



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AMPOULE VERTICAL ULTRASONIC WASHING
MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AMPOULE VERTICAL ULTRASONIC
WASHING MACHINE**

EQUIPMENT ID. No.	
LOCATION	Ampoule Washing & Sterilizing Room
DATE OF QUALIFICATION	
SUPERSEDE 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 provide documented evidence for the Installation Qualification of **Ampoule Vertical Ultrasonic 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 **Ampoule Vertical Ultrasonic 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 Ampoule Vertical Ultrasonic 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, Approval 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	Vertical Ultrasonic Ampoule Washing Machine
Equipment	
Manufacturer's Name	TruKing Technologies Ltd.
Model	
Supplier's Name	TruKing Technologies Ltd.
Location of Installation	Ampoule Washing & Sterilization Room



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6.0 SYSTEM DESCRIPTION:

The Automatic Washing Machine finishes the procedures from bottle infeed, ultrasonic coarse cleaning, external precision cleaning, internal precision cleaning, 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 needles and nozzles.

The washing machine consists of the following parts, such as infeed conveyor belt, ultrasonic cleaning part, scroll lifting part, water & rinsing part, out feed part and water & air circulation system.

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	Ampoule Washing & Sterilizing Room		
Room Condition	RH : NMT 55% TEMP : 23 ± 2 °C		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

**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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8.2 EQUIPMENT VERIFICATION

TECHNICAL SPECIFICATIONS

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Machine Specification			
Model	AQCL20/6		
Dimension	2400 mm x 2400 mm x 1650mm		
Orientation	Left to right		
Main Motor			
Make	Siemens		
Model	ILE0001-0EB42-1AA6		
MMI			
Make	Siemens		
Model	6ES7-2BD23-0XB8		
Water Pump			
Make	Grundfos		
Model	CM10-4A-R-G-E-AQQE		
Filters			
Make	Pall		
Model	SASM031G15J -01 qty SAS011GBP15J-03 qty		
Size	Compressed Air-0.22 μ Purified water-0.22 μ WFI – 0.22 μ Recirculated Water- 3 μ		
Transducer			
Make	Schneider		
Model	ATV12H037M2 -01 qty ATV12HU15M2 -01 qty		
Pneumatic Cylinder			
Make	Festo		
Pressure Transmittor			
Make	Duwei		
Model	DW801 -03 qty DW803 -01 qty		
Manual Diaphragm valve			
Make	Gemu		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	61215D88C31701TS 1507 -02 qty 67325D88C31702TS 1507 -06 qty		
Pneumatic Diaphragm valve			
Make	Gemu		
Model	650 15D88345A20T1 1507 -01 qty 687 40D88C317 2 1507 -01 qty 650 15D 88 34 5A 1 0T1 1507 - 06 qty		
Conveyor			
Length	361 mm		
Liquid level Sensor			
Make	Fanyi		
Model	DHRE-ABS		
Ultrasonic Generator			
Make	Leishi		
Model	LASP-E10-1000		
RTD Sensor			
Range	0-100 °C		
Infeed Motor			
Make	Fenghua		
Capacity	0.37 kw		
RPM	1350		
Sound Alarm Indicator			
Red Indicator	Machine Stop & Alarm start		
Orange Indicator	Warning		
Green Indicator	Machine is working		
PLC			
Make	Siemens		
Model	57200 CN		
Contactor			
Make	Scheinder		
Safety Relay			
Make	Scheinder		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
MCB			
Make	People		
Power Switch			
ON/OFF Switch	Black		
Green Indicator on HMI	Machine ON		
Red Mashroom Button on HMI	Emergency stop		

**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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8.3 INSTALLATION CHECKS

S. No.	SPECIFICATION	OBSERVATION		OBSERVED BY (ENGINEERING) (SIGN/DATE)
		Tick (√ / ×)	(Yes/No)	
1.	All the M.S base bolts provided for packing purpose to be replaced by SS base bolts with rubber pad.			
2.	Check the height of the machine by adjusting the base bolts to match the height.			
3.	Also proper leveling of the machine should be done using appropriate spirit level by adjusting the base bolts.			
4.	Carefully examine the wiring diagram of the machine before making any connection.			
5.	Connect the cables to the panel to their respective connectors.			
6.	Check wires for proper polarity of the AC motor.			
7.	Connect the sensor cables to the terminal in the panel.			
8.	Make sure that 'earthing' is provided.			
9.	After all wires connected, connect the mains cable.			
10.	Check wires for proper polarity on the AC motor			
11.	Check equipment has easy access for maintenance cleaning			
12.	Check the filters installed according to flow direction.			
13.	Check the surface is smooth and clean.			
14.	Check the installed room should meet the Grade D cleanliness.			

**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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8.4 MOC Verification List:

Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
SS Belt	SS304		
pipes	SS316L		
Mesh belt	SS316L		
Scew Conveyor	POM		
Sealing Gasket	Silicon Rubber		
Roller	SS304		
Guide Sleeve	SS316L		
Nozzles	SS316L		

**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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8.5 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 440 V Phase : 3 Phase Frequency : 50 HZ		
Room Condition	Temperature : 23 ± 2 °C RH : NMT 55 %		
Compressed Air	6 Bar		

**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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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		

**Checked By
(Production)**

Sign/Date:

**Verified By
(Quality Assurance)**

Sign/Date:

Inference:

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Sign/Date:



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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		

**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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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.

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
V	:	Volt
HZ	:	Hertz
AC	:	Alternating Current
Db	:	Decibel



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17.0 PROTOCOL POST 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)			