



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL
FOR
DOUBLE HEAD TUBE FILLING
MACHINE**

PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:



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Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Double Head Tube Filling Machine has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:



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The objective of developing and executing this protocol is to collect sufficient data pertaining to the Double Head Tube Filling Machine and define the installation qualification requirements and acceptance criteria for the Double Head Tube Filling Machine. Successful completion of these installation qualification requirements will provide assurance that the Double Head Tube Filling Machine was installed as required in the manufacturing area.

The Qualification of Double Head Tube Filling Machine performed in view of Ointment filling area of manufacturing facility of

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Double Head Tube Filling Machine system received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

This Protocol is applicable to installation of Double Head Tube Filling Machine in ointment filling area of the manufacturing facility at & the subsequent documentation.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- The production operator/supervisor shall carry out the cleaning and operation of machine.



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Head – Production/Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory installation of the Double Head Tube Filling Machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Double Head Tube Filling Machine is installed satisfactorily.

Execution team is responsible for the execution of installation of Double Head Tube Filling Machine

Execution team comprises of:



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NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

- 3.1 The Double Head Tube Filling Machine shall meet the system description given in design qualification.
- 3.2 The Double Head Tube Filling Machine shall meet with the acceptance criteria mentioned under the topic "Identification of major components"
- 3.3 The Double Head Tube Filling Machine system shall be operated by PLC.
- 3.4 All material of constructions of the contact parts to be checked as per the specifications.



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4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule

5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

- | | | | |
|---|------------------------|---|---|
| 1 | Equipment Name | : | Double Head Tube Filling Machine |
| 2 | Supplier/Manufacturer | : | Wimco Limited |
| | Model | : | GAN COMBI |
| 3 | Serial no. | : | 299/15 |
| 4 | Machine Speed | : | 120 tube per minute (approx.). Actual output will depend upon the fill weight, product viscosity, MOC of the tube & skill of the operator. For 15 gm/ 30 gm- 100 tubes/ minute (approx.) Machine speed is controlled through VFD. |
| 5 | Location | : | Ointment Filling area |
| 6 | Products can be filled | : | Cream, Gel, Toothpaste, Ointment, Adhesive |
| 7 | Viscosity | : | 20 K- 300 K CPS |
| 8 | Packing Style | : | Lami & Metal tubes |
| 9 | Filling Range | : | 1 cc to 200 cc with corresponding change of pistons- 15 mm (1-6 cc), 30 mm (6-72 cc) & 45 mm (20-150 cc), 60 mm (25-200 cc) |

10 Tube Sizes

Parameters	Lami/Plastic Tubes		Aluminium Tubes	
	Min	Max	Min	Max
Diameter (mm)	16	50	10	50
Cylindrical length for conical cap or total length including cap for inline cap tube (mm)	80	205	80	205

11 Product Filling Accuracy: ± 1% of fill weight



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System Description:

Double Head Tube Filling Machine is used for filling & sealing/ closing of Lami tube of dia. 16-40 mm with filling variation of 1 cc to 150 cc depending on the material properties.

The Double Head Tube Filling Machine consists of following Components:

1) Automatic Tube Loading on Machine:

Consist of polycarbonate cassettes in SS/ Al frame, Al tube tilter, Cassette motor & SS rocker.

2) Tube Registration Device:

Two stepper motors attached to magnetic lifting head, SS cone, colour mark sensors.

3) Tube filling Device:

SS 316 Jacked hopper with 75 liters capacity supported on the machine.

SS 316 make nozzle with air blow off device attached to the reciprocating ss pump.

Complete material transfer device (from hopper to filling nozzle) is made of SS 316.

4) Tube Closing Device

5) Combi Sealer:

The system is fitted with aluminium tube folding stations with coding station. Lami tube sealing system is fitted with heating, sealing, coding & trimming stations. Trim collector is used for collecting the trims from the trimming station.



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5.2 INSTRUCTION FOR FILLING THE CHECKLIST:

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.



