OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

VIAL WASHING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Vial Washing & Sterilization Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

1.0 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)			

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 Vial 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 **Vial Washing Machine (Make: Ambica Pharma Machines Pvt. Ltd., Capacity: 240 Vials per minute)** installed in the **Vial Washing & Sterilization Room.**
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Vial Washing Machine.
- Successful completion of this Protocol will verify that Vial Washing Machine meet all acceptance criteria and ready for Performance 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, 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	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum report after Execution.
Engineering	• 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.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Washing Machine
Equipment ID.	……
Manufacturer's Name	Ambica Pharma Machines Pvt. Ltd
Supplier's Name	Ambica Pharma Machines Pvt. Ltd
Model	……..
Location of Installation	Washing & Sterilization Room

6.0 EQUIPEMENT DESCRIPTION:

The Automatic High Speed linear External Vial Washing Machine is located in the Washing Room with restricted access.

INFEED TURN TABLE

Supporting Frame made out of rigid SS rectangle pipe structure having two compartments, one for all mechanical drives and other for infeed conveyor.

All drive gear boxes & pumps are securely mounted on frame for vibration free, balanced and rigid machine. Supporting frame designed to have complete balanced machine hence it does not call for any foundation. Load the bottles directly on Infeed Conveyor Belt.

Infeed conveyor is in fine stainless steel wire mesh, move the Bottles to the overturning drum, through Poly-pic Guides. An oscillating lever system known as wedge breaker assembly assists the bottles in entering the Vial Holders. System consists of two stainless steel link chains carrying the channels on which the Vial holders are mounted.

Shafts and sprockets imparting the inching movement to the chains in the washing area are also made of Stainless Steel and are supporting by the two anticorodal shoulders. The chains are supporting by Polypic guide which does not need any lubrication. At the turning point of the chains at the unloading sides bottles leave their holders by gravity. The slide down short shaped chute until laying their bottom against arched supports called unloading platform. The erectors lift the upright bottles on output platform into the outfeed system. The shaped chute moves them along the arched supports lifting the bottles on the output platform. The outlet is on Platform is equipped with Polypic guides.

WASHING MACHINE

One of the main features of this machine is that all manifolds carrying the spray nozzles for internal wash are mounting on a vertically moving cart. It is possible to introduce the nozzles into the Vial neck for better cleaning of bottles. Also this additional movement is imparting by the same timing mechanism synchronized with all other movements over the full speed range of the machine.

Wash stations (utility recommended):

Station 1- Compressed Air

Station 2 - Recirculated filtered water

Station 3 - Recirculated filtered water

Station 4 - Compressed Air

Station 5 - Purified water

Station 6 - Filtered compressed air

Station 7 - Filtered Purified water

Station 8 - Filtered compressed air

Station 9 - Fresh WFI

Station 10 - Filtered compressed air

The external washing takes place by means of stationary manifolds carrying spray nozzles. The whole hydraulic circuit is in Stainless Steel. Except the flexible hoses connecting the moving parts is made of Teflon inner tube covered by S.S. braided wire. All manifolds are equipped with Globe valve. This Globe valves will operate only when nozzles enter the neck of the bottles. The entry of nozzles and its withdrawals are regulated through Solenoid Valves. All straight and reciprocating movements of the machine are synchronies by a single timing system.

1) Introduction of the bottles into the holders
2) Washing nozzle movement
3) Bottles erecting movement

The rotary intermittent motion of the transport system is imparted by an indexing box that gives the time for the above three described movements. The timing is through limit switch which operates solenoid valves. The limit switches mounted on various places. Hence, it’s synchronized with main conveyor. The numbers of strokes per minute are multiply by the fluids, before touching the Bottles are filtered. According, to the porosity of the filtering cartridges. The filter housings are mounted in an extremely accessible position for easy cleaning, cartridge substitution and maintenance. Filter Cartridges are not part of the machine; same has to be purchased by the Customers.

