



PHARMA DEVILS

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
DOUBLE HEAD FULLY AUTOMATIC FILLING,  
CLOSING AND SEALING MACHINE**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
DOUBLE HEAD FULLY AUTOMATIC  
FILLING, CLOSING AND SEALING  
MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>FILLING ROOM</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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**1.0 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 provide documented evidence for the Installation Qualification of Double Head Fully Automatic Filling, Closing And Sealing Machine.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

**3.0 SCOPE:**

- The scope of this installation qualification protocol cum report is limited to qualification of Double Head Fully Automatic Filling, Closing And Sealing Machine (Make: ..... ) to be installed in the Double Head Fully Automatic Filling, Closing And Sealing Machine .
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Double Head Fully Automatic Filling, Closing and Sealing Machine.



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**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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li><li>• Post Approval of Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Qualification Protocol after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in VFS Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Qualification Protocol after Execution.</li></ul>

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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Double Head Fully Automatic Filling, Closing And Sealing Machine
<b>Equipment ID.</b>	
<b>Model</b>	
<b>Serial No.</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Location of Installation</b>	Filling Area

**6.0 SYSTEM DESCRIPTION:**

The Automatic linear plastic & aluminum tube filling machine is heavy duty machine designed with high speed for filling the plastic as well as aluminum tubes.

The operator has to feed the product inside the jacketed hopper. The tube from the cassette box passes to each and every station for performing the filling operation of filling is described thoroughly.

A separate control and operator panel with HMI screen is supplied with this machine. The panel contains electronic as well as electrical components which are highly rated.

All the safety features are provided in the machine, which are as per the GMP standard and is in compliance with set industrial standards.

**FUNCTION DESCRIPTION OF MACHINE:**

1. Jacketed Hopper
2. Auto feeding Unit
3. Tilters
4. Tube pusher
5. Orientation station
6. Hot air station
7. Sealing unit
8. Trimming unit
9. Ejecting / discharge unit
10. Cam unit
11. Operator panel
12. HMI screen



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**Components for aluminum Tube filling**

1. First Crimping
2. Second Crimping
3. Batch Code

**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**


- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

**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 IQ 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 Installation Qualification Checklist:**

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Grouting and Mounting</b>	Should be properly grouted and mounted.		
<b>Leveling</b>	Should be properly balanced and leveled.		
<b>Edges of parts</b>	Metal parts should be properly ground without any sharp edges.		
<b>Welding of Joints</b>	Welding of joints should be without any welding burrs.		
<b>Place of Installation</b>	Filling Area		
<b>Room Condition</b>	RH: NMT 55 % TEMP: NMT 25 °C		
<b>Illumination</b>	NLT 300 Lux		
<b>Working space around the Equipment.</b>	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

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**Manager QA**  
**Sign/Date:** .....





