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1.0 Purpose

This procedure describes the operation, and cleaning of the Carr Pilot Viafuge.

2.0 Scope

This SOP applies to production personnel operating, decontaminating, and cleaning the Carr Pilot Viafuge.

3.0 Authority and Responsibility

3.1 The Technical Operations Director, Late Process Sciences, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 BDP Supervisors are responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 Production and other qualified personnel are responsible for the implementation of this procedure.

NOTE: All personnel operating this equipment must be familiar with the proper safety procedures.

3.4 BQA is responsible for quality oversight of this procedure.

4.0 Assembly of the Viafuge

- 4.1 When the clean components are dry, grease the Bowl Retaining Nut O-Ring with a lubricant approved per **SOP 21537 - Acceptance and Control of Materials Used in Operation and Maintenance of Facilities and Equipment** in the BDP such as Saf-T-Eze, BDP PN 21232, , and install O-Ring in the nut.
- 4.2 Re-lubricate the 3 Bowl Hub O-Rings and fit them into their slots on the Bowl Hub. Coat the bottom threads of the Bowl Hub, and the top edge of the Bowl Retaining Nut with Saf-T-Eze, BDP PN 21232.
- 4.3 Steady the Bowl Retaining Nut with one hand while using the other hand to screw the threaded end of the Bowl Hub into the matching threads on the Bowl Retaining Nut. Using torque wrench and adapter tool, tighten to 140 lb-in.
- 4.4 Replace O-Ring in top of base and install Bowl Case.
- 4.5 Using the Bowl Lock Pins, secure the Bowl Hub in place.
- 4.6 Lubricate the bottom threads inside the Bowl Shell (which screw onto the Bowl Hub) with Saf-T-Eze, BDP PN 21232. Also lubricate the smooth surface just above the bottom threads which will contact the uppermost O-Ring of the Bowl Hub; this is to prevent the O-Ring from binding during reassembly.
- 4.7 Install Bowl Shell onto Bowl Hub and secure with Bowl Wrench.
- 4.8 Remove the Bowl/Hub lock pins from the lower ferrules on the Bowl Case and install them into the upper ferrules in preparation for installing the Bowl Baffle.
- 4.9 Check the O-Ring on the Centrate Case, ensuring it is securely in place and well lubricated, and then place the Centrate Case onto the Bowl Case.
- 4.10 Check that the O-Ring on the Bowl Baffle is securely in place and well lubricated. Also check and lubricate the O-Ring at the top of the Bowl Shell.
- 4.11 Install Bowl baffle into Bowl shell. Tighten securely with the Bowl Baffle Wrench.
- 4.12 Remove the Bowl/Hub lock pins, then cap the four ferrules on the Bowl Case and secure with clamps. Use gaskets under the caps for a tight connection.
- 4.13 Replace the Case Cap with the Feed Tube assembly and secure it in place with the remaining 8" clamp. Reconnect all piping, valves, and related Tri-Clamps.
- 4.14 If the house vacuum system is to be connected to the Viafuge, check to make sure that a hydrophobic filter (e.g. 5" Pall Emflon PFR, PN 21429) is connected in the correct orientation on the vacuum line between the Viafuge and vacuum source. If during operation the vacuum strength is observed to decrease, the filter may have become wetted out and if so should be replaced.
- 4.15 The centrifuge is now ready to operate.

5.0 Operation of the Carr Pilot Viafuge

- 5.1 Before Operating the Centrifuge
 - 5.1.1 Connect a chilled water supply to the inlet of the rotor housing.
 - 5.1.2 Connect an air supply to the Air inlet fitting on the side of the Drive Unit and set the red valve to the SUP position. Check the gauge and confirm that it reads 65 psi.
 - 5.1.3 Close the Drain Valve attached to the Bowl Case Drain Port.
 - 5.1.4 Ensure that the Vent Port on the Case Cap is OPEN and that an appropriate filter is attached.
 - 5.1.5 Install a cap and gasket on the Accessory Port.
 - 5.1.6 Circulate the cooling solution for 5-10 minutes to stabilize temperature in the Bowl Case.
 - 5.1.7 Connect feed line inlet tubing. Details regarding inlet and outlet tubing configuration can be found in the Master Production Record.
- 5.2 Plug in the unit.
 - 5.2.1 Run a short simulation with RO water or better.
 - 5.2.2 Check that there are no leaks, no unusual noises, and no excessive vibrations.
- 5.3 Separation Cycle
 - 5.3.1 Set the BOWL SPEED switch to the FILL position.
 - 5.3.2 To start the centrifuge, push the FWD (Forward) Key on the Drive Control Pad. The Bowl should accelerate to the preset fill speed (1000 RPM) and hold there.

NOTE: If you need to STOP at the Pilot during Fill Mode, turn off the feed pump; press the STOP key on the Drive Control Pad. To continue with FILL mode, press the FWD button on the Control Panel.
 - 5.3.3 Check the digital display on the Control Pad and verify that the centrifuge is running at 1000 RPM.
 - 5.3.4 Turn on the pump to supply feed solution into the Centrifuge.
 - 5.3.5 Wait until the Bowl is filled with feed solution (centrate will begin flowing out from the Centrate Port).
 - 5.3.6 Turn the BOWL SPEED switch to the PROCESS setting; the centrifuge will accelerate to the process speed.
 - 5.3.7 Normal stopping sequence during process mode is done by first turning off the feed pump and set Bowl speed to fill position.



