DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

VIAL WASHING MACHINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

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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 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 **Vial Washing Machine (Make: Ambica Pharma Machines Pvt. Ltd., Capacity: 240 Vials per minute)** for ……..
- 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.

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 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	• 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	• 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. ➢ 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.

5.0 BRIEF EQUIPMENT 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 in-feed 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 In-feed Conveyor Belt.

In-feed 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared ……. The manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Vial Washing Machine is designed to wash the inner and outer surface of round shaped Vials before filling operation.	Should be able to eliminate the particle from inner and outer surface of vials.	Process Requirement
Working: The machine washes the inner and outer sides of Vials and eliminates the particles that are formed on the Vials, which are to be filled and sealed.	Vials should be free of any particle from both inner and outer side of vials.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 440 V KW : 5 Kw Phase : 3 Phase Frequency : 50 Hz	GMP Requirement
Room Condition	Temperature : NMT - 25°C RH : NMT – 55%	Process Requirement
Purified Water	Pressure : 1.5 Kg /cm² to 2.5 Kg /cm²	Process Requirement
Water For Injection	Pressure : 1.5 Kg /cm² to 2.5 Kg /cm²	Process Requirement
Compressed Air	Pressure : 1.5 Kg /cm² to 2.5 Kg /cm²	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
Model	AHLVW-240
Dimensions	2291 mm x 1574 mm 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 Parameters : **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 coveyer	Make : Bonfiglioli S. No. : 830720106
A.C. Frequency Drive	Make : T-Verter
Chain	Make : Rolon Pitch : ½”
Infeed turn table	Quantity : 40 Channels Cups : 20 Cup/ channel

Critical Variables	Acceptance Criteria
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.)
Limit switches	Make : Bhoman
Main MCB	Make : Hager
Relay	Make : Telemechanique
Push Buttons	Make : Telemechanique
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.

Critical Variables	Acceptance Criteria
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

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
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		
15.	Gear box & motor	Aluminum ,Die Cast
16.	Machine Covering and doors	SS304
17.	Cam	EN-8
18.	All Shafts	S.S.304

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
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.	Safety Requirement
Low level controllers	Stop the pump if liquid level is not sufficient and will indicate the same on display screen.	Safety Requirement

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Vial 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 PO and URS.

(2) Operating and service manual for Vial Washing Machine.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- 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
cGEP	:	Current Good Engineering 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
MCB	:	Miniature circuit breaker
db	:	Decibel
C.I.	:	Cast Iron
RH	:	Relative Humidity
VWM	:	Vial Washing Machine
MMI	:	Man Machine Interface
HP	:	Horse Power
SS	:	Stainless steel
HDPE	:	High Density Poly Ethylene
AC	:	Alternating current
VWM	:	Vial Washing Machine
Hz	:	Hertz
V	:	Volt
WFI	:	Water for Injection
DC	:	Direct current

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			