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**8.2 Installation Checks:**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Check the machine as per the arrangement plan	Should be as per drawing		
Check the connecting line, wiring & piping of machine confirm to the safety clause and cGMP regulation.	Should be as per the cGMP regulation.		
Check all electrical wires are rooted properly.	Should be rooted in proper manner.		
Check all the wires have ferule numbering.	Should have ferule numbering.		
Check earthing line	Earthing line should be provided		
Check the components or assemblies are mounted on machine on their position.	Assemblies to be mounted on their desire position.		
Check the Assemblies or components mounted on machine not damaged	Should have good surface finishing and running condition.		
Model	PK 120 COMBO LINEAR		
Dimensions	2765 X 1300 X 2480		
Machine serial no.	PKMPL/00049		
Power source	415 VAC, 3 phase , 50Hz and 51.0 amp.		
Main motor Drive	Make : Mitsubishi Model : FR-D740S- 080-EC Sr. No. : D5Z159047		
Stirrer drive	Make : Mitsubishi Model : FR-D720S- 042-EC Sr. No. : D5X13B015		
Main Motor	Make : M.G.M Motor Model : BA100LA4		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Motor Gear box	Make : Varvel Model : SRT08515G635 Sr. no. : 0000193898		
Stirrer Motor	Make : Zhjiang Taizhou Model : Y2-905-6 814 Sr. No. : 0100004 RPM : 910 r/m		
Stirrer motor gear Box	Make : Zhjiang Taizhou Model : NMRV 063 Sr. No. : 2010100003 RPM : 910 r/m		
PLC	Make : Allen Bradley Model : FX-3U/32MT-ESS Sr. No. : 1570184		
HMI	Make : Mitsubishi Model : GT1455-QTBDE Sr. No. : 180001		
Hot Air Heater-01	Make : Leister Model : LHS 21 L Sr. No. : 1511240777		
Hot Air Heater-01	Make : Leister Model : LHS 21 L Sr. No. : 1511240760 (3300 W , 14 amp.)		
Vacuum motor	Make : Remi Model : 80A/4T Sr. No. : D1156N (0.75KW , 1.0 HP) RPM : 1390		
Vacuum Pump	Make : Shree Siddhivinayak Model : RVD -300 Sr. No. : 151804 (0.75 kw / 1.0 HP) RPM : 1440 Vacuum : 650		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Blower Pump-01	Make : Shree Siddhivinayak Model : SVR – 35 N Sr. No. : 16J809 (0.75 kw / 1.0 HP RPM : 2800 Vacuum : 55		
Blower Pump-02	Make : Shree Siddhivinayak Model : SVR – 35 N Sr. No. : 16J809 (0.75 kw / 1.0 HP RPM : 2800 Vacuum : 55		
Nozzles	Quantity : 02 Nos.		
Sealing head assembly	Quantity : 1 Nos.		
Folding Assembly	Quantity : 02 Nos.		
Cutter	Quantity : 1 Nos.		
Jacketed Hopper	Quantity : 1 Nos.		
Tower Lamp	Quantity : 1 Nos. 220 VAC		
MCB	Quantity : 1 Nos. 6 Amp. , 2Pole		

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**8.3 MOC Verification List:**

Parts Name	MOC	Observation	Observed By Engineering Sign/Date
Syringe mounting bracket	SS 316		
Outlet filling bracket	SS 316		
Ring	SS 316		
Bearing housing-01	SS 316		
Piston (right)	SS 316		
Piston (right)	SS 316		
Filling block	SS 316		
Knurling nut	SS 316		
Capillary lock bracket	SS 316		
Hopper	SS 316		
Tube leveling rod	SS 316		
Syringe	SS 316		
Nozzle	SS 316		


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**8.4 Utility Verification List:**

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
<b>Electrical Supply</b>	Voltage : 415 VAC Phase : 3 Phase Frequency : 50 HZ & 51 Amp.		
<b>Room Condition</b>	Temperature NMT 25 °C RH : NMT 55 %		
<b>Compressed Air supply</b>	6 Kg/cm <sup>2</sup>		

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**Production**  
**Sign/Date: .....**

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**Manager QA**  
**Sign/Date: .....**

**8.5 Safety:**


Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Caution labels electrical panel cover on main machine and on accumulator electrical enclosure terminal boxes motor	The labels should be available on terminal box		
Moving components and drives enclosure for operator safety	Should be available		
SS doors on the machine Body	Should be easily openable		
Polycarbonate Door on the machine	Should be easily openable		
Proper ferruling's on the cable for proper traceability	Should be Provided		
Emergency stop switch on the operator panel	Should be Available in working condition		
MCB inside the control panel to cut off the power supply if any short circuit occurs.	Should be available		
Check the safety guard available	Should be available		

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**Manager QA**  
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**8.5.1 Control Panel Check:**

Test Particulars	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Check that Machine is connected with control panel. Record the details of PLC	Machine should be connected with control panel. PLC make, model no. , serial no should be checked and		
Check the input output against Wiring Diagram visually during installation	All the input output shall meet the Requirements		

**Checked By**  
**Production**  
**Sign/Date:** .....

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**Quality Assurance**  
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**Inference:**

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**9.0 REFERENCES:**

**The Principle References 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:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.

**11.0 DEVIATION FROM PRE-DEFINED 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:**

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
VFD	:	variable frequency drive
HP	:	Horse Power
Hz	:	Hertz
Amp.	:	Ampere
SS	:	Stainless steel
AC	:	Alternate Current
MMI	:	Man Machine interface
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
db	:	Decibel
RH	:	Relative Humidity
OFS	:	Double head fully automatic filling, closing and sealing machine
SS	:	Stainless Steel
NMT	:	Not More Than

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**17.0 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)			