USER REQUIREMENT SPECIFICATION FOR VIAL WASHING MACHINE

LOCATION:	**DRY POWDER LINE**
SUPERSEDES URS No.	**NIL**

URS CONTENTS

 PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR VIAL WASHING MACHINE	URS No.:

1.0 PROTOCOL 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:

- The User Requirements Specification (URS) is provided to aid the user through the critical aspects of Fabrication, Facility for Installation of Required Equipments, Cleaning/Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional Vial washing machine that meets the user's needs in the most cost-effective method possible.
- The URS to be provided to Vendor to submit a Price Quote for procurement of Vial washing machine.
- The URS shall help Vendor in understanding the end user requirement in details. This document shall help vendor for developing the Design Specification, which on approval will become a Contractual Agreement between vendor and Site.
- This URS shall be recognized as an integral part of the procurement agreement with the vendor. The vendor will abide by the information and conditions set forth by this document as well as the Standard Purchase Terms and Conditions of the Site.

3.0 SCOPE:

- The Scope of this document is limited to the User Requirement Specification (URS) of Vial washing machine of the Site.
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Manufacturing Practices (cGMP) and safety.

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 URS:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, and Approval of User Requirement Specification. • Co-ordination with Production, Engineering and Quality Control to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS.
Production	• Review of User Requirement Specification for compliance with the Process Requirement.
Engineering	• Review of User Requirement Specification. • Assist in preparation of User Requirement Specification.

5.0 GMP / REGULATORY REQUIREMENTS:

The purpose of Vial washing machine is to wash the inner and outer surface of round shaped Vials before filling operation.

Vial washing machine shall comply to the "Current Good Manufacturing Practices".

- WHO GMP - "Good Manufacturing Practices for Pharmaceutical Products".
- Schedule –M–"Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."

6.0 SYSTEM OVERVIEW:

- Vial washing machine shall be able to wash the inner and outer surface of round shaped Vials before filling operation.

6.1 TECHNICAL SPECIFICATION:

S.No.	SYSTEM DESCRIPTION	MOC	TECHNICAL SPECIFICATION
	Model	----------	As per equipment requirement
	Dimensions	----------	As per equipment requirement
	Conveyor Height	----------	As per equipment requirement
	Production Rate	----------	Up to200- 250 Vials/Min.
	Vial Size	----------	5ml - 20ml
	MMI	----------	As per equipment requirement
	Pressure Gauge		
	Quantity	----------	3 Nos.
	Range	----------	0- 60 Kg/cm^2
	MOC	----------	SS316 L
	Main motor	----------	As per equipment requirement
	Gear box	----------	As per equipment requirement
	Infeed turn table	----------	20 Cup/ channel
	Quantity	----------	40 Channels
	Filters	----------	4 Nos
	Spray Pipe	----------	2 Nos.
	Nozzle	----------	20 nozzle
	Sampling valve	----------	2 Nos.
	Motor		
	Quantity	----------	3 Nos.
	For Purified Water Pump	----------	1 Nos.
	For Re-circulated Water Pump	----------	1 Nos.
	For WFI tank Pump	----------	1 Nos.

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 LAY OUT:

- Should accommodate Size of equipments, utility services to be provided, Operating space and clearance for maintenance activity.
- Should be suitable such that after placement of equipments in the area the scope for personal movement and maintenance activity is not disturbed.

7.2 FUNCTIONAL REQUIREMENTS:

- Vial washing machine shall comply with the "Current Good Manufacturing Practices".

7.3 UTILITY REQUIREMENTS:

- System shall accept Three Phase 415 ± 10% V supplies.

7.4 SAFETY REQUIREMENTS:

- Emergency push button shall be provided.
- Electric panels shall not have any unsecured joints.
- Double earthing shall be provided for all electrically operated equipments.
- Noise pollution shall be kept below 80 db.

7.5 MAINTENANCE:

- The Equipment shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- The supplier shall provide all spare parts at the production site before the start of Vial washing machine.
- The supplier shall replace the parts found to be damaged/ broken during installation.
- The supplier shall be available at the site when asked in case of major breakdown.

8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

- The supplier shall follow cGMP practices in design, development, construction and Installation of the system.

8.2 TESTING:

- The system shall be Factory tested by the supplier with approval witness.
- The system shall be commissioned and qualified at site for Installation and Operation by the supplier with approval witness.

8.3 SUPPORT

- Supplier shall provide support for Preventive maintenance plan development, Operator training, Cleaning of the equipment etc.

8.4 DELIVERY

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification and other qualification documents (DQ, IQ & OQ) in soft copy.

9.0 DOCUMENTS TO BE ATTACHED:

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer’s calibration certificate.
- Electrical unit Diagram.
- P&ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.
- Warranty Certificate of machine
- Test Certificate of SS Materials

10.0 REVIEW / COMMENTS:

- The supplier should make/design the Vial washing machine as per technical specification mentioned in the URS.
- For any changes in the design/make of the Vial washing machine, if not as per the URS, prior intimation/approval should be taken by the supplier from the Site.
- All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.

Approved By ……
Head - QA
Sign & Date

11.0 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practices
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
SS	:	Stainless Steel
WHO	:	World Health Organization
°C	:	Degree centigrade
µ	:	microne
V	:	Volt
%	:	percentage
P&ID	:	Piping & instrumentation
GA	:	General arrangement

PO	:	Purchase Order
mm	:	Millimeter
SS	:	Stainless Steel
VWM	:	Vial Washing Machine
MMI	:	Man Machine Interface
IPR	:	Intellectual Property Right
AC	:	Alternating current
V	:	Volt
WFI	:	Water for Injection