DESIGN QUALIFICATION

NAME OF THE ITEM: Dose Measure Fixing Machine

FUNCTIONAL AREA: Production Block

PROTOCOL No. :

CONTENT

1.0 PROTOCOL APPROVAL:

Protocol Prepared By:

Functional area	Name	Signature	Date
Engineering			

DQ Reviewed By:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality Assurance			

DQ 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.

3.1 Preparation of Document

- User department to prepare the DQ.
- 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 DQ.

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: Dose Measure Fixing Machine.

4.2 Purpose: Purpose of equipment is to carry out the fixing of dose measuring cup on the bottles.

4.3 SYSTEM DESCRIPTION

Automatic Dose Measure Fixing machine is versatile self-supported on stainless steel leg with height adjustment system. The machine is precision equipment on sturdy welded steel frame completely enclose in stainless steel sheet and doors are provided to facilitate to servicing of the machine. The containers moving on conveyor belt are diverted to the Center Turret. The Center turret has slots on its periphery to match with the bottle size. The center turret is rotating Continuously. The bottle enters in to the center turret and is carried between the turret and the Bottle guide. The bottle then passes under the cup chute trap where the cups are kept with Mouth down inclined position. The bottle picks up the cup from the cup trap. The cups are Oriented in the cup orienter, the oriented cups are moved to the cup trap thru' the cup chute. The bottle passing under the cup trap picks up the cup. The bottle with loosely held cup passes Under the cup pressing head. The 1st roller of the cup pressing head drives the cup half way on The cap. The 2nd roller presses the cup fully on the cap. The bottle with cup fixed on the top then moves further with the center turret and then on the exit side of the conveyor. This Completes the dose measure cup fixing operation.

5.0 USER REQUIREMENTS

5.1 System Requirements:

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
1	Identification (In case of Equipment /Instrument)	Dose Measure Fixing machine
2	Model/Type	DMR
3	Capacity	Max. 240 bottles per minute.
4	Potential Suppliers	JP machine Tools
5	Non-contact parts (In case of Equipment)	SS304 with matt finish
6	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.
7	Motor & Electrical installations (In case of Equipment /Instrument)	Machine should be operated through mounted on electrical control panel.
8	Machine assemblies (In case of Equipment /Instrument)	Must be covered with SS 304
9	Machine adjustments (In case of Equipment /Instrument)	Setting with Zero clearance with good accuracy.
10	Packaging & Transport	Should be packed and transported in such a

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
		way to avoid any damage during transportation.
11	No. of requirements	01
12	Requirements for any power failure backup's (In case of Equipment /Instrument)	To be backed up by installed in-house DG set.
13	Gear box specifications(In case of Equipment /Instrument)	As per cGMP model
	Machine specification	
14	Operation	Automatic with Manual operation facility during PLC failure
15	Door Position	Vertical Transparent Acrylic. Magnetic door switches to sense door open
16	Control System	·Enclosure : SS304

Verified By & date:

5.2 Technical Description

Sr. No.	Heading	Specification
1	Application	Dose Measuring cup fixing on bottles with cGMP norms.
2	Machine dimensions	2150L x 1100W x 2090mm(H)
3	Capacity	Max. 240 bottle per minute.
4	Drive motor	Make: HAVELLS, HP:-1, RPM:- 1390
5	Gearbox	Make: Chamunda, Ratio: 20:1 ratio , FLANGE mounted
6	Orienter geared motor	Make: Newteck , H.P:- 0.25, RPM:-40, flange mounted
7	Cup Pressing head assly	MOC : SS-304, plastics
8	Center turret and Bottle Guide	Rotating star wheel for movement of bottles MOC- UHMWPE
9	Cup feeder	Cup orienter device MOC: Al. + SS-304
10	Chute	To convey & place the cup to the cup trap. MOC : SS-304

Sr. No.	Heading	Specification
11	Cup level detector in the chute.	Make: Shiva Electronics. Photo Sensor- PNP/NO
14	Conveyor chain	MOC: SS-304
15	Leveling bolt	5/8" BSW x3" long MOC-SS-304

