



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation & Cleaning of Clean In Place Module (CIP) & Sterilization In Place (SIP) System

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 OBJECTIVE:

To lay down a procedure for Operation of Clean in Place (CIP) & Sterilization In place (SIP) system.

2.0 SCOPE:

This SOP is applicable for Operation & Cleaning of CIP & SIP system (Make: **Pharmatech**) in Production area of

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

CIP	Clean In Place
ID	Identification
Ltd.	Limited
No.	Number
PLC	Programmable Logic Control
Pvt.	Private
QA	Quality Assurance
IPQA	In Process Quality Assurance
SIP	Sterilization in Place
SOP	Standard Operating procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 CHECK & PRECAUTION FOR CIP:

- 6.1.1 Ensure the availability of utility for CIP operation like Purified Water, Water for Injection, Pure Steam, Compressed Air and Electricity.
- 6.1.2 Open the Steam Inlet Valve and check the Pressure of Pure Steam. (It should be between 1.0 to 2.0 Kg / cm²).
- 6.1.3 Open the Compressed Air Inlet Valve and check the Pressure of Compressed Air. (It should be between 4.0 to 6.0 Kg / cm²).
- 6.1.4 Open compressed air Supply valve & Purified water Loop line valve main valve in Pre-rinse & Intermediate Cycle.
- 6.1.5 Open WFI Loop line valve in Final Rinse of the cycle.



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6.1.6 Ensure all the Pneumatic valve connection and operation is OK.

6.1.7 Ensure the printer connection & operation is OK.

6.1.8 To enter at the Operator Level, press the “NAME” button in the Login Menu and enter the Operator level. The following are the operator levels:

1. A - Operator Level
2. B - Supervisor Level
3. C - Manager Level
4. D - Engineering Level

6.1.9 Before start Each Cycle parameter should be checked by production & Verified by IPQA. By printout.

6.2 OPERATION OF CIP:

6.2.1 Switch ON the Instrument

6.2.2 Press on Login tab to go to the Main Menu. Enter user name & password. & tab on login icon.





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6.2.3 After successfully Login press on back tab & following screen shall display.



6.2.4 The Main menu has the following options as explained below:

MODE		DESCRIPTIONS
Semi auto Mode	:	The auto mode button allows the operator to run the process in Semi auto mode.
Maintenance Mode	:	The Maintenance Mode allows to operate the machine in Maintenance mode.
Login/ Log Out	:	To gain access to certain parameters, login to the system with correct password. When successfully logged in, login level shall display on the screen. Allows to logout. Once desired changes are completed, it is recommended to press this key and log out so that unauthorized persons cannot change data.
P& ID	:	Allows Pictorial diagram of system & allow Operation of valve in Maintenance mode.
Set Parameter	:	Allow To set parameter on Higher Level Access. On operator Level it is not accessible.

6.2.5 Select Maintenance mode for the maintenance of the CIP & SIP system.



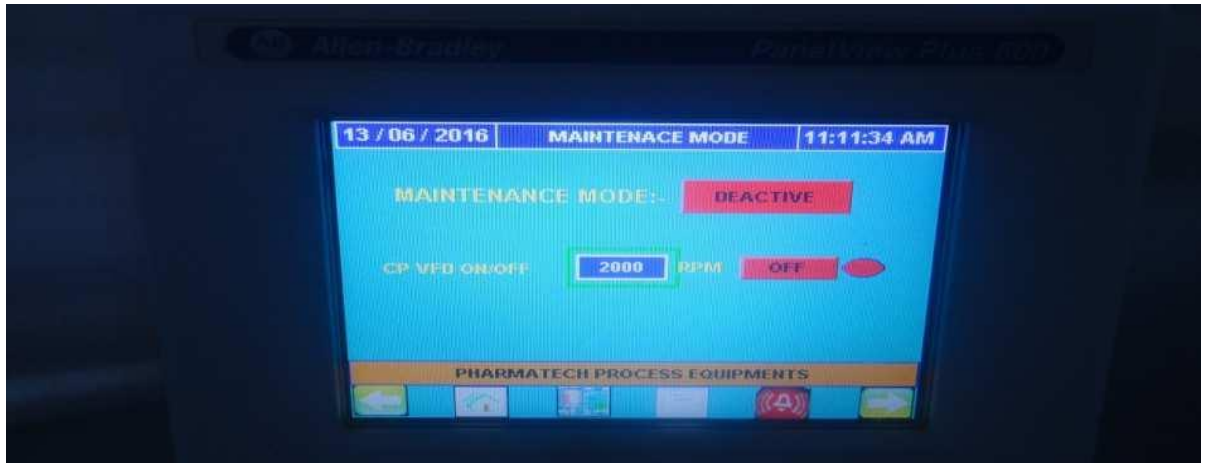
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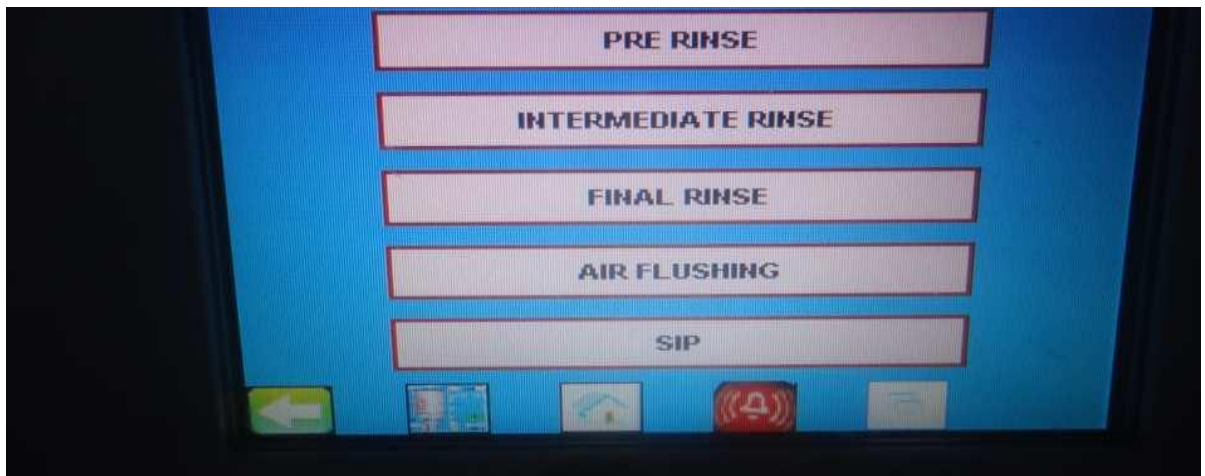
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6.2.6 Select Semi auto mode Following Screen Will is displayed.



6.2.7 To Start CIP select Pre rinse cycle.





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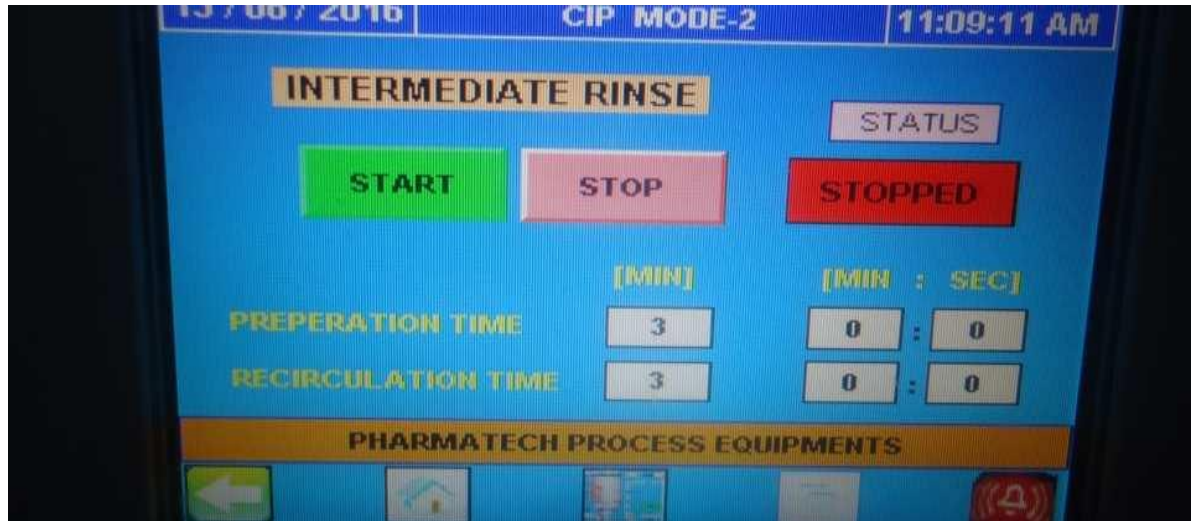
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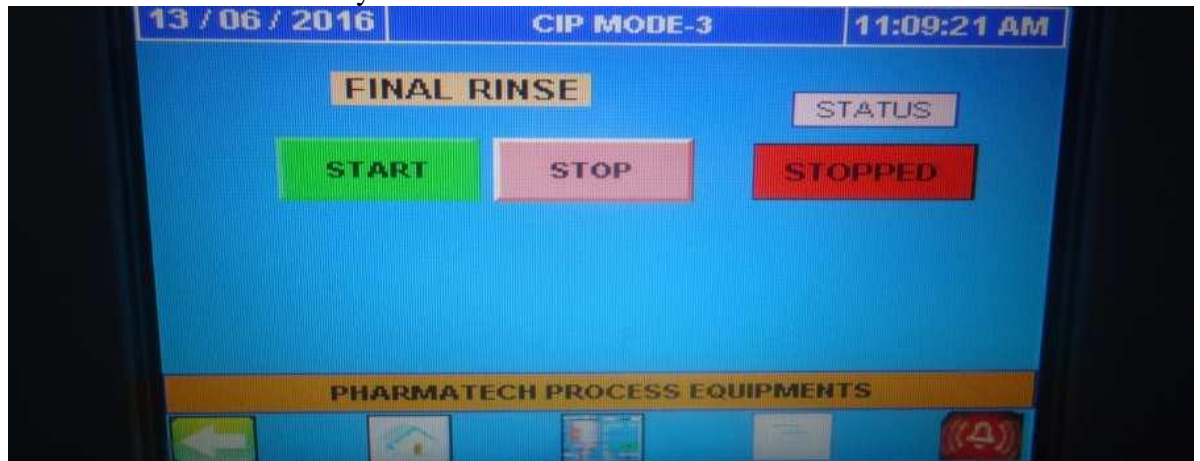
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6.2.8 After completion Of Pre rinse cycle, Next Select Intermediate Cycle.



6.2.9 After Completion of Intermediate Cycle Select Final Rinse Cycle. Close the Valve of Purified Water & Open Valve of WFI & Start the cycle. Cycle will automatically Completed after The set valve of The Conductivity.



6.2.10 After Complete of Final Rinse select Air Flushing Cycle to break pressure & Remove Stem & water Droplet.

6.2.11 To Monitor CIP use P & ID diagram.



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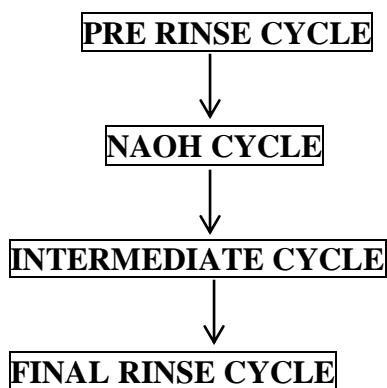


6.2.12 After Completion of CIP cycle, Change Connection.

6.2.13 In case of conductivity is not within limits process will be stop. In this case abort the process and start again until conductivity doesn't comply and process completed successfully.

6.3 CLEANING PROCEDURE FOR NON AQUEOUS TO AQUEOUS PRODUCT CHANGE OVER.

6.3.1 SEQUENTIAL STEPS INVOLVED



6.3.2 Start CIP module and select the PRE RINSE CYCLE.

6.3.3 At the end of the cycle collect the sample and send to the QC for oil traces.

Note: If results not complies repeat the pre rinse cycle.

6.3.4 Prepare the 0.1% NAOH (0.4 gm in 100 ml) in the pressure vessel. Take about 2.0 kg of NAOH and 50 liters of WFI.



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NOTE: USE SAFETY GOGGLE AND MASK WHILE PREPARING THE SOLUTION.

- 6.3.5 Pressure vessel connected to the CIP module and Flush NAOH solution in the vessel interconnecting pipe lines and buffer tank through compressed air.
- 6.3.6 Disconnect the pressure vessel from the CIP MODULE.
- 6.3.7 Start the CIP Module select the intermediate cycle. After completion close the purified water valve.
- 6.3.8 Select the Final rinse cycle. Collect the sample and check the pH and ensure the traces of NAOH removed. If the pH is not in neutral again perform the final rinse cycle till clear from the NaOH.
- 6.3.9 Send the sample to QC for pH verification. Verify the cycle printout and attached the respective BMR.

6.4 OPERATION & CLEANING OF SIP:

- 6.4.1 Close Valve of Purified water, & WFI open valve of steam.
- 6.4.2 Select SIP Icon & Start the cycle.



- 6.4.3 After completion of Cycle Print should be checked by production & verified by IPQA.
- 6.4.4 Attach print out in concerned BPCR.
- 6.4.5 But In this module only have CIP system



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6.4.6 SIP is not done by CIP/SIP Module although it is performed by in built facility for SIP in manufacturing/Holding tanks.

6.4.7 During CIP and SIP operation, if cycle abort during power fluctuation/ Overshoot then following steps to be taken

6.4.7.1 If cycle abort condition comes then inform to Engg department and take out the running printout from printer.

6.4.7.2 Review this printout and store in a file.

6.4.7.3 If power resume immediately then start new cycle of CIP or SIP.

6.5 CLEANING OF CIP & SIP SYSTEM:

6.5.1 Before starting cleaning of the CIP & SIP Module (Panel and SS Pipe lines) ensure that the System is cooled up to Room Temperature.

6.5.2 Before startup of cleaning, check that all the openings of the CIP & SIP System are closed.

6.5.3 Switch “OFF” the CIP & SIP Module before Startup of Cleaning Activity.

6.5.4 Clean the external surface of the CIP & SIP System & SS Pipelines with Clean Lint Free Mopping Pad dipped in Water for Injection.

6.5.5 While Cleaning Do Not Open / Touch the Electrical Parts.

6.5.6 Dry Mop all the Electrical Parts and PLC Screen with Clean Lint Free Mopping Pad.

6.5.7 Dry the CIP & SIP System (Panel & Pipelines) with Dry & Clean Lint Free Mopping Pad to ensure complete cleaning of the CIP & SIP System.

6.5.8 After Cleaning write the Status Label on the CIP & SIP System.

6.5.9 Check and Verify the CIP & SIP Cycle Print Out and record the Operation Details as per “Machine Utilization Record” of SOP.....

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance



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- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By