INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

CIP/SIP MODULE

CAPACITY (500 LITER)

EQUIPMENT ID. No.	
LOCATION	**CIP/SIP ROOM FFS LINE**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
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PROTOCOL CONTENTS

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

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 provide documented evidence for the Installation Qualification of CIP/SIP Module.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification Protocol cum Report is limited to qualification of CIP/SIP Module (**Make:** Pharmatech Process Equipments) to be installed in the CIP/SIP Room.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform Installation qualification activity of CIP/SIP Module.

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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	• Initiation, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in CIP/SIP Module Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	CIP/SIP Module
Equipment	
Manufacturer's Name	Pharmatech Process Equipment
Model	cGMP Model
Job No.	
Supplier's Name	Pharmatech Process Equipment
Location of Installation	CIP/SIP Room

6.0 SYSTEM DESCRIPTION:

CIP-SIP Module 500 Ltr is fully automatic unit used for washing and Sterilizing different capacity of vessel (Capacity from 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

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- Centrifugal pump
- SS skid
- Panel
- Pure steam line
- 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
- Auto Steam Trap unit
- Air filter

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- Level switch
- Conductivity sensor with analyzer
- Pressure Gauge
- Variable Frequency Drive for pump
- Interconnection piping
- Pressure Sensor with Transmitter
- Angle Control Valve
- Temperature Sensor with Transmitter
- 3 Way Control Valve
- Sterile Safety Valve
- Air Filter
- Sterile Steam Trap
- Pressure Gauge
- Interconnecting Piping

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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Instrumentation diagram
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	CIP/SIP room FFS Line		
Room Condition	General working condition		
Illumination in area	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
(Production)
(Sign/Date):…….

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

Inference:

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Reviewed By
(Manager QA)
Sign & Date:……

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

8.2 Equipment Verification:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	CIP/SIP Module 500L			
Model	cGMP Model			
ELECTRICAL INSTALLATION:				
Electricity	Voltage	415±10% V		
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
All terminals are tightened	Should be tightened			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			
UTILITY INSTALLATION FOR CIP				
Purified water connections have been provided	Should be provided @ 1.5 to 2.5 Bar(g) Pressure			
WFI connections have been provided	Should be provided@ 1.5 to 2.5 Bar(g) Pressure			
Filtered Compressed air connections have been provided	Should be provided (6-8 bar) pressure			
Pure Steam connections	Dry and saturated at defined pressure. @1.5 to 2.5 Bar(g)			

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have been provided	Pressure		
UTILITY INSTALLATION FOR SIP			
Instrument air	6-8 Bar(g)		
Pure Steam	1.5 Bar(g) @ 122.6° C		
N2/Air	3 Bar(g)		

Checked By
(Production)
(Sign/Date):…….

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

Inference:

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Reviewed By
(Manager QA)
Sign & Date:……

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

8.3 Installation Checks:

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Verify that the "As built" drawings are complete and represent the design concept		
2.	Check the proper mechanical installation CIP/SIP Module		
3.	Check the proper electrical installation of CIP/SIP Module		
4.	Check the parts are working properly.		
5.	Check the equipment is free from any defects		
6.	Check the finishing of product contact parts		
7.	Check that all parts are getting lubricated		
8.	Verify that major components are securely anchored and protected from shock		
9.	Verify that all parts and materials used for the equipment are as per GMP requirements. Surfaces are easy to clean and non-particle shedding		
10.	Verify that there is no observable physical damage		
11.	Verify that "Room layout" drawing		

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	is OK and sufficient space for servicing is provided		
12.	All bought out components (motors, pneumatics, starters, relays, timers, switches, circuit breakers etc.) adhere to the specifications/ brands mentioned in the equipment manual		

Checked By
(Production)
(Sign/Date):…….

