



**PHARMA DEVILS**

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

**PROTOCOL No.:**

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**1.0 PROTOCOL APPROVAL:**

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following signatories.

This Installation Qualification protocol of lifting & positioning device has been reviewed and approved by the following signatories:

| <b>FUNCTION</b>    | <b>NAME</b> | <b>DESIGNATION</b> | <b>DEPARTMENT</b>        | <b>SIGNATURE</b> | <b>DATE</b> |
|--------------------|-------------|--------------------|--------------------------|------------------|-------------|
| <b>PREPARED BY</b> |             |                    | <b>QUALITY ASSURANCE</b> |                  |             |
| <b>REVIEWED BY</b> |             |                    | <b>QUALITY ASSURANCE</b> |                  |             |
|                    |             |                    | <b>ENGINEERING</b>       |                  |             |
|                    |             |                    | <b>PRODUCTION</b>        |                  |             |
| <b>APPROVED BY</b> |             |                    | <b>HEAD OPERATION</b>    |                  |             |
|                    |             |                    | <b>QUALITY ASSURANCE</b> |                  |             |



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**2.0 OVERVIEW:**

**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to the lifting & positioning device and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the lifting & positioning device was installed as required in granulation area.

**2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the lifting & positioning device received matches the Design specification and also to ensure that it is properly and safely installed.

**2.3 SCOPE:**

The installation qualification protocol shall be followed for lifting & positioning device. This protocol defines the methods and documentation that shall be used to evaluate the system installation in accordance with the specifications and intended use. Successful implementation of this protocol shall verify that the systems installed meet the requirements specified.

**2.4 RESPONSIBILITY:**

In accordance with protocol, following functions shall be responsible for the qualification of system.

**Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:**

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons.





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**3.0 ACCEPTANCE CRITERIA:**

- 3.1 The lifting & positioning device shall meet the system description given in design specification.
- 3.2 The lifting & positioning device shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.

**4.0 REVALIDATION CRITERIA:**

The machine has to be revalidated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown, maintenance is carried out.
- As per revalidation date and schedule.

**5.0 INSTALLATION QUALIFICATION PROCEDURE:**

**5.1 EQUIPMENT DESCRIPTION:**

|                         |   |                              |
|-------------------------|---|------------------------------|
| Equipment Name          | : | Lifting & positioning device |
| Supplier / Manufacturer | : | SAAN Engineers Pvt. Ltd.     |
| Model                   | : |                              |
| Serial No.              | : |                              |
| Capacity                | : | SWL- 500 kg                  |
| Location                | : | Granulation area             |

**Process Equipment Description**

Lifting & positioning device is used for lifting the product container & positioning it above the charging port of granulation equipment.

The equipment comprises of a vertical column/ mast, swiveling between two fixed ends. A carriage with an arm slides over the mast, lifting the product container from the floor level to the required height. Once, lifted the mast can be swiveled to the required direction by disengaging the foot lock provided at the base of the column. A double acting hydraulic cylinder operated by a power pack lifts the carriage with an arm. Control panel operates the power pack through push buttons provided on mast in SS enclosure.



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Once the container reaches to the charging port of the equipment, the operation of IPC/Bin butterfly valve can be done manually for product discharge.

**5.2 INSTRUCTION FOR FILLING THE CHECKLIST:**

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the Installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.

**5.3 INSTALLATION CHECKLIST:**

Installation checklist is as follows:

| <b>S.No.</b> | <b>Statement</b>  | <b>Method of verification</b> | <b>Actual observation</b> | <b>Checked By Sign/Date</b> |
|--------------|---|-------------------------------|---------------------------|-----------------------------|
| 1.           | Verify the purchase order copy and PO no. Shall be written in observation column      | Physically                    |                           |                             |
| 2.           | Verify that the "As Built" drawing is complete and represents the design concept.     | Physically                    |                           |                             |
| 3.           | Verify that major components are securely anchored and shock proof.                   | Physically                    |                           |                             |
| 4.           | Verify that there is sufficient room provided for servicing.                          | Physically                    |                           |                             |
| 5.           | Verify that all piping and electrical connections are done according to the drawings. | Physically                    |                           |                             |



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|     |  |            |  |  |
|-----|--|------------|--|--|
| 6.  | All access ports are examined and cleared of any debris.                                 | Physically |  |  |
| 7.  | Safe electrical connections.   | Physically |  |  |
| 8.  | Sufficient room provided for maintenance.  | Physically |  |  |
| 9.  | Equipment identification name plate should be visible.                                   | Physically |  |  |
| 10. | Units installed on foundation are secure in place as per manufacturer's recommendations. | Physically |  |  |
| 11. | Verify that there is no observable physical damage                                       | Physically |  |  |

