



PHARMA DEVILS

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

PROTOCOL No.:

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1.0 REPORT 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 Performance 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		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this report is to check and document the performance of the Double Head tube Filling Machine (GAN COMBI) in the established/ predetermined operating ranges.

2.2 PURPOSE:

The purpose of this report is to provide the documented evidence that the functions of the Double Head tube Filling Machine (GAN COMBI) which affect the product quality, equipment integrity, and safety of operating and maintenance personnel is taken into consideration.

2.3 SCOPE:

The scope of this report shall define the test procedures, documentation and acceptance criteria to establish that the operational parameters of Double Head tube Filling Machine (GAN COMBI) is as per the requirement in the

2.4 RESPONSIBILITY:

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

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

- Prepares the performance 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 analysis of sample shall be carried out by quality control department.
- Engineering department shall support for execution.
- The production operator/supervisor shall carry out the cleaning and operation of machine.



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Head – Quality control/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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3.0 GENERAL CONSIDERATION/PREREQUISITE:

- 3.1 Approved Standard operating procedure of Automatic Filling & Sealing Machine.
- 3.2 The impact analysis of the equipment's shall be recorded in the summary sheet.
- 3.3 The installation and operational qualification of Automatic Filling & Sealing Machine shall be successfully completed before the execution of the performance qualification.
- 3.4 All the deficiencies and discrepancies related to Automatic Filling & Sealing Machine which affects the product quality and corrective action taken shall be recorded in the appropriate section of the report.
- 3.5 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.
- 3.6 All the measuring parameters shall be verified.
- 3.7 All the safety features shall be verified.
- 3.8 The availability of utilities for the equipment shall be verified.

4.0 REVALIDATION CRITERIA:

The machine shall be qualified if:

- There are any major changes, which affect the performance of the equipment.
- After major breakdown maintenance is carried out.
- As per re-validation date and schedule.

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 EQUIPMENT DESCRIPTION:

The Double Head Tube Filling Machine- (GAN COMBI) 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 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 aluminum 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.



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The Double Head tube Filling Machine GAN (COMBI) 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 aluminum 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 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 RISK ANALYSIS:

- Tube In feed automatically inserts the empty tubes in the holder. After insertion it also presses the tube in the holder to ensure firm hold.
- I mark / Orientation ensures the correct printed panel of the tube is always visible. The device is lifted with optical sensors, controller & stepper motor.
- Double jacketed hopper with cover fitted with electrical heater, thermometer and thermostat.
- No tube No fill sensor is built-in feature provided in the machine with the help of sensors. It prevents tube free dosing.

S.No.	Risk Identified	Control Measures
1.	Power failure	The machine shall be stop and will not start until engage the clutch.
2.	In case of an emergency stop	The machine shall automatically lift up the segment system.
3.	Temperature fluctuation	Thermostats and temperature controllers are installed at hopper for temperature regulation.
4.	Unavailability of tube	The machine will stop and an alarm appeared on the PLC.
5.	Open guard during filling	Machine will automatically stop when any door is opened and alarm appeared on the screen.
6.	Low Air Pressure	Machine will stop in case of low air pressure supply and will not start until pressure level would be up to 6.0 kg/cm ² and alarm appeared on the screen.
7.	Lower level of cream in the hopper	Machine shall be stop and alarm appeared on the screen.
8.	Higher level of cream in the hopper	Metering pump will stop.

EVALUATION AND CONCLUSION:

All the risks associated with Automatic Filling & Sealing Machine (GAN COMBI) have been evaluated and control/preventive measures have been taken.

5.3 METHODOLOGY:

Methodology of the tube filling process is as follows:

- Maintain the filling area temperature at 22°C ± 3°C and Humidity 50%± 5 %.
- Check the all gaskets and Change Parts.



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- Dummy batches manufactured of higher batch size shall be fill with all available change parts which shall be used in different products.
- Details of the dummy batches and change parts details shall be mentioned under the heading of “**Product Details**”.
- Start the filling process as per the BPR.
- Run the machine at different speed with a combination of different temperature to establish the operation range of the machine.
- Challenge run mentioned in the qualification matrix shall be performed with all change parts individually and shall be record under the heading of “**Observations and Results of Challenge Tests**”.
- Transfer the intermediate product from storage tank to the machine hopper with the help of transfer pump.
- Temperature $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and Relative Humidity $50\% \pm 5\%$ maintained through out the process.
- Before starting the filling operation stir the cream at 10 RPM for 15 minutes.