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

Inference:

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Reviewed By
(Manager QA)
Sign & Date:……

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

8.4 EQUIPMENT VERIFICATION

S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.0	**Body:**			
	Contact part	AISI SS 316 L		
	Non contact	AISI SS 304		
2.0	**Surface Finish**			
	Internal	Ra ≤ 0.5 µm electro finish (electro polish)		
	External	Ra ≤ 0.9 µm matt finish (mechanical polish)		
3.0	**Volume**			
	Working	Approx 500 ltr.		
4.0	**Basic CIP tank data**			
	Heads	Top torispherical ,4 mm thick Bottom torispherical , 5 mm		
5.0	**Insulation**			
	Type	Arm flex		
	Thickness	38 mm		
	Cladding	2 mm thick SS welded cladding on shell & 3 m on		
6.0	**Support**			
	TYPE	4 NOS. SS 304 legs		
7.0	**Spray Ball**			
	Make	LEACHER		
	Qty.	01 NOS.		
	Type	self rotating , 360° rotating ,detachable		
	MOC	SS 316		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Size	Ø 61		
	Mounting	On top		
8.0	**Compound Gauge**			
	Make	BAUMER		
	Qty.	01 NOS		
	Type	Sterile diaphragm gauge		
	Contact	SS 316 L		
	Non contact	SS 304		
	Range	760 to 10 Kg/cm^2		
	Accuracy	± 1.6% F.S.		
9.0	**Sterile Safety Valve**			
	Make	PHARMATECH		
	Qty	01 NOS		
	Type	Sterile diaphagram		
	MOC	Contact –SS 316 L Non contact SS 304		
	Set pressure	2.5 barg and 60 M^3/ hr of air 3.25 bar (g)		
10.0	**Plain Vent Filter**			
	Make	Pall		
	Qty	01 NOS		
	Type	Emflon, code 7 Hhydrophobic		
	Rating	0.2 micron		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Size	5 “long		
	MOC	Housing SS 316 L Cartridge double layer PTFE		
	Mounting	Gasket Silicon		
	Model	Cartridge AB05HTPFR2PVH4		
	Housing	VSVNLI05G723H4		
11.0	**Auto Diaphragm Valve**			
	Type	Pneumatic optd. diaphragm valve		
	MOC	Contact part SS 316 L Non Contact Part SS 304		
	Application	For WFI inlet		
	Diaphragm	PTFE with EPDM Backup		
	End connection	T/C end		
	Size	Ø 25		
12.0	**Capacitance Type Level Sensor**			
	Type	Capacitance Type Level Sensor		
	Application	Level measurement		
13.0	**Auto Diaphragm Valve**			
	Make	Gemu		
	Qty	01 Nos.		
	Type	Pneumatic optd. Diaphragm valve.		
	MOC	Contact part SS 316L Non contact parts SS 304		
	Application	For outlet line		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Size	Ø 38		
	Diaphragm	PTFE with EPDM Backup		
	End connection	T/C end		
14.0	**Auto Diaphragm Valve**			
	Make	Gemu		
	Qty	01 Nos.		
	Type	Pneumatic optd. Diaphragm valve.		
	Size	Ø 25		
	MOC	Contact part SS 316L Non contact parts SS 304		
	Application	For vessel drain		
	Diaphragm	PTFE with EPDM Backup		
	End connection	T/C end		
15.0	**Temperature Sensor With Transmitter**			
	Make	RADIX		
	Qty	01 nos		
	Type	PT 100		
	MOC	Thermo well SS 316 L Sensor		
	Range	0° to 200 ° C		
	Accuracy	Class “A”		
	Connection	3Wire		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Sheath Dia & Length	12 Ø x 105Lg		
16.0	**Ball valve**			
	Make	Micro		
	Qty	01 Nos.		
	Type	Pneumatic operated ball valve		
	Application	Air vent at jacket side		
	MOC	Contact parts SS 304 Non Contact Parts SS 304		
	End Connection	T/C Ended		
	Size	15NB		
17.0	**Pressure Gauge for Jacket**			
	Make	Baumer		
	Qty	01 nos.		
	MOC	SS 304		
	Range	0 to 7 bar (g)		
	Accuracy	± 1.6 % FSD		
	End Connection	1/4” BSP Threaded		
	Size	Ø 65 mm Dial		
18.0	**Safety Valve For Jacket**			
	Make	Fainger leser		
	Qty	01 nos		
	Model	06/CS44SS2		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	MOC	SS 304		