The system includes:

1) Piping’s.
2) Pumps.
3) Ball Valves.
4) Globe Valves.
5) Fittings.

Piping is assembled with S.S. ferrules and can be promptly dismantled in parts and easy to get cleaned. Pumps are sanitary type, without porosity, with mechanical seals. Globe valves are in S.S. with gaskets in Vi-ton. The piloting air is filtered, regulated and lubricated compressed air. The washing fluids are kept at constant level in the tanks by means of fully automatic gauges, float valves and level sensors. Washing liquids is pumped to the washing station through fine filters. S.S. Tanks are located underneath the washing section and mounted on castors to facilitate easy removal for cleaning and maintenance. The pressure of all fluids is measured by pressure gauges placed on top of the machine. Air pressure is at 2 kg/cm^2 and washing fluid pressure is 1.5 kg/cm^2.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Vial Washing Machine
- Draft SOP for Preventive Maintenance of Vial 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.

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 Vial Washing Machine.				
4.	Draft SOP for Preventive Maintenance Vial Washing Machine				

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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 ID.	Calibration On	Due On	Observed By Sign/Date

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 Operational and Functional Checks:

Operate the Vial Washing Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Component	Acceptance Criteria	Observations	Observed By (Engineering) Sign/Date
Emergency Stop			
Press emergency stop button.	Display will show "Emergency stop" & feed pump will stop.		
Release emergency stop button.	Display will show "Process OK" & feed pump will start.		
Air Pressure Low			
Air pressure switch is set at higher value than actual air pressure.	Display will show "Air pressure low' & feed pump will stop.		
Air pressure switch is set at Lower value than actual air pressure	Display will show "Process ok" & feed pump will start.		
Infeed mechanism			
Vial holder channel	Each Vial holder channel has 20 washing cups for each channel for 40 channels. One washing cups will hold one vial		
Washing scheme			
Washing with purified water	Internal + external washing of vials		
Washing with recirculating filtered purified water	Internal washing of vials		
Washing with compressed air	Internal + external washing		
Washing with fresh WFI	Internal + external washing of vials		
Washing with compressed air	Internal washing of vials		
Alarms			

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Component	Acceptance Criteria	Observations	Observed By (Engineering) Sign/Date
Main motor overload	Machine stops & raises alarms		
Conveyer Trip	Machine stops & raises alarms		
Purified water pump Trip	Machine stops & raises alarms		
WFI Water Pump Trip	Machine stops & raises alarms		
Recirculated water pump Trip	Machine stops & raises alarms		
Tunnel Jam	Machine stops & raises alarms		
Air Pressure Low	Machine stops & raises alarms		
Purified Water Pressure Low	Machine stops & raises alarms		
Purified Water Low	Machine stops & raises alarms		
WFI Water Level Low	Machine stops & raises alarms		
Recirculated Water Level Low	Machine stops & raises alarms		
Infeed Drum Overload	Machine stops & raises alarms		
Outfeed Pusher Overload	Machine stops & raises alarms		
Outfeed Lifter Overload	Machine stops & raises alarms		

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL WASHING MACHINE	PROTOCOL No.:

Component	Acceptance Criteria	Observations	Observed By (Engineering) Sign/Date
Outfeed Prism Overload	Machine stops & raises alarms		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Checking of Auto Mode Operation

Item	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, dm 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:

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

8.5 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:

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

8.6 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the Emergency Stop Pressed in, in Try to cause movement of an Operating function.	The Equipment will be inoperative.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of Draft SOPs.
- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED 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:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
mm	:	Millimetre
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo Gram
Ltrs	:	Liters
MCB	:	Miniature Circuit Break
MMI	:	Man Machine Interface
PLC	:	Programmable Logic Controller
VWM	:	Vial Washing Machine
WFI	:	Water for Injection
ISPE	:	International Society of Pharmaceutical Engineering

17.0 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)			