USER REQUIREMENT SPECIFICATION FOR THREE PIECE VIAL FILLING MACHINE

LOCATION	**Three Piece Vial Line**
SUPERSEDES URS No.	**NIL**

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1.0 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 Instruments, Cleaning/Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional Three Piece vial filling Machine that meets the user's needs in the most cost-effective method possible.
- The URS is then provided to Vendor to submit a Price Quote for procurement of Three Piece Filling 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 by the Site, will become a Contractual Agreement between Vendor and the 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 Three Piece vial Filling 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 Team, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation and Approval of User Requirement Specification. • Co-ordination with User Department to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS.
User Department	• Review of User Requirement Specification for compliance with the Product Requirement.

5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Three Piece vial Filling Machine is to perform filling of solution as well as dropper fixing & screw capping of vials in injection Block.

- Three Piece vials Filling Machine should complies with the "Current Good Manufacturing Practices".
- Schedule–M "Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products".

6.0 SYSTEM OVERVIEW:

Three piece filling compact filling machine which consists of Orientator, Filling, Dropper Fixing and Screw Capping on a single frame.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	-----	Three Piece Vial Filling Machine suitable for 5 ml/10 ml vial with orientator, dropper fixing & screw capping machine with all types of single seal and double seal caps.PTS filling system with PLC.
2.0	Modal /Type	-----	Should be in compliance with cGMP.
3.0	Overall Size of the Machine	-----	As per your specification
4.0	Top & bottom frame	SS 316 L	As per CGMP Requirement
5.0	**Filing Heads**		
	No. of head filling	SS 316 L	6 Head
	MOC of filling nozzle	SS 316 L	As per CGMP Requirement
	Nitrogen Pre Gassing	-----	6 Nos.
	Nitrogen Post Gassing	-----	6 Nos.
6.0	**Turn Table**		
	MOC	SS-304	As per CGMP Requirement
	Qty.	-----	05 Nos
	Turn table size	-----	As per your specification
7.0	**Dropper Feeder Bowl**		
	MOC	SS-316 L	As per CGMP Requirement
	size	-----	As per your specification
	Storage Capacity	-----	As per your specification
	No. of bowl	-----	01
8.0	**Cap Feeder Bowl**		
	MOC	SS-304	As per CGMP Requirement
	Size	-----	As per your specification

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S.No.	Name of the Component	MOC	Technical Specification
	Storage Capacity	-----	As per your specification
	No. of bowl	-----	01
9.0	Feed height	-----	800 -850 mm approx
10.0	Panels	SS304	As per CGMP Requirement
11.0	Speed	-----	120 PCS/min (5 ml)
12.0	Indexer	-----	As per your specification
13.0	Machine body	SS316L	Contact Parts
		SS304	Non Contacts
14.0	Storage capacity of orientator	-----	200 -300 vials
15.0	Motor	-----	As per your specification & suits for equipment design
	Indexer	-----	01 Nos.
	Vibrator Controllers	-----	As per your specification & suits for equipment design
	Gear Box	-----	04 Nos.
16.0	Drive	-----	AC Variable drive
17.0	Emergency Switch	-----	Push Button
18.0	Safety Features	-----	➢ Emergency push button shall be provided. ➢ Machine shall not be started without safe earthing. ➢ All moving parts to be protected with safety guards. ➢ All upper guards provided with interlocks. ➢ Noise pollution shall be kept below 80 db. ➢ Alarm should be provided
19.0	Limit Switch / Inter Locking System	-----	As per your specification
20.0	Indicating lamp	-----	As per your specification
21.0	Safety Guard	-----	As per your specification

S.No.	Name of the Component	MOC	Technical Specification
22.0	Earthing	-----	Whole body Earthing
23.0	**Utilities**		
	Electrical Configuration & Cabling		
	Power Supply	-----	As per your specification and Finalized Purchase order.
	Power cable	-----	
	Power / Inverter	-----	Should be Provided as per your specification and Finalized Purchase order.
24.0	Special feature	-----	As per Purchase order.

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

➢ FUNCTIONAL REQUIREMENTS:

- Three Piece vial Filling Machine shall comply as per ISPE, cGMP, cGEP Guidelines.

➢ RELIABILITY AND AVAILABILITY:

- The system shall be available for continuous operation.
- Material of construction used shall be suitable for the intended service so as to withstand the working stress without frequent break down.

➢ MAINTENANCE:

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- 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 in design, development, construction and Installation of the Machine.

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, Operation & cleaning procedure for Three Piece vial Filling Machine, Assembly and Operator training.
- Supplier shall provide Safety Manuals during Installation, Operation & Calibration at the site.

8.4 DELIVERY:

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification (MOC & Calibration Certificates) and Operation Manual in Soft as well as Hard Copy.

9.0 DOCUMENTS TO BE PROVIDED:

- 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

Note: The whole URS is a tentative document. Manufacturer or Vendor will be solely responsible for performance of machine specified in the catalogue or during discussion at the time of finalization of purchase order. Specifications and details mentioned in the DQ, duly signed by Vendor/ Manufacturer and duly signed by Head QA will be treated as final specifications of the machine.

The said DQ will be treated as an integral part of purchase order.

10.0 REVIEW COMMENTS:

- For any changes in the design/make of the Three Piece vial Filling Machine if not as per the URS, prior intimation/approval should be taken by the supplier 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
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
HP	:	Horse power
TPF	:	Three Piece Filling machine
Hz	:	Hertz
AC	:	Alternative Current