OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

CIP/SIP MODULE

CAPACITY: 500 LITER

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CIP/SIP MODULE (500 LITER)	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CIP/SIP MODULE (500 LITER)	PROTOCOL No.:

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)			

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/SIP Module 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/SIP Module (**Make:** ……...) installed in the CIP/SIP Room.
- This Protocol will define the methods and documentation used to perform OQ activity of CIP/SIP module for OQ. Successful completion of this protocol will verify that CIP/SIP Module 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, Approval 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 Approval of Operational Qualification Protocol cum report after Execution.
Production	• Review & 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 & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in CIP/SIP Module Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational Qualification Protocol cum report after Execution.

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM DESCRIPTION:

CIP-SIP Module 250 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
- 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
- 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

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

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

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

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

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

Inference:

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

8.2 Test /Measuring Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

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:

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Reviewed By
(Manager QA)
Sign/Date:……

8.3 Operational and Functional Checks:

Operate the CIP/SIP Module 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.		
Spray Ball Test	Spray pattern of water found all over 360° uniformly & All the surface of vessel internal should be free from Riboflavin dye.		
Hooter	Audio / Visual Alarm		
Pressure Switch	For water supply		
Pressure Switch	For Compressed Air		
Solenoid valve	For operating process valves		
Steam inlet solenoid valve	Open/Close Steam Solenoid valve		
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	To stop the return pump in		

Flow switch	absence of water		

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

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

Inference:

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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.		
Operator Level	Operator level should have access to process selection, process start & stop in auto, manual mode, print start & stop, alarm, visualization. It should have access to acknowledge the alarm & reset the process.		
Supervisory Level	Supervisory level should have access to operator level all menu and in addition to that, should have excess to set the process parameter, batch info, recipe preparation & recipe upload		
Administrative Level	Administrative should have access to supervisory level all menu and in addition to that, should have excess to change the password.		

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

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

Inference:

……

……

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

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master 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:

- Operation and Maintenance Manual.
- 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
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
No.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
SIP	:	Sterilization in Place
SOP	:	Standard operating procedure
WHO	:	World health organization

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)			