



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL  
FOR  
BOTTLE LOADER MACHINE**

**PROTOCOL No.:**

# **DESIGN QUALIFICATION**

**NAME OF THE ITEM: BOTTLE LOADER MACHINE**

**FUNCTIONAL AREA: PRODUCTION BLOCK**

**PROTOCOL No.:**



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**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			



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**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.

**2.0 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 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:** Bottle Loader Machine

**4.2 Purpose:** Purpose of equipment is to carry out the loading of bottles in turn table.

**4.3 SYSTEM DESCRIPTION**

In this equipment one cylinder, solid oil valves are fitted. The working of equipment to lift the bottle up and down.

**5.0 USER REQUIREMENTS**

**5.1 System Requirements:**

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
1	Identification (In case of Equipment /Instrument)	Bottle Loader Machine
2	Model/Type	cGMP
3	Capacity	1000 bottles at a time
4	Potential Suppliers	JP machine Tools
5	Contact parts (In case of Equipment)	SS-304 with matt finish
6	Non contact parts (In case of Equipment)	SS-304 with matt finish
7	Non metallic contact parts (In case of Equipment /Instrument)	Any material with food grade quality having no potential impact on the products.  Durable.



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S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
		Must be easily cleanable.
8	Motor & Electrical installations (In case of Equipment /Instrument)	Machine should be operated through PLC mounted on electrical control panel.
9	Machine assemblies (In case of Equipment /Instrument)	Must be covered with SS-304
10	Machine adjustments (In case of Equipment /Instrument)	Setting with Zero clearance with good accuracy.
13	Packaging & Transport	Should be packed and transported in such a way to avoid any damage during transportation.
14	No. of requirements	01
15	Requirements for any power failure backup's (In case of Equipment /Instrument)	To be backed up by installed in-house DG set.
16	Gear box specifications(In case of Equipment /Instrument)	As per cGMP model
	Machine specification	
17	Operation	Manual operation facility
18	Door Position	Vertical Transparent Acrylic. Magnetic door switches to sense door open
19	Control System	<input type="checkbox"/> Enclosure : SS-304

**Verified By & date:**

**5.2 Technical Description**

S.No.	Heading	Specification
1	Application	Load the bottles desired quantity with cGMP norms.
2	Machine dimensions	2440L x 1320W x 2090mm(H)
3	Capacity	1000 bottles at a time
4	M/C Frame	MOC : SS-304

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**5.3 MATERIAL OF CONSTRUCTION:**

S.No.	DESCRIPTION	MOC SPECIFIED
1	Covers	SS-304
2	Table Top	SS-304
3	M/C Frame	SS-304

**5.4 Utility Details:**

S.No.	UTILITY	SUPPLY
1.	AIR SUPPLY	CONSUMPTION: COMPRESSED AIR @ 4kg/cm <sup>2</sup> , 200LPM free air, QUALITY: Oil, water & dust free. PRESSURIZED AIR Due point -20 Deg. C or lower. Flow pressure : 6 kg/ cm <sup>2</sup>

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**6.0 COMPLEMENTARY ASPECTS**

**6.1 Training**

S.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: <ul style="list-style-type: none"><li>• Operator/Supervisor training</li><li>• Manager Training</li><li>• Electrical maintenance training</li><li>• Mechanical Maintenance training</li></ul>	YES

**6.2 Pre Delivery Qualifications (FAT)**

S.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



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**6.3 Supplier Technical Documentation Requirements:**

S.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**

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

**Verified By & date:**

**7.0 SAFETY AND ENVIRONMENTAL PROTECTION**

S.No.	Specification	Requirements
1.	Environment	NA

**7.1 Safety features.**

1.	Air On/Off	Stop moving.
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**8.0 CLEANING MAINTENANCE AND SERVICE**

S.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:**

S.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. .... 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

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**11.0 INSTALLATION, COMMISSIONING AND TESTS**

**11.1 General**

S.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**

S.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 ..... will attend and participate in the commissioning tests as required.	YES
3	The installation and commissioning of the system will be performed at the ..... Facility by the supplier.	YES
4	The commissioning can only start once all the foreseen documents have been delivered by the supplier to .....	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	A equipment (instrument) used for qualification must be listed and approved by .....	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 practices and dirt and all points of product contact meet the specified material requirements.	YES
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	YES



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S.No.	Specification	Requirements
	configuration	
15	The commissioning should demonstrate that the system supplied by the supplier 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
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**

S.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 on .....	YES
3	Time Schedule for IQ/OQ execution will be developed by ..... 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 approved by .....	YES
7	All equipment used for qualification must be listed and approved by ..... The calibration equipment should be well documented.	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 by .....	YES
10	IQ will be carried out by .....during Installation phase. IQ will include the tests performed by the supplier.	YES
11	Part of the OQ will be carried out by .....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**

<b>S.No.</b>	<b>Specification</b>	<b>Requirements</b>
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

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**14.0 Deviation**

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**15.0 Annexure**

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**16.0 Summary and Conclusion**

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**17.0 Approval of Design Qualification.**

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

**18.0 Acceptance By vendor**

Name of Vendor:

Sign/Date: