
Location of Installation	Ointment Section

6.0 EQUIPEMENT DESCRIPTION:

Model SHPF-1 Single Head Powder Filling Machine is designed to fill powder in pharmaceutical bottles. The basic machine has a fabricated frame with SS cladded table top. The table is fitted with SS covers all around.it houses Electrical Motor, Gear Box, Electrical Panel Box and Control station at convenient place. The Conveyor has adjustable size to match with bottle size.

Empty sterile bottles are conveyor fed via turn table to the star wheel which conveyors bottles from conveyor to the filling head for till the desired quantity of powder.

The model SHPF-1 can handle a bottle size range from 22 mm diameter to 85 mm diameter with the appropriate change parts. Bottle height adjustable from 50 mm to 200 mm. filling range starts from 01 gm To 1000 gm Can be accommodated with the appropriate change parts.

"DMEC" Automatic Powder Filling is designed for accurate volumetric filling of dry syrup powder, granule substances in quantities from 01 gm to 1000 gm per fills. Any type of container like tin, jar, bottles, bags, pouches, cardboard drums can be utilized for filling the powder. General accuracy of filling ranging between 1.5 % to 2.5 % depending upon the density of powder and quality of powder with control humidity and temperature of the room.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Single Head Automatic Powder Filling Machine.
- SOP for Preventive Maintenance of Single Head Automatic Powder Filling Machine.

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.

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	COMPLETED (YES/NO)	VERIFIED BY (QA) SIGN/DATE
1.	Executed and approved Design Qualification cum report		
2.	Executed and approved Installation Qualification cum report		
3.	SOP for Operation & Cleaning of Single Head Automatic Powder Filling Machine		
4.	SOP for Preventive Maintenance of Single Head Automatic Powder Filling Machine		

Inference:

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Reviewed By
Manager QA
Sign/Date: _____

8.2 Test / Measuring Equipment Calibration:

INSTRUMENTS NAME	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 for Single Head Automatic Powder Filling Machine are Following:

Test to be carried out & Procedure	Activity Specification	Observation	Observed By (Engineering) Sign/Date
Start Machine	Machine should started by pressing the ON button.		
Stop Machine	Machine should stop by pressing the OFF button.		
Machine Support	Able to support machine frame Structure from SS 304 square Pipe.		
Machine Support Setting	Able to adjust the height of the machine.		
Feeding Bottle	On the Conveyor through the turn table/by hand		
Powder filling	By funnel & Augur through Servo motor.		
Conveyor bottle Guide	Conveyor Bottle guide adjust to bottle as per bottle size.		
Star Wheel	After Receiving bottle from conveyor and turn table it stops bottle till filling & release after fill bottle.		
Clutch Assembly	Clutch Assembly provided for safety against bottle jammed Around star wheel.		
Sensors	Sensor is provided on Conveyor for bottle Sense for no bottle no fill system & Proximity on star wheel for servo motors Signal.		
Emergency Shut off	Machine Stop Immediately when Emergency Stop Pressed & should Start without releasing it.		
Conveyor Drive Button	Provide in HMI		
Agitator Drive Button	Press to Start & Stop Agitator		

Test to be carried out & Procedure	Activity Specification	Observation	Observed By (Engineering) Sign/Date
HMI	Set the parameter of the All Servo Motor Speed & Time and Set as a Programmed in the PLC.		

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. Press Again Login and cycle restart.		

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:

- 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.
- Any other Relevant Documents.

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:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
Kgs.	:	killo grams
LTD.	:	Limited
No.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
SOP	:	Standard operating procedure
WHO	:	World Health Organization

17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE			
HEAD (ENGINEERING)			
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