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5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down PO number	Visually/Documental		
2	Verify that the "As Built" drawing is complete and represents the design concept.	Visually/Physically		
3	Verify that there is no observable physical damage	Physically		
4	Examine All access ports are cleared of any debris.	Physically		
5	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
6	Verify that all electrical connections are properly done and safe	Physically		
7	Verify that the equipment is properly earthed	Physically		
8	Verify that utility line is properly connected	Physically		
9	Verify the proper leveling of equipment	Physically		
10	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
11	Equipment/system identification no. Is visible	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification	Method of Verification	Actual Observation	Checked By Sign/Date
Automatic Double Head Tube In-feed Device/ System				
Cassettes	Qty.	02 Nos.	Physically	
	MOC	Polycarbonate	Physically	
	Frame MOC	Stainless Steel & Aluminium	Physically	
Tube Tilter	Qty.	02 Nos.	Physically	
	MOC	Aluminium	Physically	
Rocker	Qty.	02 Nos.	Physically	
	MOC	SS	Physically	
Tube Holders	No. of stations	54 Nos.	Physically	
	MOC	Anodized Aluminium	Physically/ Technical Specification	
Ferguson Drive	Spec.	Input- 120 Degree Output- 90 Degree	Physically/ Technical Specification	
Cassette Motors	Make	Associate	Physically	
	Qty.	02 Nos.	Physically	
	Spec.	220 V, 50 Hz, 0.22 A, NFLP, 0.06 KW	Physically	
	Sr. No.	To be recorded	Physically	



