

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

EQUIPMENT ID. No.	
LOCATION	FILLING ROOM
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	Nil



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1.0	REPORT PRE	E – APPROVAL:
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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		
Quality Assurance	Preparation, Pre-Approval and Compilation of the Performance		
	Qualification Report.		
	 Co-ordination with Quality Control, Production and Engineering to 		
	carryout Performance Qualification Activity.		
	 Monitoring of Performance Qualification. 		
	• Post Approval of Performance Qualification Report after Execution.		
Production	Review of Performance Qualification Report.		
	• To co-ordinate and support Performance Qualification Activity.		
	• Post Approval of Performance Qualification Report after Execution.		
Quality Control	 Analytical Support (Microbiological Testing/Analysis). 		
Engineering	Reviewing of qualification protocol for correctness, completeness and		
	technical excellence		
	 Responsible for trouble shooting (if occurred during execution). 		
	• Maintenance & preventive maintenance as per schedule.		
	• Post Approval of Performance Qualification Report after Execution.		



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DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI

5.0 EQUIPMENT DETAILS:

Equipment Name	Double Head Tube filling machine GAN combi
Equipment	
Manufacturer's Name	Wimco Ltd.
Model	GAN COMBI
Serial No.	
Supplier's Name	Wimco Ltd.
Location of Installation	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.



PERFORMANCE QUALIFICATION **REPORT FOR**

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Verified By

Checked By

DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI

Completed

6.2	Verification	of Documents:
V.=	, critication	or bocuments.

Record the observations for documents in the below mentioned table.

S.No.	Document Name	(Yes/No)	(Engineering) Sign/Date	(QA) Sign/Date
1.	DQ Protocol approved			
2.	IQ Protocol approved			
3.	OQ Protocol approved			
4.	PQ Protocol approved			
5.	SOP for Operation & Cleaning of			
	Double Head Tube Filling machine			
	GAN combi			
6.	SOP for Preventive Maintenance			
	Double Head Tube Filling machine			
	GAN combi			
Checko Produo Sign/D	-		Verified By Quality Ass Sign/Date:	
Inferer	nce:			
•••••		• • • • • • • • • • • • • • • • • • • •		
•••••		• • • • • • • • • • • • • • • • • • • •		
			Reviewed B Manager Q Sign/Date:	



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7.	0	TESTS	AND	CHECKS:

Trial No.: **Date of Test Equipment ID Total Tubes taken for** Pack Size / Type of Tube test Low Speed (**Parameter Optimum Speed(High Speed (** Sample after (min) Machine jam **Tube Damaged** Rejection Sample after (min) Machine jam **Tube Damaged** Rejection Sample after (min) Machine jam **Tube Damaged** Rejection **Total rejection Acceptance Criteria:** Rejection should not be more than 2.0%. **Checked By** Verified By **Production Quality Assurance** Sign/Date: Sign/Date:.... **Inference: Reviewed By** Manager QA Sign/Date:



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7.2 Fill Weight Variation At Full Hopper:

Date of test	
Product Name	
Batch No.	
Standard. Fill Weight	
(Limit: ± % of standard Filled Weight)	
Total Operation Time	

TRIAL No.:

TUBE	Low Speed (40 tubes/ min)		Optimum Speed (80 tube / min)			High Speed (120 Tubes / Min)			
No.	Gross wt.	Empty	Net	Gross wt.	Empty	Net wt.	Gross wt.	Empty	Net wt.
1	wt.	wt	wt.		wt		Wt.	wt	Wi.
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									



PROTOCOL No.:

TUBE	Low Speed (40 tubes/ min)			Opt	timum Spe tube / min	ed	High Speed (120 Tubes / Min)		
No.	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 Quality Assurance Sign/Date: Sign/Date									
Inference:									

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••••••	•••••
	Reviewed By
	Manager QA
	Manager QA Sign/Date:



DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI

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7.3	Fill Weight	Variation	At Half	Hopper :	:
		,			•

Date of test	
Product Name	
Batch No.	
Standard. Fill Weight	
(Limit: ± % of standard Filled Weight)	
Total Operation Time	

TRIAL No.:

TUBE	Low Speed BE (40 tubes/ min)		Optimum Speed (80 tube / min)			High Speed (120 Tubes / Min)			
No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									



