



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL
FOR
TIPLER DEVICE**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL**

TIPPLER – 1000 Kg



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1.0 Pre-Approval

Signing of this Approval page of Design Qualification Protocol indicates agreement with the Design approach described in this document. Should Modifications to the Design Qualification become necessary, an addendum will be prepared and approved.

Written By	Signature	Date

Approved By	Signature	Date



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2.0 Overview:

2.1 Objectives:

To design, engineer, and supply the TIPLING DEVICE, as per cGMP guidelines, to be used for

2.2 Scope:

The design of the TIPLING DEVICE shall cover the locking of the conical arm with the 1000 kg bowl, lifting of both the arm and the bowl together and tipping of the 1000 kg FBD bowl with the conical arm and lowering just above the sifting machine.

2.3 Responsibilities:

Client:

1. To provide the URS for the equipment.
2. To perform the Factory Acceptance test (FAT).

Manufacturer:

To design, engineer and provide the complete technical details of the equipment pertaining to its design qualification viz.

1. Machine overview,
2. Equipment orientation with layout,
3. Specifications of the sub-components/ bought out items, and their make, model & quantity, and backup records/ brochures,
4. Details of Utilities,
5. Identification of components for calibration
6. Material of construction of all components
7. Brief process description
8. Safety features.
9. Pre-installation requirements
10. To facilitate the client for the Factory acceptance test of the Machine at their works/ site.
11. To confirm the safe delivery of the equipment to the user site.



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12. To ensure that no un-authorized or unrecorded design modifications shall take place. If any point of time, any change is desired in the agreed design, change control procedure shall be followed and documented.

2.4 User requirements specifications (URS):

DESCRIPTION	SPECIFICATIONS
Model	The equipment should be a cGMP compliant model.
Required Output & Configuration	Container Volume 1000 KG.
Process	Equipment should be able to perform all the process of Lifting, Tippling & positioning smoothly.
Sizes	The equipment should be able to handle the 1000 kg bowl sizes of the 1000 kg FBD with suitable change parts.
Calibration	All components, which require calibration, shall be identified and calibrated. Calibration certificates to be provided at the time of Installation qualification.
Qualifications	The manufacturer shall complete and provide the documents pertaining to Design, Installation, Operation & performance Qualification.
Safety features	Adequate Safety features in machine for men and material shall be provided along with the equipment.
Electrical system	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards.



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2.5 Machine Description:

This is a TIPPLING DEVICE with the Round conical Arm. It is used to tipple the 1000 kg bowl of the 1000 kg FBD.

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 tipping and lowering of the 1000 kg FBD 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.

The Tipling Device:

- 1) **Arm** - A conical round shape assembly matching the dimensions with the FBD BOWL is connected with the bowl and locked with the bowl. This assembly rotates to 180 degree supporting the discharge of the complete material of the bowl into the sifter. A valve connected to the conical part is further used to discharge the material.
- 2) **Drive**- Two numbers suitable 1.5 HP, 3 phase, 415 V, 50 cycles, 1440 RPM TEFC motors coupled to individual worm reduction gear boxes imparts motion to the Arm and the Bowl through a bull gear arrangement. Output RPM of is variable 5 to 10. The drive assembly is mounted on a square plate, which is bolted to the inside carriage.



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- 3) The Column- A square column is used to house the hydraulic cylinder and the guide box to lift the drive head to the desired height. The front of the column is covered with a belt.
- 4) Lifting Arrangement- A system mounted on the hydraulic cylinder head lift the arm with a heavy designed carriage. The 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.
- 5) Power pack- An MS Painted tank act as the oil reservoir and also support the hydraulic circuit. The hydraulic power pack unit consist of a single gear pump coupled to flange mounted 3 phase electric motor suitable capacity with suitable bell housing and gear coupling.

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 6-8 metres.



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3.0 Identification of major Parts:

S.No.	Item	Part Description	Part Material
1.	Contact Parts	Cone	SS 316
		Flange	
		Valves	SS 316
		TC	
2.	Non contact Exposed Parts	Clamps	S.S 304
		Bin holding ARM' covers	SS 304
		Column covers	
		Base plate Covers	
		Motor Covers	
		Gear Box Covers	
3.	Non Contact Internal Parts	Column	MS
		Base plate	
4.	Elastomers in Contact with material	Valve Gasket	Food Grade Silicon

4.0 Technical specifications of sub components/ bought outs

S.No.	Particulars	Specifications
1.	Main – Motor 1.5 HP (1)	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V
	Others	NON FLP
	Sr. No.	
2.	Main – Motor 1.5 HP (2)	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V
	Others	NON FLP
	Sr. No.	
3	Gear Box (1)	
	Make	Bonfiglioli
	Type	W-63 Ratio 10 P 90 B5
	Sr. No.	
4	Gear Box (2)	



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S.No.	Particulars	Specifications
	Make	Bonfiglioli
	Type	W-63 Ratio 10 P 90 B5
	Sr. No.	
5	Discharge Valve	
	Type	Butterfly
	Size	Dia. 8inch mm
	MOC	SS 316
6	Hydraulic – Motor 1.5 HP (2)	
	Type	Flange Mounted
	HP	1.5 HP
	RPM	1440 RPM, 415 V
	Sr. No.	
7	Proximity Sensor 5 nos	
	Make	Hi- Tech Electronic System
	Size	30 mm OD --4 NO

5.0 Details of Utilities.

Power input 3 phase 415V, 50 Hz

Total Power Consumption 6 HP

Detection / Safety Features: -

1. Cylinder is locked in the same position if the oil pipe breaks through the control valve mounted on the cylinder.
2. The machine is stopped for a required lower height through proximity sensors. Similarly if the proxy fails then the machine is stopped by a mechanical stopper.
3. The machine is stopped for a required top height through proximity sensors. Similarly if the proxy fails then the machine is stopped by a mechanical stopper.
4. Fuse arrangement for any uncontrolled supply of electricity.
5. Complete enclosure of running or moving parts by an arrangement of cover, other than the arm with bowl.



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6.0 Identification of components for calibration:

In tipping machine, there are no components required to be calibrated.

7.0 Material of construction:

S.No.	Item	Part Description	Part Material
1.	Contact Parts	Cone	SS 316
		Ring	
		Valves	SS 316
		TC	
2.	Non-contact Exposed Parts	Clamps	S.S 304
		Bin holding ARM' covers	
		Column covers	
		Base plate Covers	
		Motor Covers	
		Gear Box Covers	
3.	Non-Contact Internal Parts	Column	MS
		Base plate	
4.	Elastomers in Contact with material	Valve Gasket	Food Grade Silicon

9.0 FAT PROCEDURE:

Factory Acceptance Test Procedure shall be as follows:

After the completion of the work of the machine, client shall be informed to perform the factory acceptance test (FAT).

Client shall perform the FAT at the manufacturer site and record all the data in the prescribed FAT document as per the details given below:

1. Test criteria
2. Design Verification Check list
3. Deficiency & Corrective Action report
4. Pre-installation requirements
5. Final report

10.0 CHANGE CONTROL PROCEDURE:

Change in the agreed design shall be addressed through the well-defined change control procedure.



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11.0 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA

Description of deficiency:

Corrective actions to be taken:

Documents and Procedures provided were found unto acceptance criteria.

12.0 Remarks (if any):

13.0 Summary:

13.1 Post-Approval Signatures:

Name	Signature	Date