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1.0 Purpose

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

2.0 Scope

This SOP applies to Fermentation Personnel operating, decontaminating, and cleaning the Carr Pilot Powerfuge.

3.0 Authority and Responsibility

3.1 The Director, Technical Operations, 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.

3.4 BQA is responsible for quality oversight of this procedure.

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

4.0 Assembly of the Powerfuge

4.1 When the clean components are dry, grease the bowl hub threads, the inside threads on the inside of the bowl, and the O-rings with an approved lubricant such as Saf-T-Eze, BDP PN 21232. Place the O-ring into the base ring, followed by the bowl case. Rotate the bowl case so that the sight glass is opposite the drive motor. Tighten the 8" triclamp.

4.2 Fib the bowl hub O-rings into their slots on the bowl hub (See Attachment 1, Figure 1)

4.3 Place the bowl hub on the spindle and lock it in place with the bowl lock handles.

4.4 Screw the bowl hub bolt with its O-ring into the threads in the spindle. (See Attachment 1, Figure 2). Torque the bowl bolt to 145 ± (5) inch-lbs.

4.5 Slowly lower down the bowl onto the bowl hub and screw it on hand-tight. Use the bowl wrench to secure the two parts together.

4.6 To ensure proper O-ring alignment, remove the bowl hub bolt and remove the bowl hub/bowl unit with the “T” shaped bowl hub removal tool. Ensure that the lower bowl O-ring maintains proper orientation.

4.7 Place the bowl hub/bowl unit into the spindle and secure with the bowl hub bolt according to the specification in Step 4.5.

4.8 Secure the centrate case, case cap, and end cap with triclamps.

4.9 Connect all piping and related triclamps with their gaskets and tighten.

5.0 Operation of the Carr Pilot Powerfuge

NOTE: Never restrict the 1.5 inch “Centrate Out” connection. Fittings used should allow unrestricted flow of centrate to avoid damage to the centrifuge.

5.1 Before Operating the Machine

5.1.1 Make sure that the machine is at rest on a level surface.

5.1.2 Verify that all triclamps are properly aligned and tight.

5.1.3 Connect a chilled water supply to the inlet of the rotor housing.

5.1.4 Connect a hose to the outlet of the rotor housing for draining or recirculation of the chilled water supply.

5.1.5 The two drain ports are ½” triclamps connections provided for draining overflow material from the bowl case and base ring areas. A valve must be attached to the bowl case drain port. Cap the base right drain during operation.

5.1.6 Close the drain valve located at the bottom of the hosing (Attachment I, Figure 4). Open the valve occasionally to prevent any bowl overflow form accumulating in the case. Discard any material collected as waste.

5.1.7 Check that the two bowl lock handles are disengaged from the bowl hub. Rotate bayonet pins 90° away from the insertion slots to prevent accidental pushing in of the bowl locks during the run (See Attachment I, Figure 3).

5.1.8 Attach the required discharge air barrier housing and associated filter per Attachment 3. Supernatant flowing into the barrier housing is to be pumped to an appropriately sized container.

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 Don appropriate PPE prior to connecting the production broth to the feed supply tube.

5.3.2 Connect the fee supply to the feed tube on top of the case cap and secure.

5.3.3 Prior to executing the separation cycle, ensure cooling solution circulation.

5.3.4 To start the separation cycle, push the FWD Key on the Control Pad (Attachment 2, Figure 5). Ramp the FWD Key to the setpoint speed specified in the Master Production Record (MPR) or by the Supervisor. The digital display will indicate the current RPM value. To change the value, simply press the white Up or Down arrow for the desired speed.

5.3.5 When the machine has reached the setpoint speed, turn on the feed pump and adjust the starting flow rate from the supply tank accordingly. Set the flow rate to the value specified in the MPR or by the Supervisor. Do not exceed 1L per minute.

5.3.6 Divert and collect a small amount of supernatant being discharged and check the sample visually for turbidity to confirm quality of centrifugal separation.

