



**PHARMA DEVILS**

**USER REQUIREMENT SPECIFICATION  
FOR  
THREE PIECE FILLING MACHINE**

**URS No.:**

**USER REQUIREMENT SPECIFICATION  
FOR  
THREE PIECE FILLING MACHINE  
(THREE PIECE SECTION)**

<b>LOCATION</b>	<b>THREE PIECE SECTION</b>
<b>SUPERSEDES URS No.</b>	



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**1.0 APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (PRODUCTION)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



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**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 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 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.



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**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.

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Initiation and Approval of User Requirement Specification.</li><li>• Co-ordination with User Department to prepare User Requirement Specification.</li><li>• To check the completeness and Technical Accuracy of the URS.</li></ul>
<b>User Department</b>	<ul style="list-style-type: none"><li>• Review of User Requirement Specification for compliance with the Product Requirement.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of User Requirement Specification.</li><li>• Assist in preparation of User Requirement Specification.</li></ul>



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**5.0 GMP/REGULATORY REQUIREMENTS:**

The Purpose of procuring Three Piece Filling Machine is to perform filling of bulk in vials as well as sealing with nozzle and capping of three piece vials in Three Piece Section.

- Three Piece Filling Machine should comply 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 Machine which consists of following machines:

- 1. Combined vial Orientator, Filling, Dropper Fixing**
- 2. Screw Capping Machine.**

**1. Combined vial Orientator, Filling , Dropper Fixing**

This machine should be suitable for filling in plastic vials. The state-of-art syringeless, Valveless, PTS (Pressure & time setting) filling system with PLC should be provided. Filling volume should be adjustable with the PLC screen while machine running. No vial-No filling control for each filling nozzle should be achieved in this system. This unit should consist of rotary dropper fixing system.

**2. Screw Capping Machine.**

This unit should consist of rotary screw capping system to holds the cap, straighten it and then screw it properly applying required torque. As the capping head goes up the exit star wheel releases the vials at the outlet end.



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**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	-----	CFL-200
3.0	Overall Size of the Machine		As per your specification
4.0	Top & bottom frame		As per cGMP Requirement
5.0	<b>Filing Heads</b>		
	No. of head Filling	SS 316 L	10 Head
	MOC of Filling nozzle	SS316 L	As per CGMP Requirement
	Nitrogen Pre Gassing	--	10
	Nitrogen Post Gassing	--	10
6.0	<b>Turn Table</b>		
	MOC	SS-304	As per CGMP Requirement
	Turn table size	-----	As per your specification
7.0	Orientator	-----	Two track system Capacity : As Per Requirements
8.0	Dropper fixing	----	12
9.0	<b>Dropper Feeder Bowl</b>		
	MOC	SS316 L	As per CGMP Requirement
	size	---	As per your specification
	Storage Capacity	---	As per your specification
	No. of bowl	---	01
10.0	<b>Cap Feeder Bowl</b>		
	MOC	SS-304	As per CGMP Requirement
	Size	-----	As per your specification
	Storage Capacity	-----	As per your specification