	Gasket	PTFE		
	Set pressure	2.7 bar(g)		
	Service	Steam		
	Temperature	150°		
	Over pressure	10% of pressure		
	End Conn.	Screwed		
	Inlet Conn. rating	¾" BSP (M)		
	Outlet Conn	1" BSP (F)		
19.0	**Ball Valve**			
	Make	Micro		
	Qty	01 nos		
	Type	Pneumatic operated ball valve		
	Application	Jacket steam inlet		
	MOC	Contact parts –SS 304 Non contact parts –SS304		
	Size	25 NB Dia		
	End Conn	T/C Ended		
20.0	**Steam Trap Unit**			
	Make	Rex		
	Qty	01 nos		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Type	Steam trap thermodynamic		
	MOC	Body –SS 420 strainer –SS304		
	Size	20 NB		
	End connection	3/4” BSP threaded		
21.0	**Ball Valve for Steam trap Unit**			
	Make	Micro		
	Qty	02 nos		
	Type	Pneumatic ball valve		
	MOC	Contact parts –SS 304 Non contact parts –SS304		
	Make	Pharmatech		
	Qty	1 lot		
	Type	ERW		
	MOC	SS 304		
22.0	**Centrifugal Pump For CIP Supply**			
	Make	Inoxpa		
	Qty	01 nos		
	Type	Centrifugal		
	Model No.	SE-28		
	Capacity	4.5 m3/hr		
	Head	30 MWC		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	MOC	AISI 316 impeller		
	Rating of motor	2.2 KW-2 pole /415 V, AC/50HZ/3 phase		
	End Connection	T/C End		
23.0	**Variable Frequency Drive For Centrifugal Pump**			
	Make	ABB		
	Qty	01 Nos.		
	Series	ACS550		
	Rating	3HP		
	Ambient Temperature	-10 TO 55°C		
	Power Supply	380-500 V AC +10% / -15%, 3 ph		
	Output Frequency	50 … 60 Hz ±5%		
	Protection	IP20		
	Ambient humidity	max 95% non-condensing		
	EMC	Filter Inbuilt		
24.0	**Auto Diaphragm Valve**			
	Make	Gemu		
	Qty	02 Nos.		
	Type	Pneumatic optd. diaphragm valve		
	Size	Ø 25		
	MOC	Contact part SS 316 L Noncontact Part SS 304		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Application	For air filter		
	End connection	T/C end		
	Diaphragm	PTFE with EPDM Backup		
25.0	**Auto Diaphragm Valve**			
	Make	Gemu		
	Qty	02 Nos.		
	Type	Pneumatic optd. diaphragm valve		
	Size	Ø 38		
	MOC	Contact part SS 316 L Noncontact Part SS 304		
	Application	For air filter		
	End connection	T/C end		
	Diaphragm	PTFE with EPDM Backup		
26.0	**Auto Diaphragm Valve**			
	Make	Gemu		
	Qty	02 Nos.		
	Type	Pneumatic optd. diaphragm valve		
	Size	Ø 12		
	MOC	Contact part SS 316 L Noncontact Part SS 304		
	Application	For air filter		
	End connection	T/C end		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Diaphragm	PTFE with EPDM Backup		
27.0	**Pressure Gauge**			
	Make	BAUMER		
	Qty	01 nos		
	Type	Sterile diaphragm		
	MOC	Contact –SS 316 L Non contact –SS 304		
	Range	0-7 kg/cm^2		
	Mounting:	1” T/C End		
	Accuracy	± 1.6% FSD		
28.0	**Air Filter**			
	Make	Pall		
	Qty	01		
	Rating	0.2µ		
	Cartridge	125 mm emflon MCY 4463 PFR PVH4		
	Model	Housing MDSCU110607007 Cartridges MCY4463PFR		
	End connection	Ø 25 T/C		
29.0	**Pressure Gauge for Air Filter**			
	Make	Baumer		
	Qty.	01		
	Type	Glycerin Filled Gauge		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	MOC	Contact parts SS 316L Non contact parts SS 304		
	Size	Ø 2.5" Dial		
	Mounting:	1/2" BSP		
	Range	0 to 10 Kg/cm2		
	Accuracy	± 1.6% FSD		
30.0	**Conductivity Sensor With Analyzer**			
	Make	Mettler toledo		
	Qty	01		
	Cell constant measurement	0.1 cm-1		
	Principal	2-electro sensor		
	Body	SS316		
	Temperature device	Pt 1000 IEC Class A		
	Accuracy of cell	± 1%		
	Constant	0.02 to 20.00µS/cm		
	Measuring range	85 mm		
	Model	Single channel analyzer		
	Type	110 to 240VAC		
	Power Supply	4-20 Ma		
	Display	Panel mounted		
31.0	**PLC (Common For CIP And SIP System)**			