5.3.7 Based upon observation in Step 5.3.4, adjust the speed of the feed pump to optimize the balance between the flow rate and the supernatant solid content.

5.3.8 Continue the operation until the feed vessel is empty or the bowl is full of solids. Monitor supernatant as in Step 5.3.4 as the Powerfuge bowl fills with solids.

6.0 Bowl Removal

6.1 Disconnect or isolate the feed connection.

6.2 Push the stop button on the control panel and unplug the unit after stopping.

6.3 Removed the bowl case cap and the centrate case by loosening the associated large triclamps (Attachment 2, Figure 6).

6.4 Lock the bowl hub by engaging both bayonet pins with the bowl lock handles.

6.5 Place the bowl wrench over the bowl and unscrew the bowl (counterclockwise) from the bowl hub and lift out the bowl (Attachment 2, Figure 7).

6.6 The bowl is now ready for removal of cell paste. Remove the cell paste by scraping the bowl with the scraper.

6.7 Reinstall the bowl; reattach the centrate case and bowl case cap taking care to assure that all O-rings are seated properly. Release the bowl lock handles, and continue harvesting or proceed to decontamination and cleaning.

7.0 Decontamination and 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 or reduced life.

7.1 Unplug or verify that the unit is unplugged.

7.2 Remove the bowl per Step 6.0. Remove the bowl hub by first removing the bolt and then use the "T" shaped bowl hub removal tool to free the bowl hub from the spindle.

7.3 Soak the case cap, centrate coast, bowl, bowl hub, and any miscellaneous sanitary fittings in approved cleaning agent, for a minimum of 45 minutes.

7.3.1 Alternatively, the above parts may be cleaned via ***SOP 19411 - Operation and Maintenance of the Girton Parts Washer.***

7.4 Clean the bearing housing, spindle, and bowl case by wiping down with an approved cleaning agent per the Supervisor's instructions.

7.5 After soaking, rinse parts with RO or better water to a conductivity of less than 5 μS, and collect a rinse water sample as per ***SOP 12169 - Rinse Water Sampling for Production Equipment***, to submit to Biopharmaceutical Process Analytics (BPA) per ***SOP 22002 - Request for Quality Control Testing.***

7.6 Refer to the Master Production Record for disposition of solids and supernatant.

7.7 For product changeover, refer to ***SOP 21529 - Equipment Interproduct Cleaning and Clearance.***

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

SOP 12169	Rinse Water Sampling for Production Equipment
SOP 22002	Request for Quality Control Testing
SOP 21529	Equipment Interproduct Cleaning and Clearance
SOP 12149	General Cleaning of Process Equipment
SOP 19411	Operation and Maintenance of the Girton Parts Washer

