



PHARMA DEVILS

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

PROTOCOL No.:

**DESIGN QUALIFICATION
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FOR
AMPOULE VERTICAL ULTRASONIC
WASHING MACHINE**

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 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 **Ampoule Vertical Ultrasonic Washing Machine (Make: TruKing Technology Limited)**.
- 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.



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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 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	<ul style="list-style-type: none"> • Review 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	<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. • Reviewed of Qualification Protocol cum Report after Execution.



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5.0 BRIEF EQUIPMENT 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification. 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: Ampoule Washing Machine is designed to wash the inner and outer surface of ampoules before filling operation.	Should be able to eliminate the particle from inner and outer surface of ampoules.	Process Requirement
Working: The machine washes the inner and outer sides of ampoules and eliminates the particles that are formed on the Ampoules, which are to be filled and sealed.	Ampoules should be free of any particle from both inner and outer side of ampoules.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement



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7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 440 V \pm 5% Phase : 3 Phase Frequency : 50 Hz \pm 3%	GMP Requirement
Room Condition	Temperature : NMT - 25°C RH : NMT - 55%	Process Requirement
Purified Water	Pressure : 0.2 to 0.65 Mpa	Process Requirement
Water For Injection	Pressure : 0.2 to 0.5 Mpa	Process Requirement
Compressed Air	Pressure : 0.2 to 0.6 Mpa	Process Requirement
Recirculated water	Pressure : 0.2 to 0.5 Mpa	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
Machine Specification	
Model	AQCL20/6
Dimensions	2400 mm x 2400 mm x 1650 mm
Production Rate	(12000-34000) pcs/h. adjusting speed according
Loading Ampoule Size	1 ml, 2 ml, 3 ml and 5ml
Machine 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
Filter	
Make	Pall
Model	SASM031G15J -01 qty, 3 micron SAS011GBP15J-03 qty, 0.2 micron
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



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Critical Variables	Acceptance Criteria
Manual Diaphragm valve	
Make	Gemu
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	
Make	Truking
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



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Critical Variables	Acceptance Criteria
Model	57200 CN
Contactor	
Make	Scheinder
Safety Relay	
Make	Scheinder
MCB	
Make	People
Power Switch	
ON/OFF Switch	Black
Green Indicator on HMI	Machine ON
Red Mushroom Button on HMI	Emergency stop



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7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Infeed Conveyor	SS304
2.	Nozzles	SS316L
3.	pipe	SS316L
4.	Sealing gasket	Silicone Rubber
5.	Water tank	SS316
6.	Interconnecting piping valves	SS316
7.	Filter housing for re-circulatory water	SS316
8.	Filter housing for WFI	SS316
9.	Filter housing for air	SS316
10.	Machine Covering and doors	SS304



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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
Temperature sensor	Temp sensor sense the temperature and sense temperature being displayed on MMI.	Safety Requirement
Ampoule Feeding Sensor	Stops the machine when the level of the Ampoules on the feed belt drops to below the level of interception of the machine.	Safety Requirement
Low level controllers	Stop the pump if liquid level is not sufficient and will indicate the same on display screen.	Safety Requirement



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7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Ampoule 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 Ampoule 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



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MCB	:	Miniature circuit breaker
RH	:	Relative Humidity
Mpa	:	milli pascal
AWM	:	Ampoule Washing Machine
MMI	:	Man Machine Interface
KW	:	Kilowatt
SS	:	Stainless steel
Hz	:	Hertz
V	:	Volt
WFI	:	Water for Injection



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			