



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
AUTOMATIC INJECTABLE POWDER FILLING WITH
RUBBER STOPPERING MACHINE**

URS No.:

**USER REQUIREMENT SPECIFICATION
FOR
AUTOMATIC INJECTABLE POWDER
FILLING WITH RUBBER
STOPPERING MACHINE
(DRY POWDER SECTION)**

LOCATION	FILLING ROOM, (DRY POWDER SECTION)
SUPERSEDES URS No.	



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1.0 PREPARATION, REVIEW AND APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (PRODUCTION)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANGER (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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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 Automatic Injectable Powder Filling with Rubber Stoppering 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 Automatic Injectable Powder Filling with Rubber Stoppering 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 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 Automatic Injectable Powder Filling with Rubber Stoppering 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.

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

5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Automatic Injectable Powder Filling with Rubber Stoppering Machine is to perform filling of powder in glass vials as well as stoppering with rubber stopper in Dry Powder Section.

- Automatic Injectable Powder Filling with Rubber Stoppering Machine should comply with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.



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6.0 SYSTEM OVERVIEW:

Automatic Injectable Powder Filling with Rubber Stoppering Machine consisting Two Tracks for Vial Filling Operation with Two Powder Wheels & Two Powder Hoppers.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	----	Automatic Injectable Powder Filling with Rubber Stoppering Machine.
2.0	Modal /Type	----	NKPF – 250D
3.0	Overall Size of the machine	----	As per room dimension specification
4.0	No. of filling head	----	16 Head
5.0	Filling accuracy	----	50 mg To 1500 mg in single dose. Weight variation limit $\pm 2\%$.
6.0	Speed	----	220-240 vials /minute (10 ml in Single dose)
7.0	Media Filling System	----	To be provided Online media filling
8.0	Filling	----	Powder Filling System with Pre & Post Nitrogen Purging. No Vacuum No Fill & No purging No fill system.
9.0	PLC & HMI	----	Allen Bradley or equivalent With three label password.
10.0	Machine Body	SS316L	Contact Parts.
		SS304	Non Contacts parts.
11.0	Emergency Switch	----	Push Button
12.0	Safety Features	----	<ul style="list-style-type: none">➤ 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 85 db.➤ Alarm should be provided.
13.0	Limit Switch / Inter Locking System	----	As per Standard specification
14.0	Indicating lamp	----	As per Standard specification



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S.No.	Name of the Component	MOC	Technical Specification
15.0	Safety Guard	-----	As per Standard specification
16.0	Earthing	-----	Whole body Earthing.
17.0	Utilities		
	Electrical Configuration & Cabling		
	Power Supply	-----	As per Standard specification and Finalized Purchase order.
	Power cable	-----	
	Power / Inverter	-----	Should be Provided as per your specification and Finalized Purchase order.
18.0	Special feature	-----	As per Purchase order.

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

- “No Vial – No Filling” system eliminates wastage of costly powder.
- Multiple Dosing system with the help of Change Parts.
- Eight variation limit $\pm 2\%$ of uniform density Injectable Powder should be ensured by setting the depth of piston in the port of the Powder Wheel.
- Built – in Rubber Stoppering Unit saves lot of space in the sterile area & reduces the length of the Laminar Flow.
- Individual drives for Scrambler & Un – scrambler to match the speed of filling and sealing.
- All Motors should be provided with appropriate Contactors and Relays for the protection against any overload or jamming.
- Safety clutch system to avoid vial breakage.
- Variable Frequency Drive for speed control.
- All contact parts should be easily removable for autoclaving/ sterilization.
- Pure Air Filter.
- Vacuum Pump – 500 LPM.
- Online media filling arrangement.
- Pre & Post Gassing Arrangement.
- Acrylic Cabinet.
- Dust Extraction Unit provided with stainless steel 304 contact parts.
- All product contact part should be SS 316L and noncontact part SS 304.
- Swing Type Conveyor With Independent Drive



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7.1 FUNCTIONAL REQUIREMENTS:

Automatic Injectable Powder Filling with Rubber Stoppering Machine must comply as per ISPE and cGMP Guidelines.

7.2 RELIABILITY:

- 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 Automatic Injectable Powder Filling with Rubber Stoppering Machine., Assembly and Operator training.
- Supplier shall provide Safety Manuals during Installation, Operation & Calibration at the site.



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8.4 DELIVERY:

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification.

9.0 DOCUMENTS TO BE PROVIDED:

- All MOC Certificates, Manual for Bought out items.
 - Design Qualification and FAT protocol at the time of FAT.
 - Installation Qualification protocol.
 - Operational Qualification protocol.
 - Schematic Diagram of machine showing Overall Dimensions.
 - Instrument list with manufacturer's calibration certificate.
 - G.A & Electrical 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 Powder Filling with Rubber Stoppering 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