OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CIP SYSTEM

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

PROTOCOL CONTENTS

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PHARMA DEVILS	OPERATIONAL 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 verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of CIP System and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of CIP System (**Make:** …….) installed in the Equipment Washing Room.
- This Protocol will define the methods and documentation used to perform OQ activity of CIP System for OQ. Successful completion of this protocol will verify that CIP System meets all acceptance criteria and ready for Performance Qualification.

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 Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity. • Post Authorization of Operational Qualification Protocol cum report after Execution.
Production	• Pre Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum report after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in CIP System Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Review of Operational 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:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP for operation & Cleaning of CIP SYSTEM.
- SOP for Preventive Maintenance of CIP SYSTEM.

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 OQ 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 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY QA SIGN/DATE
1.	Executed and approved Design Qualification document			
2.	Executed and approved Installation Qualification document			
3.	SOP for operation & Cleaning of CIP System.			
4.	SOP for Preventive Maintenance of CIP System.			

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……

Inference:

……

……

Reviewed By
Manager QA
Sign & Date:……

8.2 Test /Measuring Equipment Calibration:

EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENT I.D.	CALIBRATION ON	DUE ON	OBSERVED BY SIGN/DATE

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……

Inference:

……

……

Reviewed By
Manager QA
Sign & Date:……

8.3 Operational and Functional Checks:

Operate the CIP System as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

OPERATION	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Hydro test	No Leakage from any joint at specified Hydro test pressure within 30 minutes of observation.		
Mains Indication Lamp	Check all 3 phases supply is incoming		
Key operated Control Circuit Switch	Control circuit on/off switch		
MCB's (Control/Power)	Circuit Breakers		
Contactors	Contactor switches		
Relays	Initiators		
DC Power Source	For 24V DC control voltage		
Pressure Switch	For water supply		
Pressure Switch	For Compressed Air		
Solenoid valve	For operating process valves		
Supply Pump Motor overload trip relay	To trip the supply pump motor during overload		
Return Pump Motor overload trip relay	To trip the return pump motor during overload		
Supply Pump Flow switch	To stop the supply pump in absence of water		
Return Pump Flow	To stop the return pump in		

OPERATION	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
switch	absence of water		

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……

Inference:

……

……

Reviewed By
Manager QA
Sign & Date:……

8.4 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……

Inference:

……

……

Reviewed By
Manager QA
Sign & Date:……

9.0 REFERENCES:

- Validation Master Plan
- Design Qualification Protocol
- Installation Qualification Protocol
- Operating manual

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificate of Test & Measuring Instrument.
- Any Other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED 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:

CIP	:	Clean in Place
DQ	:	Design qualification
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
No.	:	Number
OQ	:	Operational Qualification
PVT	:	Private
SIP	:	Sterilization in Place
SOP	:	Standard operating procedure
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)			