



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOTTLE WASHING MACHINE**

EQUIPMENT ID. No.	
LOCATION	Washing Room
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)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of **Bottle Washing Machine**.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Bottle Washing Machine** to be installed in the **Ampoule Washing & Sterilization Room**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Bottle Washing Machine.



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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, Authorization and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Qualification Protocol after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in VFS Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Bottle Washing Machine
Equipment ID	
Manufacturer's Name	
Model	
Supplier's Name	
Location of Installation	Washing Room Liquid Line

6.0 SYSTEM 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



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 GENERAL CHECKS AND LOCATION SUITABILITY:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Washing Room Liquid Line		
Room Condition	RH : NMT 65% TEMP : NMT 25°C		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

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8.2 EQUIPMENT VERIFICATION

TECHNICAL SPECIFICATIONS

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Machine Specification			
Name	Roatary Bottle Washing Machine		
Model			
Sr. No.	4450		
Dimensions	2085 mm x 1885 mm x 1252 mm		
Capacity	96 bottle /min.		
Bottle Size	10 ml to 250 ml		
Machine orientation	Left to Right		
Nos. of jet	96		
Maximum Height of bottle	300 mm		
No. of Indexing Station	16 Nos.		
Speed Variation	3 step pulley		
Mobility of Machine	Anti vibrating pad		
No. of Washing Station	04 Nos.		
Machine Tank #01	MOC SS 304		
	Capacity 75 liters.		
Machine Tank #02	MOC SS 304		
	Capacity 75 liters.		
Water Level Control	Float Valve		
Main Motor			
Make	Crompton Greaves		
Type	3 PH TEFC induction Motor		
Power	0.3 kw / 0.5 HP 3 Phase 415 V AC		
RPM	1410		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Sr. No.	IUA10731		
Gear Box			
Make	Chamunda		
Model	1 2017		
Ratio	50:1		
Centre Distance	58:5		
Pump			
Make	CRI		
Model	JTS-3/07T		
Type	Self Priming Jet pump		
RPM	2850`		
Sr. No.	12216I93189 12216I92715		
Qty.	02 Nos.		
Pressure Gauge			
Make	Suzhik		
Capacity	0-150 PSI (0-10.6 kg/cm ²)		
Qty.	04 Nos.		
MCB			
Make	L & T		
Model	BB30160C		
Capacity	C16AMP, 440 V		
Type	3 pole		
Relay			
Make	Pla Relay		
Supply	240 V		
Type	2C/O-MPC		
Main ON / OFF switch			
Make	L & T		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	Salzer		
Rating	16 AMP, 440 V AC		
Contactor			
Make	L & T		
Model	MNX-A2		
Rating	10A, 440 V AC		
Qty.	03 Nos.		
Contactor			
Make	L & T		
Model	MNX 12		
Rating	10 A, 440 V AC		
Heater			
Make	Theeta		
Watt	3000		
Volt	230 / 400		
Overload Relay			
Make	L & T		
Model	MNX -A2		
Rating	10 A, 415 V AC		
Solenoid Coil and Valve			
Make	Usha Pneumatic		
Model	Cruzex		
Type	2/2 NC		
MOC	SS 304		
Pressure	0-10 kg/cm ²		
Temp.	0-80 °C		
Thermostat			
Make	Girish Eng. Co.		
Model	210 C		
Range	0-6080 °C		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
V Belt			
Make	Shavison		
Size	A1128LP/A43		
SMPS			
Make	Shavison		
Model	G31-120-24		
I/P	230V AC, 1.5A, 50- 60Hz		
O/P	24 V DC , 5A		

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8.3 INSTALLATION CHECKS:

S.No.	Specification	Observation	Observed By Engineering Sign/Date
1.	Verify that the "As built" drawings are complete and represent the design concept		
2.	Check the proper mechanical installation		
3.	Check the proper electrical installation of		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		
6.	Verify that major components are securely anchored and protected from shock		
7.	Verify that there is no observable physical damage		
8.	Verify that "Room layout" drawing is OK and sufficient space for servicing is provided		

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8.4 MOC Verification List:

Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Machine and Drive Panel Cover	SS 304		
Drive and Non drive shaft	EN-24		
Platform & Top head	SS 304		
Ball Valve	SS 304		
All nuts and Bolts	SS 304		
Water storage tank	SS 304		
Float Valve	SS 304		
Motor and Pump cover	SS 304		
Machine structure	M.S.		
Heater and Suction strainer	SS 304		
All Nozzles & Circulation Pipe line	SS 304		
All Pipe fittings	SS 304		
Top Guide for Bottle adjustment	SS 304		

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8.5 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 440 V \pm 5% Phase : 3 Phase Frequency : 50 Hz \pm 3%		
Room Condition	Temperature : NMT - 25°C RH : NMT – 55%		
Hot Water	Pressure : 0.5 kg/cm ² to 1.5 kg/cm ²		
Purified Water	Pressure : 0.5 kg/cm ² to 1.5 kg/cm ²		
Compressed Air	Pressure : 2 to 4 kg/cm ²		
Re-circulated water	Pressure : 1.0 kg/cm ² to 2.0 kg/cm ²		

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8.6 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
MCB	MCB for equipment protection.		
Earthing	Earthing to be provided to Control Panel.		
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be Properly grounded without any sharp edges.		
Leveling And Balancing	Equipment should be properly balanced & leveled		
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		
Guards	Guards for all Moving Parts		
Noise Level	Below 80 db		

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8.7 Control Panel Checks:

Test Particulars	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Check that Machine is connected with control panel. Record the details of PLC	Machine should be connected with control panel. PLC make, model no. , serial no should be checked and verified		
Check the input output against Wiring Diagram visually during installation	All the input output shall meet the Requirements		

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Quality Assurance
Sign/Date:

Inference:

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Manager QA
Sign/Date:

9.0 REFERENCES:

- Design Qualification
- Vendor Documents

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.



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11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
mm	:	Millimeter
PLC	:	Programmable Logical Control
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
RH	:	Relative Humidity
SS	:	Stainless Steel
URS	:	User requirement specification
UWM	:	Ultrasonic Washing Machine
IQ	:	Installation Qualification
No	:	Number
NLT	:	Not less than
NMT	:	Not more than
MCB	:	Miniature Circuit breaker
PVT.	:	Private
LTD.	:	Limited
V	:	Volt
HZ	:	Hertz
AC	:	Alternating Current
Db	:	Decibel



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17.0 PROTOCOL POST 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)			