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Make	Alen bardley		
	Qty	01		
	Type	Programmable logic		
	Model no.	1766-L32BXB		
	Software	RS logix 500		
	NO. of DI	20		
	NO of DO	12		
	Temperature	-20 to +65°C		
32.0	**HMI (Common For CIP And SIP)**			
	Make	Allen Bradley		
	Qty	01		
	Type	Color touch screen		
	Model No.	PVP-600		
	Resolution	320X240,18bit color graphics		
	Backlight	CCFL,50,000h		
	Software	RS view factory		
	Operation Temperature	0-55°C		
	Power Supply	24 VDC		
	User Data Space	10 K		
	Ports:	Serial and Ethernet		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
33.0	**Control Panel (Common For CIP And SIP)**			
	Make	Pharmatech		
	Type	Dust Proof		
	Qty	01		
	MOC	SS 304		
	Gasket	Rubber		
	Size	As per design		
	Finish	Mirror		
34.0	**FRL Unit (Common For CIP AND SIP)**			
	Make	Festo		
	Qty	01		
	Model	FRC1/4-D-MINI		
	Range	0-16 bar		
	Mounting Location	Panel mounted		
35.0	**Hooter (Common For CIP And SIP)**			
	Make	Reputed		
	Qty	01		
	Type	Panel mounted		
36.0	**Printer (Common For CIP And SIP)**			
	Make	Epson		
	Qty	01		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Type	Dot matrix/online printer		
	Model no.	LX-300+II		
	Power supply	230 VAC,sinfle phase		
	Location	On SS printer stand		
37.0	**Skid (Common For (CIP And SIP)**			
	Make	Pharmatech		
	Qty	01		
	Type	Rectangular		
	MOC	SS 304		
	Size	As per drawing		
38.0	**SS Castors**			
	Make	Pharmatech		
	Qty	01		
	Type	2 Nos. Swivel, 2 Nos. with		
	Size	Brake		
	MOC	PU coated , SS 304		
	Internal	Electro polished		
39.0	**Pipe Holding Tank**			
	Make	Pharmatech		
	Qty	With in skid		
	MOC	SS 304		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Size	Suitable to 1.5” tube		
40.0	**Hose Pipe**			
	Make	Ami polymer		
	Qty	01		
	Type	Flexible hose pipe		
	MOC	Silicon wire braided		
	Size	1.5”		
	Length	1000 mm long		
TECHNICAL SPECIFICATION OF SIP				
1.0	**Temperature Sensor With Transmitter**			
	Make	Radix		
	Qty	02		
	Type	PT 100		
	MOC	Sensor SS 316 L		
	Range	0° to 200°C		
	Accuracy	Class A		
	Sheath Dia & Length	8 Ø x 65Lg		
	Mounting	Mini T/C		
2.0	**Auto Diaphragm Valve**			
	Make	Gemu		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Qty.	01 nos		
	Type	Pneumatic optd.diaphragm valve.		
	MOC	Contact part SS 316L Non contact parts SS 304		
	Application	For steam supply		
	End connection	T/C end		
	Diaphragm	PTFE with EPDM Backup		
3.0	**Pressure Gauge**			
	Make	BAUMER		
	Qty	01 nos		
	Type	Sterile diaphragm gauge		
	MOC	Contact –SS 316 L Non contact –SS 304		
	Range	0-7 kg/cm^2		
	Size	Ø 2.5” Dial		
	Mounting	1” T/C End		
4.0	**Angle Control Valve**			
	Make	Pharmatech		
	Qty	02 Nos.		
	Type	Diaphragm, Sterile, Single acting SS actuator, Angle type, Spring Loaded,3 port		
	MOC	Contact –SS 316 L (inside EP) Non contact – SS 304		
	Diaphragm	Silicon		

