



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL  
CUM REPORT  
FOR  
LIFTING & POSITIONING DEVICE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
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<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PRE – APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



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**2.0 OBJECTIVE:**

- To prepare the Design Qualification document for Lifting & Positioning Device on basis of URS and information given by Supplier and as per cGMP guidelines, to be used for lifting of IPC bins of 300 liter max.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification of Lifting & Positioning Device (**Make: .....**).
- The equipment shall cover the lifting capacity of the bins of product with different nature by mounting IPC bin of 300 liter capacity in the Machine Arm.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Initiation, Authorization and Approval of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Qualification Protocol cum Report after Execution.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Post Approval of Qualification Protocol cum Report after Execution</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of the Protocol cum Report.</li><li>• Assist in the Preparation of the Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none"><li>➤ GA Drawing</li><li>➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures.</li><li>➤ Details of utilities Required.</li><li>➤ Identification of components for calibration</li><li>➤ Material of construction of Product Contact Parts</li><li>➤ Brief Process Description</li><li>➤ Safety Features</li></ul></li><li>• Review of Qualification Protocol after Execution.</li></ul>



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**5.0 BRIEF EQUIPMENT 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 a 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 consists of a single gear pump coupled to flange mounted 3 phase electric motor suitable capacity with suitable bell housing and gear coupling.
- 4) 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 meters.



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**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.

**6.0 EQUIPMENT SPECIFICATION:**

Equipment Specifications are based on User Requirement Specification prepared. The manufacturer of equipment ensures complies with User Requirement Specification.

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 IDENTIFICATION OF MAJOR PARTS:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
Contact Parts	Shell, Cone,	Process Requirement
	Top, Valves	
	Lid	
	TC	
Non contact Exposed Parts	Clamps	Process Requirement
	Trolley	
	Bin holding ARM' covers	
	Column covers	
	Base plate Covers, Break paddle and assy	
Non Contact Internal Parts	Column	Design Requirement
	Base plate	
	Revolving circle.	
	Inside carriage Chain sprocket	
Elastomers in Contact with material	Valve Gasket	Process Requirement
	Lid Gasket,	
Elastomers not in Contact with material	Front Curtain	Process Requirement



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**7.2 TECHNICAL SPECIFICATIONS OF SUB COMPONENTS/ BOUGHT OUTS:**

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

**7.3 UTILITY DEATAIL AND SAFETY FEATURE:**

**Power input** 3 phase 415V, 50 Hz

**Total Power Consumption** 2 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 IPC Bin.

**7.4 IDENTIFICATION OF COMPONENTS FOR CALIBRATION:**

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

1. No Parts for Calibration.





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7.5 MATERIAL OF CONSTRUCTION:

S.No.	Item	Part Description	Part Material
1.	Contact Parts	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	Column	MS
		Base plate	
4.	Elastomers in Contact with material	Valve Gasket	Food Grade Silicon
		Lid Gasket	
5.	Elastomers not in Contact with material	Front Curtain	P.V.C 2mm

7.6 BRIEF PROCESS DESCRIPTION:

**Operation:** This is a Hydraulic device. Its function is to lift a bin of capacity 300 liters 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 rise 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.



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**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.

**7.7 VENDOR SELECTION:**

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Dust Extractor	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

**Reference:** (1) User Requirement Specifications (URS).  
(2) Design & Functional Specifications provided by Vendor.

**8.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

**9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):**

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**10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:**

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**11.0 RECOMMENDATION:**

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**12.0 ABBREVIATIONS:**

- URS : User Requirement Specification.
- cGMP : Current Good Manufacturing Practice
- Ltd. : Limited
- QA : Quality Assurance
- PO : Purchase Order
- mm : Millimeter
- SS : Stainless Steel
- MOC : Material of Construction
- GA : General Arrangement
- P & ID : Piping and Instrumentation Diagram
- STD : Standard
- LPD : Lifting & Positioning Device
- DQ : Design Qualification
- IPC : In-Process container
- HP : Horse power
- RPM : Resolution per minute
- V : Volt
- PVC : Poly vinyl chloride



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<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (ENGINEERING)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			

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<b>HEAD (QUALITY ASSURANCE)</b>			