



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

PROTOCOL No.:

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

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



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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 provide documented evidence for the Installation Qualification of Double Head Tube filling machine GAN Combi.
- 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 Tube filling machine GAN Combi (Make: Wimco Ltd.) to be installed in the Double Head Tube filling machine GAN Combi .
- 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 Tube filling machine GAN Combi.



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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
Quality Assurance	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	Double Head Tube filling machine GAN Combi
Equipment ID.	
Model	GAN COMBI
Manufacturer's Name	Wimco Ltd.
Supplier's Name	Wimco Ltd.
Location of Installation	Filling Area

6.0 SYSTEM DESCRIPTION:

Application:

Double Head Tube Filling Machine is used for filling and sealing / closing of Lami/ Plastic tube of Dia.16-50 mm (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 Jacketed 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, 1st Fold & 2nd 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:

- 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
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 25 °C		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

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Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

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Manager QA
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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	GAN Combi		
Machine serial no.	20334		
Power source	420 VAC, 3 phase , 50Hz		
Main motor	Make : Crompton Greaves Rating – 1.5HP, 1410 RPM		
Gear Box	Make : Premium Ratio – 15:1		
PLC	Make : Allen Bradley Model : Micrologix 1400		
MMI	Make : Mitsubishi Model : PVP400 /component c600		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
V.F.D.	Make : Allen bradely Model : Power flex 4 Sr. No. : 1511240777		
Power supply	Make : Shavison		
Encoder	Make : Kubler Rating – 10-30 vdc, 100 mA,		
Air pressure switch	Make : Festo Model : Pev ¼ B		
Stirrer Motor	Make : Bonfiglioli Rating – 0.5HP,415v		
Stepper Motor	Make : Unimech, Model : B-2028Model		
Cassette Motor	Make :Associate Engineers Rating -220V, 50Hz, 0.45 A, NFLP, Type –TEXT		
Lubrication Pump Motor	Make :Paragon Rating -220V, 50 HZ, 0.45 A, 1350 RPM.		
Hot air Blower Motor	Make : Leister 230v, 50 Hz, 0.25 kw		
Hot air gun	Make : Leister 415 v, 3.3 kv		
J. Heater	Make : Girish Rating-230VA.C.750W,		
No tube No Fill sensors	Make :P & F 10-4 vdc PNP		
Print Mark Scanner	Make :PEPPERL+FUCHS DK – 20-9, 30V DC, class 2		
Rat Tail Switch	Make : Jai balaji Bc 9 limit s/ w		
Level Sensor in Hopper	Make : Carlo Gavazzi UA18CAD09 NK TI		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Temp. Sensor in hot air Nozzle	Radix Thermocouple K type		
Temp. Sensor in hopper	Microcon RTD type / PT 100, 3 wire type		
Door Safety Switch	Telemecanique (xcs) 240 v,3A		
Micro Switch for machine O/L	Pepper +Fuchs 10-4 vdc PNP		
No Tube No Fill	Festo AEVULQZ-20-15		
Hot Air Sealing	Festo ADVU-32-50		
Tube Ejection	Festo DGS-25-100		
Tube filling – Blow-off	Festo AEVU-20-20		
Compact cylinder	Festo ADVC-50-10		

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Sign/Date:**

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
Electrical Supply	Voltage : 415 VAC Phase : 3 Phase Frequency : 50 HZ & 51 Amp.		
Room Condition	Temperature NMT 25 °C RH : NMT 55 %		
Compressed Air supply	6 Kg/cm ²		
Chilled Water	8-10°C		

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8.5 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Machine Overload Clutch	To stop the machine in case of overload.		
Machine is enclosed with SS 304 structural members with Polycarbonate sheet.	For Operator Safety.		
Pressure Gauge Make:- Festo Model:- LFR-5D-Mini Range:- 0-16 bar	To Indicate pressure of air.		
Lock for SS control Panel	For Instruments safety		
Position stop.	To stop the machine when the tube holder Position is on lower side.		
Emergency Switch	To stop the machine in case of emergency Stoppage.		
No Tube no fill Sensor	To give signal to filling station for filling.		
Safety during tube ejection	Machine stop when not ejected.		

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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		


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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:

- 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
PKMPL	:	Parle Kovai Machinery Pvt. Ltd.
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:

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)			