



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
CIP/SIP MODULE (500 LITER)**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
CIP/SIP MODULE  
(CAPACITY- 500 LITER.)**

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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**1.0 PROTOCOL PRE- APPROVAL:**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

**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 CIP/SIP modules 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 & IDs 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:

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



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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-SIP Module 500 Ltr is fully automatic unit used for washing and Sterilizing different capacity of vessel (Capacity 500 Ltr), piping & inline devices.

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

The complete module will be operated through PLC provided in the control panel. The HMI will display the various setting for the processes programmed. The annual mode also can be run through HMI.

The sequences logic will have following control philosophy.

- Purified Water once through Pre wash cycle – Fixed
- Purified Water Re-circulated wash cycle – Optional
- WFI once through rinse cycle - Fixed

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-SIP Module is also used to sterilize in place Mixing tank, Holding tank, product pipeline, and filter housing transfer/circulation pump by passing clean steam and connecting the outlet valve through flexible hose by SIP system

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

The CIP/SIP unit contains:

- Pipe line
- Centrifugal pump
- SS skid
- Panel



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- Pure steam line
- Angle Control Valve
- Temperature Sensor with Transmitter
- 3 Way Control Valve
- Sterile Safety Valve
- Air Filter
- Sterile Steam Trap
- Pressure Gauge
- Condensate line
- Inlet Connection
- Spray Ball
- Compound gauge
- Safety valve
- Vent Filter
- Level sensor
- Spare connection
- Thermo well connection
- Outlet connection
- Jacket AV
- Jacket PG safety valve
- Jacket Inlet Connection
- Jacket outlet connection
- Pneumatic operated diaphragm valves
- Pneumatic Ball Valve



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- Auto Steam Trap unit
- Air filter
- Level switch
- Conductivity sensor with analyzer
- Pressure Gauge
- Variable Frequency Drive for pump
- Interconnection piping
- Pressure Sensor with Transmitter
- Interconnecting Piping





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**7.0 EQUIPMENT SPECIFICATION:**

Equipment Specification is a document provided to manufacturer for Pharmatech Process 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
<b>Application</b> The purpose of CIP/SIP Module is to clean & sterilized manufacturing & holding vessel in place	CIP/SIP module should be Able to clean & sterilized Mfg. & holding vessel.	Process Requirement
<b>Working</b>	Should work smoothly and should run without producing any unwanted sound.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement

**8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Utility connections should be available as per the manufacturer's specification. for CIP</b>		
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
plant steam	1.5 to 2.5 Bar(g)	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
WFI	1.5 to 2.5 Bar(g)	Design Requirement
<b>Utility connections should be available as per the manufacturer's specification. for SIP</b>		
Instrument air	6-8 Bar(g)	Design Requirement
Pure Steam	1.5 Bar(g) @ 121° C	Design Requirement
N2/Air	3 Bar(g)	Design Requirement



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**8.3 GENERAL DESCRIPTION OF CIP SYSTEM :**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Equipment	CIP /SIP Tank	Design Requirement
Job No.	15-16/ SJ/000365	Design Requirement
Working Capacity	500 ltr.	Design Requirement
Gross capacity	625 Ltr.	Design Requirement
Gross Weight (Empty)	655 kg	Design Requirement
Application	Storage of PW / WFI for CIP	Design Requirement
Hazard area classification	Non Flameproof	Design Requirement
<b>Pipe Line</b>		
Size	Ø 38, 16 G,	Design Requirement
MOC	SS316 L	Design Requirement
Inside surface finish	Mirror (electro polish) RA<0.5µm	Design Requirement
Outside surface finish	Matt ( mechanical polish) RA<0.9µm	Design Requirement
<b>Centrifugal Pump</b>		
Make	Inoxpa	Design Requirement
Centrifugal pump capacity	4.5 KLPH@30MWC,	Design Requirement
MOC	Contact part MOC SS 316	Design Requirement
<b>SS SKID</b>		
MOC	SS304 with SS castor wheels for above component	Design Requirement
<b>Operating panel</b>		
Make	Pharamatech	Design Requirement
MOC	SS 304skid mounted operating panel	Design Requirement
<b>Processor</b>	ML 1400 with Input/output module	Design Requirement
	5.7 color touch screen	Design Requirement
	Phase indication lamps, On off switch , Out put relays ,transformers , SMPS , panel lights, emergency button, hooter, air pressure switch,FRL, MCB, contractors and other electrical and pneumatic accessories.	Design Requirement
	dot matrix online printer	Design Requirement
	5 meters route length cables from each instruments and motors to control panel and 5 meters route length pneumatic tubing from each valves to control panel	Design Requirement



