



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER
FILLING MACHINE**

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



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PROTOCOL CUM REPORT
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MACHINE**

PROTOCOL No.:

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol pre-approval	03
2.0	Objective	04
3.0	Scope	04
4.0	Responsibility	05
5.0	Equipment detail	06
6.0	System description	06
7.0	Pre-qualification requirement	06-07
8.0	Critical variables to be met	07-15
9.0	Reference	16
10.0	Documents to be attached	16
11.0	Deviation from pre-defined specification, if any	16
12.0	Change control, if any	16
13.0	Review (inclusive of follow up action, if any)	16
14.0	Conclusion	17
15.0	Recommendation	17
16.0	Abbreviations	18
17.0	Protocol post approval	19



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**INSTALLATION 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)			



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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

2.0 OBJECTIVE:

- To prepare the installation Qualification on basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Equipment/Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Installation Qualification for Single Head Automatic Powder Filling Machine (**Make:** D.M. Engineering Co.) to be installed, Ointment Section.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of manufacturing vessel



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**INSTALLATION QUALIFICATION
 PROTOCOL CUM REPORT
 FOR
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 MACHINE**

PROTOCOL No.:

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	<ul style="list-style-type: none"> • Preparation, Review and Approved of Installation Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification activity. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none"> • Review and Approval of Installation Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none"> • Review of Installation Qualification Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e. <ul style="list-style-type: none"> • Details of Utilities • Material of Construction of all components • Brief Equipment Description • Safety Features and Alarms • Post Approval of Installation Qualification Protocol cum Report after Execution.



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PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM 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 clad 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 conveys 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:

- Executed and approved Design Qualification document
- Verification of Certificate of material of construction of components.
- Verification of Calibration Certificate of test Instrument.

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.



**INSTALLATION QUALIFICATION
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PROTOCOL No.:

- Approved Drawings and supporting documents would form a part of the IQ 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 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Uncarting	Should be carefully uncrated at the desired operation location. While uncrating remove all packing material & inspect carefully before discharging to make certain that all components shipped have been removed, Please check all the parts as per the packing list.		
Leveling	Once in place, the machine should be Levelled utilizing the adjustable screws incorporated in each leg. an appropriate bubble level should be used to make certain that levelling has been properly accomplished.		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Power Connection	Carefully examine the wiring diagram to determine the machine voltage, frequency, phase and other power requirements. Refer to electrical diagram for components specification & requirements. Connect the power cord to an appropriate outlet, being certain to provide as earthing and nature		



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**INSTALLATION QUALIFICATION
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MACHINE**

PROTOCOL No.:

	to avoid a shock hazard.		
Machine Adjustments	Unless otherwise stated all adjustment and repair are to be perform with the machine stopped and the power off. This Machine is fully self-contend.it does not need any installation simply arrange the machine between two runs table at working site and align the conveyor with turn and closing machine with help of height adjusting bolts. Connect power Supply to the panel box and see that the conveyor, filling head (Anti clock wise), turn table unit move in correct direction.		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

Reviewed By
Manager QA
Sign/Date: _____



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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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MACHINE**

PROTOCOL No.:

8.2 Utility Verification:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	Single Head Automatic Powder filling Machine		
Model	cGMP Model		
ELECTRICAL INSTALLATION:			
Electricity	Voltage	415± 5% V	
	Phases	3 Phase	
	Frequency	50 Hz	
Electrical connections have been provided and secured.	Should be provided & secured		
All components in the panel are properly secured	Should be properly secured		
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.		