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S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Size	∅ 12 mm		
	End Connection	T/C End		
5.0	**Angle Control Valve**			
	Make	Pharmatech		
	Qty	02 Nos.		
	Type	Diaphragm, Sterile, Single acting SS actuator, Angle		
	MOC	Contact –SS 316 L (inside EP) Non contact – SS 304 ,diaphragm silicon		
	Diaphragm	Silicon		
	Size	∅ 25 mm		
	End Connection	T/C End		
6.0	**3 Way Angle Control Valve**			
	Make	Pharmatech		
	Qty	01 Nos.		
	MOC	Contact –SS 316 L (inside EP) Non contact – SS 304 ,diaphragm silicon		
	End Connection	T/C End		
	Type:	Diaphragm, Sterile, Single acting SS actuator, Angle type, Spring Loaded,3 port		
	Size	∅ 12 mm		
	End Connection	T/C End		

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

S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
7.0	**Sterile Safety Valve**			
	Make	Pharmatech		
	Qty	01 Nos.		
	Type	Sterile diaphragm		
	MOC	Contact –SS 316 L (inside EP) Non contact – SS 304 ,diaphragm silicon		
	Capacity	100 M^3/hr of steam @2.5 Bar (g)and 60 $M^{3/}$hr of air		
	Set pressure	2.7 Bar (g)		
	Diaphragm	Silicon		
8.0	**Pressure Sensor With Transmitor**			
	Make	JUMO		
	Qty.	01 Nos.		
	Type	D TRANS p31 ,402050		
	Output	4-20 mA ,2 wire		
	Pressure range	-1 to 5 barg		
	Product No.	43000679		
	Model no.	402050/000-482-405-613-20-61/000		
	Process conn.	T/C Clamp		
	Response time	3 msec max.		
	Protection	IP65 to EN 60 529		
9.0	**Air Filter**			
	Make	PALL		
	Qty.	01 Nos.		
	Rating	0.2µ		
	Cartridge	125 mm Emflon		

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

S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Area	0.28 M2		
	Model	Housing MDSCU1106010		
	End connection	15 NBT/C		
10.0	**Sterile Steam Trap**			
	Make	JORDAN		
	Qty.	01 Nos.		
	Type	Bellows type thermostatic steam trap		
	MOC	SS 316 L		
	Max. Allowable Pressure	145psig		
	Max. Allowable Temp	350º F		
	End conn	T/C end		
11.0	**Pressure Gauge for Air Filter**			
	Make	Baumer		
	Qty.	01		
	Type	Glycerin Filled Gauge		
	MOC	Contact parts SS 316L Non contact parts SS 304		
	Size	Ø 2.5” Dial		
	Mounting:	1/2” BSP		
	Range	0 to 10 Kg/cm2		
	Accuracy	± 1.6% FSD		

Checked By
(Production)
(Sign/Date):…….

