



PHARMA DEVILS

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

PROTOCOL No.:

**OPERATIONAL 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



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

PROTOCOL No.:

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6
7.0	Pre-Qualification Requirements	6-7
8.0	Critical Variables to be Met	7-15
9.0	References	16
10.0	Documents to be Attached	16
11.0	Deviation from Pre-Defined Specification, If Any	16
12.0	Change Control, If Any	16
13.0	Review (Inclusive of follow up action, If Any)	16
14.0	Conclusion	17
15.0	Recommendation	17
16.0	Abbreviations	18
17.0	Protocol Post Approval	19



PHARMA DEVILS

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

PROTOCOL No.:

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)			



PHARMA DEVILS

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

PROTOCOL No.:

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Ampoule Vertical Ultrasonic Washing Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of Ampoule Vertical Ultrasonic Washing Machine (**Make- TruKing Technologies**) installed in the Ampoule Washing & Sterilization Room.
- This Protocol will define the methods and documentation used to perform OQ activity of Ampoule Vertical Ultrasonic Washing Machine for OQ.
- Successful completion of this Protocol will verify that Ampoule Vertical Ultrasonic Washing Machine meet all acceptance criteria and ready for Performance Qualification.



PHARMA DEVILS

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

PROTOCOL No.:

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 operational Qualification protocol cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process.• Post Approval of Operational Qualification Protocol cum Report after Execution
Production	<ul style="list-style-type: none">• Review of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.• Execution & Review of operational qualification protocol cum report.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.• Post Approval of Operational Qualification Protocol cum Report after Execution



PHARMA DEVILS

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

PROTOCOL No.:

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

6.0 EQUIPEMENT 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:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation and Cleaning of Ampoule Vertical Ultrasonic Washing Machine.
- Draft SOP for Preventive Maintenance of Ampoule Vertical Ultrasonic Washing Machine.
- Electrical circuits diagram.
- Technical specification of equipment.

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 OQ Protocol cum report.



PHARMA DEVILS

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

PROTOCOL No.:

7.1.2 Acceptance Criteria:

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol cum Report				
2.	IQ Protocol cum Report				
3.	Draft SOP for Operation & Cleaning of Ampoule Vertical Ultrasonic Washing Machine				
4.	Draft SOP for Preventive Maintenance of Ampoule Vertical Ultrasonic Washing Machine				

Checked By (Production)
Sign/Date:

Verified By (Quality Assurance)
Sign/Date:.....

Inference:

.....
.....
.....

Reviewed By (Manager QA)
Sign/Date:



PHARMA DEVILS

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

PROTOCOL No.:

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment / Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:
.....
.....
.....

**Reviewed By
(Manager QA)
Sign/Date:**



PHARMA DEVILS

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

PROTOCOL No.:

8.3 Operational & Functional Checks:

Component	Procedure	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Switch with Key	Open the main switch and revolve the knob the position '1'	Power ON & Power (Green) Indicator will glow		
	Revolve the knob the position '0'	Power OFF and Green Indicator will not glow		
Inching Switch P2	Press the Button P2	Machine will run		
Operating Panel of Ultrasonic	Cut off the ultrasonic power manually	Machine will not run		
Water absence protection	Lower the level of water and Start the Machine	Machine will not start when the water level is too low or absence.		
Pressure Regulating Valve	Rotate the valve in clock wise direction	Pressure will increase		
	Rotate the valve in anti clock wise direction	Pressure will decrease		
Manual Diaphragm valve	Adjust the flow rate of pipeline	Flow rate should increase/decrease as per respective rotation.		
Pressure of WFI and Compressed air	Decrease the pressure of WFI and Compressed air under 0.2mpa manually.	Machine will not start when the pressure below 0.2Mpa		
Temperature Control Module	Add the cold water manually to reduce the water temperature. Water temperature limit-40°C -60°C	Temperature should be controlled between 40°C -60°C.		
Emergency Stop	Press the button	Machine will stop when emergency stop is pressed.		

**Checked By
(Production)**

Sign/Date:

**Verified By
(Quality Assurance)**

Sign/Date:

Inference:

.....
.....
.....

