USER REQUIREMENT SPECIFICATION

NAME OF THE ITEM: POWDER INJECTION FILLING & PLUGING MACHINE

FUNCTIONAL AREA: STERILE FILLING AREA

PROTOCOL No. :

CONTENT

1.0 URS APPROVAL:

Protocol Prepared By:

Functional area	Name	Signature	Date
Production			

URS Reviewed By:

Functional area	Name	Signature	Date
Production			
Quality Assurance			
Engineering			

URS Approved By:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

2.0 Objective:

The purpose of this document is to ensure that all the critical aspects of the Equipment, cGMP & Safety features have been considered in designing the equipment/instrument and is properly documented.

3.0 Responsibilities:

In accordance with the document, following functions shall be responsible for initiation and finalization of Equipment user requirement specification. When the work is carried by contract/ consulting staff, all the work is to be performed under the oversight of ……...

3.1 Preparation of Document

- User department to prepare the URS
- Ensures that the document is in compliance with current policies and procedures of cGMP regulations.
- Ensures that the content is sufficient, clearly defined, technically sound and accurate.
- It is a Guidance document to prepare the URS.

3.2 Review of Document

- To be reviewed by Head of the user department and functional department (Engineering & Quality assurance)

3.3 Approval of Document

- Approval of document by Head Manufacturing/Head Engineering/Head Quality.

4.0 Equipment Description & Identification:

4.1 Scope:

This document covers all aspects of Users requirements for the Equipment/Instrument along with all Attachment, Spare Parts, Change Parts and Accessories to be used in ……

Scope incorporates understanding and documentation of critical requirements such as system requirements, cGMP requirements, safety requirements, documentation requirements and operational requirements.

4.2 Purpose:

For the filling of Dry powder injection in sterile filling area.

5.0 USER REQUIREMENTS

5.1 System Requirements:

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
1.	Identification (In case of Equipment /Instrument)	Details of Make, Name, Serial. No., Capacity, Model and Year of manufacture should be available
2.	Model/Type	High speed injection powder filling with rubber stoppering machine**.** Confirming to current CGMP requirements.
3.	Capacity	7.5 ml to 30 ml molded & tubular vials with Minimum speed 300 vials/ minute
4.	Potential Suppliers	1.Ambica 2.N.K.P pharma
5.	Contact parts (In case of Equipment)	SS316L with mirror finish
6.	Non contact parts (In case of Equipment)	SS304 with mirror finish
7.	Non metallic contact parts (In case of Equipment /Instrument)	1. Any material with food grade quality having no Potential impact on the products. 2. Durable. 3. Must be easily cleanable.
8.	Motor & Electrical installations (In case of Equipment /Instrument)	Machine should be operated through PLC mounted on separate electrical control panel.
9.	Machine assemblies (In case of Equipment /Instrument)	Must be covered with SS 304 with mirror finish.
10.	Machine adjustments (In case of Equipment /Instrument)	Setting with Zero clearance with good accuracy.
11.	Packaging & Transport	Should be packed and transported in such a way to avoid any damage during transportation.
12.	No. of requirements	01
13.	Requirements for any power failure backup's (In case of Equipment /Instrument)	To be backed up by installed in-house DG set. After any power failure PLC show continuous counting of all filled & sealed vials.
14.	Gear box specifications(In case of Equipment /Instrument)	As per cGMP model

5.2 Technical Description

S.No.	SPECIFICATION	SYSTEM REQUIREMENTS
1.	Machine should be operated through PLC.	YES
2.	21 CFR part 11 compliant software	YES
3.	Machine should be provided vial inspection table with vial counter.	YES
4.	Double track for filling operation	YES
5.	Double 12 port powder wheel & double primary & secondary hopper.	YES
6.	Port cleaning system (purging unit)	YES
7.	Multiple dosing system (up to maximum 4 dose in one track)	YES
8.	Media filling system (with 2 nos. of standard S.S syringes -10 ml, 30 ml)	YES
9.	Pre & post gassing system	YES
10.	Machine should be provided vial inspection table with vial counter.	YES
11.	Double track for filling operation	YES

6.0 COMPLEMENTARY ASPECTS

6.1 Training

S.No.	Specification	SYSTEM REQUIREMENTS
6.1.1	The vendor Shall supply all available information for the adequate exploitation of equipment. For the Compliance of this purpose at the Job site and/ or at the Vendors Shop. Vendor's technical staff shall train customer's personnel. The scope of the Training will be agreed during the contract signature.	YES
6.1.2	The supplier is to include the personnel training activities. The contractor is to specify the foreseen time for: • Operator/Supervisor training • Manager Training • Electrical maintenance training • Mechanical Maintenance training	YES
6.1.3	The contractor is to specify the personnel background needed for each of the operators maintenance.	YES