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**8.4 TECHNICAL SPECIFICATIONS:**

<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
<b>Spray Ball</b>		
Make	Lechler	Design Requirement
Qty	01 Nos.	Design Requirement
Sr.No.	569.139.1Y.AL.00.3	Design Requirement
Type	self rotating , 360° rotating ,detachable	Design Requirement
MOC	SS 316	Design Requirement
Size	Ø 61	Design Requirement
Mounting	On top	Design Requirement
Water flow	73 LPM @2 BAR (g)	Design Requirement
End connection	¾ “ BSP female	Design Requirement
Part No.	569 -139-1Y-AL	Design Requirement
<b>Compound Gauge</b>		
Make	Baumer	Design Requirement
Qty.	01 Nos.	Design Requirement
Sr.No.	1336 PG 150063	Design Requirement
Type	Sterile diaphragm gauge	Design Requirement
Contact	SS 316 L	Design Requirement
Non contact	SS 304	Design Requirement
Size	2.5” Dial	Design Requirement
Mounting	Ø 38 mm T/C end	Design Requirement
Range	-760 mm Hg to 6 bar (g)	Design Requirement
Accuracy	± 1.0 % FSD	Design Requirement
<b>Sterile Safety Valve</b>		
Make	Shakti	Design Requirement
Qty.	01 Nos.	Design Requirement
Type	Sterile diaphragm	Design Requirement
MOC	Contact –SS 316 L Diaphragm Silicon Non contact SS 304	Design Requirement
Size	Ø 9.3 X 12.5 mm	Design Requirement
Mounting	Inlet / Outlet	Design Requirement



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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
Capacity	Ø 25 T/C 60 M <sup>3</sup> / Hr of steam	Design Requirement
Set pressure	2.7 bar	Design Requirement
<b>Plain Vent Filter</b>		
Make	Pall	Design Requirement
Qty	01 NOS	Design Requirement
Type	Emflon , code , hydrophobic	Design Requirement
Rating	0.2 micron	Design Requirement
Size	5 “long	Design Requirement
Filter area	0.29 M <sup>2</sup>	Design Requirement
MOC	Housing SS 316 L Cartridge double layer PTFE	Design Requirement
Mounting	Gasket Silicon	Design Requirement
Model	25 mm T/C Cartridge – AB05CPFR2PVH1	Design Requirement
<b>Auto Diaphragm Valve</b>		
Make	Gemu	
Qty	01 Nos.	
Type	Pneumatic optd. diaphragm valve	Design Requirement
Size	Ø 25	Design Requirement
MOC	Contact part SS 316 L Non Contact Part SS 304	Design Requirement
End connection	T/C End	Design Requirement
Application	For vent Filter Isolation	Design Requirement
<b>Auto Diaphragm Valve</b>		
Make	Gemu	Design Requirement
Qty	01 Nos.	Design Requirement
Type	Pneumatic optd. diaphragm valve	Design Requirement
Size	Ø 25	Design Requirement
MOC	Contact part SS 316 L Non Contact Part SS 304 Diaphragm PTFE with EPDM backup	Design Requirement
End connection	T/C End	Design Requirement
Application	For inlet	Design Requirement