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	Low Speed			Opt	timum Spe	ed	High Speed			
TUBE	(40 tubes/ min)			tube / min		(120 Tubes / Min)				
No.	Gross	Empty	Net	Gross wt.	Empty	Net wt.	Gross	Empty	Net	
	wt.	wt	wt.		wt	- 1.00 1.00	wt.	wt	wt.	
12	1,700	,,,,	.,, .,		.,, 5		., .,	,,,,	1,700	
12										
13										
14										
4.5										
15										
16										
10										
17										
18										
19										
20										
20										
				I.	<u> </u>	1		I .		
Checked	Rv					7	erified By	J		
Producti							Quality As			
	e:						Zuanty 115. Sion/Date	sur ancc		
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Inference	e:									
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DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI

7.4 Fill Weight Variation At $\frac{1}{4}$ th Hopper:

Date of test	
Product Name	
Batch No.	
Standard. Fill Weight	
(Limit: ± % of standard Filled Weight)	
Total Operation Time	

TRIAL No.:

TUBE	L (40	ow Speed tubes/ min	1)	Opt (80	imum Spe tube / min	ı)	(120	High Speed Tubes / M	in)
No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									



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TUBE					imum Spe tube / min		High Speed (120 Tubes / Min)		
No.	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 Producti Sign/Dat						(Verified By Quality Ass Sign/Date.		
Inference	e:								
			•••••		•••••		Reviewed F		•••••
						N S	Ianager Q ign/Date:) A 	•••••



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7.5	Leakage Test	
. ••	Ecanage rest	•

Date of tes	t	Product Name						
Batch No.				Fill Weight				
Temperatu	ıre			Type of Tube				
Trial No.:.	•••••							
Tube No.	Low S (40 tube			imum Speed tube / min)		Speed bes / 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 p	per Specification.				
Checked B Production Sign/Date: Inference:					Verified By Quality Assura Sign/Date			
•••••	•••••	•••••	•••••	•••••	•••••	•••••		
					Reviewed By Manager QA Sign/Date:			



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7.6 Phy	ysical Te	est:				
Date of tes	st			roduct ame		
Batch No.			Fi	ll Weight		
Trial No.:	•••••					
Tube No.	Printi	ing matter	Engraving	Dent	Wrinkle	Folding
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
RESULTS	S: The te	st results Cor	mplies / Not Complie	s as per Specification	on.	
Checked I Production Sign/Date:	n				Verified By Quality As Sign/Date.	
Inference:						
••••••	••••••					
••••••	••••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••••••		•••••
					Reviewed R	V

Reviewed By
Manager QA
Sign/Date:



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8.0	CHECKLIS	T OF ALL	TESTS &	CHECKS
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Perification of Documents Ill Weight Variation Leakage Test Checked By Production Lign/Date: Inference: Reviewed By Manager QA Sign/Date: Reviewed By Manager QA Sign/Date:	Tests or Checks	Executed (Yes/No)	Remarks
eakage Test hysical Test hecked By roduction gn/Date: Sign/Date. Reviewed By Manager QA	erification of Documents	(
hecked By roduction	ll Weight Variation		
hecked By roduction Quality Assurance sign/Date: Sign/Date. Reviewed By Manager QA	eakage Test		
roduction Quality Assurance Sign/Date: Sign/Date	hysical Test		
Reviewed By Manager QA	roduction	Quali	ty Assurance
Reviewed By Manager QA	nference:		
Reviewed By Manager QA			
Manager QA			
Manager QA			
Manager QA	•••••	•••••	
		Man	ager QA



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9.0	DOCUMENTS TO BE ATTACHED:
	Executed Raw Data.
	Any Other Relevant Documents.
10.0	NON COMPLIANCE:
11.0	DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:
12.0	CHANGE CONTROL, IF ANY:
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):



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14.0	CONCLU	SION:			
	•••••				
15.0	RECOM	MENDA	TION:		
	• • • • • • • • • • • • • • • • • • • •				
16.0	ABBREVIATIONS:				
10.0	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		
	SOP SS	:	Standard Operating Procedure Stain less Steel		
	SS	:	Stain less Steel		



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	17.0	'.0 REPORT	POST-A	APPRO	VAL
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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)			