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.4 IDENTIFICATION OF MAJOR COMPONENTS:**

Describe each critical component and check them and fill the inspection checklist.

| <b>System Components</b>  | <b>Design Specification</b> |   | <b>Method of Verification</b>        | <b>Actual Observation</b> | <b>Checked By Sign/Date</b> |
|---------------------------|-----------------------------|---|--------------------------------------|---------------------------|-----------------------------|
| Lifting arm               | Spec.                       | Double point lifting for 600 ltrs. Capacity IPC/Bin   | Physically                           |                           |                             |
| Safe working load         | Spec.                       | 500 kgs   | Physically                           |                           |                             |
| Carriage                  | Spec.                       | Plate sections guided through rollers having bearing on which the lifting arm is bolted     | Physically                           |                           |                             |
| Projection of lifting arm | Spec.                       | 1150 mm   | Physically/<br>Technical Certificate |                           |                             |
| Fully lowered arm height  | Spec.                       | 405 mm (Arm centre)   | Physically/<br>Technical Certificate |                           |                             |
| Fully lifted arm height   | Spec.                       | 2950 mm (Arm centre)  | Physically/<br>Technical Certificate |                           |                             |
| Base                      | Spec.                       | 290 mm x 265 mm x 155 mm  | Physically/<br>Technical Certificate |                           |                             |
| Swivel arc (Mast Swivel)  | Spec.                       | 0-270 degrees with position lock on the base, operated from ground by foot manual swiveling | Physically                           |                           |                             |
| Column/ Mast              | Spec.                       | 225 X 250 X 4700 mm.  | Physically                           |                           |                             |





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|   |          |   |                                     |  |  |
|---|----------|---|-------------------------------------|--|--|
| Hydraulic Cylinder  | Spec.    | Double acting- 63 mm ID with piston rod of 45, Stroke- 1400 mm  | Physically/ Technical Certificate   |  |  |
| Lifting system  | Spec.    | The arm to be lifted by a double acting hydraulic cylinder by a vane pump through a solenoid operated directional control valve | Physically                          |  |  |
| Mast swiveling/ positioning                                 | Spec.    | Manual  | Physically                          |  |  |
| Control   | Spec.    | Push button control for UP- DOWN movements. SS enclosure  | Physically                          |  |  |
| Travel speed UP & DOWN                                      | Spec.    | 1.5 to 2 mtrs./ minute  | Physically/ Technical Specification |  |  |
| Power Pack<br>1. M.S. reservoir<br>2. Vane pump<br>3. Motor | Capacity | 25 ltrs.  | Physically/ Technical Certificate   |  |  |
|   | Make     | STD   | Physically/ Technical Certificate   |  |  |
|   | Capacity | 6 ltrs./ minute   | Physically/ Technical Certificate   |  |  |
|   | Make     | Hindustan   | Physically                          |  |  |
|   | Spec.    | RPM-1420, 415 V, 50 Hz, 2 HP, flange mounted  | Physically                          |  |  |
|   | Sr. No.  | To be recorded  | Physically                          |  |  |
|   | Make     | Rexroth   | Physically                          |  |  |



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|   |       |   |            |  |  |
|---|-------|---|------------|--|--|
| 4. Control valve  | Spec. | Relief valve, flow control valve, pilot operated check valve, oil level indicator, filter cum breather, suction filter, pressure gauge  | Physically |  |  |
| 5. Other accessories                                      |       |   |            |  |  |
| Hydraulic cylinder  | Spec. | MS honed pipe with hard chrome plated piston rod  | Physically |  |  |
| <b>Power Pack &amp; Panel</b><br>Power cum Operator Panel | Spec. | Housed in MS painted enclosure along with power pack having main isolator switch, contactor, overload relay for the motor, backup fuses for the motor, relays for the hydraulic & pneumatic solenoid valve etc, | Physically |  |  |
|   | Spec. | In SS enclosure with push buttons for ON/OFF, UP/DOWN movement etc.   | Physically |  |  |
| Power Pack  |       |   |            |  |  |

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:** should be verified by test certificates of respective material apart from that SS material should be verified by molybdenum kit in absence of test certificate.

