

PROTOCOL No.:

# PERFORMANCE QUALIFICATION REPORT FOR AIRJET BOTTLE CLEANING MACHINE

EQUIPMENT ID No.	
LOCATION	'Q' BLOCK
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	



PROTOCOL No.:

### **REPORT CONTENTS**

S.No.	TITLE	PAGE No.
1.0	REPORT PRE APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	EQUIPMENT DETAILS	5
6.0	SYSTEM DESCRIPTION	6
7.0	PRE-QUALIFICATION REQUIREMENT	6
8.0	TESTS & CHECKS	8
9.0	CHECKLIST OF ALL TESTS & CHECKS	14
10.0	DOCUMENTS TO BE ATTACHED	14
11.0	NONCOMPLIANCE	14
12.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY	14
13.0	CHANGE CONTROL, IF ANY	14
14.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	15
15.0	CONCLUSION	15
16.0	RECOMMENDATION	15
17.0	ABBREVIATIONS	15
18.0	REPORT POST APPROVAL	16



PROTOCOL No.:
---------------

### 1.0 REPORT PRE- APPROVAL:

### **INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

### **REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

### **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



PROTOCOL No.:

### **2.0 OBJECTIVE:**

- To provide documented evidence that the Equipment is performing as per the parameter defined in Performance Qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

### **3.0 SCOPE:**

This Report is applicable for performance qualification of Airjet Bottle Cleaning machine installed in Bottle Washing Area.



PROTOCOL No.:

### 4.0 RESPONSIBILITY:

The Qualification team, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES					
Quality Assurance	<ul> <li>Preparation, Review and Approval of the Performance Qualification Protocol.</li> <li>Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li> <li>Provide Training to qualification team.</li> </ul>					
Production	To co-ordinate and support Performance Qualification Activity.					
Engineering	<ul> <li>To provide the required Utility and Engineering support.</li> <li>Responsible for trouble shooting (if occurred during execution).</li> <li>Maintenance &amp; preventive maintenance as per schedule.</li> </ul>					

### **5.0 EQUIPMENT DETAILS:**

Equipment Name	Airjet Bottle Cleaning machine
Equipment ID.	
Manufacturer's Name	Bhavani Engineering
Location of Installation	Bottle washing Machine



PROTOCOL No.:

### **6.0 SYSTEM DESCRIPTION:**

The Automatic Airjet Bottle Air and Vacuum Cleaning Machine is compact unit totally made of SS structure with height adjustment legs, are provided to adjust the machine height and highly efficient machine with elegant look. This multifunctional multi featured machine meets the GMP requirements of washing for glass and plastic Bottles. The machine requires manual loading and automatic unloading of Bottles

### **PROCESS:**

A Machine is inbuilt with Turntable for smooth transfer of round Bottle and suite is provided for noncircular Bottle to the Cleaning Section. This machine works with the principal of back pressure of container. Bottle feed by the Turntable or suit to reach to the star wheel, which transfers the Bottle to the cleaning section one after the. Bottle reaches to the cleaning section, air nozzles starts to flush the air inside towards the Bottle and simultaneously vacuum will suck the particles, disturbed by the air.



DD	_		_	~	~	_		-	
PR	1 1	' " '	1 1	•	1 1			Λ	•
1 1/	<b>,</b> ,	1	<b>,</b>	v	v.		1.4	v.	

### **7.0 PRE-QUALIFICATION REQUIREMENTS:**

### 7.1 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.

### 7.2 SYSTEM PRE-REQUISITES:

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Airjet Bottle Cleaning machine has been prepared.

S. No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (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 Airjet Cleaning Machine			
6.	SOP for Preventive Maintenance Airiet Cleaning Machine			

Checked By	Verified By
Production	Quality Assurance
Sign / Date:	Sign / Date:
Inference:	
•••••	
	Reviewed By
	Manager QA
	Sign / Date:



PR	(0)	T	()(	CO	$\mathbf{L}$	N	0.	:

8.0 TESTS a	& CHECKS:
-------------	-----------

**8.1** Machine Speed Optimization:

8.1.1 Trial No.: 01:			
Date of Test		<b>Equipment ID</b>	
Total Bottles taken for test		Bottle Size	
Parameter	Low Speed ( )	Optimum Speed( )	High Speed ( )
Sample after( mi	(n)		
Machine jam			
Bottle Breakage			
Rejection			
Sample after ( mi	n)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after( mi	n)		
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			
Checked By		Verified By	
Production Production		Quality Assur	ance
Sign/Date:			
Inference:			
•••••	•••••	•••••	•••••
		•••••	
•••••	•••••	Daviowad Pv	••••••
		Reviewed By Manager QA	
		~-8	