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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
<b>Rope Type Capacitance Level Sensor</b>		
Make	E+H	Design Requirement
Type	Capacitance Type Level Sensor	Design Requirement
Sr. no.	L4008C010F1	Design Requirement
Application	Level measurement	Design Requirement
Total length	Capacitance continues rod probe, fully insulated. L -1277 mm (L1+L3) Precalibrated 0% -100% at factory for conductive	Design Requirement
<b>Auto Diaphragm Valve</b>		
Make	Gemu	Design Requirement
Sr.No	68725D88405E12/N1537	
Qty	01 Nos.	Design Requirement
Type	Pneumatic optd. Diaphragm valve .	Design Requirement
Size	Ø 38	Design Requirement
MOC	Contact part SS 316L	Design Requirement
	Non contact parts SS 304 Diaphragm PTFE with EPDM backup	Design Requirement
End Connection	T/C end	Design Requirement
Application	For outlet line	Design Requirement
<b>Auto Diaphragm Valve</b>		
Make	Gemu	Design Requirement
Qty	01No.	Design Requirement
Sr.No.	68725D88405E11/N1537	Design Requirement
Type	Pneumatic optd. Diaphragm valve.	Design Requirement
Size	Ø 25	Design Requirement
MOC	Contact part SS 316L	Design Requirement
	Non contact parts SS 304 Diaphragm PTFE with EPDM backup	
End Connection	T/C end	Design Requirement
Application	For vessel drain	Design Requirement
<b>Temperature Sensor With Transmitter</b>		
Make	Radix	Design Requirement
Qty	01Nos.	Design Requirement



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CRITICAL VARIABLE	SPECIFICATION	REFERENCE
Type	PT 100	Design Requirement
MOC	Thermo well SS 316 L Sensor	Design Requirement
Mounting	Mini T/C	Design Requirement
Range	0° to 200 ° C	Design Requirement
Accuracy	Class “A”	Design Requirement
Stem dia	12 mm ØX 105 long	Design Requirement
Connection	3 wire	Design Requirement
<b>Ball valve</b>		
Make	Micro	Design Requirement
Qty	01 nos	Design Requirement
Type	Pneumatic operated ball valve	Design Requirement
Application	Air vent at jacket side	Design Requirement
MOC	Contact parts SS 304 ,Non Contact Parts SS 304	Design Requirement
size	15 Dia	Design Requirement
End connection	T/C END	Design Requirement
<b>Pressure Gauge for Jacket</b>		
Make	Baumer	Design Requirement
Qty	01 nos.	Design Requirement
Type	Bourden	Design Requirement
MOC	SS 304	Design Requirement
size	Ø 4” dial	Design Requirement
Range	0 to 7 bar (g)	Design Requirement
Accuracy	± 1.0 %FS	Design Requirement
End connection	½ “ BSP threaded	Design Requirement
<b>Safety Valve For Jacket</b>		
Make	Fainger leser	Design Requirement
Qty	01 nos	Design Requirement
Type	Conventional FLS -549	Design Requirement
Model	06/CS44SS2	Design Requirement
MOC	AISI304	Design Requirement
Inlet body	SS TO ASTM A 351 CF 8	Design Requirement
Outlet Body	SS TO ASTM A 351 CF 8	Design Requirement



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CRITICAL VARIABLE	SPECIFICATION			REFERENCE
Bonnet	A1S1 304			Design Requirement
Trim	A1S1 304			Design Requirement
Spring	Stainless steel			Design Requirement
Gasket	PTFE			Design Requirement
Inlet con. Rating	¾” BSP (M)			Design Requirement
Outlet con rating	1” BSP (F)			Design Requirement
Over Pressure	10%			Design Requirement
Set pressure	2.65 bar			Design Requirement
Service	Steam			Design Requirement
Temperature	150°			Design Requirement
Cap type	Closed ,H2			Design Requirement
<b>Ball Valve</b>				
Make	Micro			Design Requirement
Qty	01 nos			Design Requirement
Type	Pneumatic operated ball valve			Design Requirement
Application	Jacket steam inlet			Design Requirement
MOC	Contact parts –SS 304, Non contact parts –SS304			Design Requirement
Size	1”			Design Requirement
End connection	T/C End			Design Requirement
<b>Steam Trap Unit</b>				
Make	Rex	Micro	Pharmatech	Design Requirement
Qty	01 nos	02 nos	1 lot	Design Requirement
Type	Steam trap thermodynamic	Pneumatic ball valve	ERW	Design Requirement
MOC	Body –SS 420 strainer – SS304	Contact parts –SS 304 Non contact parts	SS 304	Design Requirement
Size	20 NB	¾”	-	Design Requirement
End connection	¾” BSP threaded	T/C End	T/C End	Design Requirement
<b>Centrifugal Pump For CIP Supply</b>				
Make	Inoxpa			Design Requirement



