INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CIP SYSTEM

EQUIPMENT ID. No.	
LOCATION	**Equipment Washing Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

 PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CIP SYSTEM	PROTOCOL No.:

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)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of CIP System.
- 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 System (**Make:** ……) to be installed in Equipment Washing 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 System.

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	• Preparation, Review, Authorization 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 Review and Authorization of Installation Qualification Protocol cum Report after Execution.
Production	• 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 of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in CIP SYSTEM Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Review of Installation Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	CIP SYSTEM
Equipment	
Manufacturer's Name	
Model	cGMP Model
Supplier's Name	
Location of Installation	Equipment Washing Room

6.0 SYSTEM 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

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.

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	Equipment Washing Room Ointment Section		
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:……

8.2 Equipment Verification:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	CIP SYSTEM 300 L			
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 have been provided	Dry and saturated at defined pressure. @1.5 to 2.5 Bar(g) Pressure			

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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 System		
3.	Check the proper electrical installation of CIP system		
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 is OK and sufficient space for servicing is provided		

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
12.	All bought out components (motors, pneumatics, starters, relays, timers, switches, circuit breakers etc.) adhere to the specifications/ brands mentioned in the equipment manual		

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8.4 EQUIPMENT VERIFICATION

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	CHECKED BY ENGINEERING SIGN/DATE
CIP Feed Tank (T-101):			
Quantity	01 No.		
Make	Hydro pure Systems		
Capacity	300 Ltrs.		
Type	Vertical Tank with Ceramic Band Heater		
MOC	SS 316L		
Tank Diameter	600 mm		
Tank Height	1000 mm		
Cladding Diameter	750 mm		
Cladding Height	900 mm		
Thickness of Top Dish	2 mm		
Thickness of Shell	2 mm		
Thickness of Bottom Dish	2 mm		
Thickness of Cladding	1.6 mm		
Power Rating of Ceramic band heater (CBH-101)	24 kW		
Operating Condition:			
Max. Operating Pressure for vessel	1.5 kg/cm^2 (g)		
Design Pressure for vessel	3.0 kg/cm^2 (g)		
Hydrotest Pressure for vessel	3.9 kg/cm^2 (g)		
Max. Temperature for vessel	150^0 C		
Design Temperature for vessel	200^0 C		
Insulation	2” Rockwool duly cladded with SS Sheet		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CIP SYSTEM	PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	CHECKED BY ENGINEERING SIGN/DATE
Surface Finish	Internally - < 0.4 Ra, Externally – Matt Finish		
CIP Feed Pump (CIPFP-101)			
Quantity	01 No.		
Make	Grundfos		
Model No.	CM 3-4 A-R-G-V AQQV		
Flow Rate	2.5 m^3/hr		
Head	28 mWC		
MOC of Impeller	SS 316		
MOC of Casing	SS 316		
Motor Rating	0.46 kW		
SS SKID:			
MOC	SS304 with SS castor wheels for above component		
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.		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CIP SYSTEM	PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	CHECKED BY ENGINEERING SIGN/DATE
Level Switch			
Make	Mahalaxmi		
Location	For CIP feed Tank		
Range	1150 mm		
Type	Rod Type Magnetic Switch		
MOC	SS 316L		
Diaphragm Valve			
Make	Avcon/ Crane		
Location	Drain line of T-101		
	Suction line of CIPFP-101		
	Discharge line of CIPFP-101		
Range	40 mm		
	25 mm		
MOC	SS 316L		
Qty.	03 Nos.		

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Inference:

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Reviewed By
Manager QA
Sign & Date:……

8.5 MATERIAL OF CONSTRUCTION:

S.No.	Component	Acceptance Criteria	Observation	Checked by Engineering Sign Date
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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8.6 Supporting Utilities:

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

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Inference:

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Manager QA
Sign & Date:……

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		

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Verified By
Quality Assurance
Sign/Date:……

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Manager QA
Sign & Date:……

9.0 REFERENCES:

- Validation Master Plan
- Design Qualification Protocol
- P & ID
- Electrical Wiring Diagram

10.0 DOCUMENTS TO BE ATTACHED:

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

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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16.0 ABBREVIATIONS:

°C	:	Degree centigrade
µ	:	Micron
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
No.	:	Number
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

17.0 PROTOCOL POST -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)			