$\mathbf{r}$	-	$\sim$ r		$\sim$	$\sim$	•	•	r	
ν	v		 1	٠,				•	
	1.	.,	 ,,		•		1.4	0.3	

Trial No.: 02			
Date of Test		<b>Equipment ID</b>	
Total Bottles taken for test		Bottle Size	
Parameter	Low Speed ( )	Optimum Speed( )	High Speed ( )
Sample after( mi	n)		
Machine jam			
Bottle Breakage			
Rejection			
Sample after( mi	n)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after( mi	n)		
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			
Checked By Production Sign/Date:		Verified By Quality Assura Sign/Date:	nce
Inference:			
	•••••		
•••••	•••••	•••••	•••••
••••••	••••••	Reviewed By Manager QA Sign/Date:	



DD	$\sim$		$\sim$	~	$\sim$	_	TA 1	_	
PR	. 1	1	. 1					Λ	•
1 17	.,,	1	.,	•			1.4	v.	•

8.1.2 Trial No.: 03

6.1.2 IIIai No 03			
Date of Test		Equipment ID	
Total Bottles taken for test		Bottle Size	
Parameter	Low Speed ( )	Optimum Speed( )	High Speed ( )
Sample after mi	n)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after( mi	n)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after( mi	n)		
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			
Checked By		Verifie	d Bv
Production			Assurance
Sign/Date:		-	ate
Inference:			
	,		
•••••	•••••	Reviewed By	••••••
		Manager QA	
		_	



### PERFORMANCE QUALIFICATION REPORT

PROTOCOL No	٠.:	٠
-------------	-----	---

DHADMA	DEVIL C	AIRJET :	REPO FOI BOTTLE CL	R	ACHIN	Œ	
	Air Pressu  Trial no.01					<u> </u>	
Date of	test			Product			
Batch N	<b>O.</b>			name Pack Size			
A	t Air Pres	sure 1.5 kg/cm <sup>2</sup> :					
Date	Time	Qty. Taken	0	bservation		Checked By	Verified By
			Foreign	Fabrics	Paper		·
			Particle	material	Piece		
A	t Air Pres	sure 2.0 kg / cm <sup>2</sup> :					
Date	Time	Qty. Taken	0	bservation		Checked By	Verified By
		<b>C</b> -3, - 1,	Foreign	Fabrics	Paper		,
			Particle	material	Piece		
A	t Air Pres	sure 2.5 kg / cm <sup>2</sup> :					
Date	Time	Qty. Taken	0	bservation		Checked By	Verified By
			Foreign	Fabrics	Paper		
			Particle	material	Piece		
Checked	d Bv				Verifie	d Bv	
Product						Assurance	
Sign / D	ate: :					Date: :	
Inference	:e:	••••		•••••	•••••	•••••	
•••••	•••••	•••••		•••••	•••••	•••••	•••••
•••••	•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	•••••	• • • • • • • • • •	•••••	•••••
					Review	ed Bv	
					Manag		
						Date: :	



DD	$\sim$ r	$\mathbf{r}$	~~		T T	
νv					No.	•
1 1/	<b>\</b> /		~.	,,,	TAO.	