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CRITICAL VARIABLE	SPECIFICATION	REFERENCE	
Qty	01 nos	Design Requirement	
Type	Centrifugal	Design Requirement	
Model No.	SE-28	Design Requirement	
Capacity	4.5 m <sup>3</sup> /hr	Design Requirement	
Head	30 MWC	Design Requirement	
MOC	AISI 316 impeller	Design Requirement	
Shaft Seal	Carbon /silicon carbide	Design Requirement	
End connection	T/C end	Design Requirement	
Rating of motor	2.2 KW-2 pole /415 V, AC/50HZ/3 phase	Design Requirement	
<b>Variable Frequency Drive For Centrifugal Pump</b>			
Make	ABB	Design Requirement	
Qty	01 nos	Design Requirement	
Series	ACS550	Design Requirement	
Rating	3HP	Design Requirement	
Power supply	380-500V AC+10%/-15%3ph	Design Requirement	
Output frequency	50.....60 H ± 5%	Design Requirement	
Protection	IP20	Design Requirement	
Ambient Temperature	-10 TO 55°C	Design Requirement	
Ambient humidity	Max95% non condensing	Design Requirement	
EMC Filter	inbuilt	Design Requirement	
<b>Level Switch</b>			
Make	Baumer	Design Requirement	
Qty.	01 nos	Design Requirement	
Model no.	LFFS	Design Requirement	
Process conn.	T/C Ended	Design Requirement	
Temperature	-40...200 °C	Design Requirement	
MOC	stainless steel and PEEK	Design Requirement	
Power supply	12.5.36 VDC, 35 mA max.	Design Requirement	
Application	For pump dry run protection	Design Requirement	
<b>Auto Diaphragm Valve</b>			
Make	Gemu	Gemu	Design Requirement
Qty	05 nos	02 nos	Design Requirement





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CRITICAL VARIABLE	SPECIFICATION		REFERENCE
Type	Pneumatic optd. diaphragm valve	Pneumatic optd. diaphragm valve	Design Requirement
Size	Ø 38	Ø 12	Design Requirement
MOC	Contact part SS 316 L Non contact Part SS 304 Diaphragm PTFE with	Contact part SS 316 L Noncontact Part SS 304 Diaphragm PTFE with EPDM backup	Design Requirement
End connection	T/C end	T/C end	Design Requirement
Application	For CIP Piping	For Pump Drain	Design Requirement
<b>Auto Diaphragm Valve</b>			
Make	Gemu		
Qty	01 nos		Design Requirement
Type	Pneumatic optd. diaphragm valve		Design Requirement
Size	Ø 25		Design Requirement
MOC	Contact part SS 316 L Non contact Part SS 304 Diaphragm PTFE with EPDM backup		Design Requirement
End connection	T/C end		Design Requirement
Application	For Air Filter		Design Requirement
Qty	01 nos		Design Requirement
<b>Pressure Gauge</b>			
Make	BAUMER		Design Requirement
MOC	Contact –SS 316 L Non contact –SS 304		Design Requirement
Type	Sterile Diaphragm Valve		Design Requirement
Size	2.5” dial		Design Requirement
Mounting	1” T/C		Design Requirement
Area	0-7 kg/cm <sup>2</sup>		Design Requirement
<b>Air Filter</b>			
Make	Pall		Design Requirement
Qty	01		Design Requirement
Rating	0.2µ		Design Requirement
Cartridge	12 mm emflon		Design Requirement
Area	0.28 M <sup>2</sup>		Design Requirement



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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
Model	Housing MDSCU110607007 Cartridges MCY4463PFR PVH4	Design Requirement
End connection	Ø 25 T/C	Design Requirement
<b>Conductivity Sensor With Analyzer</b>		
Make	Mettler toledo	Design Requirement
Qty	01	Design Requirement
Series	Conductivity sensor thoroton	Design Requirement
Cell constant	0.1 cm-1	Design Requirement
Principal	2-electro sensor	Design Requirement
Body	SS316	Design Requirement
Temperature device	Pt 1000 IEC Class A	Design Requirement
Accuracy of cell	± 1%	Design Requirement
Constant	0.02 to 20.00µS/cm	Design Requirement
Measuring range	85 mm	Design Requirement
Insertion length	1" T/C Clamp	Design Requirement
Connection	58031234	Design Requirement
Part no.	243E233	Design Requirement
Model	Single channel analyzer	Design Requirement
Type	110 to 240VAC	Design Requirement
Power Supply	4-20 Ma	Design Requirement
Current output	Blackist LCD, 4 Lines	Design Requirement
Display	Panel mounted	Design Requirement
Mounted Part No.	58002301	Design Requirement
<b>PLC (Common For CIP And SIP System)</b>		
Make	Alen bardley	Design Requirement
Qty	01	Design Requirement
Type	Programmable logic	Design Requirement
Model no.	controller	Design Requirement
Power supply	1766-L32BXB	Design Requirement
User data space	24 VCD	Design Requirement
Ports	10K	Design Requirement
Software	Serial and Ethernet	Design Requirement