| <b>Name of Components</b>     | <b>Material of Construction</b> | <b>Method of Verification</b>    | <b>Observation</b> | <b>Checked By Sign/Date</b> |
|-------------------------------|---------------------------------|----------------------------------|--------------------|-----------------------------|
| Column/ Mast                  | MS + SS 304 sheet               | Molybdenum kit/ Test Certificate |                    |                             |
| Structure & base plate        | MS + SS 304 sheet               | Molybdenum kit/ Test Certificate |                    |                             |
| Carriage                      | SS 304 clad                     | Molybdenum kit/ Test Certificate |                    |                             |
| Lifting arm                   | SS 304                          | Molybdenum kit/ Test Certificate |                    |                             |
| Bottom hub                    | MS + SS 304                     | Molybdenum kit/ Test Certificate |                    |                             |
| Top hub                       | MS + SS 304                     | Molybdenum kit/ Test Certificate |                    |                             |
| Top fixing jack               | CI + SS 304                     | Molybdenum kit/ Test Certificate |                    |                             |
| Carriage lifting (Leaf chain) | Alloy steel                     | Physically/ Test Certificate     |                    |                             |
| Rollers                       | MS                              | Physically                       |                    |                             |

**Remark:** -----  
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**5.6 IDENTIFICATION OF SUPPORTING UTILITIES:**

| Utility   | Method of verification | Observation | Checked by Sign/ Date |
|---|------------------------|-------------|-----------------------|
| Electricity: 3 phase, 415V AC, 50Hz supply with neutral and proper earthing | Physically             |             |                       |

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.7 IDENTIFICATION OF SAFETY FEATURES:** Identify and record the safety features (if any) and their function in following tables:

| Safety Features Description | Function  | Method Of Verification | Observation | Checked By Sign/ Date |
|-----------------------------|---|------------------------|-------------|-----------------------|
| Earthing                    | To avoid electrical shocks due to leakage of current. | Physically             |             |                       |

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:**

| Name of Components | Range | Make | ID | Location | Identified By<br>Sign/Date |
|--------------------|-------|------|----|----------|----------------------------|
|                    |       |      |    |          |                            |
|                    |       |      |    |          |                            |
|                    |       |      |    |          |                            |
|                    |       |      |    |          |                            |

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)**

The following Standard Operating Procedures were identified as important for effective performance of Lifting & positioning device.

| S.No. | SOP TITLE | IDENTIFIED<br>BY | DATE |
|-------|-----------|------------------|------|
|       |           |                  |      |
|       |           |                  |      |
|       |           |                  |      |
|       |           |                  |      |

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.10 VERIFICATION OF DRAWING AND DOCUMENTS:**

Following documents are reviewed and attached as listed below:

| <b>S.No.</b> | <b>DRAWING AND DOCUMENT<br/>DETAIL</b> | <b>CHECKED BY (SIGN)</b> | <b>DATE</b> |
|--------------|--|--------------------------|-------------|
|              |  |                          |             |
|              |  |                          |             |
|              |  |                          |             |
|              |  |                          |             |
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**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.11 LIST OF ANNEXURES:**

| <b>Annexure No.</b> | <b>Document Title</b> |
|---------------------|-----------------------|
|                     |                       |
|                     |                       |
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**Remarks (if any):**

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**Done By & Date:**

**Verified By & Date:**



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**5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):**

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

**Description of deficiency:**

**Corrective action(s) taken:**

**Deviation accepted by  
(Sign/Date)**

**Deviation Approved by  
(Sign/Date)**





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**6.0 INSTALLATION QUALIFICATION FINAL REPORT:**

**6.1 SUMMARY:**

**6.2 CONCLUSION:**

**Prepared By  
Sign/ Date**

**Checked By  
Sign/ Date**



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**6.3 FINAL REPORT APPROVAL:**

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol. If applicable signature in the block below indicates that all items in this qualification report of Lifting & positioning device have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

| <b>FUNCTION</b>        | <b>NAME</b> | <b>DESIGNATION</b> | <b>DEPARTMENT</b>    | <b>SIGNATURE</b> | <b>DATE</b> |
|------------------------|-------------|--------------------|----------------------|------------------|-------------|
| <b>REVIEWED<br/>BY</b> |             |                    | QUALITY<br>ASSURANCE |                  |             |
|                        |             |                    | ENGINEERING          |                  |             |
|                        |             |                    | PRODUCTION           |                  |             |
| <b>APPROVED<br/>BY</b> |             |                    | HEAD<br>OPERATION    |                  |             |
|                        |             |                    | QUALITY<br>ASSURANCE |                  |             |