INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR LIFTING & POSITIONING DEVICE

EQUIPMENT ID. No.	
LOCATION	**Compression**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR LIFTING & POSITIONING DEVICE	PROTOCOL No.:

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PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR LIFTING & POSITIONING DEVICE	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Lifting & Positioning Device.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Lifting & Positioning Device to be installed in the Compression.
- 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.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Lifting & Positioning Device.

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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Authorization, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution

5.0 EQUIPMENT DETAILS:

Equipment Name	Lifting & Positioning Device
Equipment	
Manufacturer's Name	Shefa Industries
Supplier's Name	Shefa Industries
Location of Installation	Compression

6.0 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 carrage, 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.

5) A pilot operated check valve is provided to lock the pressure in the cylinder so that it will not come down when not desired.

6) 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.

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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Compression		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
Sign & Date: ……

8.2 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
2	**Discharge Valve**	
	Type	Butterfly
	Size	Dia. 8inch & 4inch
	MOC	SS 316
3	**Proximity Sensor 2 nos**	
	Make	Hi- Tech Electronic System
	Size	30 mm OD --2 Nos.

8.3 Verification of Utility Supply

Objective: To verify that necessary utility supplies required for equipment operation are as per the desired specification and connected properly.

S.No.	Utility	Specifications	Observations (Comply/ Non Comply)
1.	**Power Input**	415 V, 3PH, 50Hz	
2.	**Total Power Consumption**	2 HP	

Checked By
Sign & Date: ……

8.4 INSTALLATION CHECKS:

S.No.	Specification	Observation	Observed By Sign & Date
1.	Check the proper mechanical installation of LPD.		
2.	Check the proper electrical installation of LPD.		
3.	Check the parts are working properly		
4.	Check the equipment is free from any defects		
5.	Check that all parts are getting lubricated		

Checked By
Sign & Date: ……

8.5 MOC VERIFICATION LIST:

S.No.	Machine Parts	Acceptance Criteria	Observation	Observed by (Engineering) Sign & Date
1.	Shell, Cone,	SS 316L		
2.	Top, Valves	SS 316L		
3.	Lid	SS 316L		
4.	TC	SS 316L		
5.	Clamps	SS 304		
6.	Trolley	SS 304		
7.	Bin holding ARM' covers	SS 304		
8.	Column covers	SS 304		
9.	Base plate Covers, Break paddle and assy	SS 304		
10.	Column	MS		
11.	Base plate	MS		
12.	Revolving circle.	MS		
13.	Inside carriage Chain sprocket	MS		

Checked By
Sign & Date: ……

8.6 SAFETY:

Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Position switch	For a single level for attending the desired height.		
Proximity switches	For safe operation		
Drive elements	Fully covered or kept in separate area		
Overload relay for motors	Must be present in equipment		
Zero Leak valve for hydraulic system	Must be present in equipment		
Pressure relief valve for hydraulic system	Must be present in equipment		

Checked By
Sign & Date: ……

Inference:

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Reviewed By
Sign & Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates
- Operation and Maintenance Manual

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

URS	:	User Requirement Specification.
cGMP	:	Current Good Manufacturing Practice
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
IQ	:	Installation Qualification
IPC	:	In-Process container
HP	:	Horse power
RPM	:	Resolution per minute
V	:	Volt

17.0 POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
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