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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
NO. of DI	RS logix 500	Design Requirement
NO of DO	20	Design Requirement
Oper.	12	Design Requirement
Temperature	-20 to +65°C	Design Requirement
<b>HMI (Common For CIP And SIP System)</b>		
Make	Allen Bradley	Design Requirement
Qty	01	Design Requirement
Type	Color touch screen	Design Requirement
Model No.	PVP-600	Design Requirement
Power supply	18-30 VDC	Design Requirement
Inch	5.7"	Design Requirement
Resolution	320X240,18bit color graphics	Design Requirement
Backlight	CCFL,50,000H	Design Requirement
Common port	RS232,USBand Ethernet port	Design Requirement
Software	RS view factory	Design Requirement
Operation Temp.	0-55°C	Design Requirement
Relative humidity	5-95%	Design Requirement
<b>Control Panel (Common For CIP And SIP System)</b>		
Make	Pharmatech	Design Requirement
Qty	01	Design Requirement
Type	Dust proof	Design Requirement
MOC	SS 304	Design Requirement
Mounting	Suitable	Design Requirement
Gasket	Rubber	Design Requirement
Size	As per design	Design Requirement
Finish	Mirror	Design Requirement
Protection	IP 54	Design Requirement
<b>FRL Unit (Common For CIP And SIP System)</b>		
Make	Festo	Design Requirement
Qty	01	Design Requirement
Model	FRC1/4-D-MINI	Design Requirement



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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
Range	0-16 bar	Design Requirement
Mounting Location	Panel mounted	Design Requirement
<b>Hooter (Common For CIP And SIP System)</b>		
Make	Reputed	Design Requirement
Qty	01	Design Requirement
Type	Panel mounted	Design Requirement
Supply	220 VAC	Design Requirement
Size	96 X 96 m2	Design Requirement
<b>Printer (Common For CIP And SIP System)</b>		
Make	Epson	Design Requirement
Qty	01	Design Requirement
Type	Dot matrix/online printer	Design Requirement
Model no.	LX-300+II	Design Requirement
Power supply	230 VAC,sinfle phase	Design Requirement
Location	On SS printer stand	Design Requirement
Communication pin	25 pin –RS232	Design Requirement
<b>Skid (Common For CIP And SIP System)</b>		
Make	Pharmatech	Design Requirement
Qty	01	Design Requirement
Type	Rectangular	Design Requirement
MOC	SS 304	Design Requirement
Size	As per drawing	Design Requirement
<b>Tube</b>		
Make	TG-Pro/equipment	Design Requirement
Qty	Within skid	Design Requirement
Type	ERW	Design Requirement
MOC	SS 316	Design Requirement
Size	1.5”ODX16 Gauge	Design Requirement
Internal	Electro polished	Design Requirement
<b>TC Union (Comprising For Ferrule, Clamp And Gasket)</b>		
Make	Pharmatech	Design Requirement
Qty	With in skid	Design Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
CIP/SIP MODULE (500 LITER)**