Foreign Particle Material Piece  Checked By Verified By Production Quality Assurance Sign / Date: Sign / Date: Reviewed By Manager QA	8.2.2	Trial No.0	2:					
At Air Pressure 1.5 kg / cm²:    Date   Time   Qty. Taken   Foreign   Fabrics   Piece	Date of	test						
Date   Time   Qty. Taken     Observation   Foreign   Fabrics   Paper   Piece   Particle   Paper   Piece   Particle   Paper   Piece   Paper   Piece   Paper   Piece   Paper   Piece   Paper   Paper   Piece   Paper   Paper   Paper   Paper   Piece	Batch N	[O.			Pack Size			
Date   Time   Qty. Taken     Observation   Foreign   Fabrics   Paper   Piece   Particle   Paper   Piece   Particle   Paper   Piece   Paper   Piece   Paper   Piece   Paper   Piece   Paper   Paper   Piece   Paper   Paper   Paper   Paper   Piece		At Ain Dno	aguno 1 5 kg / om².					
At Air Pressure 2.0 kg / cm²:  Date Time Qty. Taken Observation Foreign Particle Fabrics Paper Piece  At Air Pressure 2.5 kg / cm²:  Date Time Qty. Taken Observation Foreign Fabrics Paper Piece  At Air Pressure 2.5 kg / cm²:  Date Time Qty. Taken Observation Foreign Fabrics Paper Piece  Checked By Paper Piece  Verified By Verified By Paper Piece  Checked By Production Sign / Date: Sign / Date: Inference: Sign / Date:		•	_		bsamatian		Charled Dv	Varified Dv
At Air Pressure 2.0 kg / cm²:  Date Time Qty. Taken Foreign Particle Material Piece  At Air Pressure 2.5 kg / cm²:  Date Time Qty. Taken Observation Piece  At Air Pressure 2.5 kg / cm²:  Date Time Qty. Taken Foreign Fabrics Piece  At Air Pressure 2.5 kg / cm²:  Date Time Qty. Taken Observation Piece  Checked By Particle Material Piece  Checked By Production Sign / Date: Sign / Da	Date	line	Qty. Taken			Paper	_ Checked by	vermed by
Date Time Qty. Taken Observation Paper Particle Foreign Paper Particle Foreign Particle Foreign Particle Foreign Particle Foreign Particle Foreign Paper Particle Foreign Particle Foreign Paper Particle Foreign Paper Piece Foreign Paper Pape				_	material	Piece		
Date Time Qty. Taken Observation Paper Particle Foreign Paper Particle Foreign Particle Foreign Particle Foreign Particle Foreign Particle Foreign Paper Particle Foreign Particle Foreign Paper Particle Foreign Paper Piece Foreign Paper Pape								
Date Time Qty. Taken Observation Paper Particle Foreign Paper Particle Foreign Particle Foreign Particle Foreign Particle Foreign Particle Foreign Paper Particle Foreign Particle Foreign Paper Particle Foreign Paper Piece Foreign Paper Pape								
Date Time Qty. Taken Observation Paper Particle Foreign Paper Particle Foreign Particle Foreign Particle Foreign Particle Foreign Particle Foreign Paper Particle Foreign Particle Foreign Paper Particle Foreign Paper Piece Foreign Paper Pape								
Date Time Qty. Taken Observation Paper Particle Foreign Paper Particle Foreign Particle Foreign Particle Foreign Particle Foreign Particle Foreign Paper Particle Foreign Particle Foreign Paper Particle Foreign Paper Piece Foreign Paper Pape	A	t Air Pres	sure 2.0 kg / cm <sup>2</sup> :					
At Air Pressure 2.5 kg / cm²:  Date Time Qty. Taken Observation Foreign Particle Fabrics Paper Piece    Date   Time   Qty. Taken   Checked By   Verified By Procee				0	hservation		Checked Rv	Verified Rv
At Air Pressure 2.5 kg / cm²:  Date Time Qty. Taken Observation Foreign Fabrics Particle material Piece  Checked By Production Sign / Date: Inference:	Dute		Qty. Tunen			Paper	- Checked By	vermed by
Date Time Qty. Taken Observation Foreign Fabrics Paper Piece Particle Material Piece Paper Piece Particle Sign / Date:  Inference:  Reviewed By Manager QA				Particle	material	Piece		
Date Time Qty. Taken Observation Foreign Fabrics Paper Piece Particle Material Piece Paper Piece Particle Sign / Date:  Inference:  Reviewed By Manager QA								
Date Time Qty. Taken Observation Foreign Fabrics Paper Piece Particle Material Piece Paper Piece Particle Sign / Date:  Inference:  Reviewed By Manager QA								
Date Time Qty. Taken Observation Foreign Fabrics Paper Piece Particle Material Piece Paper Piece Particle Sign / Date:  Inference:  Reviewed By Manager QA								
Foreign Fabrics Paper Particle material Piece  Checked By Verified By Production Quality Assurance Sign / Date: Sign / Date: Sign / Date: Reviewed By Manager QA	A	t Air Pres	sure 2.5 kg / cm <sup>2</sup> :	·	•			
Foreign Particle Fabrics Paper Piece  Checked By Verified By Quality Assurance Sign / Date: Sign / Date: Sign / Date: Reviewed By Manager QA	Date	Time	Qty. Taken	0	bservation		Checked By	Verified By
Checked By Production Sign / Date:  Inference:  Reviewed By Manager QA				_		_	]	
Production Sign / Date:  Inference:  Reviewed By Manager QA				Particle	material	Piece		
Production Sign / Date:  Inference:  Reviewed By Manager QA								
Production Sign / Date:  Inference:  Reviewed By Manager QA								
Production Sign / Date:  Inference:  Reviewed By Manager QA								
Sign / Date:  Inference:  Reviewed By Manager QA	Checked	d By				Verified	Ву	
Inference:  Reviewed By Manager QA								
Reviewed By Manager QA	Sign / D	ate:	<del></del>			Sign / Da	ite:	
Manager QA	Inference	e:		•••••		•••••	•••••	•••••
Manager QA	•••••	•••••	•••••	•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••	•••••
Manager QA	•••••	•••••	• • • • • • • • • • • • • • • • • • • •	•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••	•••••
							•	
Sign / Date:								