**Reviewed By
(Manager QA)**

Sign/Date:



PHARMA DEVILS

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

PROTOCOL No.:

8.4 Operational Checks in Auto Operation:

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Make the machine in Auto Mode through MMI.	Machine should response in auto mode viewed in MMI.		
Set the parameters like main motor, conveyer motor, water pump, WFI water pump on, recirculated water pump, spray valve and save it with a particular recipe name.	PLC should accept the set parameters.		
Go to main screen and press auto Start.	Machine should start automatically following the sequence and as per the set parameters to PLC.		

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

.....

**Reviewed By
(Manager QA)
Sign/Date:**



PHARMA DEVILS

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

PROTOCOL No.:

8.5 Operational Checks for Safety Features :

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
ALARMS			
Pressure (WFI, Purified Water, Compressed Air) is too low	When the Pressure (WFI, Purified Water, Compressed Air) is below the lower limit, the alarm appears respectively.		
Pressure (WFI, Purified Water, Compressed Air) is too high	When the Pressure (WFI, Purified Water, Compressed Air) is above the upper limit, the alarm appears respectively.		
Ultrasonic Overload	When the ultrasonic overloads or power of ultrasonic disconnects, the alarm appears as 'Ultrasonic Overload'		
Recycled water pump overload	When the recycled water pump is running in status of overload, circuit breaker of motor will trip, 'Recycled water pump overload' Alarm appears.		
Recycled water level too low	If the water level of recycled water tank is below the level detection switch, "Recycled water level too low" alarm appears.		



PHARMA DEVILS

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

PROTOCOL No.:

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Recycled water temperature too low or too high respectively	Alarm appears respectively when the temperature will altered from the set value		
Tunnel doesn't reach the set value	When Tunnel doesn't reach the set temperature, alarm information " Tunnel temperature not reaching" appears.		
Ampoules jamming for tunnel	When ampoules jam in tunnel inlet, the alarm information appears "Ampoules jamming for tunnel" appears.		
Ampoules absent in machine	When ampoules are absent in inlet "Ampoule absent for machine" alarm appears.		



PHARMA DEVILS

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

PROTOCOL No.:

8.6 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

.....

.....

.....

.....

**Reviewed By
(Manager QA)
Sign/Date:**



PHARMA DEVILS

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

PROTOCOL No.:

8.7 Verification of user Levels controls & Emergency operation :-

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Emergency Stop	Machine should stop when Emergency button is pressed		
Operator Level	Operator level should have access to process selection, process start & stop in auto, manual mode, print start & stop, alarm, visualization. It should have access to acknowledge the alarm & reset the process.		
Supervisory Level	Supervisory level should have access to operator level all menu and in addition to that, should have excess to set the process parameter, batch info, recipe preparation & recipe upload		
Administrative Level	Administrative should have access to supervisory level all menu and in addition to that, should have excess to change the password.		

**Checked By
 (Production)
 Sign/Date:**

**Verified By
 (Quality Assurance)
 Sign/Date:**

Inference:

.....

**Reviewed By
 (Manager QA)
 Sign/Date:**



PHARMA DEVILS

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

PROTOCOL No.:

9.0 REFERENCES:

- Installation Qualification
- Operation and Maintenance Manual.

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

.....

.....

.....

.....

.....

.....

12.0 CHANGE CONTROL, IF ANY:

.....

.....

.....

.....

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

.....

.....

.....

.....

.....



PHARMA DEVILS

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

PROTOCOL No.:

14.0 CONCLUSION:

.....

.....

.....

.....

.....

.....

15.0 RECOMMENDATION:

.....

.....

.....

.....

.....

.....



PHARMA DEVILS

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

PROTOCOL No.:

16.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
WFI	:	Water for injection
PLC	:	Programmable Logical Control
ID.	:	Identification
MMI	:	Man Machine Interface
UWM	:	Ultrasonic Washing Machine
MCB	:	Miniature Circuit Breaker



PHARMA DEVILS

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

PROTOCOL No.:

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)			