



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**OPERATIONAL 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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**CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
1.0	Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	Equipment Description	6
7.0	Pre-Qualification Requirements	7
8.0	Critical Variables to be Met	8
9.0	References	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	17
17.0	Post Approval	18



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**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
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**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)			



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**PROTOCOL No.:**

**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 Double head fully automatic filling, closing 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 **Double head fully automatic filling, closing 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 Double head fully automatic filling, closing and sealing machine.
- Successful completion of this Protocol will verify that Double head fully automatic filling, closing and sealing machine meet all acceptance criteria and ready for Performance Qualification.



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**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:

<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>

 <b>PHARMA DEVILS</b>	<b>OPERATIONAL QUALIFICATION          PROTOCOL CUM REPORT          FOR          DOUBLE HEAD FULLY AUTOMATIC FILLING,          CLOSING AND SEALING MACHINE</b>	<b>PROTOCOL No.:</b>
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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>	Parle Kovai Technologies Pvt. Ltd.
<b>Supplier's Name</b>	Parle Kovai Technologies Pvt. Ltd.
<b>Location of Installation</b>	Filling Area

### 6.0 EQUIPEMENT 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. Filters
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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**PROTOCOL No.:**

*Components for aluminum Tube filling*

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

**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	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) 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 Double head fully automatic filling , closing 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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**PROTOCOL No.:**

**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 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:** .....






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**PROTOCOL No.:**

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

Operate the Double head fully automatic filling, closing 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 Both LAMI and Aluminum 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.		
Tube Heater ON	Press Tube Heater 1 & 2 OFF key Tube Heater 1 & 2 Should be ON respectively.		
Cream melt heater	Press Cream melt Heater OFF key Cream melt Heater Should be ON.		
Auto feeder ON	Press Auto feeder 1 and 2 OFF key Auto feeder 1 & 2 Should be ON respectively.		
Stirrer Motor ON	Press Stirrer motor OFF key Stirrer motor Should be ON.		
Vacuum Pump ON	Press Vacuum pump OFF key Vacuum pump Should be ON.		
Tube level Low	Machine stop immediately red light blows on tower lamp and "TUBE LEVEL LOW 1 & 2" alarm is generated on HMI.		
Material Level low	Machine stop immediately red light blows on tower lamp and "MATERIAL LEVEL LOW" alarm is generated on HMI.		
Tube Not Ejected	Machine stop immediately red light blows on tower lamp and "TUBE NOT EJECTED" alarm is generated on HMI.		
Motor Overload	Machine stop immediately red light blows on tower lamp and "MOTOR OVER LOAD" alarm is generated on HMI.		
HMI Panel	After Pressing ON button on the HMI panel Machine should start operating. After Pressing OFF button on the HMI panel Machine should stop operating		

 <b>PHARMA DEVILS</b>	<b>OPERATIONAL QUALIFICATION          PROTOCOL CUM REPORT          FOR          DOUBLE HEAD FULLY AUTOMATIC FILLING,          CLOSING AND SEALING MACHINE</b>	<b>PROTOCOL No.:</b>
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**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 Test for LAMI Tube / Aluminum Tube:**

**8.3.1 Tube Loading Test:**

**Objective:** To demonstrate the behavior of Machine during Tube loading.

**Method:**

- Initially empty tubes loaded in the cassette box with proper tube directions.
- Switch on the power.
- Press the auto feeder 1 & 2 OFF key in production mode on HMI.
- Press ON button and check behavior.

**Acceptance Criteria:**

- Tube should not get damage during tube loading operation.
- After starting of the machine, tubes are passes from the help of loading arm.
- Tubes get loaded into the tube holder automatically.
- Tube level cylinder levels the tube and forwards it for tube presence sensor and also I mark sensor.

**8.3.2 Tube Cleaning test:**

**Objective:** To check there is no dust particle inside the after cleaning.

**Method:**

- Keep the in running condition and ensure proper compressed air pressure.
- Put some foreign particle inside the tube and pass through the machine.



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**PROTOCOL No.:**

- Check the same container after passing through machine.

**Acceptance Criteria:**

No foreign particle should be observed.

**8.3.3 Tube orientation test:**

**Objective:** To ensure tube is properly got oriented at tube orientation station.

**Method:**

- Keep the machine in running condition.
- Keep on loading tubes manually on tube holder.
- Check tubes stops rotating once the eye mark come exactly in front of the eye mark sensor.
- Check tube I mark is centre of the tube.

**Acceptance Criteria:**

Tube should stop orient once the eye mark is detected by the eye mark sensor.

The tube I mark matter should be centre of the tubes.

**8.3.4 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.

**8.3.5 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.



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**PROTOCOL No.:**

- 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

**8.3.6 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.

**8.3.7 No tube no folding test for aluminum tubes:**


**Objective:** To ensure when there is no tube available in tube holder on wheel assembly, there will not be folding operation.

**Method:**

- Keep the machine in operational condition.
- Keep loading on tube manually.
- Stop the machine.
- Remove the loaded tube manually from the tube holder after tube loading.
- Start the machine and check the behavior.

**Acceptance Criteria:**

Folding unit should not operate, where tube is unavailable at below folding unit.

 <b>PHARMA DEVILS</b>	<b>OPERATIONAL QUALIFICATION          PROTOCOL CUM REPORT          FOR          DOUBLE HEAD FULLY AUTOMATIC FILLING,          CLOSING AND SEALING MACHINE</b>	<b>PROTOCOL No.:</b>
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**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
<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 <ul style="list-style-type: none"> <li>• Press Stop Push Button</li> <li>• Release ON Push Button</li> </ul>	Equipment should Stop		
	Equipment should Start		
With the Emergency Stop Pressed in, in Try to cause movement of an Operating function.	The Equipment will be inoperative.		
Emergency Stop Alarm <ul style="list-style-type: none"> <li>• Press emergency Stop switch</li> </ul>	Machine stop immediately and red light blow ON tower Lamp.		

**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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**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:**

- 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 : Double head fully automatic filling, closing 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)			