



**INSTALLATION QUALIFICATION FOR AUTOMATIC AIRJET BOTTLE AIR AND VACUUM  
CLEANING MACHINE**

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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 Installation Qualification protocol of Automatic airjet bottle air and vacuum cleaning 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		



## **INSTALLATION QUALIFICATION FOR AUTOMATIC AIRJET BOTTLE AIR AND VACUUM CLEANING MACHINE**

### **2.0 OVERVIEW:**

### **2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Automatic airjet bottle air and vacuum cleaning machine and define the installation qualification requirements and acceptance criteria for the Automatic airjet bottle air and vacuum cleaning machine. Successful completion of these installation qualification requirements will provide assurance that the Automatic airjet bottle air and vacuum cleaning machine was installed as required in the manufacturing area.

The Qualification of Automatic airjet bottle air and vacuum cleaning machine performed in view of Dry Syrup in manufacturing facility.

### **2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the Automatic airjet bottle air and vacuum cleaning machine system received matches the Design specification and also to ensure that it is properly and safely installed.

### **2.3 SCOPE:**

This Protocol is applicable to installation of Automatic airjet bottle air and vacuum cleaning machine in Dry Syrup in Production Cepha Oral Block of the manufacturing facility.

### **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.



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- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- 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.

**2.5 EXECUTION TEAM:**

The satisfactory installation of the Automatic airjet bottle air and vacuum cleaning machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Automatic airjet bottle air and vacuum cleaning machine is installed satisfactorily.

Execution team is responsible for the execution of installation of Automatic airjet bottle air and vacuum cleaning machine Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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**3.0 ACCEPTANCE CRITERIA:**

- 3.1 The Automatic airjet bottle air and vacuum cleaning machine shall meet the system description given in design qualification.
- 3.2 The Automatic airjet bottle air and vacuum cleaning machine shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.

**4.0 REQUALIFICATION CRITERIA:**

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule

**5.0 INSTALLATION QUALIFICATION PROCEDURE:**

<b>5.1</b>	<b>SYSTEM DESCRIPTION:</b>
1.	Equipment Name : Automatic airjet bottle air and vacuum cleaning machine
2.	Supplier/Manufacturer : Parth Engineers & Consultant
3.	Model : PAJC-120
4.	Serial no. : .....
5.	Capacity : 80-100 bottles per minute
6.	Dimension : 2172 mm (L) X 600 mm (W) X 1045 mm (H)
7.	Location : Dry Syrup-1

**5.1.1 Brief process description:**

The machine is inbuilt with turntable for smooth transfer of container to the cleaning section. This machine works with the principle of back pressure of container. Container feed by the turntable to reach the separator assembly, which transfers the container to the cleaning section one after the other. Machine consists of two inverters which inverts container & push it to cleaning section through back pressure of other container. Cleaning section is equipped with continuous vacuum system. Container reaches to the cleaning section & a pair of air nozzles start to flush the air inside the neck of the container & simultaneously vacuum will suck the particles, distributed by



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the air. Then container passes to the inverter, where the containers are re-invented in upright position and then after container moves for next operation.

### **5.1.2 MACHINE 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 & highly efficient machine with elegant look. This multifunctional multifeatured machine meets the GMP requirements of washing for glass & plastic bottles. The machine operates on the linear principle with “INVERTER” mechanism & requires manual loading & automatic unloading of bottles.

### **5.2 INSTRUCTION FOR FILLING THE CHECKLIST**

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used ‘NA’ shall be used.



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**5.3 INSTALLATION CHECKLIST:**

Installation checklist is as follows:

S.No.	Statement	Method Of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Physically		
2	Verify that there is no observable physical damage	Physically		
3	Examine All access ports are cleared of any debris.	Physically		
4	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
5	Verify that all electrical connections are properly done and safe	Physically		
6	Verify that the equipment is properly earthed	Physically		
7	Verify that utility line is properly connected	Physically		
8	Verify the proper leveling of equipment	Physically		
9	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
10	Equipment/system identification no. Is visible	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.4 IDENTIFICATION OF MAJOR COMPONENTS:**

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Main Motor	Location	Coupled to the main gearbox	Physically		
	Make	Bonfiglioli	Physically		
	Spec.	1.87 A/0.75 KW/230-400 V/ 3 Phase/ 50 Hz/ 1400 RPM	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Blower Motor	Location	Bottom of the Machine	Physically		
	Make	Crompton Greaves	Physically		
	Spec.	0.85 A/0.37 KW/415 V/ 3 Phase/ 50 Hz/ 2815 RPM	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
A.C Drive	Make	Allen Bradley	Physically		
	Spec.	1 HP, 220 V, Single phase, Output: 3 Phase	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Main Gear Box	Location	Bottom of the Machine	Physically		
	Make	Bonfiglioli	Physically		
	Ratio	14:1	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Gear Box with	Make	Bonfiglioli	Physically		