Verified By & date:

5.3 MATERIAL OF CONSTRUCTION:

Sr. No.	DESCRIPTION	MOC SPECIFIED
1.	Cup Pressing head assly	MOC : SS-304, plastics
2.	Center turret and Bottle Guide.	MOC- UHMWPE
3.	Cup feeder	MOC: Al. + SS-304
4.	Chute	MOC : SS-304
5.	Conveyor chain	MOC: SS-304

5.4 Utility Details:

Sr.No.	Utility	Supply
1.	Electrical Supply	Phase: 3 Phase, Voltage: 415 V AC, Frequency: 50 Hz
2.	AIR SUPPLY	CONSUMPTION: COMPRESSED AIR @ 6kg/cm2, free air, QUALITY: Oil, water & dust free. Flow pressure : 4 kg/ cm^2

Verified By & date:

6.0 COMPLEMENTARY ASPECTS

6.1 Training

Sr. No.	Specification	SYSTEM REQUIREMENTS
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
2	The supplier is to include the personnel training activities. The supplier is to specify the foreseen time for: • Operator/Supervisor training • Manager Training • Electrical maintenance training • Mechanical Maintenance training	YES

6.2 Pre Delivery Qualifications (FAT)

Sr. No.	Specification	SYSTEM REQUIREMENTS
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:

Sr. No.	COMPONENTS	REQUIREMENTS
1	Technical Documents	FAT,IQ,OQ Electrical Drawing P & ID diagram GA diagram Calibration certificates of instruments Hydro test certificates Bought out components detail and certificates MOC certificates

6.4 Technical Manuals

Sr. No.	Specification	Requirements
1.	Operation manual 01 copy	

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7.0 SAFETY AND ENVIRONMENTAL PROTECTION

Sr. No.	Specification	Requirements
1.	Environment	NA
7.1 Safety features.		
1	Door	• Both the Doors do not open concurrently • Doors do not open until the required temperature in the chamber is attained • Doors do not open during the process. • Doors do not open until room pressure is attained in the chamber
2	Emergency off	• Machine should stop immediately.
3	Operational Safety	• Emergency off • Air Pressure low • Power failure • Door open

7.2 List of Audio/Visual Alarms and Interlocks

Sr. No.	List of alarms	Results
1	Emergency	Alarm sounds HMI displays "Emergency"
2	Air Pressure low	Alarm sounds HMI displays "Air Pressure Low"
3	Power Failure	Alarm sounds HMI displays "Power failure" It restarts

Verified By & date:

8.0 CLEANING MAINTENANCE AND SERVICE

Sr. No.	Specification
1.	In accordance with cGMP guidelines the units must be easy to clean, to disinfect, and where necessary.
2.	The Supplier should guarantee that, if required, a service team can be on site within one working day.
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.
4	All machine parts, in particular instrumentation, should be constructed so that they can be easily removed and calibrated.
5	All special tools required for running and maintenance should be best.
6	A spare parts delivery guarantee with in time.

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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

Verified By & date:

10. SCOPE OF DELIVERY

Sr. No.	Specification	Requirements
1.	Units described in the specific system requirements including all necessary controls and instrumentation.	YES
2.	The complete mechanical and electrical installation.	YES
3.	The Connections to all the necessary utilities, exhaust, and waste lines necessary for its operation.	Yes
4.	All piping and cabling of the units itself.	YES
5.	Wiring and cable run: all wiring and cable run is part of the supply. Pharma Devils will supply the main power switches to be located in correspondence to the electrical and control cabinets delivered by the equipment supplier.	YES
6.	All internal contacts of the supplied equipment for the required utilities.	YES
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
8.	Assembling operation: the required consumable, the internal transportation, the assembling tools and the required personal are part of the supply.	YES
9.	A complete set of commissioning spare parts.	YES
10.	All special tools necessary for use and maintenance of the supplied equipment.	YES
11.	A complete set of two years spare parts should be listed quoted and offered as option.	YES
12.	All test activities as specified in this document.	YES
13.	Training in the use and maintenance of the equipment.	YES
14.	A complete set of documentation as specified In this document.	YES