10.0 Attachments

11.0 Change Summary

ATTACHMENT I

Bowl Hub Assembly

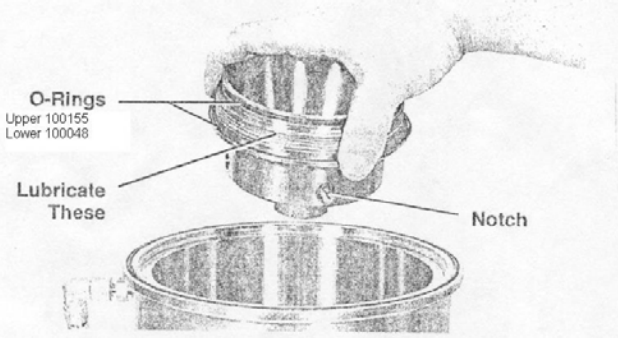

Figure 1
Installing the Bowl Hub

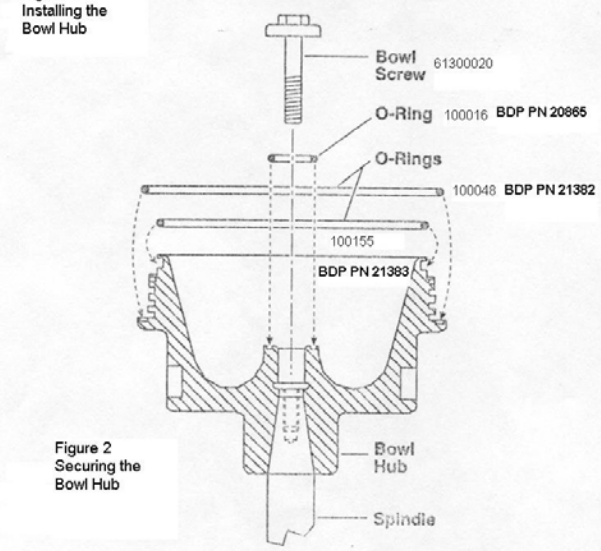

Figure 2
Securing the Bowl Hub

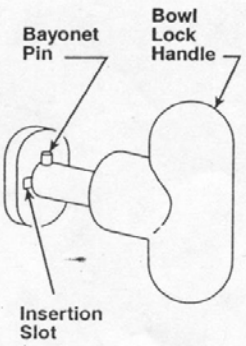

Figure 3
Bowl Lock Handle— Unlocked Position. Note: Position of handle relative to pin may vary.

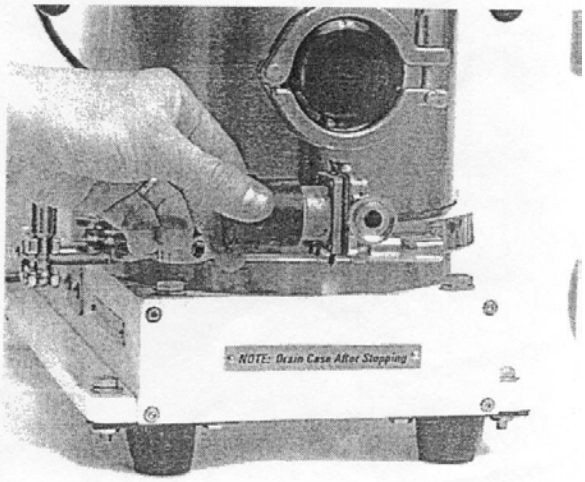

Figure 4
Bowl Overflow Drain Valve

ATTACHMENT 2

Centrate Case Assembly

Figure 5

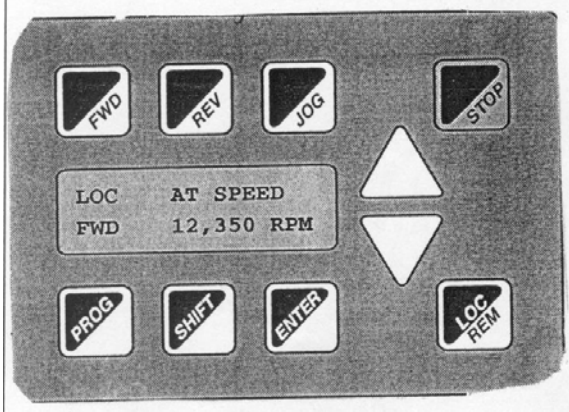

Figure 6

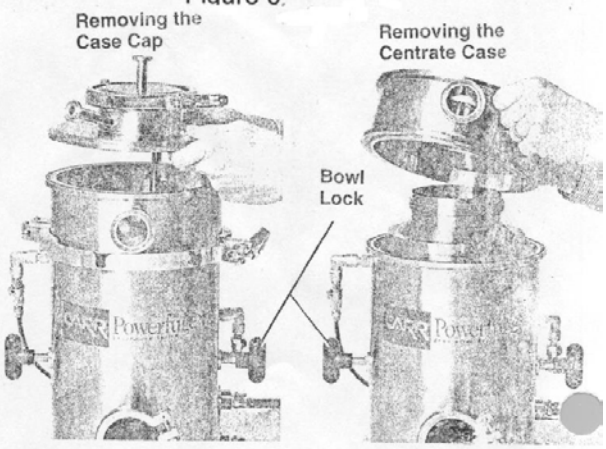

Figure 7

ATTACHMENT 3

Complete Centrifuge Setup