



PHARMA DEVILS

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION  
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>SUPERSEDES PROTOCOL No.</b>	<b>Nil</b>



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**PROTOCOL No.:**

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**1.0 REPORT 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 that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

**3.0 SCOPE:**

- The scope of this report is limited for qualification of Double Head Tube filling machine GAN combi installed in filling room.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.



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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 execution of Performance Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Pre-Approval and Compilation of the Performance Qualification Report.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification.</li><li>• Post Approval of Performance Qualification Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Performance Qualification Report.</li><li>• To co-ordinate and support Performance Qualification Activity.</li><li>• Post Approval of Performance Qualification Report after Execution.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Analytical Support (Microbiological Testing/Analysis).</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Reviewing of qualification protocol for correctness, completeness and technical excellence</li><li>• Responsible for trouble shooting (if occurred during execution).</li><li>• Maintenance &amp; preventive maintenance as per schedule.</li><li>• Post Approval of Performance Qualification 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</b>	
<b>Manufacturer's Name</b>	Wimco Ltd.
<b>Model</b>	GAN COMBI
<b>Serial No.</b>	
<b>Supplier's Name</b>	Wimco Ltd.
<b>Location of Installation</b>	Filling Room

**6.0 PRE – QUALIFICATION REQUIREMENTS:**

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

**6.1 Training Record of Validation Team:**

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

**6.2 Verification of Documents:**

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	<b>DQ Protocol approved</b>			
2.	<b>IQ Protocol approved</b>			
3.	<b>OQ Protocol approved</b>			
4.	<b>PQ Protocol approved</b>			
5.	<b>SOP for Operation &amp; Cleaning of Double Head Tube Filling machine GAN combi</b>			
6.	<b>SOP for Preventive Maintenance Double Head Tube Filling machine GAN combi</b>			

**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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**PROTOCOL No.:**

**7.0 TESTS AND CHECKS:**

**7.1 Performance Evaluation For Machine Speed Optimization:**

**Trial No.:**

<b>Date of Test</b>		<b>Equipment ID</b>	
<b>Total Tubes taken for test</b>		<b>Pack Size / Type of Tube</b>	
<b>Parameter</b>	<b>Low Speed (        )</b>	<b>Optimum Speed(        )</b>	<b>High Speed (        )</b>
<b>Sample after .....( min)</b>			
<b>Machine jam</b>			
<b>Tube Damaged</b>			
<b>Rejection</b>			
<b>Sample after .....( min)</b>			
<b>Machine jam</b>			
<b>Tube Damaged</b>			
<b>Rejection</b>			
<b>Sample after .....( min)</b>			
<b>Machine jam</b>			
<b>Tube Damaged</b>			
<b>Rejection</b>			
<b>Total rejection</b>			
<b>Acceptance Criteria:</b> Rejection should not be more than 2.0%.			

**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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**PROTOCOL No.:**

TUBE No.	Low Speed ( 40 tubes/ min )			Optimum Speed (80 tube / min )			High Speed (120 Tubes / Min )		
	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
12									
13									
14									
15									
16									
17									
18									
19									
20									

**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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**PROTOCOL No.:**

TUBE No.	Low Speed ( 40 tubes/ min )			Optimum Speed (80 tube / min )			High Speed (120 Tubes / Min )		
	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
12									
13									
14									
15									
16									
17									
18									
19									
20									

**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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**PROTOCOL No.:**

TUBE No.	Low Speed ( 40 tubes/ min )			Optimum Speed ( 80 tube / min )			High Speed ( 120 Tubes / Min )		
	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
12									
13									
14									
15									
16									
17									
18									
19									
20									

**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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**PROTOCOL No.:**

**7.5 Leakage Test :**

<b>Date of test</b>		<b>Product Name</b>	
<b>Batch No.</b>		<b>Fill Weight</b>	
<b>Temperature</b>		<b>Type of Tube</b>	

**Trial No.:**.....

Tube No.	Low Speed ( 40 tubes/ min )		Optimum Speed (80 tube / min )		High Speed (120 Tubes / min )	
	Nozzle-01	Nozzle-02	Nozzle-01	Nozzle-02	Nozzle-01	Nozzle-02
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

**RESULTS:** The test results Complies / Not Complies as per Specification.

**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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**PROTOCOL No.:**

**7.6 Physical Test:**

<b>Date of test</b>		<b>Product Name</b>	
<b>Batch No.</b>		<b>Fill Weight</b>	

**Trial No.:**.....

Tube No.	Printing matter	Engraving	Dent	Wrinkle	Folding
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

**RESULTS:** The test results Complies / Not Complies as per Specification.

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:**.....

**Inference:**

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**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



**8.0 CHECKLIST OF ALL TESTS & CHECKS:**

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of Documents		
Fill Weight Variation		
Leakage Test		
Physical Test		

**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 DOCUMENTS TO BE ATTACHED:**

- Executed Raw Data.
- Any Other Relevant Documents.

**10.0 NON COMPLIANCE:**

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**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:**

- Asst. : Assistant
- cGMP : Current Good Manufacturing Practices
- CQA : Corporate Quality Assurance
- PQ : Performance Qualification
- Vol. : Volume
- i.e. : That is
- SS : Stainless steel
- Ltr. : Litre
- Nos. : Numbers.
- SOP : Standard Operating Procedure
- SS : Stain less Steel
- OFS : Double Head fully automatic Filling, closing and Sealing machine
- WHO : World Health Organization



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**17.0 REPORT 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)			