



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION FOR TIPLING DEVICE**

**INSTALLATION QUALIFICATION  
PROTOCOL  
TIPLING DEVICE  
1000 KG**



## **INSTALLATION QUALIFICATION FOR TIPLING DEVICE**

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**INSTALLATION QUALIFICATION FOR TIPLING DEVICE**

**1.0 Pre-Approval**

Signing of this Approval page of Installation Qualification Protocol No. 02 indicates agreement with the Installation Qualification approach described in this document. Should Modifications to the Installation Qualification become necessary; an addendum will be prepared and approved.

Written By	Signature	Date

Checked By	Signature	Date

Approved By	Signature	Date



## **INSTALLATION QUALIFICATION FOR TIPLING DEVICE**

### **2.0 Overview**

#### **2.1 Purpose:**

The purpose of this protocol is to provide an outline for the Installation Qualification of equipment for static attributes to verify that

- ◆ Each installed sub component complies with the engineering design and equipment data sheets/specifications, agreed upon with the manufacturer.
- ◆ All supporting utilities are connected.
- ◆ All critical Instruments have been identified for calibration.
- ◆ The equipment is installed as per the laid down specifications.
- ◆ No unauthorized or unrecorded modifications have taken place.
- ◆ Required testing reports are available.
- ◆ Standard Operating procedures (SOPs) have been identified and listed.



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### **2.2 Responsibility:**

The validation group comprising of a representative from each of the following departments shall be responsible for the overall compliance with this protocol:

- ◆ Project Department
- ◆ Engineering Department
- ◆ Production Department
- ◆ Quality Assurance Department

The Projects and Engineering Department shall be responsible for checking proper installation and recording installation data as per the procedures outlined in this protocol.

The Quality Assurance Department shall be responsible for the final review of the qualification documents and its compliance to meet the acceptance criteria of the Installation Qualification protocol.

The head of Project, Engineering, Production and Quality Assurance shall approve the summary report.

### **2.3 Requalification:**

#### **Installation Qualification to be re qualified on:**

- ◆ Replacement of major component of the equipment with a new component.
- ◆ Any major modification in the existing equipment.
- ◆ Shifting of the equipment from one location to another.



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### 2.4 System Description

This is a TIPLING DEVICE with the Round conical Arm. It is used to tipple the 1000 kg bowl of the 1000 kg F.B.D.

#### General Description of Machine Parts-

- **Column with the complete assembly:-**
- - 1) **Main Column** -The column is an assembly of a vertical pillar designed strong enough to support the process of lifting tipling and lowering of the 1000 kg F.B.D. BOWL. It is clad with S.S 304 sheet
  - 2) **Outside carriage**- It is an assembly of the drive and driven gear, coupled with a bull gear. Clad with S.S. 304 sheet. It holds the arm flange.
  - 3) **Arm** – It is a Conical round shape assembly made of S.S 316 material. It is welded with a flange and is fitted on the bull gear assembly on the outside carriage. It has a butterfly valve, which is used for further discharge of the material.
  - 4) **Inside carriage** – it is an assembly of a structure which is mounted on the hydraulic cylinder. It is connected with a chain and pulley assembly inside the column. It supports the vertical movement of the Arm with bowl.

#### Technical Details

Motor	1.5 + 1.5 HP / 1440 RPM STD
Electrical Services	415 V/3 Phase, 50Hz AC supply
Foundation	Required
Overall Dimension	H - 2600 mm
	L - 2186 mm
	W-1396 mm



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Net Weight                      800 Kgs Approx

**3.0 Equipment Specification**

Detailed Equipment Specification for Machine No.11 is mentioned

**4.0 Equipment Identification**

The subjected equipment is identified as

In-house Tag No. \_\_\_\_\_ (To be given by M/s. \_\_\_\_\_.)

