



PHARMA DEVILS

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

**PROTOCOL No.:**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
SINGLE HEAD SEMI AUTOMATIC TUBE  
FILLING, CRIMPING 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 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 Semi Automatic Tube Filling, Crimping and Sealing 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 Semi Automatic Tube Filling, Crimping and Sealing Machine (**Make: .....**) installed in the Filling Room.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Single Head Semi Automatic Tube Filling, Crimping and Sealing Machine Successful completion of this Protocol will verify that Single Head Semi Automatic Tube Filling, Crimping and Sealing Machine meet all acceptance criteria and ready for Performance Qualification.



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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 operational Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Operational Qualification.</li><li>• Monitoring of Operation Process.</li><li>• Post Approval of Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.</li><li>• Post Approval of Operational Qualification Protocol after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Operational Qualification.</li><li>• To co-ordinate and support Operational Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Post Approval of Qualification Protocol cum Report after Execution.</li></ul>

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### 5.0 EQUIPMENT DETAILS:

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

### 6.0 EQUIPEMENT 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.

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**7.0 PRE - QUALIFICATION REQUIREMENTS:**

**7.1 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)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	DQ Protocol cum Report			
2.	IQ Protocol cum Report			
3.	Draft SOP for Operation & Cleaning of Double head fully automatic filling, closing and sealing machine.			
4.	Draft SOP for Preventive Maintenance automatic filling ,Crimping and sealing machine			


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

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

**Inference:**

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 .....

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

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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Test Equipment Calibration:**

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument ID	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:** .....





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**8.2 Operational and Functional Checks for Lami / plastic tubes:**

Operate the Single Head Semi Automatic Tube Filling, Crimping and Sealing Machine as per Manufacturer’s Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired for LAMI tubes.

<b>Test to be carried out &amp; Procedure</b>	<b>Activity Specification</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
Start Machine	Machine should started by pressing the ON button.		
Stop Machine	Machine should stop by pressing the OFF button.		
Motor Overload	Machine stop immediately red light blows on tower lamp and “MOTOR OVER LOAD” alarm is generated on HMI.		

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

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

**Inference:**

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



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**8.3 Operational Test for LAMI Tube:**

**8.3.1 Tube filling test:**

**Objective:** To check the behavior of machine during filling of machine.

**Method:**

- Ensure unfilled tubes weight is tarred on checkweigher and same has been loaded on tube holder.
- Run the machine and filled the product inside the tube and collect the final sample from the ejection tray.
- Check the weight of the filled tube on checkweigher.

**Acceptance Criteria:**

Syringe pump and filling station does not operate when tube is absent in particular tube holder.

Tube filled weight should be within range of  $\pm 1$  gm or as specified limit in Pharmacopoeial standards.

**8.3.2 Tube heating / Tube sealing test for LAMI tube:**

**Objective:** To ensure Tube is heating properly to perform proper sealing operation.

**Method:**

- Check proper required heating temperature is kept on heater.
- Keep the machine in running condition.
- Keep manual loading of the tubes in the tube holder on wheel assembly.
- Collect final sample from the exit tray of the machine.
- Check sealing surface of the tube along with the batch coding.


**Acceptance Criteria:**

No burning should Observe on I mark or sealing areas of the tube.

There is no leakage of the tube or opening of the tube at sealing areas.

Batch code should be clear.

Tube should not be damaged

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**8.3.3 Tube trimming test for LAMI tube:**

**Objective:** To ensure tube is properly trimmed on machine.

**Method:**

- Keep the machine in operation condition.
- Keep of tube loading manually.
- Collect final filled tube sample.
- Check the trimming visually.

**Acceptance Criteria:**

There should not be sharp edges on the tube after trimming operation.

Trimming edges should be parallel to the cap edges.

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

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


**Inference:**

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

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**8.4 Power Failure Verification:**

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Main Power Shut Down</b>	Equipment stops in a safe and secure condition.		
<b>Main Power Restored</b>	Equipment can be restarted with no problems or adverse conditions.		

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

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


**Inference:**

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

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**8.5 Emergency Operation Verification:**

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		

**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.



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**10.0 DOCUMENTS TO BE ATTACHED:**

- 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:**

- No. : Number
- WHO : World Health Organization
- cGMP : Current Good Manufacturing Practices
- DQ : Design Qualification
- IQ : Installation Qualification
- OQ : Operational Qualification
- SOP : Standard Operating Procedure
- MOC : Material of Construction
- SS : Stain less Steel
- OFS : Automatic filling, Crimping and sealing machine
- ID : Inner Diameter

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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)			