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S.No.	Name of the Component	MOC	Technical Specification
	No. of bowl	-----	01
<b>11.0</b>	Screw Capping head	----	12 Head
<b>12.0</b>	Speed	-----	200 vials /minute (for 5ml &10ml)
<b>13.0</b>	<b>Machine body</b>	SS316L	Contact Parts
		SS304	Non Contacts
<b>14.0</b>	Motor	-----	1H.P.A.C /50Hz. / Make:Siemens – 3 nos ½ H.P.A.C /50Hz. / Make:Siemens -1no.
<b>15.0</b>	Indexer	---	01 Nos.
<b>16.0</b>	Vibrator Controllers	----	As per your specification & suits for equipment design
<b>17.0</b>	Gear Box	---	W75 Make: Bonfiglioli – 3 nos W63 Make: Bonfiglioli – 1 nos Qty. 04 Nos.
<b>18.0</b>	Drive	---	AC Variable drive Make:Schneider
<b>19.0</b>	Vibrator	---	Bowl dia 450mm-1 no 550mm -1no
<b>20.0</b>	Feed Height	--	800-850mm
<b>21.0</b>	PLC	----	Schneider with three label password
<b>22.0</b>	Emergency Switch	-----	Push Button
<b>23.0</b>	Safety Features	-----	<ul style="list-style-type: none"> <li>➤ Emergency push button shall be provided.</li> <li>➤ Machine shall not be started without safe earthing.</li> <li>➤ All moving parts to be protected with safety guards.</li> <li>➤ All upper guards provided with interlocks.</li> <li>➤ Noise pollution shall be kept below 85 db.</li> <li>➤ Alarm should be provided</li> </ul>
<b>24.0</b>	Limit Switch / Inter Locking System	-----	As per your specification
<b>25.0</b>	Indicating lamp	-----	As per your specification
<b>26.0</b>	Safety Guard	-----	As per your specification
<b>27.0</b>	Earthing	-----	Whole body Earthing
<b>28.0</b>	<b>Utilities</b>		
	<b>Electrical Configuration &amp; Cabling</b>		
	Power Supply	-----	As per your specification and Finalized





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S.No.	Name of the Component	MOC	Technical Specification
	Power cable	-----	Purchase order.
	Power / Inverter	-----	Should be Provided as per your specification and Finalized Purchase order.
<b>29.0</b>	Special feature	-----	As per Purchase order.

**7.0 OTHER REQUIREMENTS AND CONSTRAINTS:**

- Complete Change Parts: for 5ml, 10 ml and 15 ml vials.
- Filling accuracy i.e. volume variation should be  $\pm 1.0\%$ .
- One set of tools.
- Gauges, flow meters, filters for nitrogen and compressed air.
- Pre and post Nitrogen purging facility.
- Pressure Vessel control system to stop the machine if the pressure lower than the set level.
- **Sensor required**
  1. No vial no filling sensor.
  2. No dropper no cap sensor.
- Emergency OFF, ON, INCH pendent box for all the AC motors.
- Door Interlock system should also be provided.
- Height adjustment system with lead screw should be provided for Dropper and Cap feeder wheel units for easy change over setting.
- Digital pressure switch provision is required for maintaining accurate pressure and volume.
- Pressure adjustment should be controlled in PLC touch screen.
- Centre setting adjustment should be given in the filling nozzle holder.
- One common INCH button should be provided to operate all solenoid valves at a time to release the air initially in the filling circuit.
- Easy change over system should be provided.
- Provision for Online CIP/SIP system for filling system.
- All the liquid contact parts should be of S.S.316 materials.
- All other contact parts and covers should be of S.S.304 materials.
- Filling, Dropper Fixing and Capping machines should be provided with Acrylic Cabinet.
- All machines should be provided with A.C variable speed system and mechanical safety clutch arrangement.



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**7.1 FUNCTIONAL REQUIREMENTS:**

- Three Piece filling Machine must be comply as per ISPE and cGMP Guidelines.

**7.2 RELIABILITY AND AVAILABILITY:**

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

**7.3 MAINTENANCE:**

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- 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 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.



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**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.
- 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 Three Piece Filling 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**



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**11.0 ABBREVIATIONS:**

<b>URS</b>	User Requirement Specification
<b>cGMP</b>	Current good manufacturing practices
<b>GMP</b>	good manufacturing practices
<b>MOC</b>	Material of construction
<b>ml</b>	Milliliter
<b>mm</b>	Millimeter
<b>HP</b>	Horse power
<b>A.C</b>	Alternative current
<b>Hz</b>	Hertz
<b>PLC</b>	Programmable logical controller
<b>CIP</b>	Clean in place
<b>SIP</b>	Sterilization in place
<b>SS</b>	Stainless steel
<b>ISPE</b>	International society of pharmaceutical engineering
<b>DQ</b>	Design qualification
<b>QA</b>	Quality assurance