Name of the Supplier                      **SHEFA INDUSTRIES.**

**The major components of the Equipment are identified as:**

S.No.	Item	Part Description	Part Material
<b>01.</b>	<b>Contact Parts</b>	<b>CONE</b>	<b>SS 316L</b>
		<b>FLANGE</b>	
		<b>VALVE</b>	
			<b>SS 316</b>
<b>02.</b>	<b>Non contact Exposed Parts</b>	<b>Clamps</b>	<b>SS 304</b>
		<b>Covers</b>	
		<b>Column covers</b>	
		<b>Base plate Covers</b>	
		<b>Motor Covers</b>	
		<b>Gear Box Covers</b>	
<b>03.</b>	<b>Non Contact Internal Parts</b>	<b>Column</b>	<b>MS</b>
		<b>Base plate</b>	



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<b>04.</b>	<b>Elastomers in Contact with material</b>	<b>Valve Gasket</b>	<b>Food Grade Silicon</b>

**Technical specifications of sub components/ bought outs**

S. No.	Particulars	Specifications
<b>1</b>	<b>Main – Motor 1.5 HP (1)</b>	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V
	Others	NON FLP
	Sr. No.	
<b>2</b>	<b>Main – Motor 1.5 HP (2)</b>	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V
	Others	NON FLP
	Sr. No.	1216/389305
<b>3</b>	<b>Gear Box (1)</b>	
	Make	Bonfiglioli
	Type	
	Sr. No.	
<b>4</b>	<b>Gear Box (2)</b>	
	Make	Bonfiglioli
	Type	
	Sr. No.	
<b>5</b>	<b>Discharge Valve</b>	
	Type	Butterfly
	Size	Dia. 8inch mm
	MOC	SS 316
<b>6</b>	<b>Hydraulic – Motor 1.5 HP (1)</b>	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V





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**5.0 Equipment Location:**

Location : \_\_\_\_\_

Floor : \_\_\_\_\_

Area : \_\_\_\_\_

Room Name : \_\_\_\_\_

**6.0 Installation Qualification Procedure**

**6.1 Inspection Checklist**

**Instructions:**

- 6.1.1 Identify the critical components of equipment and verify that the components are complying as per desired specifications. Record the observations in the Data Sheet of section 6.2.1.
- 6.1.2 Check the MOC of the component as per the instruction mentioned in the section 6.2.2.1. Record the observation of the MOC in the Data Sheet of section 6.2.2.



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- 6.1.3 Identify the utility supplies required for equipment operation. Verify that utilities are as per the specification mentioned in the Check Point 6.2.3. Record the observation in the Data Sheet of section 6.2.3
- 6.1.4 Check the installation of equipment:
- To verify the proper assembly of the components as per the equipment drawings attached as **Attachment No. 'A'**. Record the installation location and verification of assembly in Test Data section 6.2.5.1.
  - To check the leveling and alignment as per the procedure given in the section 6.2.5.3. Record the observation in the Data Sheet of section 6.2.5.2.
- 6.1.5 Identify the SOPs and assign SOP Numbers, record the SOP Title and Number in Section No. 6.2.7.
- 6.1.6 Record the deficiency (if any) in section number 6.2.8 and report the details of action taken.

### **Note:**

1. *Record all the observations against the respective specifications, mentioned in the specific checkpoints, under section 6.2 (The specifications are extracted from the Purchase order / Manual / Manufacturer's Recommendations).*
2. *Wherever specifications are not mentioned, record the observations as per the statement of the data sheet.*
3. *Incase of non-compliance, give the explanation / justification in the deviation format under section 6.2.8.*
4. *When more than one unit of the same type exist, replicate the corresponding data sheet to match and uniquely identify each page.*
5. *Incase of multiple options; clearly identify the one, which has been supplied.*
6. *The calibration certificates of the instruments shall be traceable to National/International standards.*
7. *Define all technical terms and abbreviations in the appendix under section 10.0.*



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### 6.1 Installation Qualification

#### 6.1.1 Major Component Verification

**Objective:** - To verify that major components as identified below are complying as per the desired specifications.

S.No.	Item	Part Description	Part Material
01.	Contact Parts	CONE	SS 316L
		FLANGE	
		Valves	SS 316
02.	Non contact Exposed Parts	Clamps	SS 304
		Covers	
		Column covers	
		Base plate Covers	
		Motor Covers	
		Gear Box Covers	
03.	Non Contact Internal Parts	Column	MS
		Base plate	
04.	Elastomers in Contact with material	Valve Gasket, Lid Gasket	Food Grade Silicon



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### Technical specifications of sub components/ bought outs

