



**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**PROTOCOL No.:**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
DOUBLE HEAD TUBE FILLING  
MACHINE GAN COMBI  
FILLING LINE**

<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:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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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 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 Tube Filling Machine GAN Combi (Make: Wimco Ltd.)** installed in the Filling Room.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of **Double Head Tube Filling Machine GAN Combi**.
- Successful completion of this Protocol will verify that **Double Head Tube Filling Machine GAN Combi** 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:

DEPARTMENTS	RESPONSIBILITIES
<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>	Double Head Tube filling machine GAN Combi
<b>Equipment ID.</b>	
<b>Model</b>	GAN COMBI
<b>Manufacturer's Name</b>	Wimco Ltd.
<b>Supplier's Name</b>	Wimco Ltd.
<b>Location of Installation</b>	Filling Area

**6.0 EQUIPEMENT DESCRIPTION:**

**Application:**

Double Head Tube Filling Machine is used for filling and sealing / closing of Lami/ Plastic tube of Dia.16-50mm (beyond Ø42 tube machine will operate on single head) with filling variation of 2 cc to 250 cc depending on the material properties.

**Major System Components:** Tube filling Machines is comprised of following major subassemblies/ Components.

**Automatic Tube Loading on Machine:**

Consist of Polycarbonate Cassettes with S.S.304frame, Al tube tilter, Cassette motor and S.S.304 Rocker.

**Tube Registration Device:**

Two Stepper motors attached to Magnetic lifting head, S.S 304 cone, and Color mark Sensors.

**Tube Cleaning:**

Tube cleaning by means of suction & ionized compressed air by ionized system.

**Tube Filling Device.**

S.S 316L Jacked Hopper with 75 liters capacity having surface finish of internal 0.5Ra & external 0.9 Ra, mounted on the machine. Jacketed hopper fitted with cover, electrical, digital temperature controller, level sensor, & cream stirring device which stirs the material to make it free flow with separate motor & VFD (Allen Bradley).S.S 316L-make nozzle with air blow off device attached to the reciprocating S.S. pump.

Complete material transfer device (from hopper to filling nozzle) is made of SS 316L. Tubes gets sealed and coated at tubes sealing at coding station. And extra sealed tube gets cut and removed at trimming station and required tube length dimension gets maintained. Good fill tubes can be ejected at ejection station.



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For Lami /Plastic tube, tube inner surface is heated by a hot air blowing station then tube is pressed in between two jaws by sealing unit mounted on the sealing station. Then sealed tube is cooled before the trimming operation, which is carried out by the trimming unit.

For Metal tubes folding is done three stations (Flattening, 1<sup>st</sup> Fold & 2<sup>nd</sup> Fold) which are placed adjacent to each other in sealing station. Tube is transferred after filling to the flattening station.

In case of a Combi sealer Lami sealing units will be idle during sealing however they will be placed in the same location.

For switching from Lami tube to Metal Tube or Vice-Versa, the machine requires some change over, Hence either of the tube can only manufacture in each batches. Change over should be done by Standard tooling.

In the ejection station, lifting ejection pin should be set proper, so that the tube lifted entirely Clear of the holder and is then rolled down into the chute.

DK-20 P&F (Visolex) make photo scanner is provided for ensuring wrong orientation & no Filling of tube (no I-mark no filling), tube automatically gets rejected at rejection side in empty Condition (it is in interlock).

**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 Tube filling machine.			
4	Draft SOP for Preventive Maintenance Double Head Tube filling 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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**7.2 Test Equipment Calibration:**

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: .....**

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Manager QA  
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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 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.

Test to be carried out & Procedure	Activity Specification	Observation	Observed By (Engineering) Sign/Date
Start Machine	Machine should started by pressing the ON button.		
Stop Machine	Machine should stop by pressing the OFF button.		
Machine Support	Able to support machine frame Structure from SS 304 square Pipe.		
Machine Support Setting	Able to adjust the height of the machine.		
Feeding Bottle	On the Conveyor through the turn table/by hand		
Powder filling	By funnel & Augur through Servo motor.		
Conveyor bottle Guide	Conveyor Bottle guide adjust to bottle as per bottle size.		
Star Wheel	After Receiving bottle from conveyor and turn table it stops bottle till filling & release after fill bottle.		
Clutch Assembly	Clutch assembly provided for safety against bottle jammed Around star wheel.		
Sensors	Sensor is provided on Conveyor for bottle Sense for no bottle no fill system & Proximity on star wheel for servo motors Signal.		
Emergency Shut off	Machine Stop Immediately when Emergency Stop Pressed & should Start without releasing it.		
Conveyor Drive Button	Provide in HMI		



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Test to be carried out & Procedure	Activity Specification	Observation	Observed By (Engineering) Sign/Date
Agitator Drive Button	Press to Start & Stop Agitator		
HMI	Set the parameter of the All Servo Motor Speed & Time and Set as a Programmed in the PLC.		

**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 Test for LAMI Tube / Aluminum Tube:**

**8.2.1 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.
- Check the same container after passing through machine.

**Acceptance Criteria:**

No foreign particle should be observed.

**8.2.2 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.

**8.2.3 Tube filling test:**

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

**Method:**

- Ensure unfilled tubes weight is tarred on weighing machine 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 weighing machine.

**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 Pharmacopeial standards.

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

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



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**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

**8.2.5 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.

**8.2.6 No Tube No Fill Test:**

**Objective:** To verify & document that whenever there is no tube in the holder, filling operation does not take place.

**Method:**

- Keep the machine in running condition.
- Let machine to run for minimum 1 to 2 minutes.
- Remove the tube from any one or more holders.
- Observe – filling does not take place Filling valve not actuate & filling  
Does not take place

**Acceptance Criteria:**

Filling Does not take place when tube not available in Holder.



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**8.2.7 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.

**8.3 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: .....**

**8.4 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:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			