PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Operation, CIP and SIP of Carbon Processing Vessel	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for operation, CIP and SIP of carbon processing vessel.

2.0 SCOPE:

This SOP shall be applicable to the operation, CIP and SIP of carbon processing vessel of sterile injection.

EQP.ID : ……..

Make /Model. No. : ……..

Capacity : 500 Liter

3.0 RESPONSIBILITY:

3.1 Juniors Technicians and above of the sterile injection section shall be responsible for CIP, SIP and operation of carbon processing vessel.

3.2 Associate Officer and above of the sterile injection section shall be responsible for checking and verification of operation, CIP and SIP of carbon processing vessel.

3.3 Head production / Designee of sterile injection section shall be responsible for implementation of this SOP.

4.0 ACCOUNTABILITY:

Head Production.

5.0 SAFETY REQUIREMENTS:

5.1 Ensure all connections are ok before operation.

5.2 Ensure that there is no any electric line is opened.

6.0 PROCEDURE:

6.1 Precautions

6.1.1 Check the utility of carbon processing vessel as per current version of BMR before starting.

6.1.2 Ensure that the safety valve of jacket and vessel is calibrated before use.

6.1.3 Ensure that the view lamp is working.

6.1.4 Ensure that the carbon processing vessel and accessories are cleaned before use and labelled.

6.1.5 Operate the carbon processing vessel only when the liquid level is above the mixing head.

6.1.6 In case of any abnormal sounds or smells the mixer shall be stopped immediately and inform to engineering department for necessary actions.

6.1.7 Ensure that magnetic stirrer is always connected to the process vessel.

Note: Do not run the magnetic mixture in dry condition.

6.2 Operating Procedure of Carbon Processing Vessel

6.2.1 Ensure that the vessel with head plate and agitator part is cleaned.

6.2.2 Open the head plate of the vessel and add the material in the vessel as per the instructions given in BMR.

6.2.3 Close the vessel head plate with bolts.

6.2.4 Connect the power cable to the main switch.

6.2.5 Switch “ON” the main switch.

6.2.6 Put the selector switch in “ON” position, red signal indicates “Mains ON” and the VFD-M digital display shows readings.

6.2.7 Put the control key in “ON” position and the temperature digital display shows temperature.

6.2.8 Put the “VFD-M” key in Auto or Manual mode as per requirement.

6.2.9 Press “MODE” button to display the main setup menu to set the RPM setting.

6.2.10 Set the RPM as per the instructions given in BMR.

6.2.11 Press “ENTER” key to accept a selection just made in the setup menu.

6.2.12 Press the “MODE” key again to exit the setup menu. All parameters saved upon exit.

6.2.13 Press the green colored “RUN” button after entering the RPM of the magnetic mixer to start the mixing process.

6.2.14 Operate the agitator and increase the speed to required speed by increasing RPM setting if required, as per BMR.

6.2.15 After completion of set time, the mixing operation stops automatically.

6.2.16 Open the head plate. Check the clarity of the solution.

6.2.17 Carry out the in process checks, make up the volume and stir the solution as per BMR.

6.2.18 Slowly open the out let sample valve, take out samples in sampling vial.

6.2.19 Transfer the solution from carbon processing vessel to manufacturing vessel through filter press (Eq. ID. No. .....).

6.2.20 Operate the filter press as per current version of SOP No. .....

6.2.21 Record the operation details in the log book as per Annexure-I (Format No. .....) of current version of SOP No. .....

6.2.22 Switch "OFF" the magnetic mixer and control key.

6.2.23 Switch "OFF" the mains.

6.2.24 Close all the utilities supplied to the vessel.

6.3 Cleaning Procedure of Carbon Processing Vessel (CIP)

6.3.1 For Batch to Batch Change Over

6.3.1.1 Open the lid of the vessel and clean the inside surface with purified water.

6.3.1.2 Connect the SS Wire braided hose pipe to the purified water TC Clamp, Connect the other end of the hose pipe to the TC Clamp of spray ball of the carbon processing vessel.

6.3.1.3 After cleaning with purified water, disconnect the hosepipe from purified water TC clamp and connect the SS Wire braided hose pipe to the WFI TC clamp.

6.3.1.4 Collect the WFI by opening the diaphragm valve. Run the stirrer at 100 RPM and allow the water spray for 5 minutes. Drain the water. Rinse the vessel twice with WFI.

6.3.1.5 Clean the dip stick and wash it by applying a jet of purified water with flexible silicone hosepipe from inside and outside surface, finally rinse the dip stick with WFI.

6.3.1.6 Wipe the outer surface of the vessel with lint free cloth using WFI.

6.3.1.7 Attach "CLEANED" label to the vessel.

6.3.1.8 After cleaning proceeds for vessel sterilization and batch processing as per the current version of BMR.

6.3.1.9 In case there is no activities close the vessel and attach the "CLEANED" status label.

6.3.1.10 **Frequency:** Before and after every activity.