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5.3.1 QUALIFICATION/ VALIDATION SAMPLING PLAN:

The qualification/ validation matrix is as following:

S.No.	Speed	Parameters	Sample Quantity	Test Required
1.	Minimum (60 TPM)	High Sealing Temp. (300°C)	54 Tubes	Appearance, Average Weight, Fill Weight, Sealing Quality, Batch Coding, Trimming, Leak Test
2.		Low Sealing Temp. (220°C)		
3.	Maximum (100 TPM)	High Sealing Temp. (200°C)	54 Tubes	Appearance, Average Weight, Fill Weight, Sealing Quality, Batch Coding, Trimming, Leak Test
4.		Low Sealing Temp. (80°C)		
5.	Optimum (80 TPM)	High Sealing Temp. (200°C)	54 Tubes	Appearance, Average Weight, Fill Weight, Sealing Quality, Batch Coding, Trimming, Leak Test
6.		Low Sealing Temp. (80°C)		
7.	Optimum (80 TPM)	Full Hopper	54 Tubes	Appearance, Average Weight, Fill Weight, Sealing Quality, Batch Coding, Trimming, Leak Test
		Half Hopper		
		End Hopper		
8.	Optimum (80 TPM)	At initial stage	54 Tubes	Appearance, Average Weight, Fill Weight, Sealing Quality, Batch Coding, Trimming, Leak Test
		At middle stage		
		At end stage		



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5.4 PRODUCT DETAILS:

Product details of batch size shall be verified from the BPR of the product and record in the following section:

5.4.1 Product Details:

Product Name : _____

Product Code : _____

Batch Number : _____

Batch Size : _____

Mfg. Date : _____

Exp. Date : _____

BPR Number : _____

Remark: -----

Reviewed by

(Sign/Date)



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5.4.2 Tube Holder Details:

S.No.	Size of Tube Holder	Batch Number	Number of Holder in Turret	Checked By (Sign. & Date)
1.				
2.				

Remark: -----

Reviewed by

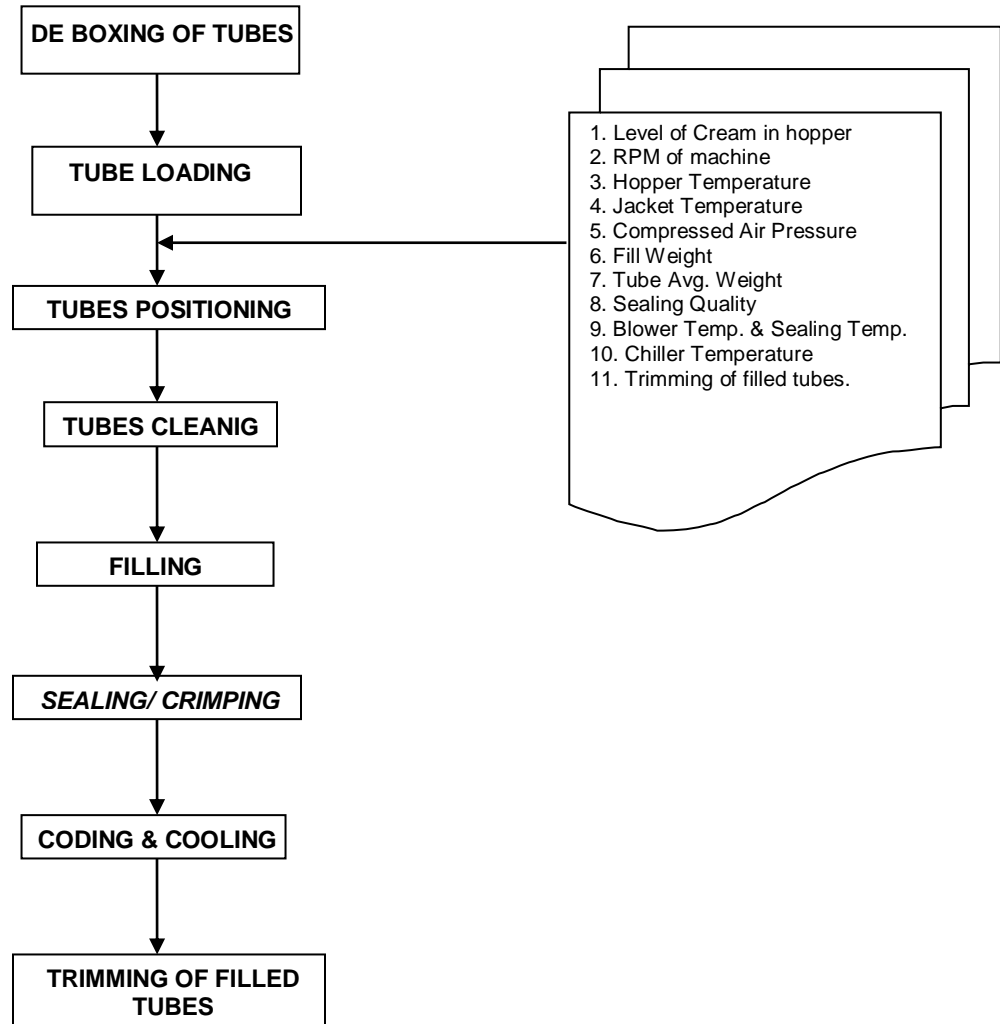
(Sign/Date)