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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
TT	Ratio	20:1	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Contactor	Make	Schneider	Physically/ Technical Specification		
Over Load Relay	Make	Schneider	Physically/ Technical Specification		
MCB	Make	Hager	Physically/ Technical Specification		
Air Filter	Make	SHAVO	Physically/ Test Certificate		
	Model	SSF13-200-M7TC-50 $\mu$	Physically/ Test Certificate		
		SSF13-200-M6TC-05 $\mu$			
		SF51-200-MOTC-0.1 $\mu$			
Air Filter Bag	Make	Parth	Physically/ Test Certificate		
	MOC	PC Satin	Test Certificate		
Solenoid Valve	Make	Rotex	Physically/ Technical Specification		
Turn Table	Size	30"	Physically/ Technical Specification		
<b>INSTRUMENTS</b>					
Pressure Gauge	Make	Shreeji	Physically/ Test Certificate		



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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<b>System Components</b>	<b>Design Specification</b>		<b>Method of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
	Range	To be recorded	Physically		
Filter Regulator for Pressure Gauge	Make	Shavo	Physically/ Test Certificate		
	Range.	To be recorded	Physically		
Air Pressure Switch	Make	Danfoss	Physically/ Technical Specification		
	Range	To be recorded	Physically		
Potentiometer	Make	Potel	Physically/ Technical Specification		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:**

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
<b>CONTACT PARTS</b>				
Inverter	UHMWPE-GUR 4130	Test Certificate		
Air Jet Nozzle	SS 316	By Molybdenum Kit/ Test Certificate		
<b>NON CONTACT PARTS</b>				
Machine Frame Structure (Square Pipe)	SS 304	By Molybdenum Kit/ Test Certificate		
Door Set	SS 304	By Molybdenum Kit/ Test Certificate		
Guide Rail	SS 304	By Molybdenum Kit/ Test Certificate		
Slate Conveyor	SS 304	By Molybdenum Kit/ Test Certificate		
Turn Table	SS 304 cladding	By Molybdenum Kit/ Test Certificate		
Star Plate	Nylon	Test Certificate		
Turn table Disc	Aluminum	Test Certificate		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.6 IDENTIFICATION OF SUPPORTING UTILITIES:**

S.No.	Utility	Method Of Verification	Observation	Checked By Sign/Date
1.	<b>Electrical Power Supply:</b> 3 phase, 415V +/- 5%, 50Hz supply with neutral and proper earthing	Physically with clamp meter		
2.	<b>Output Voltage from Transformer:</b> 220 V +/- 5%	Physically with clamp meter		
3.	<b>Compressed Air</b>	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.7 IDENTIFICATION OF SAFETY FEATURES:**

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

Safety Features Description	Location/Identification	Method of Verification	Observation	Identified By Sign/Date
Earthing	Equipment connected with earthing strip	Physically		
Roller type switch for clutch	To stop Star plate & the unit when cross bottle is fed at input	Physically		
Air Pressure Switch	To stop machine in the case of low compressed air supply	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED**

Name of Components	Range	Make	Location	Identified By Sign/Date

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):**

The following Standard Operating Procedures were identified as important for effective performance of Automatic airjet bottle air and vacuum cleaning machine operation.

S.No.	SOP Title	Verified By Sign/ Date

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.10 VERIFICATION OF DRAWING AND DOCUMENTS:**

Following documents are reviewed and attached as listed below:

<b>S.No.</b>	<b>Drawing And Document Detail</b>	<b>Verified By Sign/Date</b>

**Remark:** -----

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**Reviewed by (Sign/Date)**



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**5.11 ABBREVIATIONS:**

Following Abbreviations are used in the installation qualification protocol of Automatic airjet bottle air and vacuum cleaning machine

MOC: Material of construction

MCB: Miniature circuit breaker

Spec.: Specification

V: Voltage

Hz: Hertz

A: Ampere

TT: Turn Table

SS: Stainless Steel

RPM: Rotation per minute

HP: Horse Power

NA: Not Applicable





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**5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):**

Following deficiency was verified 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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**5.13 Annexure (S)**

<b>Annexure No.</b>	<b>Details of Annexure</b>

**Remark (if any):**

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**Done By & Date:**

**Verified By & Date:**



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**6.0 INSTALLATION QUALIFICATION FINAL REPORT:**

**6.1 SUMMARY:**

**6.2 CONCLUSION:**

**Prepared By  
Sign/Date**

**Checked By  
Sign/Date**



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**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. 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 qualification report of Automatic airjet bottle air and vacuum cleaning machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful installation qualification of the Automatic airjet bottle air and vacuum cleaning machine the equipment can be taken for operational qualification.

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>REVIEWED BY</b>			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
<b>APPROVED BY</b>			HEAD OPERATION		
			QUALITY ASSURANCE		