OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

LIFTING & POSITIONING DEVICE

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

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

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 PHARMA DEVILS	OPERATIONAL 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 verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Lifting & Positioning Device and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of Lifting & Positioning Device **(Make: …….)** 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 Protocol will define the methods and documentation used to perform OQ activity. Successful completion of this Protocol will verify that Lifting & Positioning Device meet all acceptance criteria and ready for Performance Qualification.

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 Operation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation 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 Operation 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:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for operating & Cleaning of LPD.
- Draft SOP for Preventive Maintenance of LPD.
- Electrical circuits diagram.
- Technical specification of equipment.

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 OQ 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 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By Sign & Date	Verified By Sign & Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Draft SOP for operation & Cleaning of LPD				
4.	Draft SOP for Preventive Maintenance of LPD				

8.2 Operational and Functional Checks:

Operate the Vibro Sifter as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

S.No	Function	Operation	Acceptance criteria	Observation
1.	Switch ON the mains from front panel	Connect the power supply to the equipment	3 Phase Indication lamp should come ON	
2.	Press the UP push button	Moves Vertically upwards.	Machine Arm with Bin Moves Vertically upwards.	
3.	Press the DOWN push button	Moves Vertically downwards	Machine Arm with Bin Moves Vertically downwards	
4.	Press the EMERGENCY STOP push button	Stop immediately.	Machine functions stop immediately.	
5.	On – Off operation switch	Machine should start and stop as ON/OFF switch pressed.	Machine should start when ON switch pressed. Machine should stop when OFF switch pressed	

Checked By
Sign & Date: ……

Verified By
Sign & Date: ……

8.3 SAFETY FEATURES TEST:

Item	Acceptance Criteria	Observation	Observed By Sign & Date
Earth Fault	Machine will stop.		
Overload trip fault	Panel Indication Lamp will glow		
Top Position	Panel Indication Lamp will glow & machine will not move further up wards		
Bottom Position	Panel Indication Lamp will glow & machine will not move Further		

Checked By
Sign & Date: ……

8.4 POWER FAILURE VERIFICATION:

Item	Acceptance Criteria	Observation	Observed By Sign & Date
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse		

Checked By
Sign & Date: ……

Verified By
Sign & Date:……

Inference:

……

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……

Reviewed By
Sign & Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master 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:

- Operation And Maintenance Manual
- Copy of Draft SOP's.
- Any Other Relevant Documents

11.0 DEVIATION FROM PREDEFINED 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:

No.	:	Number
WHO	:	World Health Organization
QA	:	Quality Assurance
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
HP	:	Horse Power
SS	:	Stainless Steel
ID.	:	Identification
Ltrs	:	Liters
LPD	:	Lifting & Positioning Device
Pvt.	:	Privet
Ltd.	:	Limited
cGMP	:	Current Good Manufacturing Practices
IPC	:	In-Process Container
SOP	:	Standard operating procedure
DQ	:	Design Qualification
&	:	And

17.0 POST 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)			