<b>PROTOCOL</b>	N	0.:
-----------------	---	-----

8.2.3 T	Trial No.	03:						
Date of	test			Product name				
Batch N	0.			Pack Size				
A	At Air Pr	essure 1.5 kg / cm <sup>2</sup> :						
Date	Time	Qty. Taken	0	bservation		Checked By	Verified By	
			Foreign Particle	Fabrics material	Paper Piece			
A	t Air Pre	essure 2.0 kg / cm <sup>2</sup> :						
Date	Time	Qty. Taken	0	bservation		Checked By	Verified By	
Date	Time	Qty. Taken	Foreign	Fabrics Fabrics	Paper	_ Checked By	vermed by	
			Particle	material	Piece			
1								
A	t Air Pre	essure 2.5 kg / cm <sup>2</sup> :					. <b>I</b>	
Date	Time	Qty. Taken	0	bservation		<b>Checked By</b>	Verified By	
			Foreign	Fabrics	Paper			
			Particle	material	Piece			
Checked By Production Sign / Date:					Verified By Quality Assurance Sign / Date:			
Inference	e:	•••••	•••••	•••••	•••••	•••••	•••••	
•••••	••••••	•••••	•••••	•••••	••••••	•••••	••••••	
•••••	••••••	••••••	••••••	••••••	Reviewe	d Bv	•••••	
					Manager Sign / Da	· QA		



DD	$\sim$		$\sim$	$\sim$		T
עע					_ <b>_</b>	A .
PR	<b>\</b> ,	11.	,	<b>(/</b> )		ıv.

### 9.0 CHECKLIST OF ALL TESTS & CHECKS:

The following table lists the number of tests / samples to be carried out & comments on the sample record sheet.

TESTS OR CHECKS		EXECUTED [Y/N]	COMMENT
Machine Speed Optimization			
Air P	ressure Test		
			, <u>.</u>
10.0	DOCUMENTS TO BE ATTACH	ED:	
	Any Other Relevant Documents	3	
11.0	NON COMPLIANCE:		
	•••••		•••••
	•••••		•••••
			•••••
	•••••	•••••	•••••
12.0	DEVIATION FROM PRE-DEFI	NED SPECIFICATION, IF ANY:	
	•••••	•••••••••••••••••••••••••••••••••••••••	••••••
	•••••	•••••••••••••••••	•••••
	•••••	•••••••••••••••••••••••••••••••••••••••	•••••
13.0	CHANGE CONTROL, IF ANY:	•••••••••••••••••••••••••••••••••••••••	•••••••••
13.0	CHANGE CONTROL, IF ANT.		
	•••••		•••••
	•••••		•••••
14.0	REVIEW (INCLUSIVE OF FOL	LOW UP ACTION, IF ANY):	
		••••••	•••••
			•••••
			•••••
			•••••



PROTOCOL No.:

15.0	CONCLUSION:
16.0	RECOMMENDATION:
10.0	

### 17.0 ABBREVIATIONS:

WHO : World Health Organization

FDA : Food and Drug Administration

CFR : Code of Federal Regulations

GMP : Good Manufacturing Practices

QA : Quality Assurance

SOP : Standard Operating Procedure

mm : Millimetre

Amp. : Ampere

DQ : Design Qualification

IQ : Installation Qualification

OQ : Operational Qualification

PQ : Performance Qualification



PROT	.OC	OL	N	0.3
------	-----	----	---	-----

### 18.0 REPORT POST APPROVAL:

### **INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

### **REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTI ON)			
HEAD (ENGINEERING)			

### **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			