INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL WASHING MACHINE

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

CONTENTS

PHARMA DEVILS	INSTALLATION 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 provide documented evidence for the Installation Qualification of Vial 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 **Vial Washing Machine (Make: Ambica Pharma Machines Pvt. Ltd., Capacity: 240 Vials per minute)** to be installed in the **Vial 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 Vial Washing Machine.

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 Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• 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	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in VWM Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution.

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM 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 Vials directly on Infeed Conveyor Belt.

Infeed conveyor is in fine stainless steel wire mesh, move the Vials to the overturning drum, through Poly-pic Guides. An oscillating lever system known as wedge breaker assembly assists the Vials 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 anti-corodal shoulders. The chains are supporting by Poly-pic guide which does not need any lubrication. At the turning point of the chains at the unloading sides Vials 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 Vials on output platform into the outfeed system. The shaped chute moves them along the arched supports lifting the Vials on the output platform. The outlet is on Platform is equipped with Poly-pic 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 Vials. 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 - Re-circulated Filtered water

Station 3 - Re-circulated 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 Vials. 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 Vials into the holders
2) Washing nozzle movement
3) Vials 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 Vials 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/cm² and washing fluid pressure is 1.5 kg/cm².

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.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

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 & Sterilizing Room		
Room Condition	General Room Conditions.		
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: ……

8.2 Installation Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	AHLVW-240		
Dimensions	2291 mm x 1574mm x 1625 mm		
Conveyor Height	1016 mm		
Production Rate	Up to 240 Vials/Min.		
Loading Vial Size	For 5ml-30ml.		
Machine orientation	Left to Right		
MMI	Make : Delta **Three Level Access :** Operator, Supervisor, Maintenance **Auto Mode, Manual Mode, Alarm**		
Pressure Gauge	Glycerin filled Make : Shreeji Quantity : 3 Nos. Range : 0- 60 Kg/cm^2 MOC : SS316 L **Provided for :** Compressed air supply Recirculated water Purified water Water for injection		
Main motor &Gear box	Make : Bonfiglioli		
Motor &Gear box for conveyer	Make : Bonfiglioli S. No. : 830720106		
A.C. Frequency Drive	Make : T-Verter		
Chain	Make : Rolon Pitch : ½”		

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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Infeed turn table	Quantity : 40 Channels Cups : 20 cup/ channel		
Filters	Quantity : 4 Nos. Provided For : **Re-circulatory Water Filter** (10µ Cartridges) **Purified water filter:** (5 µ Cartridges) **WFI Connection Filter:** (5 µ Cartridges) **Compressed Air Filter:** (0.2 µ Cartridges)		
Spray Pipe	Quantity : 2 Nos. Nozzle : 20 Nozzle each (located above washing station 2, 5 approx.)		
Solenoid valve	Make : Rccon Quantity : 4 Nos. Type : 2/2 way Solenoid valve 24 V DC Size : ½” Pressure : 0-70 Bar		
Sampling valve	Make : Avcon Quantity : 2 Nos.		
Push Buttons	Make : Telemechanique		
Relay	Make : Telemechanique		
Main MCB	Make : Hager		
Limit switches	Make : Bhoman		

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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Motor	**For Purified Water Pump** Make : CE Grundfos Model : A96806828- P1-1406 Type : MG71B 230/400-2 B-F Electric supply : 380- 415 V 50 Hz 0.87 HP **For Re-circulated Water Pump** Make : CE Grundfos Model : A96806828- P1-1406 Type : MG71B 230/400-2 B-F Electric supply :380- 415 V, 50 Hz 0.87 HP **For WFI tank Pump** Make : CE Grundfos Model : A96806828- P1-1406 Type : MG71B 230/400-2 D1-F Electric supply : 380- 415 V,50 Hz 1.14 HP		

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(Quality Assurance)
Sign/Date: ……

Inference:

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

8.3 MOC Verification List:

S.No.	Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
1.	Infeed Turntable	SS316		
2.	Conveyor Rubber Roller	Natural Rubber		
Washing Machine				
3.	Cassettes	SS316		
4.	Spray nozzle	SS316		
5.	Spray pipe	SS316		
6.	Vial Holder Pocket	HDPE		
7.	Flexible Pipe	Silicon		
8.	Chain wheel	Cast Nylon		
Wash scheme				
9.	Water tank	SS316		
10.	Interconnecting piping valves	SS316		
11.	Filter Housing for re-circulatory water	SS316		
12.	Filter Housing for WFI	SS316		
13.	Filter Housing for air	SS316		
14.	Pressure gauges	SS316 diaphragm type		
Machine Drive				

S.No.	Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
15.	Gear box & motor	Aluminum ,Die Cast		
16.	Machine Covering and doors	SS304		
17.	Cam	EN-8		
18.	All Shafts	S.S.304		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 440 V KW : 5 Kw Phase : 3 Phase Frequency : 50 Hz		
Room Condition	Temperature : NMT - 25°C RH : NMT – 55%		
Purified Water	Pressure : 1.5 Kg /cm² to 2.5 Kg /cm²		
Water For Injection	Pressure : 1.5 Kg /cm² to 2.5 Kg /cm²		
Compressed Air	Pressure : 1.5 Kg /cm² to 2.5 Kg /cm²		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
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.		
Temperature sensor	Temp sensor sense the temperature and sense temperature being displayed on MMI.		
Vial Feeding Sensor	Stops the machine when the level of the Vials on the feed belt drops to below the level of interception of the machine.		
Low level controllers	Stop the pump if liquid level is not sufficient and will indicate the same on display screen.		

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 References 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, General, 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, Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacturer, Version 4.0, December 2001.

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:

AC	:	Alternating Current
AMPS	:	Amperes
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
KVA	:	Kilo Volt Ampere
MCB	:	Miniature circuit breaker
MOC	:	Material of Construction
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
RH	:	Relative humidity
SOP	:	Standard Operating Procedure
URS	:	User Requirement Specification
VWM	:	Vial Washing Machine
P & ID	:	Piping & Instrumentation Diagram
NMT	:	Not More Than
NLT	:	Not Less Than
SS	:	Stain less Steel
MMI	:	Man Machine Interface
ID	:	Inner Diameter
HDPE	:	High Density Poly Ethylene

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)			