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5.5 Process Flow Diagram with Qualification Parameters of Automatic Filling & Sealing Machine (GAN COMBI):

Process flow diagram of Automatic Filling & Sealing Machine (GAN COMBI) is mentioned below:





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5.6 SET PARAMETERS:

Batch No. : _____

Maximum Batch Size			
S.No.	Parameters	Limits	Frequency
1.	Description	Off white to light yellowish smooth cream	At start of the filling
2.	Average Net Content	NLT 15.0 gm per tube	Every 2 Hour
3.	Filled Weight	15.0- 16.0gm	Every 2 Hour
4.	Sealing Quality	Should be proper	Every 2 Hour
5.	Batch Coding	Should be legible	Every 2 Hour
6.	Trimming	Should be proper	Every 2 Hour
7.	Leak Test	Nil	Every 2 Hour
8.	Machine Speed	60 – 100 TPM	Every 2 Hour
9.	Sealing Temperature	_____°C	Every 2 Hour
10.	Room Temperature	22 ± 3°C	Every 1 Hour
11.	Relative Humidity (%)	50 ± 5 %	Every 1 Hour

Done By

Reviewed By

Sign & Date

Sign & Date



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5.7 ACCEPTANCE CRITERIA:

The test will be considered failed if the actual test results do not correspond to the expected results as following:

- Description should be match with the specification.
- Average Weight should be within the specified limit as mentioned in the BPR.
- Fill Weight should be within the specified limit as mentioned in the BPR.
- Sealing Quality should be satisfactory as mentioned in the BPR.
- Batch Coding should be satisfactory as mentioned in the BPR.
- Trimming should be satisfactory as mentioned in the BPR.
- Leak Test should be satisfactory as mentioned in the BPR.



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5.9 OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:

OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Minimum Speed: _____ TPM							
				High Sealing Temp.: _____ °C							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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PROTOCOL No.:

OBSERVATION											
Batch Number:				Tube Holder No.:							
Stage of Sampling:				Minimum Speed _____ TPM							
				Low Sealing Temp.: _____ °C							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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PROTOCOL No.:

OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Maximum Speed: _____ TPM							
				High Sealing Temp.: _____ °C							
TESTS						RESULTS					
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Maximum Speed: _____ TPM							
				Low Sealing Temp.: _____ °C							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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PROTOCOL No.:

OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				High Sealing Temp.: _____ °C							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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PROTOCOL No.:

OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				Low Sealing Temp.: _____ °C							
TESTS						RESULTS					
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)										Avg. weight	
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				Initial Stage							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				Middle Stage							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				End Stage							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)										Avg. weight	
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				Full Hopper Level							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)										Avg. weight	
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

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Reviewed by (Sign/Date)



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OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				Half Hopper Level							
TESTS						RESULTS					
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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OBSERVATION											
Batch Number:				Tube Holder Size:							
Stage of Sampling:				Optimum Speed: _____ TPM							
				End Hopper Level							
TESTS				RESULTS							
Appearance											
Filled Tube Weight				Holder 1:				Holder 2:			
Fill Weight				Holder 1:				Holder 2:			
Sealing Quality				Holder 1:				Holder 2:			
Batch Coding				Holder 1:				Holder 2:			
Trimming				Holder 1:				Holder 2:			
Leakage Test (by squeezing the tube)				Holder 1:				Holder 2:			
Individual Weights of 10 Tubes (g)											Avg. weight
Filled Tube Wt.											
Empty Tube Wt.											
Fill Wt.											

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



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

Following deficiency was identified 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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PROTOCOL No.:

7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

**Prepared By
Sign/Date**

**Checked By
Sign/Date**



PHARMA DEVILS

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

PROTOCOL No.:

7.3 FINAL REPORT APPROVAL

The final report shall be signed after verifying that all the tests required in the qualification report of Automatic Filling & Sealing Machine (GAN COMBI) are completed, reconciled and attached to the Qualification report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective report (If applicable).

Signature in the block below indicate that all items in the qualification report of Automatic Filling & Sealing Machine (GAN COMBI) have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

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