S. No.	Particulars	Specifications
<b>1</b>	<b>Main – Motor 1.5 HP (1)</b>	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V
	Others	NON FLP
	Sr. No.	
<b>2</b>	<b>Main – Motor 1.5 HP (2)</b>	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V
	Others	NON FLP
	Sr. No.	
<b>3</b>	<b>Gear Box (1)</b>	
	Make	Bonfiglioli
	Type	
	Sr. No.	
<b>4</b>	<b>Gear Box (2)</b>	
	Make	Bonfiglioli
	Type	
	Sr. No.	
<b>5</b>	<b>Discharge Valve</b>	
	Type	Butterfly
	Size	Dia. 8inch mm
	MOC	SS 316
<b>6</b>	<b>Hydraulic – Motor 1.5 HP (2)</b>	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V



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**6.2.1**

	<b>Name</b>	<b>Sign.</b>	<b>Date</b>
<b>Checked by (Project)</b>			

**Checked by  
(Project)**

\_\_\_\_\_  
**Sign.**

\_\_\_\_\_  
**Date**

**Verified by  
(Engineering)**

\_\_\_\_\_  
**Sign.**

\_\_\_\_\_  
**Date**

**6.1.2 List of items for m.o.c verification**

<b>Sr. No.</b>	<b>Item</b>	<b>Part Description</b>	<b>Part Material</b>
<b>01.</b>	<b>Contact Parts</b>	<b>CONE</b>	<b>SS 316L</b>
		<b>FLANGE</b>	
		<b>Valves</b>	<b>SS 316</b>
<b>02.</b>	<b>Non contact Exposed Parts</b>	<b>Clamps</b>	<b>SS 304</b>
		<b>Covers</b>	
		<b>Column covers</b>	
		<b>Base plate Covers</b>	
		<b>Motor Covers</b>	
		<b>Gear Box Covers</b>	
<b>03.</b>	<b>Non Contact Internal Parts</b>	<b>Column</b>	<b>MS</b>



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		<b>Base plate</b>	
<b>04.</b>	<b>Elastomers in Contact with material</b>	<b>Valve Gasket,</b>	<b>Food Grade Silicon</b>

**6.2.2**

<b>Checked by (Project)</b>		_____	_____
		<b>Sign.</b>	<b>Date</b>
<b>Verified by (Engineering)</b>		_____	_____
		<b>Sign.</b>	<b>Date</b>

**6.1.3 Verification of Utility Supply**

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

<b>S. No.</b>	<b>Utility</b>	<b>Specifications</b>	<b>Observations</b>	<b>Connected and Identified (Yes / No)</b>
<b>1.</b>	<b>Power Input</b>	415 V, 3PH, 50Hz		Yes
<b>2.</b>	<b>Total Power Consumption</b>	6 HP		Yes