6.3.2 For Product Change Over

6.3.2.1 Open the lid of the vessel and clean the inside surface with purified water.

6.3.2.2 Connect the SS Wire braided hose pipe to the purified water TC clamp .Connect the other end of the hose pipe to the TC clamp of spray ball of the carbon processing vessel.

6.3.2.3 Collect 500 litre purified water by opening the diaphragm valve and run the stirrer at 100 RPM for 10 minute to wash off the mixing head.

6.3.2.4 After 10 minute drain the water.

6.3.2.5 Again collect the purified water by opening the diaphragm valve, run the stirrer. Allow the water spray for 5 minutes then drain the water

6.3.2.6 After cleaning with purified water, disconnect the hosepipe from purified water TC clamp and connect the hosepipe to the WFI TC clamp.

6.3.2.7 Collect the WFI by opening the diaphragm valve. Run the stirrer at 100 RPM and allow the water spray for 5 minutes. Drain the water. Rinse the vessel twice with WFI.

6.3.2.8 Remove the dip stick and wash it by applying a jet of purified water with flexible silicone hosepipe from inside and outside surface. Finally, rinse the dip stick with WFI and reinstall it in the vessel.

6.3.2.9 After proper cleaning give rinse water and intimate IPQA to collect sample for residual analysis.

6.3.2.10 Wipe the outer surface of the vessel with lint free mop using WFI.

6.3.2.11 Attach “CLEANED” label to the vessel.

6.3.2.12 After passing the residual test, proceed for vessel sterilization and batch processing as per the current version of BMR.

6.3.2.13 In case there is no activities close the vessel and attach the “CLEANED” status label.

6.3.2.14 **Frequency:** Before and after every activity.

6.4 Sterilization Procedure of Carbon Processing Vessel (SIP)

6.4.1 Precautions

6.4.1.1 Ensure that vessel is cleaned before sterilization.

6.4.1.2 Ensure that vessel is closed properly before start of sterilization.

6.4.1.3 Ensure that bottom discharge valve of magnetic mixing manufacturing and holding vessel is crack opened.

6.4.1.4 Ensure that filter housing along with hydrophobic 0.22µ vent filter is connected to TC end of carbon processing vessel.

6.4.2 SIP Procedure

6.4.2.1 Open the pure steam line valve and remove the pure steam line condensate.

6.4.2.2 Connect the SS Wire braided hose pipe to steam inlet TC provided on top of the vessel.

6.4.2.3 Connect the other end of SS Wire braided hose pipe to pure steam line.

6.4.2.4 Open the pure steam line diaphragm valve.

6.4.2.5 When temperature of chamber sensor reaches to 124^0C, close the steam line valve.

6.4.2.6 Maintain the chamber temperature for 40 minute from 121^0C to 124^0C by manually opening and closing of steam line valve.

6.4.2.7 Crack open vent filter housing valve of carbon processing vessel till the end of sterilization cycle.

6.4.2.8 Visually observes the pressure on compound pressure gauge fitted on carbon processing Vessel.

6.4.2.9 Visually observes the temperature on the display panel of Vessel every 5 minutes and record the same in the BMR.

6.4.2.10 After completion of 40 minutes of hold period, close the pure steam line valve. Immediately close the bottom discharge valve of the vessel.

6.4.2.11 Close the vent filter housing valve of vessel after the chamber pressure to drop down to zero.

6.4.2.12 Connect the one end of the PU tube to nitrogen line and another end to vent filter housing valve of vessel

6.4.2.13 Open the vent filter housing valve of the vessel then open the nitrogen at 1.0 kg/cm^2 and then open the bottom discharge valve of vessel and pass the nitrogen through vent filter housing to dry the filter and to cool the vessel to ambient temperature.

6.4.2.14 When the vessel cools to ambient temperature close the bottom discharge valve of vessel.

6.4.2.15 Close the vent valve of vessel and disconnect the PU tube from nitrogen line to vessel.

6.4.2.16 Attach the status label to the vessel.

6.4.2.17 Record the all details as per the current version of Annexure-I of SOP ..... and BMR.

Frequency: Once in a day when ever bath production planned and weekly once when there is no manufacturing activity.

7.0 REFERENCES:

SOP No.	Title
	Operation and Cleaning of Filter Press
	Usage of Equipment Log Book

8.0 ANNEXURES:

Not Applicable

9.0 ABBREVIATIONS:

Abbreviations	Full Forms
IPQA	In Process Quality Assurance
RPM	Round Per Minute
WFI	Water for injection
QC	Quality control
BMR	Batch Manufacturing Record
Ml	Millilitre
kg/cm^2	Kilogram Per Centimetre Square
TC	Tri Clover
SS	Stainless Steel
CIP	Clean In Place
SIP	Sterilization In Place
^0C	Degree Centigrade
µ	Micron
PU	Ploy Urethane
VFD	Variable Frequency Drive
Eq.	Equipment

10.0 REVISION HISTORY LOG:

Revision Number	Effective Date	Details of Change	Reason for Revision
00		Not Applicable	New Introduction