6.2 Pre Delivery Qualifications (FAT)

S.No.	Specification	SYSTEM REQUIREMENTS
6.2.1	The System or its parts as provided for in the scope of supply shall be pre-installed at the vendors shop prior to delivery to customer site. Installation will be completed and documented including mechanical parts as well as electrical connections of all parts to facilitate taking over tests at Vendors shop prior to delivery.	YES

6.3 Supplier Technical Documentation Requirements:

S.No.	COMPONENTS	REQUIREMENTS
6.3.1	**Drawings** • Equipment/Systems electrical drawing. • Point to point wiring diagram	Pre Installation Requirements will be supplied by Vendor
6.3.2	**LIST.** • Equipment and instrument list with Component description. • Electrical component parts list with Description. • Function check list. • Documentation list. • Spare part list	YES YES YES YES List of spares required for smooth operation will be provided by the Vendor at the time of ordering.

6.4 Technical Manuals

S.No.	Specification	Requirements
6.4.1	Operating handbook	YES
6.4.2	Trouble Shooting Guide	YES
6.4.3	Equipment Description	YES
6.4.4	Equipment specification	YES
6.4.5	Calibration Instruction	YES
6.4.6	Maintenance Instruction	YES
6.4.7	Maintenance Handbook	YES

7.0 SAFETY AND ENVIRONMENTAL PROTECTION

S.No.	Specification	Requirements
7.1	Alarm for without filled vials	YES
7.2	All motors have to be thermally Protected.	YES
7.5	All the Installation must be in accordance with the cGMP.	YES
7.6	The cGMP concerning safety must be applied.	YES
7.7	Safety interlock- • Emergency stop button should be provided in the control panel. • No vial – No filling conveyor stop. • No powder – filling stop. • Fill weight low / high from set value – Filling stop. • Nitrogen pressure low from set value – Filling stop • Vacuum low from set value – Filling stop • Sleeping vial coming – machine stop	YES

8.0 CLEANING MAINTENANCE AND SERVICE

S.No.	Specification
8.1	In accordance with cGMP guidelines the units must be easy to clean, to disinfect, and where necessary, to sterilize.
8.2	The Supplier should guarantee that, if required, a service team can be on site within one working day.
8.3	The design should be such as to allow mechanical cleaning of the surface and that the cleanliness of the surface can be checked easily.
8.4	All machine parts, in particular instrumentation, should be constructed so that they can be easily removed and calibrated.
8.5	All special tools required for running and maintenance should be best.
8.6	A spare parts delivery guarantee with in time.

9.0 RULES AND REGULATION

These standards, recommendation and requirements are considered the minimum. Specifications that are more stringent or expansive take the precedence. In case of conflict between published requirements, final determination is the responsibility of the Owners Representative.

10. SCOPE OF DELIVERY

S.No.	Specification	Requirements
10.1	Units described in the specific system requirements including all necessary controls and instrumentation.	YES
10.2	The complete mechanical and electrical installation.	YES
10.3	The Connections to all the necessary utilities, exhaust, and waste lines necessary for its operation.	Yes
10.4	All piping and cabling of the units itself.	YES
10.5	Wiring and cable run…… will supply the main power switches to be located in correspondence to the electrical and control cabinets delivered by the equipment supplier.	YES
10.6	All internal contacts of the supplied equipment for the required utilities.	YES
10.7	Unload on site of the equipment: the supplier is required to define all the necessary handling devices required to the unloading operation. The supplier will inform at least 4 weeks in advance the day of delivery and the list of required handling devices.	YES
10.8	Assembling operation: the required consumable, the internal transportation, the assembling tools and the required personal are part of the supply.	YES
10.9	A complete set of commissioning spare parts.	YES
10.10	All special tools necessary for use and maintenance of the supplied equipment.	YES
10.11	A complete set of two years spare parts should be listed quoted and offered as option.	YES
10.12	All test activities as specified in this document.	YES
10.13	Training in the use and maintenance of the equipment.	YES
10.14	A complete set of documentation as specified in this document.	YES

11.0 INSTALLATION, COMMISSIONING AND TESTS

11.1 General

S.No.	Specification	Requirements
11.1.1	The Contractor must specify for each piece of equipment the Guaranteed performance and the guaranteed system performance. These values will be tested during the acceptance tests.	YES
11.1.2	In addition the functionality described in the user requirements and detailed in the system specifications will be tested.	YES