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System Components	Design Specification	Method of Verification	Actual Observation	Checked By Sign/Date
Tube Registration Device				
I-Mark Orientation Sensor	Qty.	02 Nos.	Physically	
	Make	P&F	Physically	
	Model	DK 20	Physically	
	Spec.	10-30 VDC	Physically	
Stepper Motors				
Make	Gennext Control	Physically		
Qty.	02 Nos.	Physically		
Rating	6 vdc, 1 Amp.	Physically		
Tube Filling Device/System				
Filling System (Progressive Filling System)	This assembly contains main pump housing, sleeve (Nylon), valve & piston rod. The size of the pump- 15 mm (6 cc), 30 mm (6-72 cc) & 45 mm (20-150 cc) Qty.- All 2 Nos.	Physically/ Technical Specification		
No Tube No Fill Device (Proximity Sensors)				
Qty.	02 Nos.	Physically		
Make	P&F	Physically		
Model	NBB5-18GM50-E2	Physically		
Spec.	10-30 vdc	Physically		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Hopper	Type	Double Jacketed	Physically		
	MOC	SS 316	Physically/ Technical Specification		
	Capacity	75 liters (approx.)	Physically/ Technical Specification		
	Qty.	01 No.	Physically		
Level Sensor for Hopper	Make	Carlogavazzi	Physically		
	Model	UA18CAD09NKTI	Physically		
	Voltage	18-30 vdc	Physically		
	o/p	0 to 10 v analogue	Physically		
	Qty.	01 No.	Physically		
Jacket Heater	Make	Girish	Physically		
	Spec.	230 VAC, 750 W	Physically		
	Qty.	01 No.	Physically		
Temperature Sensor in Hopper	Make	Microcon	Physically		
	Type	PT 100, 3 Wire type	Physically		
	MOC	Thermo well SS 316 L Sensor SS 316	Physically/ Technical Specification		
	End Connection	½" BSP	Physically/ Technical Specification		
	Range	0 ⁰ -400 ⁰ C	Physically		
	Spec.	Class "A"	Physically/ Technical Specification		
Stirrer Motor	Make	Bonfiglioli	Physically		
	Spec.	0.5 HP, 415 V, N1-1380, N2- 40 RPM,	Physically		
	IP Class	IP 55	Physically		
	Type	NFLP	Physically		
	Sr. No.	To be recorded	Physically		
	Qty.	01 No.	Physically		
AC Drive For Stirrer	Make	Allen Bradley	Physically		
	Model	Power flex 4M	Physically		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Spec.				
	Spec.	1.0 HP, 415 V, 50 Hz	Physically		
	Qty.	01 No.	Physically		
Shut off Nozzle	MOC	SS 316	Physically/ Technical Specification		
	Qty.	02 Nos.	Physically		
Tube Closing Device (Combi Sealer)					
Heaters	Make	Leister	Physically		
	Qty.	02 Nos.	Physically		
	Spec.	415 v, 3.3 kw	Physically		
Hot Air Blower	Make	Leister	Physically		
	Qty.	01 No.	Physically		
	Type	G63A2	Physically		
	Spec.	230 V, 50 Hz, 0.33 kw, 2850 RPM	Physically		
Coding Unit	Qty.	01 set coding punches each for Alpha-numeric coding	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Temperature Sensors in Hot Air Nozzle/Controller	Make	Microcon	Physically		
	Qty.	2 Nos.	Physically		
	Type	2 wire type, Thermocouple 'K' type	Physically/ Technical Specification		
	MOC	Thermowell SS 316 L Sensor SS 316	Physically/ Technical Specification		
	End Connection	½" BSP	Physically/ Technical Specification		
	Range	0 ^o to 800 ^o C	Physically/ Technical Specification		
	Spec.	Class 'A'	Physically/ Technical Specification		
Central Lubrication System					
Lubrication Pump	Make	Thermodrop Engineers Pump	Physically		
	Qty.	01 No.	Physically		
Motor	Make	Paragon	Physically		
	Spec.	230 V, 50 Hz, 1.13 Amp., 1350 RPM, NFLP	Physically		
	Sr. No.	To be recorded	Physically		
Control Devices/Systems					
Main Motor	Make	Crompton	Physically		
	Qty.	01 No.	Physically		
	Spec.	1.5 HP, 415 V, 1440 RPM, 2.5 Amp.	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Encoder	Make	Kubler	Physically		
	Spec.	10-30 vdc, 100 mA, 360 ppr Type- 8.5000.B152.0360	Physically		
	Qty.	01 No.	Physically		
Gear Box for Main Motor	Make	Greaves	Physically		
	Reduction Ratio	15:1	Physically		
	Sr. No.	To be recorded	Physically		
AC Drive for Main Motor	Make	Allen Bradley	Physically		
	Qty.	01 No.	Physically		
	Model	Power flex 4M	Physically		
	Spec.	2.0 HP, 415 V, 50 Hz	Physically		
	Location	Control Panel	Physically		
PLC	Make	Allen Bradley	Physically		
	Qty.	01 No.	Physically		
	Model	Micrologix 1400	Physically		
	Spec.	IO 32 on base module/Add on IO 32	Physically		
MMI	Make	Allen Bradley	Physically		
	Qty.	01 No.	Physically		
	Model	Component C600	Physically		
	Spec.	24 vdc	Physically		
Power Supply	Make	Shavison	Physically		
	Qty.	01 No.	Physically		
	Model	G31-120-24	Physically		
	Spec.	Input- 230 v AC O/P- 24 v DC	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Home Position	Make	P & F	Physically		
	Qty.	01 No.	Physically		
	Model	NBB5	Physically		
	Spec.	10-30-vdc	Physically		
Jogging Device	Description	One machine jogging switch with cable is provided for easy machine maintenance & setup	Physically		
Indicator Tower Lamp	Description	Electrical indicator for stop/ ready/ run status is provided on the machine as tower lamp	Physically		
	Spec.	24 vdc	Physically		
Machine Guards	Description	Tubular covers provided made of SS 304 sheets with matt finish & square profile members & also fitted with polycarbonate sheets	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Mechanical Overload Clutch	Description	This is provided to stop the machine if the machine gets jam for any reason	Physically		
Hand Wheel	Description	Provided for manual setting for CAM orientation/ check machine load	Physically		
Safety Switches	Make	Telematic	Physically		
	Qty.	07 Nos.	Physically		
	Model	XCS	Physically		
	Type	Potential free contact	Physically/ technical Specification		
	Location	Mounted on frame & actuator fitted on doors	Physically		
Limit Switch	Make	Telematic	Physically		
	Qty.	01 No.	Physically		
	Model	BC9	Physically		
	Type	Potential free contact	Physically/ technical Specification		
	Location	Fitted after center ejection on machine	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Proximity Sensor for Machine O/L	Make	P & F	Physically		
	Qty.	01 No.	Physically		
	Model	N BB 5	Physically		
	Type	Potential free contact	Physically/ technical Specification		
Air Pressure Switch	Make	Festo	Physically		
	Qty.	01 No.	Physically		
	Model	Pev ¼ B	Physically		
	Type	Potential free contact	Physically/ technical Specification		
	Location	In Pneumatic panel	Physically		
Earthing	Description	Provided in electrical panel	Physically		
Machine Extension Standard	Description	Extension with 14 links with holders & necessary attachments is included in the machine. Side tube ejection system is also provided.	Physically		

Remark: -----

Reviewed by (Sign/Date)



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Name of Components	Material Of Construction	Method Of Verification	Observation	Verified By Sign/Date
Hopper	SS 316	By Molybdenum Kit/ Test Certificate		
Filling Nozzles	SS 316	By Molybdenum Kit/ Test Certificate		
Cladding	SS 304	By Molybdenum Kit/ Test Certificate		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign/Date
1.	Electricity: 3 Phase, 440v & 50 Hz with neutral and proper earthing	By using clamp meter		
2.	Compressed air Not less than 6.0 bar	Visually on pressure gauge		
3.	Chilled water line For chilled water supply	Visually/ Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety/interlocking features (if any) and their function in following tables:

Safety Features Description	Location/Identification	Method of Verification	Observation	Identified By Sign/Date
Earthing of motor	Provided to avoid the accident due to leakage of current.	Visually		
Guard Safety Switches	Machine would automatically stop when any door is opened.	Visually/ Physically		
Emergency Switch	Machine would stop in case of emergency	Visually/ Physically		
Safety Alarm	Red light of tower will glow in case of tube not ejected properly.	Visually/ Physically		
Interlock system	Machine is equipped with electrical & pneumatic interlock system. Hence until & unless the air supply is not given, the machine would not ready to run.	Visually/ Physically		
Machine Overload Clutch	Machine will stop in case of overload	Visually/ Physically		
Machine Reverse Lock	Provided to avoid motion in reverse direction for tube holder chain	Visually/ Physically		
Position Stop	Provided to stop the machine when the tube holder position is on lower side	Visually / Physically		
No tube no fill sensor	Provided to give signal to filling station for filling	Visually / Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



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5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of Double Head Tube Filling Machine operation

S.No.	SOP Title	Verified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



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5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



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5.11 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Double Head Tube Filling Machine.

MOC : Material of construction

RPM : Rotation per minute

/ : Per

V : Volts

HZ : Hertz

HP : Horse Power

Amp. : Ampere

kw : Kilo watt

mm : Millimeter

°C : Degree Centigrade

NFLP : Non Flame Proof

Spec. : Specification

Qty. : Quantity

ltrs. : Liters



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5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

**Deviation accepted by
(Sign/Date)**

**Deviation Approved by
(Sign/Date)**



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5.13 Annexure (S)

Annexure No.	Details of Annexure

Remarks (if any):

.....
.....
.....
.....

Done By & Date:

Verified By & Date:



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6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/Date**

**Checked By
Sign/Date**



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6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. All amendments and discrepancies are documented, approved and attached to this protocol. If applicable, Signature in the block below indicates that all items in this qualification report of Double Head Tube Filling Machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful installation qualification of the Double Head Tube Filling Machine the equipment can be taken for operational qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		