



**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
MANUFACTURING TANK**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
MANUFACTURING TANK
CAPACITY: 2000 Liter**

DATE OF QUALIFICATION

SUPERSEDES PROTOCOL No.

NIL



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1.0 PROTOCOL 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)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification on basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Equipment / Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

3.0 SCOPE:


- The Scope of this Qualification Document is limited to the Design Qualification for Manufacturing tank (MFV-2000 Ltr.) procured from Pharmatech Process Equipment at the site.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

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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
<p>Quality Assurance</p>	<ul style="list-style-type: none"> • Preparation, Review and Authorization of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification activity. • Review of Design Qualification Protocol cum Report after Execution.
<p>Production</p>	<ul style="list-style-type: none"> • Review & Approval of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
<p>Engineering</p>	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e. <ul style="list-style-type: none"> • GA Drawing • Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures. • Details of Utilities • Identification of components for Calibration • Material of Construction of all components • Brief Equipment Description • Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.

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5.0 PROJECT REQUIREMENTS:

To ensure that no Unauthorized and/or unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical

Products in accordance with cGMP principles. To ensure the safe delivery of the Equipment from the supplier Site.

6.0 BRIEF EQUIPMENT DESCRIPTION:

Manufacturing Vessel Comprises of Top & Bottom Torispherical Dish ends (10%) Welded with Central cylindrical shell. This is principally designed for the preparation and manufacturing of liquid preparation.

Bottom Entry Agitator of rating 5 HP, 950 RPM is provided at the bottom dish end of the tank. The bottom entry agitator is provided with mechanical seal to avoid the leakage during operation.

Top dish is provided with nozzles as per the service requirement and on the top dishend manhole with davit arm arrangement is provided for ease in cleaning the vessel. Top dish is provided with two nos. lifting hooks for ease at the time of installation.

Entire vessel is mounted on four legs support. Manufacturing tank is provided with all pipe fittings and valves with TC fittings and silicon gasket. A working platform made with S.S. Dimpled plates and SS 304 railing is also provided. The size of the working platform is 1600 mm L x 1175 mm W x 1250 mm H. it will have a ladder on one side of 850 mm length.

7.0 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided to Manufacturer for Engineering Equipment as per the specifications mentioned in User Requirement Specification.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The purpose of manufacturing vessel is mixing of pharmaceutical product with magnetic stirrer.	Manufacturing vessel shall be <ul style="list-style-type: none">• Able to dissolve the Solid content in the Solvent Media to provide solution• Leak free	Process Requirement
Working	Should work smoothly and should run without producing any unwanted sound.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Supply	kW: 3.7 , Voltage: 415 V \pm 5% , Phase:3 Phase, Frequency: 50 Hz	Design Requirement
Room Condition	Should be able to meet the requirement of Clean Environment.	cGMP Requirement



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8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S. No	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
1.	Equipment Name	Manufacturing Tank	Design Requirement
2.	Make	Pharmatech Equipment Pvt. Ltd.	Design Requirement
3.	Model	MFV-2000	Design Requirement
4.	Gross Capacity	2395 Ltr.	Design Requirement
5.	Working Capacity	2000 Ltr.	Design Requirement
6.	Contact Part	SS 316 L	Design Requirement
7.	Non Contact Part	SS 304	Design Requirement
8.	Main Shell	Ø 1350 x 4 mm thick	Design Requirement
9.	Bottom Dish end	Ø 1350 x 4 mm (10 % Torispherical)	Design Requirement
10.	Bottom Dish end	Ø 1350 x 4 mm (10 % Torispherical)	Design Requirement
11.	Leg Pipe	Ø 140 x 3 mm thick	Design Requirement
12.	Agitator shaft	Ø 38 mm	Design Requirement
13.	Agitator blade	Ø 225 sweep x 4 mm thick	Design Requirement
14.	Lifting hooks	12 mm thick	Design Requirement
15.	Baffles	1050 x 150 x 6 mm thick	Design Requirement
16.	Monkey Ladder	Ø 19mm x 300 mmx 100 mm	Design Requirement
17.	Gasket for bottom	4 mm thick	Design Requirement
18.	Gasket for Manhole	10 mm ²	Design Requirement
19.	Eye Bolt	M 12 x 65 mm long	Design Requirement
20.	Davit arm assembly	Pipe and Elbow of Ø 50 x 3 mm thick	Design Requirement
21.	Davit arm Bearing	Ø 69 x 150 mm thick	Design Requirement
22.	Davit arm swing	Ø 55 x 150 mm thick	Design Requirement
23.	Motor	5 HP , 950 RPM, 415 V, 50 Hz	Design Requirement
24.	VFD	Rating : 3.7 kw, 480 V AC 3Ph	Design Requirement
25.	Mechanical Seal	Type: Single Cartridge dry seal Seal Faces : Car-Sic Size : 38 mm	Design Requirement
26.	Outlet Valve (vessel)	Type : Flush bottom valve Outlet Conn. : 38mm	Design Requirement



