



PHARMA DEVILS

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

PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

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 Operation 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:



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2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Double Head Tube Filling Machine and define the qualification requirements and acceptance criteria for the machine and to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document.

2.2 PURPOSE:

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

2.3 SCOPE:

The Scope of this protocol is limited to the operational Qualification of Double Head Tube Filling Machine in ointment filling area of manufacturing facility at

Once the operational qualification of Double Head Tube Filling Machine has been completed successfully, the equipment shall be preceded for the performance qualification procedure.

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 operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.



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- The production operator / supervisor shall carry out the cleaning and operation of machine.

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.



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2.5 EXECUTION TEAM:

The satisfactory operation 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 operational and is satisfactorily working.

Execution team is responsible for the execution of Operational of Double Head Tube Filling Machine. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA



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- 3.1 The equipment shall be operational as per its specified operating instructions.
- 3.2 All SOPs for the equipment to be verified and checked.
- 3.3 Training is important to all the concerned personnel.
- 3.4 All the functionality of equipment components to be checked.
- 3.5 RPM of motor should be in the range of $\pm 5\%$ deviation.

4.0 REVALIDATION CRITERIA

The machine shall be revalidated if

- There are any major changes, which affect the performance of equipment.
- During preventive maintenance or break down maintenance if any major components is replaced which affects the performance of equipment.
- As per revalidation date and schedule.

5.0 OPERATIONAL QUALIFICATION PROCEDURE

5.1 SYSTEM DESCRIPTION:



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- 1 Equipment Name : Double Head Tube Filling Machine
- 2 Supplier/Manufacturer : Wimco Limited
- Model : GAN COMBI (GAN L.S 120)
- 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
16	50	10	50
80	205	80	205

Diameter (mm)
Cylindrical length for conical cap or total length including cap for inline cap tube (mm)

11 Product Filling Accuracy : ± 1% of fill weight

System Description:

The Double Head Tube Filling Machine- GAN (LS-120) is an Automatic Double head tube filling & sealing machine with an optimum speed of 120 tubes per minute. The machine is equipped with a reciprocating



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piston (Teflon) arrangement that suck the material (ointment, cream, paste etc.) from a storage hopper & delivers the same into the tube through a nozzle. The tube is held firmly in aluminium tube holder, which in turn is placed in the tube holder link. A series of the tube holder links form an endless tube holder chain. This tube holder chain moves & stops at predetermined positions (indexing operation) carrying the tube & performing various operations on the machine.

The Automatic Filling & Sealing Machine GAN (LS-120) consists of following Components:

1) Tube In feed:

This device automatically inserts the empty tubes in the holder. After insertion it also presses the tube in the holder to ensure firm hold. The system consists of rocker, motor, tilter etc.

2) I mark / Orientation:

This device ensures the correct printed panel of the tube is always visible. The device is lifted with optical sensors of P&F make & stepper motor. Optical sensor senses the eye mark printed on the tube & passes the signal to the motor.

3) Hopper:

Double jacketed hopper with cover fitted with electrical heater, thermometer and thermostat.

4) No tube No fill sensor:

This is built-in feature provided in the machine with the help of sensors. It prevents tube free dosing.

5) Tube filling station:

Holders are made from anodized aluminium with nylon grippers & stainless steel springs are used for holding tubes. There are total 54 nos. of holders.

6) Tube Closing:

Tube closing system is of two types:

1. Hot Air Tube Sealing: For laminated tubes.
2. Metal Tube Crimping: For metal tubes.

7) Jogging Device:

Inching button with cable for easy machine maintenance & set up.

This machine is equipped with center overload clutch system, which in turn switches off the machine in case of any overload. This avoids damages or breakages of components. Machine has frame guard



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fabricated in S.S. tubular form equipped with the safety switches are set on all doors. The machines will automatically stop when any door is opened. The machine is equipped with electrical & pneumatic interlock system. Hence until & unless the air supply is not given to the machine wouldn't ready to run.



