INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE

EQUIPMENT ID. No.	
LOCATION	**FILLING ROOM**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

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)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Single Head Semi Automatic Tube Filling, Crimping 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 Single Head Semi Automatic Tube Filling, Crimping and Sealing Machine (Propack Technologies Pvt. Ltd.) to be installed in the filling area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Automatic Filling, Crimping and Sealing Machine.

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 Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in VFS Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Filling, Crimping and Sealing Machine
Equipment ID.	
Model	cGMP
Manufacturer's Name	Propack Technologies Pvt. Ltd.
Supplier's Name	Propack Technologies Pvt. Ltd.
Location of Installation	Filling Area

6.0 SYSTEM DESCRIPTION:

The Automatic linear plastic tube filling machine is designed with high speed for filling the plastic tubes and Lami Tubes.

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

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

STRUCTURAL OVERVIEW:

- **Driving clutch system:** motor, speed reducer, chain, gear wheel.
- **Filling system:** Filling cam, filling travel adjusting device, filling shaft, main valve, nozzle, blowing device etc.
- **Cream Transferring system:** Cam, Transfer travel adjusting device, shaft, pump, hopper etc.
- **Heating system:** Heating cam, shaft, heating drum, heater air fan, temperature control system and cooling system.
- **Cutting system:** Cutting manipulator, cooler etc.
- **Trimming system:** Trimming manipulator
- **Tube output system:** Cam shaft pushing rod etc.
- **Electrical system;** Controlling transformer, frequency inverter PLC set.
- **Optional equipments:** 2P chiller, 0.7 Mpa air compressors.

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.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Filling Area		
Room Condition	RH: NMT 55% TEMP: NMT 25ºC		
Illumination	NLT 300 Lux		
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:

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Reviewed By
Manager QA
Sign/Date: ……

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	cGMP		
Dimensions	2220 X 1000 X 1520		
Power source	230 Voltage AC, 3 phase, 50 Hz		
Nozzles	Quantity : 01 Nos.		
Sealing head assembly	Quantity : 01 Nos.		
Folding Assembly	Quantity : 01 Nos.		
Cutter	Quantity : 01 Nos.		
Jacketed Hopper	Quantity : 01 Nos.		
MCB	Quantity : 1 Nos. 6 Amp. , 2Pole		

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Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.3 MOC Verification List:

Parts Name	MOC	Observation	Observed By Engineering Sign/Date
Hopper	SS 316 L		
Filling valve	SS 316 L		
Filling nozzle	SS 316 L		
Filling pump	SS 316 L		
Bearings	SS 304		
Sealer	MS		
Cutter	HCS		
Station cup	Polymerized Plastic		
Heater	SS 304		
Lifting shaft	2CL13		
Tube chamber	Plexiglas plate		
Piston	Teflon		

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Quality Assurance
Sign/Date: ……

Inference:

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Manager QA
Sign/Date: ……

8.4 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 230 VAC Phase : 3 Phase Frequency : 50 HZ & 1.5 Amp.		
Room Condition	Temperature NMT 25 ºC RH : NMT 55 %		
Compressed Air supply	5-6 bar		

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Production
Sign/Date: ……

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Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.5 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Safety door switch	Operator Safety.		
Torque limiter	For Operator Safety.		
Emergency stop button	For Motor, equipment protection & Operator Safety		
MCB inside the control panel to cut off the power supply if any short circuit occurs.	For Operator Safety		
Safety labels on the machine to avoid the hazards.	For Motor, equipment protection & Operator Safety		

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:

- 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
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
SS	:	Stainless Steel
NMT	:	Not More Than

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)			