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

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

Inference:

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Reviewed By
(Manager QA)
Sign & Date:……

8.5 MATERIAL OF CONSTRUCTION:

COMPONENT	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Vessel	SS 316L		
Jacket shell	SS 304		
Spiral baffles	SS 304		
N2 gas inlet	SS 316L		
Product inlet	SS 316L		
Plain Vent filter	SS 316L		
Valve for air vent	SS 316L		
Vent filter housing	SS 316L		
Compounding gauge contact part	SS 316L		
Sterile Safety valve Connection	SS 316L		
Safety valve for jacket	SS 316L		
CIP connection	SS 316L		
Spray ball	SS 316L		
Temperature Sensor with Transmitter	SS 316L		
Sampling valve	SS 316L		
Outlet valve	SS 316L		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

COMPONENT	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Pure steam line	SS 316L		
Steam trap unit for jacket side	SS 316L		
Ball Valve for Steam trap Unit	SS 316L		
Condensate line	SS 304		
Auto Diaphragm Valve	SS 316L		
Pressure Gauge for Air Filter	SS 316L		
Steam Trap Unit for Jacket Side	Strainer SS304		
Ball Valve for Steam trap Unit	SS304		
Pressure gauge	SS 316L		
Piping for Steam strap Unit	AISI 304		
Angle Control Valve	SS 316L		
3-Way Angle Control Valve	SS 316L		
Temperature Sensor with Transmitter	SS 316L		
Air Vent Ball Valve for Jacket Vent	SS 304		
Pressure Gauge for Jacket	SS 304		
Ball Valve for Jacket Steam Inlet	SS 304		
Safety Valve for Jacket	SS 304		
Gaskets	Food Grade Silicon		
Tube	SS 316L		

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

Checked By
(Production)
(Sign/Date):…….

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

Inference:

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Reviewed By
(Manager QA)
Sign & Date:……

8.6 Supporting Utilities:

UTILITY DESCRIPTION	PROPERLY CONNECTED AND IDENTIFIED	DEVIATION	OBSERVED BY ENGINEERING SIGN/DATE
Electric power supply			
Earthing			

Checked By
(Production)
(Sign/Date):…….

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

Inference:

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Reviewed By
(Manager QA)
Sign &Date:……

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

8.7 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
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.		
Guards	Guards for all Moving Parts		
Noise Level	Below 80 db		
Main Supply	Main power supply should be always switched off when not in use.		
Safety valve	Safety against over pressure		
SS cover on pump	For operator safety		
Emergency stop	Protection from abnormal condition		
Air pressure switch	Protection for low air pressure for pneumatic valves		

Checked By
(Production)
(Sign/Date):…….

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

Inference:

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Reviewed By
(Manager QA)
Sign & Date:……

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

9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.

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

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION,IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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

16.0 ABBREVIATIONS:

°C	:	Degree centigrade
µ	:	Micron
AISI	:	American Iron & Steel Institute
ASA	:	American Standard Association
ASME	:	American Society for Mechanical Engineers
BPE	:	Bio-Pharmaceutical Equipments
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practice
CIP	:	Cleaning in place
cm^2	:	Centi meter square
GA	:	General Arrangement
GMP	:	Good Manufacturing Practice
HP	:	Horse Power
Hz	:	Hertz
ID.	:	Identification
IQ	:	Installation qualification
KG.	:	Kilogram
LTD.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
NLT	:	Not less than

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

No.	:	Number
PLC	:	Programmable logical controller
PO	:	Purchase Order
PTFE Poly	:	Tetra Flouro Ethylene.
PU	:	Polyurethane
PVT.	:	Private
QA	:	Quality Assurance
Qty.	:	Quantity
Ra	:	Roughness average
SIP	:	Sterilization in place
SS	:	Stainless Steel
T/C	:	Triclover
Temp.	:	Temperature
V	:	Volt
WHO	:	World Health Organization

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

17.0 PROTOCOL POST -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)			