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5.2 INSTRUCTION FOR FILLING THE CHECKLIST

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

5.3 TEST INSTRUMENT DETAILS



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NAME OF SYSTEM COMPONENT	SPECIFIED FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN/DATE
Main Supply Switch	To ON/OFF the machine	By Challenging		
Buzzer Fault	Buzzer shall blow in case of any fault in the machine	By Challenging		
Automatic/Manual Mode	To run the machine in the automatic mode or in manual/ inching mode.	By Challenging		
Position Stop	Machine shall be freeze immediately in the instant position.	By Challenging		
Variable Frequency Drive	To adjust the frequency or RPM of the Stirrer or machine.	By Challenging		
Tube In feeder	Automatically inserts the empty tubes in the holder.	By Challenging		
Temperature Sensor	To detect the temperature of the jacket.	By Challenging		
Thermostat	To maintain the temperature of the jacketed hopper.	By Challenging		
Stirrer	For continuously stirring the product in the hopper.	By Challenging		
Tower Lamp	To indicate the current status of the machine.	By Challenging		
Jogging Device	For inching of the tube holding rail during machine setting or cleaning.	By Challenging		

Remark: -----



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Reviewed by (Sign/Date)

5.5.2 Verification of operation key functionality

NAME OF SYSTEM COMPONENT	ACCEPTANCE CRITERIA	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN/DATE
Main Switch ON	Machine should start	By twisting the main switch to ON position		
Main Switch OFF	Machine should stop	By twisting the main switch to OFF		



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AUTO METAL MODE



AUTO SEAL MODE



MANUAL MODE



MANUAL MODE SELECTED

AUTO
METAL

AUTO
SEAL

MANUAL

MAIN



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AUTO SEAL MODE:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
Visually	<p><i>On pressing the icon appears on the Main Menu following screen will be appear:</i></p> <p>xx/xx/xx AUTOSEAL MODE xx:xx:xx AM/PM</p> <p>DOOR ●●●● HOOTER ●</p> <p>CASSETE MOTOR ●● FILLING SV ●●</p> <p>P MARK SENSOR ●● SEAL SV TRIM ●●</p> <p>VACUUM/FEED PUMP ●● EJECT SV ●</p> <p>WATER /STIRRER ●● HEATER ●</p> <p>BLOWER/T. PRESS ●● BLOW OFF ●</p> <p>TUBE SENSOR ●● VACUUM ●</p> <p>PRODUCTION [xxx] LEVEL [xxx]</p> <p>ENCODER [xxx] [FILLING RESET]</p> <p>[RESET COUNT] [AUTO RESET] [MAIN] [METAL MODE]</p>		



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MANUAL:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
	<p><i>On pressing the icon appears on the Main Menu following screen will be appear:</i></p> <p>xx/xx/xx MANUAL <input type="text" value="xxx"/> xx:xx:xx AM/PM</p> <p>BLOWER MOTOR <input type="text" value="OFF"/> ●</p> <p>HEATER – 1 <input type="text" value="OFF"/> ●</p> <p>HEATER – 2 <input type="text" value="OFF"/> ●</p> <p>VACUUM PUMP <input type="text" value="OFF"/> ●</p> <p>LUBRICATION PUMP <input type="text" value="OFF"/> ●</p> <p>WATER PUMP <input type="text" value="OFF"/> ●</p> <p align="center"><input type="text" value="MAIN"/> <input type="text" value="NEXT"/></p>		
	<p><i>On pressing the NEXT icon appears on the above screen following icons will be appear:</i></p> <p>xx/xx/xx MANUAL <input type="text" value="xxx"/> x:xx:xx AM/PM</p> <p><i>HEAD – 1</i></p> <p>CASSETE MOTOR <input type="text" value="OFF"/> ●</p> <p>STEP MOTOR SIGNAL <input type="text" value="OFF"/> ●</p> <p>FILLING VALVE <input type="text" value="OFF"/> ●</p> <p>SEALING VALVE <input type="text" value="OFF"/> ●</p> <p>EJECT VALVE <input type="text" value="OFF"/> ●</p> <p>FEED PUMP <input type="text" value="OFF"/> ●</p> <p>HEAD 1 BLOW OFF SV <input type="text" value="OFF"/> ●</p> <p align="center"><input type="text" value="PREV"/> <input type="text" value="MAIN"/> <input type="text" value="NEXT"/></p>		