Verified By & date:

11.0 INSTALLATION, COMMISSIONING AND TESTS

11.1 General

Sr.No.	Specification	Requirements
1.	The Supplier 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
2	In addition the functionality described in the user requirements and detailed in the system specifications will be tested.	YES

11.2 INSTALLATION, COMMISSION

Sr. No.	Specification	Requirements
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
2	The supplier will approve successfully completed tests and will specify items requiring additional work. Site persons will attend and participate in the commissioning tests as required.	YES
3	The installation and commissioning of the system will be performed at the site. Facility by the supplier.	YES
4	The commissioning can only start once all the foreseen documents have been delivered by the supplier to site.	YES
.5	All equipment should be properly installed, adjusted, leveled, tagged, and connected with utilities.	YES
6	Point to point checks on wiring and pneumatic should be performed.	YES
7	All instruments should be properly calibrated.	YES
8	An equipment (instrument) used for qualification must be listed and approved by site.	YES
9	The calibration equipment must have all the necessary documents to demonstrate their maintenance & use.	YES
10	The last calibration of all this equipment must be less than 6 months old, and evidenced by certificate.	YES
11	Verification that the interior surfaces of equipment are free of	YES

Sr. No.	Specification	Requirements
	practices and dirt and all points of product contact meet the specified material requirements.	
12	All the clearances and tolerances specified in the drawing or recommended by component manufacturers are correct.	YES
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
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
15	The commissioning should demonstrate that the system supplied by the supplier has been properly installed. User Requirements specifications, Vendors System specifications Manuals and other Documentation.	YES

11.3 Site Acceptance Test (SAT)

Sr. No.	Specification	Requirements
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.	YES
2	The test will be carried out to verify the system response with the expected productivity of the system.	YES

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12.0 QUALIFICATION / VALIDATION

Sr.No.	Specification	Requirements
1.	The maintenance Qualification is responsibility of the customer. However, the supplier is responsible for delivering the basic documents for maintenance qualification.	YES
2.	This includes all side costs such as: calibration measuring equipment and instruments: manpower (IQ and OQ will take place completely at site).	YES
3	Time Schedule for IQ/OQ execution will be developed with the supplier.	YES
4	Suppliers personnel used for IQ/OQ must be well trained and experienced. This should be documented.	YES
5	The onsite test run performed by the supplier might become part of the IQ.	YES
6	Main IQ/OQ steps such as calibration must be performed and documented in accordance to a SOP.	YES
7	All equipment used for qualification must be listed and approved.	YES
8	The last Recalibration of all this equipment should be less than 06 month old. Proofed by Certificate.	YES
9	OQ can only start after IQ approved.	YES
10	IQ will be carried out by site. During Installation phase. IQ will include the tests performed by the supplier.	YES
11	Part of the OQ will be carried out by site. During commissioning and SAT phase. OQ will include the tests performed by the supplier.	YES
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
13	Qualification documents (In case of equipments/Instruments)	DQ, IQ, OQ,MOC and Test certificate

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13.0 GAURANTEE/WARRANTEE

Sr.No.	Specification	Requirements
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
2	The servicing companies involved for the Sub- systems maintenance must be declared and the maintenance group organization described. Furthermore, the supplier will be directly responsible of the system assistance and the required operation will be co- ordinate by him.	YES
3	In case of failures, the intervention will be guaranteed by the supplier within a maximum time limit. The supplier is asked to specify the maximum time limit.	YES
4	The supplier is asked to propose as option maintenance and assistance contract after the guarantee expiration.	YES

Verified By & date:

14.0 Deviation

15.0 Annexure

16.0 Summary and Conclusion

17.0 Approval of Design Qualification.

	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

18. Acceptance By vendor

Name of Vendor:

Sign/Date: