



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: CIP of Production Equipments	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down the procedure for Cleaning of Mixing Vessel/Holding Vessel, Cartridge Housing & Filter Housings and Pipe lines using CIP.

2.0 SCOPE:

This SOP is applicable to Cleaning of Mixing Vessel/Holding Vessel, Cartridge Housing & Filter Housings and Pipe Lines using CIP (Make: **Pharmatech**) of Production Area at

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 Ensure the CIP in working condition.

6.1.2 Ensure all the utility supply for CIP operation.

6.1.3 Ensure the mixing tank is empty.

6.2 The Cleaning of Mixing Vessel, Mobile Mixing Vessel, Holding Vessel, Filling Vessel, Filter Housing and Filtration Pipe lines with Purified water followed by rinsed with WFI. The Procedure to be adopted after and before the production processing.



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6.3 CIP OF MANUFACTURING & FILTRATION LINE:

6.3.1 MIXING VESSEL, HOLDING VESSEL, FILTRATION LINE, FILTER CARTRIDGES AND BUFFER VESSEL:

- 6.3.1.1** Connect the CIP outlet supply to inlet of mixing vessel.
- 6.3.1.2** Connect the filtration line inlet to the mixing vessel outlet and followed by connect filter cartridge.
- 6.3.1.3** Now connect the filter cartridge outlet to CIP inlet.
- 6.3.1.4** Clean the outside body of mixing vessel, holding vessel, filtration line, filter cartridge housing and Buffer vessel with Hot WFI using lint free sponge (mopping pad).
- 6.3.1.5** Clean the mixing vessel vent filter separately with hot WFI and refit it.
- 6.3.1.6** Clean the sampling valve of mixing vessel.
- 6.3.1.7** Close the manhole of the mixing vessel with air tight.
- 6.3.1.8** Now set the IPC of CIP as per following parameter and batch details:
- 6.3.1.9** 1st press of IPC as show Display.
- 6.3.1.10** 2nd Step click .User name & password entry
- 6.3.1.11** 3rd Step Login successes fully for next processing
- 6.3.1.12** 4th Step Welcome MV & MMV tank select for next processing
- 6.3.1.13** 5th Step HV with BV tank select for next processing
- 6.3.1.14** 6th Step go to mode selection for processing.
- 6.3.1.15** 7th Step semi auto mode selection for MV, MMV, HV tank and press the start CIP Pre wash. Cycle complete than after press CIP Intermediate wash mode & final wash mode.
- 6.3.1.16** 8th step Comments fill up for propose
- 6.3.1.17** Run the CIP cycle as per the SOP for Operation of CIP.
- 6.3.1.18** Remove air packets in the cartridge filter assembly by air vent valve during the operation for every 5minutes.
- 6.3.1.19** Intimate QA to collect the sample of rinse water for its analysis in QC.



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6.3.1.20 Collect the CIP sample at the end of cycle by opening the sampling valve and send immediately to rinse water test like:

1. Conductivity
2. pH
3. Absorbance

6.3.1.21 Once the process is completed the CIP IPC will display “**Final wash mode Completed successfully**”.

6.3.1.22 Now switch off the IPC.

6.3.1.23 If QC result is not OK once again repeat the CIP cycle up to get OK result form QC.

6.3.1.24 Now the Mixing Vessel, Holding vessel Filtration Line and Filter Housing are all ready for SIP operation.

6.3.1.25 Write the Status Board Manufacturing Line is ready for further processing.

6.3.1.26 Verify the CIP cycle print outs. Record the details as per “**Equipment Log SOP**”.

6.4 CIP OF FILTRATION LINE:

6.4.1 Ensure the CIP in working condition.

6.4.2 Ensure all the utility supply for CIP operation.

6.4.3 Ensure the Holding tank is empty.

6.4.4 Connect the CIP supply to inlet of Holding vessel.

6.4.5 Connect the Holding vessel outlet to the CIP outlet valve.

6.4.6 Clean the outside body of Holding Vessel with Hot WFI using lint free sponge (mopping pad).

6.4.7 Clean the Holding vessel vent filter separately with hot WFI and refit it.

6.4.8 Ensure the purified water and WFI flushing spray ball in working condition.

6.4.9 Close the manhole of the Holding vessel with air tight.

6.4.10 Open the Holding vessel CIP inlet valve and bottom CIP outlet valve.

6.4.11 Now set the IPC of CIP as per following parameter and batch details:

6.4.12 Run the CIP cycle as per SOP for Operation of CIP.

6.4.13 Remove air packets in the air vent valve during the operation.



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6.4.14 Intimate QA to collect the sample of rinse water for its analysis in QC.

6.4.15 Collect the CIP sample at the end of cycle by opening the sampling valve and send immediately to rinse water test like

1. Conductivity
2. pH
3. Clarity

6.4.16 Once the process is completed the CIP. IPC will display “**Final wash mode Completed successfully**”.

6.4.17 Now switch off the CIP.

6.4.18 If QC results are not OK once again repeat the CIP cycle up to get OK result form QC.

6.4.19 Now the Holding vessel is ready for SIP operation.

6.4.20 Write the status board Holding Vessel is ready for processing.

6.4.20.1 Verify the CIP cycle Print Outs. Record the details as per “**CIP Log Book**”.

6.5 FREQUENCY OF CIP:

After each batch changeover/product changeover.

7.0 ABBREVIATION:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
QA	Quality Assurance
CIP	Clean in Place
IPC	Industrials Programmable Control
UV	Ultraviolet
MMV	Mobile mixing vessel
MV	Mixing vessel



PHARMA DEVILS

PRODUCTION DEPARTMENT

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BV Buffer vessel
HV Holding vessel

8.0 ANNEXURES:

Not Applicable

9.0 DISTRIBUTION:

- Controlled Copy No.1 Production
- Controlled Copy No.2 Quality Assurance
- Master Copy Quality Assurance Department

10.0 REFERENCE:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		