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	<p><i>On pressing the NEXT icon appears on the above screen following icons will be appear:</i></p> <p>xx/xx/xx MANUAL <input type="text" value="xxx"/> xx:xx:xx AM/PM</p> <p>HEAD – 2</p> <p>CASSETE MOTOR <input type="text" value="OFF"/> ●</p> <p>STEP MOTOR SIGNAL <input type="text" value="OFF"/> ●</p> <p>FILLING VALVE <input type="text" value="OFF"/> ●</p> <p>TUBE CLEAN <input type="text" value="OFF"/> ●</p> <p>POSITIVE CUT OFF SV <input type="text" value="OFF"/> ●</p> <p>TRIM VACUUM PUMP <input type="text" value="OFF"/> ●</p> <p>HEAD 2 BLOW OFF SV <input type="text" value="OFF"/> ●</p> <p><input type="text" value="PREV"/> <input type="text" value="MAIN"/> <input type="text" value="NEXT"/></p>		
	<p><i>On pressing the NEXT icon appears on the above screen following icons will be appear:</i></p> <p>xx/xx/xx MANUAL <input type="text" value="xxx"/> xx:xx:xx AM/PM</p> <p>CASSETE VACUUM SV <input type="text" value="OFF"/> ●</p> <p>TRIMING SV <input type="text" value="OFF"/> ●</p> <p>STIRRER MOTOR <input type="text" value="OFF"/> ●</p> <p>JACKET HEATER <input type="text" value="OFF"/> ●</p> <p><input type="text" value="PREV"/> <input type="text" value="MAIN"/></p>		

SET DATA:



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METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
	<div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; margin: 5px;">LUBRICATION BYPASS</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">HEATER – 1 INACTIVE</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">HEATER – 2 ACTIVE</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">DOOR BYPASS</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">CONFIG</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">FEED BYPASS</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">TIMER RESET</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">COUNTER RESET</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">PREV</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">MAIN</div> </div>		