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S. No	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
		Operation : Manual MOC : SS 316 L	
27.	Butterfly Valve (For Process)	Operation : Manual MOC : SS 316 L Conn. Type : TC / TC Conn. size : 38 mm/50 mm Make : Cipriani Harrison	Design Requirement
28.	Spray Ball	Type : Dynamic self-rotating with 360° water flow : 89 LPM at 2 Bar MOC : SS 316 L Conn. size : 3/4" BSP Spray : Jet spray	Design Requirement
29.	Temperature Sensor	Type : PT 100, 3 wire , simplex Shed dia. : 6 mm Range : 0-150 °C MOC : AISI 316 L	Design Requirement
30.	Temperature Indicator	Mounting : Panel door Mode : TC 513 AX	Design Requirement
31.	Speed Indicator	Mounting: Panel Door, Mode: PIC101 N	Design Requirement
32.	Flow switch	Model: WFS-06-S1 Max, Temp.-100 °C Line Size-1/4" B.S.P Minimum flow setting- 2 Ltrs/Min	Design Requirement

8.3.1 NOZZLE SCHEDULE FOR LIQUID MANUFACTURING VESSEL 2000 LTRS:

S. No.	Service	Size 'Ø'	Type	MOC
N1	Manhole with Sight glass on cover with Davit arm fitting	450 mm / 100 mm	Davit arm/Pad.	SS 316 L
N2	Product Inlet with manually operated butterfly valve	38 mm	Tri-Clover.	SS 316 L
N3	Spare with manually operated butterfly valve	38 mm	Tri-Clover.	SS 316 L
N4	Air vent with manually operated butterfly valve	50 mm	Tri-Clover.	SS 316 L
N5	Light glass with light assembly	75 mm	Pad	SS 316 L
N6	Dynamic Spray Ball with manually operated butterfly valve	65/25 mm	Tri-Clover.	SS 316 L
N7	DM Water Inlet with manually operated butterfly valve	38 mm	Tri-Clover.	SS 316 L
N8	Bottom outlet with manually operated flush bottom ball valve	38 mm	Pad	SS 316 L

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8.3.2 VOLUME AND SURFACE AREA CALCULATIONS:

Diameter of shell (D) = 1350 mm	Height of shell (H) = 1250 mm
Straight face of dish ends (f) = 40 mm	Radius of shell (r) = D/2 = 675 mm

VOLUME:

- Volume of shell $= \pi r^2 H$ $= \pi \times (675)^2 \times 1250$ $= 1789$ Liters
- Volume of dish end straight face $= \pi r^2 f$ $= \pi \times (675)^2 \times 40$ $= 57$ Liters
- Volume of dish end $= 0.1 \times D^3$ $= 0.1 \times (1350)^3$ $= 246$ Liters

- Total Gross Volume $= 1789 + 2(57 + 246) = 2395$ Liters
- Working Volume $= \text{Gross Volume} \times 85\% = 2395 \times 85\% = 2036$ Liters
- Working Volume required $= 2000$ Liters

CONTACT SURFACE AREA:

- CSA of shell $= \pi D H$ $= \pi \times 1350 \times 1250 = 5.3021$ m²
- CSA of straight face $= \pi D f$ $= \pi \times 1350 \times 40 = 0.1697$ m²
- CSA of dish end $= \pi (1.1 r + f)^2$ $= \pi \times (1.1 \times 675 + 40)^2 = 1.9239$ m²
- Total Contact Surface Area (including top dish end and bottom dish end)
 $= 5.3021 + 2(0.1697 + 1.9239) = 9.4893$ m²



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8.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Main Shell	SS 316L
2.	Bottom Dishend	SS 316L
3.	Top Dishend	SS 316L
4.	Leg Pipe	SS316 L
5.	Agitator shaft	SS316 L
6.	Agitator Blade	SS316 L
7.	Lifting Hooks	SS316 L
8.	Baffles	SS316 L
9.	Monkey Ladder	SS316 L
10.	Gasket for Bottom Valve	Silicon
11.	Gasket for manhole	Silicon
12.	Eye Bolt	SS 304
13.	Davit arm Assembly	SS 304
14.	Davit arm Bearing Housing	SS 304
15.	Davit arm swing shaft	SS 304

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine, Panel and operator should be provided	Safety Requirement
Variable Frequency Drive	Motor safety from overload	Safety Requirement
Main Supply	Main power supply should be always switched off when not in use.	Safety Requirement
Safety valve	Safety against over pressure	Safety Requirement
Rupture Disc	Safety against Over pressure	Safety Requirement
Emergency Button	Protection against abnormal condition	Safety Requirement
Instrument air pressure	Low air pressure protection	Safety Requirement
Overload Relay	For motor & equipment protection	Safety Requirement

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8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Manufacturing vessel.	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes Vendor Background (General / Financial), Technical know -how, Quality Standards, Inspection of Site, Costing, feedback from Market.	cGMP Requirement

Reference: (1) User Requirement Specifications (URS).
 (2) Design & Functional Specifications provided by Vendor.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant Documents(Certificates)

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

11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:



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12.0 RECOMMENDATION:

13.0 ABBREVIATIONS:

BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
D	:	Depth
DQ	:	Design Qualification
GA	:	General Arrangement
HMI	:	Human Machine Interface
HP	:	Horse Power
Hz	:	Hertz
Kg	:	Kilograms
kW	:	Kilo Watt
LPH	:	Liter per Hours
LPM	:	liter per Minute
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
OD	:	outer Diameter
PO	:	Purchase Order
PT-100	:	Platinum-100
RPM	:	Revolution per Minute
SS	:	Stainless Steel
Temp.	:	Temperature
V	:	Volt
VFD	:	Variable Frequency Drive



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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY SSURANCE)			