



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
AIRJET BOTTLE CLEANING MACHINE**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
AIRJET BOTTLE CLEANING MACHINE
(OINTMENT SECTION)**

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 PROTOCOL PRE-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification document for **Airjet Bottle cleaning machine** on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for **Airjet Bottle cleaning machine**.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



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4.0 RESPONSIBILITY:

The Validation team, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Approval and Authorization of the Protocol cum Report.• Assist in the verification of Critical Process Parameters & Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Assist in the verification of Critical Process Parameters & Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Design Qualification Activity.• To assist in Verification of Critical Process Design Feature & Drawings as per the Specification.• Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.• Details of utilities• Material of construction of all components• Brief Process Description• Safety Features and Alarms• Post Approval of Qualification Protocol cum report after Execution



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5.0 BRIEF ABOUT EQUIPMENT:

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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specification document is provided to manufacturer for engineering equipment & Some critical variables to be met during designing the equipment.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Line Speed	Conveyor Speed Should be facilitate the easy and efficient as per product requirement.	Process Requirement
Working: Working on bottle Cleaning Machine	Airjet Bottle cleaning machine should be facilitate the easy & efficient Cleaning during the course of bottle cleaning process.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Approved Design Requirement

7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE	
Utility connections should be available as per the specification.			
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and GEP standards, with adequate safety. Electrical panel is to be installed in the service area.	Approved Design Requirement	
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement	
Main Motor	Specification	Blower Motor	Specification
Voltage	415	Voltage	415
Hp	1.0	Hp	0.5
Kw	0.75	Kw	0.37
Hz	50	Hz	50
Phase	3 Phase	Phase	3 Phase

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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7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S.No	Parameter	Specifications	Reference
1.	Model	PAJC-120	Design Requirement
2.	Output	80-100 CPM	Design Requirement
3.	Main Motor	Make : Bonfiglioli 1 HP/0.75KW/3.2A/230-400V/3 Phase/ 50 Hz/1400RPM	Design Requirement
4.	Blower Motor	Make: Crompton Greawers 0.5 HP/0.37KW/415V/3 Phase/ 50 Hz/ 2790RPM	Design Requirement
5.	A.C Drive	Make: Allen Bradley 1 HP, 220-240V, Input: Single Phase Output: 3 Phase	Design Requirement
6.	Main Gear Box	Make : Bonfiglioli Gear Box Ratio : 14:1	Design Requirement
7.	Gear Box for TT	Make : Bonfiglioli Gear Box Ratio : 20:1	Design Requirement
8.	Contactora	Make: Schneider	Design Requirement
9.	Over Load Relay	Make: Schneider	Design Requirement
10.	MCB	Make: Schneider	Design Requirement
11.	Air Filter	Make: SHAVO	Design Requirement
12.	Air Filter Bag	Make: Parth MOC : PC Satin	Design Requirement
13.	Machine Dimension	2210mm(L) X 775 mm(W) X 920mm(H)	Design Requirement
14.	Turn Table	Size – 30 inch	Design Requirement



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7.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine shell	SS304
2.	Door Set	SS 304 (NO PAINTED SURFACE)
3.	Head	SS 304
4.	Star Plate	Nylon

7.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB should be provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts should be provided	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling And Balancing	Equipment should be Properly balanced & leveled.	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement
Noise Level	Below 80 db.	cGMP Requirement

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:

7.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Airjet Bottle cleaning machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feed back from market (customers already using the equipment)	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement as specified in PO and URS
 (2) Operating and service manual for Airjet Bottle cleaning machine.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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11.0 CONCLUSION:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATION:

- URS : User Requirement specification
- DQ : Design Qualification
- PO : Purchase Order
- cGMP : Current Good Manufacturing Practice
- cGEP : Current Good Engineering Practice
- Ltd. : Limited
- QA : Quality Assurance
- PO : Purchase Order
- Kg : Kilogram
- mm : Millimeter
- SS : Stainless Steel
- MOC : Material of Construction
- P & ID : Piping and Instrumentation Diagram
- Db : Decibel



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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			