



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
HYDRAULIC LIFTING AND POSITIONING DEVICE
(500 Ltrs.)**

PROTOCOL No.:

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1.0 Pre-Approval:

Signing of this Approval page of Design Qualification Protocol No. 01 indicates agreement with the Design approach described in this document. Should Modifications to the Design Qualification become necessary, an addendum will be prepared and approved.

Written By	Signature	Date

Approved By	Signature	Date



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2.0 Overview:

2.1 Objectives

To design, engineer, and supply the HYDRAULIC LIFTING & POSITIONING DEVICE, as per cGMP guidelines, to be used for LIFTING OF IPC BINS OF 300 LTS MAX.

2.2 Scope

The design of the HYDRAULIC LIFTING & POSITIONING DEVICE shall cover the lifting capacity of the bins of product with different nature by mounting IBC BIN of 300 lts capacity in the Machine Arm.

2.3 Responsibilities

Client:

1. To provide the URS for the equipment.
2. To perform the Factory Acceptance test (FAT).



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Manufacturer:

To design, engineer and provide the complete technical details of the equipment pertaining to its design qualification viz.

1. Machine overview,
2. Equipment orientation with layout,
3. Specifications of the sub-components/ bought out items, and their make, model & quantity, and backup records/ brochures,
4. Details of Utilities,
5. Identification of components for calibration
6. Material of construction of all components
7. Brief process description
8. Safety features.
9. Pre-installation requirements
10. To facilitate the client for the Factory acceptance test of the Machine at their works/ site.
11. To confirm the safe delivery of the equipment to the user site.
12. To ensure that no un-authorized or unrecorded design modifications shall take place. If any point of time, any change is desired in the agreed design, change control procedure shall be followed and documented.



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2.4 User requirements specifications (URS):

DESCRIPTION	SPECIFICATIONS
Model	The equipment should be a cGMP compliant model. And the model no:- SI-500/010/2018-19
Required Output & Configuration	Container Volume. 300 LTS.
Process	Equipment should be able to perform all the process of LIFTING & POSITIONING smoothly.
Sizes	The equipment should be able to handle the 300 lts sizes of containers.
Calibration	All components, which require calibration, shall be identified and calibrated. Calibration certificates to be provided at the time of Installation qualification.
Qualifications	The manufacturer shall complete and provide the documents pertaining to Design, Operation & performance Qualification.
Safety features	Adequate Safety features in machine for men and material shall be provided along with the equipment.
Electrical system	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards.



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2.5 Machine Description

This is a lifting and positioning device, lifting is done by using hydraulic energy to perform the required function of lifting and positioning the containers mounted on the arm of the machine.

General Description of Machine Parts-

- **Bin**

- 1) Shell-The shell consist of a square central part with conical frustums at one ends. This cone is provided with a butterfly valve, which is used to discharge a powder.
- 2) Top is square in shape and has a welded lid (manhole) from the top. The manhole is provided with an air tight cover & Gasket.
- 3) Discharge- A manually operated butterfly valve is provided at the bottom for discharge.
- 4) Mounting – The bin is provided with independent trolley to facilitate the bin loading and unloading in the arm.

Lifting Device.

- 1) Two 'C' frame structures are used to build a column. Column frame is connected with each other by top & bottom Plate. The column is then connected at the base on a revolving circle mounted on a thrust bearing. The circle is connected on the base plate. A hydraulic cylinder having stroke 1400 mm & 63 bore is mounted inside the column to support the inside carriage, connected by chain and sprocket assy .Inside carriage is connected to outside carriage, the outside carriage holds the bin arm.
- 2) Lifting Arrangement- A system mounted on the hydraulic cylinder head lift the bin arm with a heavy designed carriage. The bin arm is mounted on a box inside the column which is guided by the bearing in a channel on two opposite sides inside the column.
- 3) Power pack- An MS powder coated tank act as the oil reservoir and also support the hydraulic circuit. The hydraulic power pack unit consist of a single gear pump coupled to flange mounted 3 phase electric motor suitable capacity with suitable bell housing and gear coupling.



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The pressure is controlled by 2 relief valves.
Two relief valve controls the high maximum allowable pressure and return pressure of pump.

Both relief valve are direct operated.
A pilot operated check valve is provided to lock the pressure in the cylinder so that it will not come down when not desired.

A solenoid operated direction control valve controls the cylinder movements upwards as well as downwards. This is operated by a press down push button.