I/O LIST

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE																
Visually & By pressing the soft keys	<p>On pressing the INPUT icon appears on the MAIN MENU screen, WINDOW shall be appear on the screen which consist of following content:</p> <p>xx/xx/xx xx:xx:xx AM/PM</p> <p align="center"><i>INPUTS</i></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td>I:0/0 ENCODER – 1</td><td align="center">●</td></tr> <tr><td>I:0/1 EMERGENGY STOP PANEL SIDE</td><td align="center">●</td></tr> <tr><td>I:0/2 EMERGENGY STOP EJECT SIDE</td><td align="center">●</td></tr> <tr><td>I:0/3 ENCODER SPARE</td><td align="center">●</td></tr> <tr><td>I:0/4 PRESSURE SWITCH</td><td align="center">●</td></tr> <tr><td>I:0/5 MAIN MOTOR START</td><td align="center">●</td></tr> <tr><td>I:0/6 MAIN MOTOR STOP</td><td align="center">●</td></tr> <tr><td>I:0/7 INCH PUSH BUTTON</td><td align="center">●</td></tr> </table> <div style="display: flex; justify-content: center; gap: 50px; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px;">MAIN</div> <div style="border: 1px solid black; padding: 5px;">NEXT</div> </div>	I:0/0 ENCODER – 1	●	I:0/1 EMERGENGY STOP PANEL SIDE	●	I:0/2 EMERGENGY STOP EJECT SIDE	●	I:0/3 ENCODER SPARE	●	I:0/4 PRESSURE SWITCH	●	I:0/5 MAIN MOTOR START	●	I:0/6 MAIN MOTOR STOP	●	I:0/7 INCH PUSH BUTTON	●		
I:0/0 ENCODER – 1	●																		
I:0/1 EMERGENGY STOP PANEL SIDE	●																		
I:0/2 EMERGENGY STOP EJECT SIDE	●																		
I:0/3 ENCODER SPARE	●																		
I:0/4 PRESSURE SWITCH	●																		
I:0/5 MAIN MOTOR START	●																		
I:0/6 MAIN MOTOR STOP	●																		
I:0/7 INCH PUSH BUTTON	●																		
	<p><i>On pressing the NEXT icon appears on the above screen following icons will be appear on the screen:</i></p> <p>xx/xx/xx xx:xx:xx AM/PM</p> <p align="center"><i>INPUTS</i></p> <table style="width: 100%; border-collapse: collapse;"> <tr><td>I:0/8 POSITION STOP PB</td><td align="center">●</td></tr> <tr><td>I:0/9 HOME PROXY</td><td align="center">●</td></tr> <tr><td>I:0/10 INTERCONN BACKLOG SENSOR 1</td><td align="center">●</td></tr> <tr><td>I:0/11 INTERCONN BACKLOG SENSOR 2</td><td align="center">●</td></tr> <tr><td>I:0/12 DOOR 1</td><td align="center">●</td></tr> <tr><td>I:0/13 DOOR 2</td><td align="center">●</td></tr> <tr><td>I:0/14 DOOR 3</td><td align="center">●</td></tr> </table>	I:0/8 POSITION STOP PB	●	I:0/9 HOME PROXY	●	I:0/10 INTERCONN BACKLOG SENSOR 1	●	I:0/11 INTERCONN BACKLOG SENSOR 2	●	I:0/12 DOOR 1	●	I:0/13 DOOR 2	●	I:0/14 DOOR 3	●				
I:0/8 POSITION STOP PB	●																		
I:0/9 HOME PROXY	●																		
I:0/10 INTERCONN BACKLOG SENSOR 1	●																		
I:0/11 INTERCONN BACKLOG SENSOR 2	●																		
I:0/12 DOOR 1	●																		
I:0/13 DOOR 2	●																		
I:0/14 DOOR 3	●																		



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	I:0/15 DOOR 4 ● <div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; padding: 2px 10px;">PREV</div> <div style="border: 1px solid black; padding: 2px 10px;">MAIN</div> <div style="border: 1px solid black; padding: 2px 10px;">NEXT</div> </div>		
	<p><i>On pressing the NEXT icon appears on the above screen following icons will be appear on the screen:</i></p> <p>xx/xx/xx INPUTS xx:xx:xx AM/PM</p> <p>I:0/16 PAC BYPASS ●</p> <p>I:0/17 TUBE PRESENT HEAD – 1 ●</p> <p>I:0/18 I MARK SENSOR SIGNAL 1 ●</p> <p>I:0/19 I MARK SENSOR SIGNAL 2 ●</p> <p>I:1/0 TRIM VACUUM PUMP O/L ●</p> <p>I:1/1 VFD TRIPPED SIGNAL ●</p> <p>I:1/2 BLOWER TRIPPED SIGNAL ●</p> <p>I:1/3 MACHINE OVERLOAD ●</p> <div style="display: flex; justify-content: space-around; width: 100%; margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px 10px;">PREV</div> <div style="border: 1px solid black; padding: 2px 10px;">MAIN</div> <div style="border: 1px solid black; padding: 2px 10px;">NEXT</div> </div>		
	<p><i>On pressing the NEXT icon appears on the above screen following icons will be appear on the screen:</i></p> <p>xx/xx/xx INPUTS xx:xx:xx AM/PM</p> <p>I:1/4 TUBE PRESENT HEAD 2 ●</p> <p>I:1/5 AIR FLOW S/W HEAD 2 ●</p> <p>I:1/6 WATER PUMP O/L SIGNAL ●</p> <p>I:1/7 VACUUM PUMP O/L SIGNAL ●</p> <p>I:1/8 AIRFLOW S/W HEAD 1 ●</p> <p>I:1/9 STIRRER MOTOR O/L SIGNAL ●</p> <p>I:1/10 TUBE EJECT O/L ●</p> <p>I:1/11 FEED PUMP O/L SIGNAL ●</p> <div style="display: flex; justify-content: space-around; width: 100%; margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px 10px;">PREV</div> <div style="border: 1px solid black; padding: 2px 10px;">MAIN</div> <div style="border: 1px solid black; padding: 2px 10px;">NEXT</div> </div>		



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	O:2/9 EJECTION SV ● O:2/10 CASSETE VACUUM SV ● O:2/11 BLOW OFF HEAD 1 ● <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px 10px;">PREV</div> <div style="border: 1px solid black; padding: 2px 10px;">MAIN</div> <div style="border: 1px solid black; padding: 2px 10px;">NEXT</div> </div>		
	<p><i>On pressing the NEXT icon appears on the above screen following icons will be appear on the screen:</i></p> <p><i>xx/xx/xx OUT PUTS xx:xx:xx AM/PM</i></p> O:2/12 BLOW OFF HEAD 2 ● O:2/13 HOOTER/ FAULT INDICATION ● O:2/14 TRIMMING SV ● O:2/15 POSITIVE CUT OFF SV ● <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px 10px;">PREV</div> <div style="border: 1px solid black; padding: 2px 10px;">MAIN</div> </div>		

LOG IN:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
Visually & By pressing the soft keys	On pressing the LOGIN icon appears on the MAIN MENU screen, WINDOW shall be appear on the screen which consist of following content: 1. User 2. Password 3. Virtual Keypad		

LOG OUT:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE



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UTILITY	METHOD OF VERIFICATION	OBSERVATIONS	VERIFIED BY SIGN/DATE
Electricity: 3 Phase, 440v & 50 Hz with neutral and proper earthing	By using clamp meter		
Compressed air Not less than 6.0 bar	Visually on pressure gauge		
Chilled water line For chilled water supply	Visually/Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.7 VERIFICATION OF SAFETY FEATURE

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

SAFETY FEATURES DESCRIPTION	FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN & DATE
Earthing of motor	To avoid the accident due to the leakage current.	Visually		
Overload Clutch System	Switches off the machine in case of any overload to avoid damages or breakages of components.	By Challenging		
Electrical & Pneumatic Interlock System	Until & unless the air supply is not given to the machine wouldn't ready to run.	By Challenging		
Guard Safety Switches	Machine will automatically stop when any door is opened.	By Challenging		
Emergency Stop	In case of emergency stop of machine.	By Challenging		

Remark: -----

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)



PHARMA DEVILS

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

PROTOCOL No.:

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

S.No.	SOP Title	SOP Number	Verified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S):



PHARMA DEVILS

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

PROTOCOL No.:

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Remark: -----

Reviewed by (Sign/Date)

5.10 LIST OF ANNEXURES:

Annexure No.	Document Title
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**OPERATIONAL QUALIFICATION PROTOCOL
FOR
DOUBLE HEAD TUBE FILLING
MACHINE**

PROTOCOL No.:

Description of deficiency:

Corrective action(s) taken:

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

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

5.12 Abbreviations



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

PROTOCOL No.:

Following Abbreviations are used in the Operational Qualification of Double Head Tube Filling Machine.

ID .: Identification Number

V: Voltage

Hz: Hertz

SOP: Standard Operating Procedure

mm: Milimeter

gm: Gram

MOC: Material of Construction

NA: Not Applicable



PHARMA DEVILS

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

PROTOCOL No.:

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/Date**

**Checked By
Sign/Date**

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. Verified that 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 Operational 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.



PHARMA DEVILS

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

PROTOCOL No.:

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