11.2 INSTALLATION, COMMISSION

S.No.	Specification	Requirements
11.2.1	The commissioning tests will be carried out in accordance with a written test plan developed by the supplier with clearly stated test procedures and acceptance criteria.	YES
11.2.2	The contractor will approve successfully completed tests and will specify items requiring additional work. Representatives from …….will attend and participate in the commissioning tests as required.	YES
11.2.3	The installation and commissioning of the system will be performed at the ……facility by the contractor.	YES
11.2.4	The commissioning can only start once all the foreseen documents have been delivered by the supplier to …….	YES
11.2.5	All equipment should be properly installed, adjusted, leveled, tagged, and connected with utilities.	YES
11.2.6	Point to point checks on wiring and pneumatic should be performed.	YES
11.2.7	All instruments should be properly calibrated.	YES
11.2.8	A equipment (instrument) used for qualification must be listed and approved by ……..	YES
11.2.9	The calibration equipment must have all the necessary documents to demonstrate their maintenance & use.	YES
11.2.10	The last calibration of all this equipment must be less than 6 months old, and evidenced by certificate.	YES

S.No.	Specification	Requirements
11.2.11	Verification that the interior surfaces of equipment are free of practices and dirt and all points of product contact meet the specified material requirements.	YES
11.2.12	All the clearances and tolerances specified in the drawing or recommended by component manufacturers are correct.	YES
11.2.13	On site verification that valves and other equipment with moving parts are in their normal position if in a power down condition and move in the correct direction with the correct speed and precision.	YES
11.2.14	Verification that all the Input and Output points are connected and labeled according to the documentation and that all the along the input values have been scaled in accordance with the system specification and process requirements. That all equipment components requiring configuration	YES
11.2.15	The commissioning should demonstrate that the system supplied by the contractor has been properly installed and that the functions are in accordance with …….. User Requirements specifications, Vendors System specifications Manuals and other Documentation.	YES

11.3 Site Acceptance Test (SAT)

S.No.	Specification	Requirements
11.3.1	This test will be carried out once the commissioning will be completed. The scope will be to verify the performance and the functionality of the system integrated with the other factory systems (Including sterility testing of at least 02 days).	YES
11.3.2	The test will be carried out to verify the system response with the expected productivity of the system.	YES
11.3.3	Details on the test realization will be defined during the project Phase. The supplier is asked to specify the proposed duration for SAT and the standard procedure proposed.	YES
11.3.4	During SAT the required functionality, performances and system reliability are met.	YES
11.3.5	The Functionality described in the User Requirements Specification and in the System Specifications are verified and met.	YES
11.3.6	All the documentation agreed has been delivered.	YES

12.0 QUALIFICATION/VALIDATION

S.No.	Specification	Requirements
12.1	The maintenance Qualification is responsibility of the customer. However, the supplier is responsible for delivering the basic documents for maintenance qualification.	YES
12.2	This includes all side costs such as: calibration measuring equipment and instruments: manpower (IQ and OQ will take place completely on …….)	YES
12.3	Time Schedule for IQ/OQ execution will be developed by ….. With the supplier.	YES
12.4	Suppliers personnel used for IQ/OQ must be well trained and experienced. This should be documented.	YES
12.5	The onsite test run performed by the supplier might become part of the IQ.	YES
12.6	Main IQ/OQ steps such as calibration must be performed and documented in accordance to a SOP approved by ……	YES
12.7	All equipment used for qualification must be listed and approved by ……. The calibration equipment should be well documented.	YES
12.8	The last Recalibration of all this equipment should be less than 06 month old. Proofed by Certificate.	YES
12.9	OQ can only start after IQ approved by …….	YES
12.10	IQ will be carried out by ……. During Installation phase. IQ will include the tests performed by the contractor.	YES
12.11	Part of the OQ will be carried out by …….. During commissioning and SAT phase. OQ will include the tests performed by the contractor.	YES
12.12	After installation of the equipment at customers site. Complementary IQ & OQ tests will be performed by the Customer and may be supervised by a member of Technical staff.	YES
12.13	Qualification documents (In case of equipments/Instruments)	DQ, IQ, OQ & PQ

13.0 GAURANTEE/WARRANTEE

S.No.	Specification	Requirements
13.1	The System must be guaranteed including all the sub- system and components for a period of 12 months from the date of the system acceptance for a 03- shift operation.	YES
13.2	The servicing companies involved for the Sub- systems maintenance must be declared and the maintenance group organization described. Furthermore, the contractor will be directly responsible of the system assistance and the required operation will be co- ordinate by him.	YES
13.3	In case of failures, the intervention will be guaranteed by the contractor within a maximum time limit. The contractor is asked to specify the maximum time limit.	YES
13.4	The supplier is asked to propose as option maintenance and assistance contract after the guarantee expiration.	YES