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Production
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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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MACHINE**

PROTOCOL No.:

8.3 Installation Checks:

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Verify that the "As built" drawings are complete and represent the design concept		
2.	Check the proper mechanical installation		
3.	Check the proper electrical installation of		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		
6.	Verify that major components are securely anchored and protected from shock		
7.	Verify that there is no observable physical damage		
8.	Verify that "Room layout" drawing is OK and sufficient space for servicing is provided		

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PHARMA DEVILS

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PROTOCOL CUM REPORT
FOR
SINGLE HEAD AUTOMATIC POWDER FILLING
MACHINE**

PROTOCOL No.:

8.4 Verification of Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	D.M. Engineering Co.		
Model	Single Head Automatic Powder Filling Machine		
Dimension	Length:1500 mm Width:950 mm		
Bottle Diameter	22 mm to 85 mm		
Conveyor Length	5 ft.		
Filling Range	1 Gms. To 1000 Gms.		
Height	50 mm to 200 mm		
Filling Accuracy	1 % to 2.5 %		
Hopper Capacity	15-20 Kgs. Approx.		
PLC A.C Drive	Touch Pad (HMI)		
Net Weight	270 Kgs.		
Gross Weight	550 Kgs.		
Machine Support	4 Nos.		
Machine Support Setting Screw	4 Nos.		
Machine Cover	Available		
Servo Motor Drive for Augur	1 No.		
Star Wheel	1 Set		
Star Wheel with A.C Drive	Available		



PHARMA DEVILS

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PROTOCOL CUM REPORT
FOR
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MACHINE**

PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Bottle Conveying Belt S.S Belt	Available		
Bottle Guide on Conveyor Belt	Available		
Bottle Conveying Gear Drive	Available		
Turn Table	NA		
Turn Table Support	NA		
Bottle Sensor	1 No.		
Star Wheel Sensor Valve	1 No.(Proximity)		
Machine controller	Available		
Panel Box with PLC, HMI & Servo Drive	1 No.		
PLC for servo motor housing	1 Unit		
A.C frequency Drive shaft	2 Unit		
Main ON-OFF Selector Switch	1 Unit		
Emergency Stop button	1 No.		
HMI with touch Screen Control	1 Unit		
Power Requirement	415 V 3 Phase, 50 Hz for Main Supply with neutral.		



PHARMA DEVILS

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PROTOCOL CUM REPORT
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MACHINE**

PROTOCOL No.:

8.5 MATERIAL OF CONSTRUCTION:

S.No.	COMPONENTS	MOC	OBSERVATIONS
1	Machine frame Structure	SS 304	
2	Machine Covers	SS 304	
3	Servo motors	Panasonic	
4	Hopper	SS316 L	
5	Agitator Assembly	SS316 L	
6	funnel	SS316 L	
7	Augur	SS316 L	
8	Delivery Shaft	SS316 L	
9	Delivery Shaft Housing	C.I	
10	Worm Wheel Shaft Housing	Aluminum	
11	Worm	NA	
12	Worm Wheel	NA	
13	Chain Sprocket	M.S	
14	Cross Slide	C.I with Powder Coating	
15	Motor	3000 RPM 1.3 Nm750 W Servo Motor, 1 No. 0.25 HP 1440 RPM Star/Delta motor for Star Wheel 0.50 HP 1440 RPM Star/Delta motor for Conveyor 0.50 HP 1440 RPM Star/Delta motor for Agitator	

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MACHINE**

PROTOCOL No.:

8.6 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine, Panel and operator should be provided		
Variable Frequency Drive	Motor safety from overload		
Main Supply	Main power supply should be always switched off when not in use.		
Emergency Button	Protection against abnormal condition		

**Checked By
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MACHINE**

PROTOCOL No.:

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:

- MOC & Calibration certificate
- P & ID
- Any other relevant Documents

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

12.0 CHANGE CONTROL, IF ANY:

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):



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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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MACHINE**

PROTOCOL No.:

14.0 CONCLUSION:

15.0 RECOMMENDATION:



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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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MACHINE**

PROTOCOL No.:

16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
GA	:	General Arrangement
HMI	:	Human Machine Interface
Hz	:	Hertz
Kg	:	Kilograms
mm	:	Millimeter
MOC	:	Material of Construction
RPM	:	Revolution per Minute
SS	:	Stainless Steel
VFD	:	Variable Frequency Drive



PHARMA DEVILS

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MACHINE**

PROTOCOL No.:

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			