- 5.3.8 After finishing a batch, reverse the feed pump to evacuate cell concentrate from the Bowl. If your process results in solids packed against the Bowl wall, the system will have to be partially disassembled and the solids manually scraped from the Bowl.
- 5.3.9 Open the Case Drain Valve and drain any residual liquid from the Bowl Case to a container.

6.0 Disassembly of the Vialuge

- 6.1 Remove top concentrate case.
- 6.2 Take one of the Bowl/Hub Lock Pins and insert the shorter end (labeled BAFFLE REMOVAL) into one of the upper ferrules while turning the Bowl by hand to find the mating slot in the Bowl Shell. Do not use gasket in this step for proper lock pin spacing.
- 6.3 Use the Baffle Wrench to loosen the Bowl Baffle (counterclockwise) from the Bowl Shell. Unscrew the Baffle from the Bowl Shell and lift it out of the Shell.
- 6.4 Remove the Concentrate Case with its O-Ring.
- 6.5 Loosen and remove the two clamps and two lock pins securing the Bowl Shell.
- 6.6 Take one of the lock pins and insert the longer end into one of the lower ferrules while turning the Bowl by hand to find the mating slot in the Bowl Hub. Do not use gasket in this step for proper lock pin spacing.
- 6.7 Use the Bowl Wrench to loosen and remove the Bowl Shell from the Bowl Hub.
- 6.8 Lift out the Bowl Shell
- 6.9 After removing the Bowl Shell, remove the two Bowl/Hub pins from the Bowl Case.
- 6.10 Remove the remaining large clamp securing the Bowl Case to the Base Ring, then use the two handles to lift the Bowl Case.
- 6.11 To remove the Bowl Hub from the Spindle, use one hand to secure the Spanner Wrench to the Bowl Hub and the other hand to secure the ratchet wrench to the Bowl Retainer Nut. Separate the two pieces by turning the Bowl Retaining Nut in a clockwise direction.

7.0 Cleaning

NOTE: Do not soak or immerse the bearing housing in cleaning solution. Cleaning solution that is forced or allowed to seep into the bearing area may cause bearing damage of reduced life.

- 7.1 Loosen the Lock Nut and separate the Feed Tube from the Case Cap.
- 7.2 Clean the Case Cap, Feed Tube, Concentrate Case, Bowl Components, and any miscellaneous Sanitary Fittings by immersing for > 45 minutes per **SOP 12149 - General Cleaning of Process Equipment**. Document cleaning on **Form 12149-01**.
- 7.3 Wipe down the bearing housing, spindle, and Bowl case with an approved cleaning agent such as 70% IPA. Wipe with WFI after required contact time.

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- 7.4 After soaking, rinse parts with RO or better water to a conductivity of less than 5 μ S and collect a rinse water sample as per **SOP 12169 - Rinse Water Sampling for Production Equipment**, to submit to Process Analytics (PA) per **SOP 22002 - Request for Quality Control Testing**, for conductivity and TOC.
 - 7.5 Re-lubricate the 3 Bowl Hub O-Rings and fit them into their slots on the Bowl Hub (refer to attachment 1) Coat the bottom threads of the Bowl Hub, and the top edge of the Bowl Retaining Nut with Saf-T-Eze, BDP PN 21232.
 - 7.6 For reassembly steps, refer to section 2.0.
 - 7.7 Refer to the master production record for disposition of solids and supernatant.
 - 7.8 For product changeover, refer to **SOP 21529 - Equipment Interproduct Cleaning and Clearance**. Sample schedule 09001.

8.0 Documentation

- 8.1 Document cleaning and use on the appropriate master production record, **Form 12149-01** per **SOP 12149 - General Cleaning of Process Equipment**, and the Centrifuge Usage Logbook.

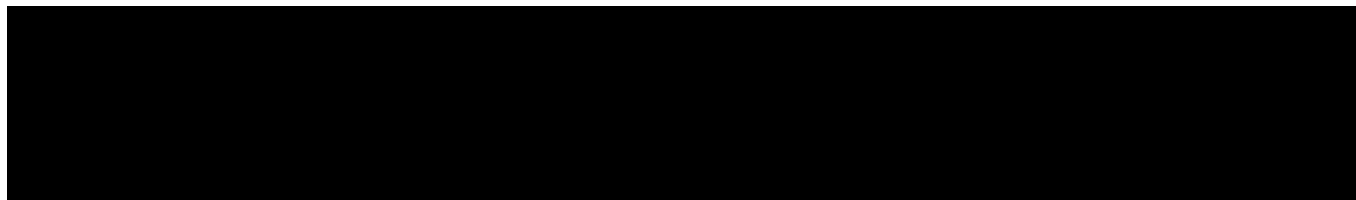
9.0 References and Related Documents

- 9.1 **SOP 12149** *General Cleaning of Process Equipment*
- 9.2 **SOP 12169** *Rinse Water Sampling for Production Equipment*
- 9.3 **SOP 21537** *Acceptance and Control of Materials Used in Operation and Maintenance of Facilities and Equipment in the BDP*
- 9.4 **SOP 21529** *Equipment Interproduct Cleaning and Clearance*
- 9.5 **SOP 22002** *Request for Quality Control Testing*

10.0 Attachment

- 10.1 **Attachment 1** **Diagram of the Carr Pilot Viafuge**

11.0 Change Summary



Attachment 1

Diagram of the Carr Pilot Vialuge