**6.2.3**

**Checked by (Project)**

\_\_\_\_\_

**Sign.**

\_\_\_\_\_

**Date**

**Verified by (Engineering)**

\_\_\_\_\_

**Sign.**

\_\_\_\_\_

**Date**

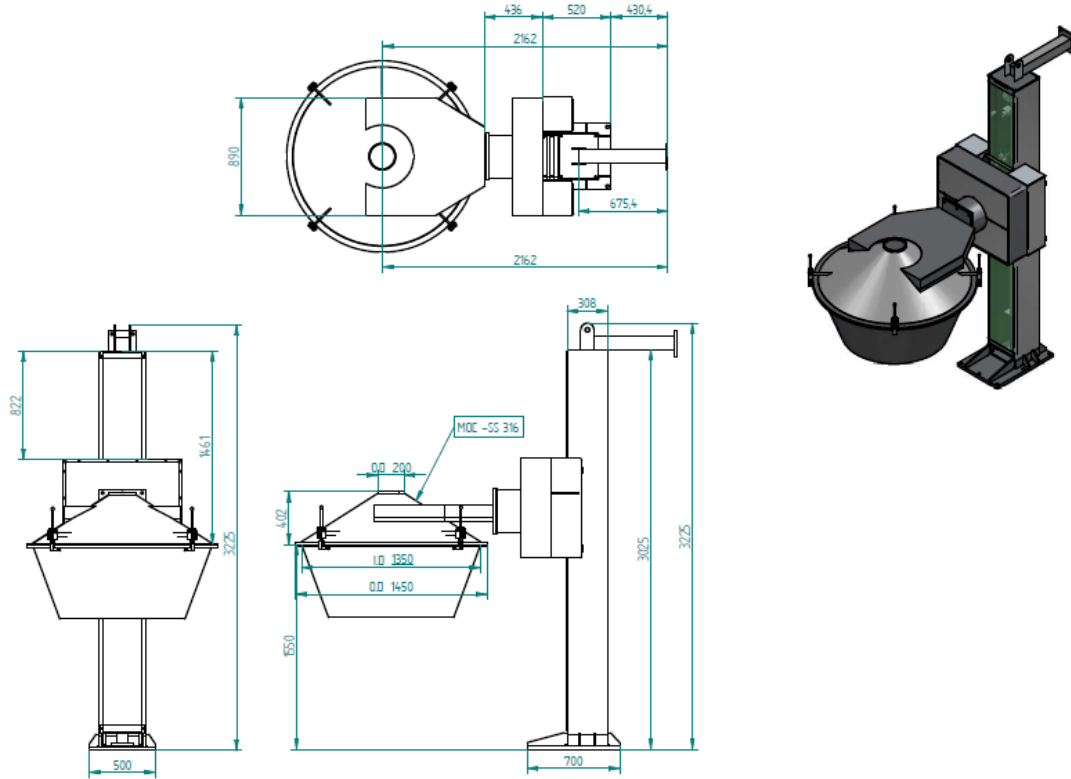


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### Attachment A





**INSTALLATION QUALIFICATION FOR TIPLING DEVICE**

**6.2.5.1**

	<b>Name</b>	<b>Sign.</b>	<b>Date</b>
<b>Checked by (Project)</b>			

**Checked by  
(Project)**

\_\_\_\_\_  
**Sign.**

\_\_\_\_\_  
**Date**

**Verified by  
(Engineering)**

\_\_\_\_\_  
**Sign.**

\_\_\_\_\_  
**Date**

**6.2.4 Verification for Installation**

**6.2.5.1.A- Method for checking the Leveling of the Equipment**

**- Using Spirit Level Indicator**

- ◆ Place the spirit level indicator at different points on the machine frame.

**Acceptance Criteria:**

The air bubble of the spirit level indicator shall be observed in the center.

**- Using Water Level Indicator**

- ◆ Place transparent tube filled with water of suitable length at various corners.

Compare the levels of water and align the equipment

**Acceptance Criteria:**

The water level at both the locations should match with the edges of those locations, if required should be repeated for other edges of the equipment on same plane.





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## INSTALLATION QUALIFICATION FOR TIPLING DEVICE

### 6.2.5.2

	Name	Sign.	Date
Checked by (Project)			

Checked by  
(Project)

\_\_\_\_\_  
Sign.

\_\_\_\_\_  
Date

Verified by  
(Engineering)

\_\_\_\_\_  
Sign.

\_\_\_\_\_  
Date

### 6.1.5 Standard Operating Procedures (SOPs) Identification:

SOPs	Location
Operating	In the manual in operation section
Cleaning	In the manual in maintenance section
Preventive Maintenance	In the manual in operation section

### 6.2.7

Checked by (Project)		_____ Sign.	_____ Date
Verified by (Engineering)		_____ Sign.	_____ Date



**INSTALLATION QUALIFICATION FOR TIPLING DEVICE**

**6.1.6 Deficiency (if any) and Corrective Action Report**

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

Description of deficiency and date observed:

Person, responsible for corrective action and date assigned:

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Corrective actions taken and date conducted:

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Conducted By: \_\_\_\_\_

Approved By : \_\_\_\_\_

Date: \_\_\_\_\_

Date : \_\_\_\_\_

---



## INSTALLATION QUALIFICATION FOR TIPLING DEVICE

### 6.2.8

Checked by  
(Project)

\_\_\_\_\_ Sign.

\_\_\_\_\_ Date

Verified by  
(Engineering)

\_\_\_\_\_ Sign.

\_\_\_\_\_ Date

### 7.0 Acceptance Criteria

Installation Qualification shall be considered acceptable when all the conditions specified in various forms under section 6.0 have been met.

Any deviation from the acceptance criteria of the specific checkpoint shall be reported and decision should be taken for the rejection, replacement or rectification of the equipment/component.

### 8.0 Remarks (if any) :

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### 9.0 Summary:

Checks	Observations	Remarks
Whether acceptance criteria of the protocol and Specific check points are met.		



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**9.1 Conclusion:**

**9.2 Post-Approval Signatures**

Name	Signature	Date