DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BOTTLE WASHING MACHINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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1.0 PROTOCOL PRE – APPROVAL:

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)			

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is 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 of **Bottle Washing machine (Make: ……..)**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

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	• Preparation, Review and Authorization of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Reviewed of Qualification Protocol cum Report after Execution.
Production	• Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Reviewed of Qualification Protocol cum Report after Execution.
Engineering	• 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. ➢ 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. • Reviewed of Qualification Protocol cum Report after Execution.

5.0 BRIEF EQUIPMENT DESCRIPTION:

The Bottle Washing Machine finishes the procedures from bottle in feed, cleaning, external precision cleaning, internal precision cleaning, and bottle out feed. It adopts the ultrasonic cleaning, uses the recycled water and compressed air to clean the internal and external of bottles by a series of nozzles. The washing machine consists of the following parts, such as

1. Water Tank -02 Nos.
2. Pump-02 Nos.
3. Control Panel
4. Indexing mechanism
5. Flow Control valve & Distribution Pipe lines

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Bottle Washing Machine is designed to wash the inner and outer surface of Bottles before filling operation.	Should be able to eliminate the particle from inner and outer surface of Bottles.	Process Requirement
Working: The machine washes the inner and outer sides of Bottles and eliminates the particles that are formed on the Bottles, which are to be filled and sealed.	Bottles should be free of any particle from both inner and outer side of Bottles.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 440 V ± 5% Phase : 3 Phase Frequency : 50 Hz ± 3%	GMP Requirement
Room Condition	Temperature : NMT - 25°C RH : NMT – 55%	Process Requirement
Hot Water	Pressure : 0.5 kg/cm^2 to 1.5 kg/cm^2	Process Requirement
Purified Water	Pressure : 0.5 kg/cm^2 to 1.5 kg/cm^2	Process Requirement
Compressed Air	Pressure : 2 to 4 kg/cm^2	Process Requirement
Re-circulated water	Pressure : 1.0 kg/cm^2 to 2.0 kg/cm^2	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Machine Specification		
Name	Rotary Bottle Washing Machine	Design Requirement
Model	…….	Design Requirement
Sr. No.	…….	Design Requirement
Dimensions	2085 mm x 1885 mm x 1252 mm	Design Requirement
Capacity	96 bottle /min.	Design Requirement
Bottle Size	10 ml to 250 ml	Design Requirement
Machine orientation	Left to Right	Design Requirement
Nos. of jet	96	Design Requirement
Maximum Height of bottle	300 mm	Design Requirement
No. of Indexing Station	16 Nos.	Design Requirement
Speed Variation	3 step pulley	Design Requirement
Mobility of Machine	Anti vibrating pad	Design Requirement
No. of Washing Station	04 Nos.	Design Requirement
Machine Tank #01	MOC SS 304	Design Requirement
	Capacity 75 liters.	Design Requirement
Machine Tank #02	MOC SS 304	Design Requirement
	Capacity 75 liters.	Design Requirement
Water Level Control	Float Valve	Design Requirement
Main Motor		
Make	Crompton Greaves	Design Requirement
Type	3 PH TEFC induction Motor	Design Requirement
Power	0.3 kw / 0.5 HP 3 Phase 415 V AC	Design Requirement
RPM	1410	Design Requirement
Sr. No.	IUA10731	Design Requirement
Gear Box		
Make	Chamunda	Design Requirement
Model	1 2017	Design Requirement
Ratio	50:1	Design Requirement
Centre Distance	58:5	Design Requirement

Critical Variables	Acceptance Criteria	Reference
Pump		
Make	CRI	Design Requirement
Model	JTS-3/07T	Design Requirement
Type	Self Priming Jet pump	Design Requirement
RPM	2850`	Design Requirement
Sr. No.	12216I93189 12216I92715	Design Requirement
Qty.	02 Nos.	Design Requirement
Pressure Gauge		
Make	Suzhik	Design Requirement
Capacity	0-150 PSI (0-10.6 kg/cm^2)	Design Requirement
Qty.	04 Nos.	Design Requirement
MCB		
Make	L & T	Design Requirement
Model	BB30160C	Design Requirement
Capacity	C16AMP, 440 V	Design Requirement
Type	3 pole	Design Requirement
Relay		
Make	Pla Relay	Design Requirement
Supply	240 V	Design Requirement
Type	2C/O-MPC	Design Requirement
Main ON / OFF switch		
Make	L & T	Design Requirement
Model	Salzer	Design Requirement
Rating	16 AMP, 440 V AC	Design Requirement
Contactor		
Make	L & T	Design Requirement
Model	MNX-A2	Design Requirement
Rating	10A, 440 V AC	Design Requirement
Qty.	03 Nos.	Design Requirement
Contactor		

Critical Variables	Acceptance Criteria	Reference
Make	L & T	Design Requirement
Model	MNX 12	Design Requirement
Rating	10 A, 440 V AC	Design Requirement
Heater		
Make	Theeta	Design Requirement
Watt	3000	Design Requirement
Volt	230 / 400	Design Requirement
Overload Relay		
Make	L & T	Design Requirement
Model	MNX –A2	Design Requirement
Rating	10 A, 415 V AC	Design Requirement
Solenoid Coil and Valve		
Make	Usha Pneumatic	Design Requirement
Model	Cruzex	Design Requirement
Type	2/2 NC	Design Requirement
MOC	SS 304	Design Requirement
Pressure	0-10 kg/cm^2	Design Requirement
Temp.	0-80 °C	Design Requirement
Thermostat		
Make	Girish Eng. Co.	Design Requirement
Model	210 C	Design Requirement
Range	0-6080 °C	Design Requirement
V Belt		
Make	Shavison	Design Requirement
Size	A1128LP/A43	Design Requirement
SMPS		
Make	Shavison	Design Requirement
Model	G31-120-24	Design Requirement
I/P	230V AC, 1.5A, 50-60Hz	Design Requirement
O/P	24 V DC , 5A	Design Requirement

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Machine and Drive Panel Cover	SS 304
2.	Drive and Non drive shaft	EN-24
3.	Platform & Top head	SS 304
4.	Ball Valve	SS 304
5.	All nuts and Bolts	SS 304
6.	Water storage tank	SS 304
7.	Float Valve	SS 304
8.	Motor and Pump cover	SS 304
9.	Machine structure	M.S.
10.	Heater and Suction strainer	SS 304
11.	All Nozzles & Circulation Pile line	SS 304
12.	All Pipe fittings	SS 304
13.	Top Guide for Bottle adjustment	SS 304

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
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
MCB	MCB should be Provided for Equipments Safety	Safety Requirement

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Bottle Washing 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, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in URS.

(2) Operation manual for Bottle Washing Machine.

Verified By
Quality Assurance
Sign/Date: ……

8.0 DOCUMENTS TO BE ATTACHED:

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

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
RH	:	Relative Humidity
Mpa	:	milli pascal
AWM	:	Bottle Washing Machine
MMI	:	Man Machine Interface
KW	:	Kilowatt
SS	:	Stainless steel
Hz	:	Hertz
V	:	Volt

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			