The power pack will be placed on the service floor at a horizontal/vertical distance of 12 to 15 metres.

Y piece.

A "Y" shape connection is made to discharge the material in two charging ports of the compression machine.

Platform.

A sturdy platform is made and installed on the machine, to allow the y piece & the IPC bin to rest on it.



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3.0 Identification of major Parts:

S.No.	Item	Part Description	Part Material
1.	Contact Parts IPC	Shell, Cone,	SS 316L
		Top, Valves	
		Lid	
		TC	
2.	Non contact Exposed Parts	Clamps	SS 304
		Trolley	
		Bin holding ARM' covers	
		Column covers	
3.	Non-Contact Internal Parts Lifting Device	Base plate Covers, Break paddle and assy	MS/S.S 304 cladded
		Column	
		Base plate	
		Revolving circle.	
4.	Elastomers in Contact with material	Inside carriage Chain sprocket	Food Grade Silicon.
		Valve Gasket	
4.	Elastomers in Contact with material	Lid Gasket,	PVC 2 mm
5.	Elastomers not in Contact with material	Front Curtain	Food Grade Silicon



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4.0 Technical specifications of sub components/ bought outs

S.No.	Particulars	Specifications
1	Power Pack Motor 2 HP (1)	
	Type	Flange Mounted
	HP	2 HP
	RPM	1440 RPM, 415 V
	Others	NON FLP
Sr. No.		
2	Discharge Valve	
	Type	Butterfly
	Size	Dia. 8 inch & 4 inch
	MOC	SS 316
3	Proximity Sensor 2 nos.	
	Make	Hi- Tech Electronic System
	Size	30 mm OD --3 NO



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5.0 Details of Utilities.

Power input 3 phase 415V, 50 Hz

Total Power Consumption 1.5 HP

Detection / Safety Features:

1. Thorough gasket ruled at any opening in the bin preventing leakage of process material.
2. Fuse arrangement for any uncontrolled supply of electricity.
3. Complete enclosure of running or moving parts by an arrangement of cover, other than IBC Bin.

6.0 Identification of components for calibration

In machine, following are the instruments which needs calibration and is carried out during installation of the instruments on the plant:

1. No Parts for Calibration.



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7.0 Material of construction

S.No.	Item	Part Description	Part Material
1.	Contact Parts IPC	Shell	SS 316L
		Cone	
		Top	
		Valves	SS 316L
		Lid	
		TC	
2.	Non contact Exposed Parts	Clamps	SS 304
		Trolley	
		Bin holding ARM'	
		Column covers	
		Base plate Covers Break paddle and assy	
3.	Non-Contact Internal Parts Lifting Device	Column	MS/S.S 304
		Base plate	Cladded
4.	Elastomers in Contact with material	Valve Gasket	Food Grade
		Lid Gasket	Silicon
5.	Elastomers not in Contact with material	Front Curtain	PVC 2mm



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8.0 Brief Process Description:

Operation:

This is a Hydraulic device. Its function is to lift a bin of capacity 300 lts from the ground level to the require height and place it on the platform.

Lifting Stage- The bin to be lifted is to be brought near the Bin lifting arm, ensure that the arm is below the lifting point & the machine is locked in position from behind. Once the bin is loaded on the arm the machine up switch should be pressed to start lifting. The arm will raise until the bin reaches the desired height and the top position sensor detects the position.

Position Stage- Open the lock from behind by pressing the break paddle downwards. This will allow the column to rotate and lock itself at the desired position after rotation. Check that the locking is done properly.

Discharge Stage- The bin will be placed on the platform for gravitational discharge and discharged directly to the tablet process through 4” butterfly valve via Y shoot.



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9.0 FAT PROCEDURE:

Factory Acceptance Test Procedure shall be as follows:

After the completion of the work of the machine, client shall be informed to perform the factory acceptance test (FAT).

Client shall perform the FAT at the manufacturer site and record all the data in the prescribed FAT document as per the details given below:

1. Test criteria
2. Design Verification Check list
3. Deficiency & Corrective Action report
4. Pre-installation requirements
5. Final report

10.0 CHANGE CONTROL PROCEDURE:

Change in the agreed design shall be addressed through the well-defined change control procedure.



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11.0 Deficiency (if any) and Corrective Action Report

If there is no deficiency, then write N. A.

Description of deficiency:

Corrective actions to be taken:

Documents and Procedures provided were found unto acceptance criteria.

12.0 Remarks (if any):



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13.0 Summary:

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Name	Signature	Date