CRITICAL VARIABLE	SPECIFICATION	REFERENCE
MOC	SS 316	Design Requirement
Ferrule	SS304	Design Requirement
Clamp	Food grade silicon	Design Requirement
Gasket	Inside and outside machine	Design Requirement
Finish	Finish	Design Requirement
Size	1 1/2"	Design Requirement
<b>Bend</b>		
Make	Alfa Laval /Equi.	Design Requirement
Qty	With in skid	Design Requirement
Type	ERW	Design Requirement
MOC	SS 316	Design Requirement
Size	1.5"OD X 16 Gauge	Design Requirement
Internal	Electro polished	Design Requirement
<b>Pipe Holding Tank</b>		
Make	Pharmatech	Design Requirement
Qty	With in skid	Design Requirement
MOC	SS 304	Design Requirement
Size	Suitable to 1.5" OD tube	Design Requirement
<b>Hose Pipe</b>		
Make	Ami polymer	Design Requirement
Qty	02	Design Requirement
Type	Flexible hose pipe	Design Requirement
MOC	Silicon wire braided	Design Requirement
Size	1.5"	Design Requirement
Length	1000 mm long	Design Requirement
<b>Utility Details For CIP</b>		
Electricity	3 phase , 50 Hz ,415 VAC	Design Requirement
Instrument air	6-8 BAR (G)	Design Requirement
Purified water	1.5 to 2.5 Bar (G)	Design Requirement
WFI	1.5 to 2.5 Bar (G)	Design Requirement
Plant steam	1.5 to 2.5 Bar (G)	Design Requirement

**TECHNICAL SPECIFICATION OF ACCESSORIES & BOUGHT UP COMPONENT FOR SIP**



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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
<b>Temperature Sensor With Transmitter</b>		
Make	Radix	Design Requirement
Qty	02	Design Requirement
Type	PT 100	Design Requirement
MOC	Sensor SS 316 L	Design Requirement
Mounting	Mini T/C	Design Requirement
Range	0° to 200°C	Design Requirement
Accuracy	Class A	Design Requirement
Sheath Dia & length	8 mm Ø x 65 Lg	Design Requirement
output	4-20 m A	Design Requirement
<b>Auto Diaphragm Valve</b>		
Make	Gemu	Design Requirement
Qty	01 nos	Design Requirement
Type	Pneumatic optd. Diaphragm valve.	Design Requirement
Size	Ø 12	Design Requirement
MOC	Contact part SS 316L Non contact parts SS 304	Design Requirement
End Connection	T/C end	Design Requirement
Application	For steam supply	Design Requirement
<b>Pressure Gauge</b>		
Make	BAUMER	Design Requirement
Qty	01 nos	Design Requirement
Type	Sterile diaphragm gauge	Design Requirement
MOC	Contact –SS 316 L Non contact –SS 304	Design Requirement
Size	2.5” dial	Design Requirement
Accuracy	1.6 % FS	Design Requirement
Mounting	1” T/C	Design Requirement
Range	0-7 kg/cm <sup>2</sup>	Design Requirement
<b>Angle Control Valve</b>		
Make	Pharmatech	Design Requirement
Qty	02 Nos	Design Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
Type	Diaphragm, Sterile, Single acting SS actuator, Angle type, Spring Loaded,3 port	Design Requirement
MOC	Contact –SS 316 L (inside EP) Non contact – SS 304 ,diaphragm silicon	Design Requirement
Size	Ø 25mm	Design Requirement
End Connection	T/C End	Design Requirement
<b>Angle Control Valve</b>		
Make	Pharmatech	Design Requirement
Qty	01 Nos.	Design Requirement
Type	Sterile ,Diaphragm, single acting SS actuator ,Angle type , spring loaded , 3 port	Design Requirement
MOC	Contact –SS 316 L (inside EP) Non contact – SS 304 ,diaphragm silicon	Design Requirement
Size	Ø 12 mm	Design Requirement
End Connection	T/C End	Design Requirement
<b>3 Way Angle Control Valve</b>		
Make	Pharmatech	Design Requirement
Qty	01 Nos.	Design Requirement
Type	Sterile ,Diaphragm, single acting SS actuator ,Angle type , spring loaded , 3 port	Design Requirement
MOC	Contact –SS 316 L (inside EP) Non contact – SS 304 ,diaphragm silicon	Design Requirement
End Connection	T/C End	Design Requirement
Size	Ø 12 mm	Design Requirement
<b>Sterile Safety Valve</b>		
Make	Shakti	Design Requirement
Qty	01 Nos.	Design Requirement
Type	Sterile diaphragm	Design Requirement
MOC	Contact –SS 316 L (inside EP) Non contact – SS 304 ,diaphragm silicon	Design Requirement
Size	Ø 9.3 x mm 12.5 mm (inlet/outlet)	Design Requirement
Mounting	Ø 25 TC	Design Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
Capacity	100 M <sup>3</sup> /hr of steam @2.5 Bar (g)and 60 M <sup>3</sup> /hr of air	Design Requirement
Set pressure	2.7 Bar (g)	Design Requirement
<b>Pressure Sensor With Transmitter</b>		
Make	JUMO	Design Requirement
Qty	01 Nos.	Design Requirement
TYPE	d TRANS p31 ,402050	Design Requirement
Output	4-20 mA ,2 wire	Design Requirement
Pressure range	-1 to 5 barg	Design Requirement
Process connection	T/C CLAP	Design Requirement
Response Time	3 msec max.	Design Requirement
Protection	IP65 to EN 60529	Design Requirement
Product No.	43000679	Design Requirement
Model no.	402050/000-482-405-613-20-61/000	Design Requirement
<b>Air Filter</b>		
Make	PALL	Design Requirement
Qty.	01 Nos.	Design Requirement
RATING	0.2μ	Design Requirement
Cartridge	125 mm Emflon	Design Requirement
Area	0.28 M <sup>2</sup>	Design Requirement
MODEL	Housing MDSCU1106010	Design Requirement
End connection	15 NBT/C	Design Requirement
<b>Sterile Steam Trap</b>		
Make	JORDAN	Design Requirement
Qty.	01 Nos.	Design Requirement
Tpye	Thermodynamic	Design Requirement
MOC	SS 316 L	Design Requirement
Size	3/4"	Design Requirement
Model	Sterilflow MK-93	Design Requirement
PMA	145 PSIG	Design Requirement
TMA	350F	Design Requirement
PMP	90 PSIG	Design Requirement





**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
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<b>CRITICAL VARIABLE</b>	<b>SPECIFICATION</b>	<b>REFERENCE</b>
End connection	T/C	Design Requirement

**8.5 MATERIAL OF CONSTRUCTION**

<b>S. No.</b>	<b>PARTS NAME</b>	<b>MOC</b>
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.	Conductivity Sensor with Analyzer	SS 316L
7.	N2 gas inlet	SS 316L
8	Diaphragm valve	SS 316L
9	Product inlet	SS 316L
10	Vent filter	SS 316L
11	Valve for air vent	SS 316L
12	Vent filter housing	SS 316L
13	Compounding gauge connection	SS 316L
14	Compounding gauge	SS 316L
15	Safety valve Connection	SS 316L
16	Safety valve	SS 316L
17	CIP connection	SS 316L
18	Spray ball	SS 316L
19	Product temp. Sensor	SS 316L
20	Sampling valve	SS 316L
23	Outlet valve	SS 316L
24	Pure steam line	SS 316L
26	Steam trap	SS 316L
27	Condensate line	SS 304
28	Pressure gauge	SS 316L
29	Hose pipe	Grade Silicon



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
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S. No.	PARTS NAME	MOC
30	Gaskets	Grade Silicon
31	Tube	SS 316L

**8.6 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

**8.7 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

**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: .....**





**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
CIP/SIP MODULE (500 LITER)**

**12.0 RECOMMENDATION:**

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**13.0 ABBREVIATIONS:**

- °C : Degree centigrade
- μ : Micron
- ASA : American Standard Association
- cGMP : Current Good Manufacturing Practices
- CIP : Cleaning in place
- cm<sup>2</sup> : Centi meter square
- CQA : Corporate Quality Assurance
- DQ : Design Qualification
- EPDM : Ethylene Propylene Diene Monomer
- GA : General Arrangement
- HP : Horse Power
- Hz : Hertz
- IB : Injection block
- ID. : Identification



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
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KG.	:	Kilogram
LTD.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
NLT	:	Not less than
No.	:	Number
O.D.	:	Outside Diameter
PLC	:	Programmable logical controller
PO	:	Purchase Order
PTFE	:	Tetra Fluoro Ethylene.
PU	:	Poly urethane
PVT.	:	Private
QA	:	Quality Assurance
Qty.	:	Quantity
Ra	:	Roughness average
SIP	:	Sterilization in place
SS	:	Stainless Steel
SV	:	Safety Valve
T/C	:	Triclover
URS	:	User Requirement Specification
V	:	Volt



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
CIP/SIP MODULE (500 LITER)**

**14.0 REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			