



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
CIP SYSTEM**

PROTOCOL No.:

**DESIGN QUALIFICATION
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FOR
CIP SYSTEM**

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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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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 CIP Tank procured.
- 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
Quality Assurance	<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. • Reviewed of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none"> • Approval of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Approval of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none"> • Review of Design Qualification 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 • Reviewed of Design Qualification Protocol cum Report after Execution.



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5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the Equipment from the supplier Site. 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.

6.0 BRIEF EQUIPMENT DESCRIPTION:

CIP tank is fully automatic unit used for cleaning different capacity of vessel (Capacity from 100 to 500 Ltr), piping & inline devices.

The CIP technology involves the use of chemicals, high pressure pumps; tanks to ensure that large scale process are free of dirt & organic contaminants.

The design of each and every part are carried out considering the safety, required output, optimum utility and energy saving. The different utilities needs to be controlled as required.

The CIP tank is also used to clean in Place of Mixing tank, Holding tank, product pipeline, transfer/circulation pump by passing clean steam and connecting the outlet valve through flexible hose by CIP system

CIP system and its components are designed to process pharmaceutical products in accordance with cGMP Principles. CIP unit is used for carrying out CIP of manufacturing vessels & holding vessel.

The CIP unit contains:

- Pipe line
- CIP feed pump
- SS skid
- Temperature Sensor with Transmitter
- 3 Way Control Valve
- Safety Valve
- Pressure Gauge
- Inlet Connection
- Compound gauge
- Safety valve
- Level sensor
- Thermo well connection
- Outlet connection
- Pneumatic operated diaphragm valves
- Level switch
- Pressure Gauge



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7.0 EQUIPMENT SPECIFICATION:

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application The purpose of CIP Tank is to clean manufacturing & holding vessel in place	CIP Tank should be Able to clean Mfg. & holding vessel.	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
Utility connections should be available as per the manufacturer's specification. for CIP		
Electrical Supply	415 ±10% Volts AC , 50 Hz & 3 phase	Design Requirement
Room Condition	Should be able to meet the requirement of Clean Environment.	cGMP Requirement
Compressed Air Supply	6-8 bar pressure	cGMP Requirement
Instrument air	6-8 Bar(g)	Design Requirement
Purified Water	1.5 to 2.5 Bar(g)	Design Requirement



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8.3 TECHNICAL SPECIFICATION CIP SYSTEM :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
CIP Feed Tank (T-101):		
Quantity	01 No.	Design Requirement
Make	Hydro pure Systems	Design Requirement
Capacity	300 Ltrs.	Design Requirement
Type	Vertical Tank with Ceramic Band Heater	Design Requirement
MOC	SS 316L	Design Requirement
Tank Diameter	600 mm	Design Requirement
Tank Height	1000 mm	Design Requirement
Cladding Diameter	750 mm	Design Requirement
Cladding Height	900 mm	Design Requirement
Thickness of Top Dish	2 mm	Design Requirement
Thickness of Shell	2 mm	Design Requirement
Thickness of Bottom Dish	2 mm	Design Requirement
Thickness of Cladding	1.6 mm	Design Requirement
Power Rating of Ceramic band heater (CBH-101)	24 kW	Design Requirement
Operating Condition:		
Max. Operating Pressure for vessel	1.5 kg/cm ² (g)	Design Requirement
Design Pressure for vessel	3.0 kg/cm ² (g)	Design Requirement
Hydrotest Pressure for vessel	3.9 kg/cm ² (g)	Design Requirement
Max. Temperature for vessel	150 ⁰ C	Design Requirement
Design Temperature for vessel	200 ⁰ C	Design Requirement
Insulation	2" Rockwool duly cladded with SS Sheet	Design Requirement
Surface Finish	Internally - < 0.4 Ra, Externally – Matt Finish	Design Requirement
CIP Feed Pump (CIPFP-101)		
Quantity	01 No.	Design Requirement
Make	Grundfos	Design Requirement
Model No.	CM 3-4 A-R-G-V AQQV	Design Requirement
Flow Rate	2.5 m ³ /hr	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Head	28 mWC	Design Requirement
MOC of Impeller	SS 316	Design Requirement
MOC of Casing	SS 316	Design Requirement
Motor Rating	0.46 kW	Design Requirement
SS SKID:		
MOC	SS304 with SS castor wheels for above component	Design Requirement
Pressure Gauges		
Make	Baumer	
Location	Discharge Line of CIP feed Pump	
Range	0-7 kg/cm ²	
Dial Size	100 mm	
QTY.	01 Nos.	
Temperature Transmitter		
Make	Radix/wika	
Location	Discharge Line of CIP feed Pump	
Range	0-200°C	
Type	Pt 100 RTD Sensor	
MOC	SS 316L	
QTY.	02 No.	
Level Switch		
Make	Mahalaxmi	
Location	For CIP feed Tank	
Range	1150 mm	
Type	Rod Type Magnetic Switch	
MOC	SS 316L	
Valve Schedule		
Diaphragm Valve		
Make	Avcon/ Crane	Design Requirement
Location	Drain line of T-101	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	Suction line of CIPFP-101	
	Discharge line of CIPFP-101	
Range	40 mm	Design Requirement
	25 mm	
MOC	SS 316L	Design Requirement
Qty.	03 Nos.	Design Requirement

8.4 MATERIAL OF CONSTRUCTION

S.No.	PARTS NAME	MOC
1.	Vessel shell	SS 316L
2.	Vessel top	SS 316L
3.	Vessel bottom	SS 316L
4.	Jacket shell	SS 304
5.	Spiral baffles	SS 304
6.	Diaphragm valve	SS 316L
7.	Pressure gauge	SS 316L
8.	Hose pipe	Grade Silicon
9.	Gaskets	Grade Silicon
10.	Tube	SS 316L



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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 Motors) and operator should be provided	Safety Requirement
Guards	Guards for all Moving Parts	Safety Requirement
Noise Level	Below 80 db	Safety Requirement
Main Supply	Main power supply should be always switch off when not in use.	Safety Requirement
Safety valve	Safety against over pressure	Safety Requirement
SS cover on pump	For operator safety	Safety Requirement
Emergency stop	Protection from abnormal condition	Safety Requirement
Air pressure switch	Protection for low air pressure for pneumatic valves	Safety Requirement

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for CIP& SIP System	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

9.0 REFERENCE:

- The equipment shall confirm to the Specifications and Requirement as specified in URS.
- Operating and service manual for manufacturing vessel.

**Verified By
(Quality Assurance)
Sign/Date:**



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10.0 DOCUMENTS TO BE ATTACHED:

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

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

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12.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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13.0 RECOMMENDATION:

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14.0 ABBREVIATIONS:

°C	:	Degree centigrade
μ	:	Micron
cGMP	:	Current Good Manufacturing Practices
CIP	:	Cleaning in place
cm ²	:	Centimeter square
DQ	:	Design Qualification
EPDM	:	Ethylene Propylene Diane Monomer
GA	:	General Arrangement
HP	:	Horse Power
Hz	:	Hertz
ID.	:	Identification
KG.	:	Kilogram
LTD.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
NLT	:	Not less than
No.	:	Number
OD	:	Outside Diameter
PLC	:	Programmable logical controller
PO	:	Purchase Order
PTFE	:	Tetra Flouro Ethylene.
PU	:	Poly urethane
PVT.	:	Private
QA	:	Quality Assurance
Qty.	:	Quantity
Ra	:	Roughness average
SS	:	Stainless Steel
SV	:	Safety Valve
T/C	:	Triclover
URS	:	User Requirement Specification
V	:	Volt



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15.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			