



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

PROTOCOL No.:

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FOR
AUTOMATIC AIRJET BOTTLE
CLEANING MACHINE**

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	



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PROTOCOL No.:

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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
MANAGER (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification on basis of Equipment Specification, Purchase Order 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 is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for **Automatic Airjet Bottle Cleaning Machine** procured from
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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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 overall compliance of this Protocol cum Report:

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

5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the equipment from the supplier Site. To ensure that no unauthorized and /or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.



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6.0 BRIEF PROCESS DESCRIPTION:

The purpose of Automatic Airjet Bottle Cleaning Machine is to provide a facility for cleaning of bottles with the help of 6 nos. air nozzles and continuous vacuum system. The machine is inbuilt with Turntable for smooth transfer of bottles to the cleaning section. The bottles fed on the turntable reach to the bottle separator assembly through conveyor belt, which transfers the bottle in spaced manner to Pressing belt device. The bottles get inverted in mouth down position at the entrance of the pressing belt device. Here from the bottles held in mouth down position between pressing belt passes through cleaning section. Cleaning section is equipped with 6 nos. air nozzles and continuous vacuum system. While moving over the air nozzles, the pressurized and the ionized air is flushed inside the neck of the bottle and simultaneously vacuum suck the particles/ foreign particles, disturbed by the air. The bottle so cleaned moves to the inverter of the exit end of pressing belt device and get re-inverted in upright position and moves further for next operation.

The output speed is increased/ decreased by A.C. frequency drive.

7.0 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided to manufacturer for engineering equipment as per the specifications mentioned in PO.

The reference PO No. for this Equipment is:



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Automatic Airjet Bottle Cleaning Machine should be able to supply the condition required for online cleaning of bottles	Automatic Airjet Bottle Cleaning Machine should meet the requirement for online cleaning of bottles. (To be assured by Supplier).	Process Requirement
Working: Working of Automatic Airjet Bottle Cleaning Machine	Should be below 80 dB	Process Requirement
Electrical Control Panel: (Switch Panel)	The system should have Electrical Control Panel (Switch Panel).	Design Requirement

8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Three Phase Plus Earthing, 3 Wire Line Up To The Panel Board Terminal. Voltage- 415 V Frequency- 50 Hz (To be assured by Engineering Department)	cGMP Requirement
Room Condition	Temp.: NMT 25.0°C RH: NMT 55 % Should be able to meet the requirement of Clean Environment.	



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8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Equipment	Automatic Airjet Bottle Cleaning Machine	Supplier
Manufacturer	M/S Chamunda Pharma Tech G-22, Rudrax Complex OPP. Annapurna Restaurant Near Trikamputa Patiya, PH. III G.I.D.C Industrial area, Vatva, Ahmedabad-382 445	Supplier
Main Motor and Gearbox	<ul style="list-style-type: none"> • Make: Bonfiglioli • 1.0 HP • 1400 RPM • 3 Phase • 415 V • 50 HZ 	Design Requirement
Vibrator Unit	<ul style="list-style-type: none"> • 6 amp Vibrator card • 230 V 	Design Requirement
Ionizer	SK Electronic	Design Requirement
Vacuum pump	Baldora (Chamunda make)	Design Requirement
Main MCB	<ul style="list-style-type: none"> • Make: Hager • No of pole: 4 • Ampere: 10A 	Design Requirement
Relay	<ul style="list-style-type: none"> • Make: Telemecanique • Relay: 4 	Design Requirement
Push Buttons	<ul style="list-style-type: none"> • Make: Telemecanique 	Design Requirement
Air Pressure Controller	<ul style="list-style-type: none"> • Make: Baldora • Range: 2-5 KG 	Design Requirement
Machine Dimensions	Length: 2250 mm	Design Requirement
	Width 650 mm 750 mm(From Turntable Side)	
	Height 850 mm	



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8.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine Frame Structure	S.S. 304 Square Pipe 40X40X16
2.	Door Set	S.S. 304
3.	Geneva Cam	M.S. duly nitride
4.	Conveyer Chain	S.S. 304
5.	All Shafts	M.S. & S.S
6.	Chain Wheel for conveyer	Nylo Cast
7.	Chain Wheel	M.S.
8.	Chain	Rollon make, 1/2" pitch
9.	All bearing make	NACHI
10.	All oil seal	Pioneer Make
11.	Orientation Pate	Aluminium
12.	Ionizer	S.K. Electronics Make
13.	Cabinet	Acrylic

8.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
Earthing	Earthing to be provided to Control (Switch) Panel.	Safety Requirement
Joints	Welding of joints without any welding burrs.	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	NMT 80db	Safety Requirement



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8.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Automatic Airjet Bottle Cleaning Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review is included in 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.
(2) Operating and service manual for Automatic Airjet Bottle Cleaning Machine pump.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy

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

11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

12.0 RECOMMENDATION:



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13.0 PROTOCOL POST APPROVAL :

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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14.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
Ltd.	:	Limited
QA	:	Quality Assurance
PO	:	Purchase Order
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
SS	:	Stainless Steel
No.	:	Number
V	:	Volt
Hz	:	Hertz
RPM	:	Revolution Per Minute
MCB	:	Miniature Circuit Breaker
NMT	:	Not More Than