BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title:	**Operation and Maintenance of the Panda Bench-top Homogenizer**
SOP Number:	**12111**
Revision:	**03**

TABLE OF CONTENTS

1. PURPOSE 1
2. SCOPE 1
3. RESPONSIBILITIES 1
4. MATERIALS AND REAGENTS 2
5. EQUIPMENT 2
6. PROCEDURE OR USE 2
7. PREVENTATIVE MAINTENANCE 4
8. CLEANING 4
9. DOCUMENTATION AND RECORDS 6
10. REFERENCES AND RELATED DOCUMENTS 6

1. PURPOSE

This procedure describes the operation of the Panda Bench Top Homogenizer.

2. SCOPE

This Standard Operating Procedure (SOP) applies to Production personnel who will be using the Panda Bench Top Homogenizer.

3. RESPONSIBILITIES

3.1 The Manager, Manufacturing, Late Process Sciences, Biopharmaceutical Development Program (BDP)

- Defines the procedure.
- Trains personnel and document this training to BQA.

3.2 BQA

- Provides Quality oversight of this procedure.

4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
10001	0.5 N NaOH	☒ YES ☐ NO
10106	100% Ethanol	☒ YES ☐ NO
20763	½" Sanitary EPDM gaskets	☒ YES ☐ NO
20956	¾" Sanitary EPDM gaskets.	☒ YES ☐ NO
WFI Use Point	Water For Injection (WFI)	☒ YES ☐ NO

5. EQUIPMENT

- Niro Panda Benchtop Homogenizer.
- Jacketed feed hopper.
- Jacketed product cooler.
- Cooling water hoses with ½" sanitary connections (4)
- Feed and Collection tanks.
- Conductivity meter
- Clamps for sanitary gaskets.

6. PROCEDURE OR USE

6.1 Setup

6.1.1 Connect cooling water from chilled water bath or building chilled water system to the jacketed feed hopper and the product cooler.

6.1.2 Connect the main power cord to the wall outlet.

6.1.3 If the volume to be processed is greater than the volume in the feed hopper, the hopper can be fed at a flow rate less than the product flow from the homogenizer (100 mL/minute).

6.2 Pre-Run Water Test

6.2.1 Fill up the feed hopper with Water For Injection (WFI). Alternatively, the hopper can be filled with lysis buffer as specified in Master Production Record (MPR).

6.2.2 Before starting the homogenizer, locate the pressure regulating hand wheel and ascertain it has been rotated counterclockwise and is completely loose. The pressure prior to starting the motor should be 0 bar, as indicated by the digital pressure gauge.

6.2.3 Start the machine by turning on the power switch on the front of the machine.

6.2.4 Observe the outlet pipe to see that water is flowing out.

6.2.5 If water is not flowing out, it may be due to trapped air in the homogenizing head. To eliminate this problem, back out the hand wheel for the homogenizer valve until the pressure gauge shows 0 bar. Unscrew the delivery valve while running the machine. Once water is flowing, screw the delivery valve back in. Refer to the equipment manual for further information.

6.2.6 Increase the homogenization pressure by rotating the regulating hand wheel clockwise until the desired pressure (max 1500 bar) can be read on the pressure gauge.

6.2.7 If, after performing the above procedure, the pressure gauge does not show any pressure, or a very low pressure, and water is not flowing, switch off the machine and repeat steps 6.2.1 to 6.2.6.

6.2.8 If the machine fails to operate properly, it is probably due to imperfect closure of the suction and delivery valves. Refer to the equipment manual for disassembly. Remove any debris present using a lint free wipe.

6.3 Product Run

6.3.1 For batch operations, set up two tanks for feeding and collection of the homogenate.

6.3.2 Follow section 6.2 using lysis buffer to set the homogenizing pressure as indicated by the Batch Production Record (BPR).

6.3.3 Monitor the temperature at the outlet. Refer to the batch production record for allowable temperatures.

6.3.4 Take a retention sample (minimum 1 mL) after each pass of material through the homogenizer for lysis efficiency determination, if desired.

6.3.5 When all of the feed has been processed and collected in the collection tank, additional passes can be processed.

6.3.6 Refer to the experimental procedure or batch production record for number of passes to be processed.

7. PREVENTATIVE MAINTENANCE

7.1 Proper and prompt cleaning is crucial for reducing the amount of work needed for maintenance of this piece of equipment.

7.2 Perform the cleaning if the machine will remain idle for more than 2 hours.

7.3 Perform the cleaning between different products.

8. CLEANING

8.1 Procedure

8.1.1 Set the homogenizer pressure to 0 by turning the homogenizer pressure hand wheel counterclockwise.

8.1.2 Start the machine by turning the main power knob. Run the machine until any accumulated fluid has been discharged through the outlet pipe.

8.1.3 Turn the machine off.

8.1.4 WFI Rinse:

8.1.4.1 Fill the feed hopper with room temperature WFI.

8.1.4.2 Start the machine and run it until all WFI has run through.

8.1.4.3 Stop the machine.

8.1.4.4 Repeat steps 8.1.4.1 through 8.1.4.3 two more times.

8.1.5 0.5 N NaOH Rinse

8.1.5.1 Prepare a 0.5 N solution of sodium hydroxide (NaOH) in WFI.

8.1.5.2 Fill the feed funnel with the 0.5 N NaOH solution.

8.1.5.3 Start the machine and run it until all NaOH has run through.

8.1.5.4 Repeat steps 8.1.5.1 through 8.1.5.3 two more times.

8.1.5.5 Stop the machine.

8.1.5.6 Close off the outlet, fill the hopper with 0.5 N NaOH and let the flow path of the machine sit in 0.5 N NaOH for a minimum of 1 hour.

8.1.6 WFI Rinse

8.1.6.1 Fill up the machine with room temperature WFI.

8.1.6.2 Start the machine and run it until all WFI has run through.

8.1.6.3 Repeat steps 8.1.6.1 through 8.1.6.2 two more times.

8.1.7 Conductivity Check and Sample Collection

8.1.7.1 Use a conductivity meter to check if the conductivity of the rinse water coming out of the homogenizer is less than 5 µS. If it is not, continue rinsing until the conductivity drops below 5 µS.

8.1.7.2 Collect a 300 mL minimum rinse sample for pH and conductivity, and a 40 mL rinse sample for TOC analysis per SOP 12169, Rinse Water Sampling for Production Equipment.

8.1.7.3 Stop the machine.

8.1.8 Storage

8.1.8.1 Fill the hopper with 100% ethanol.

8.1.8.2 Run the machine until the feed hopper is empty.

8.1.8.3 Stop the machine.

8.1.9 Interproduct Cleaning and Swab Sampling

Perform interproduct cleaning per SOP 21529, Equipment Interproduct Cleaning and Clearance, sample schedule 51.

9. DOCUMENTATION AND RECORDS

9.1 Document cleaning on Form 12149-01. Record cleaning, processing, maintenance, repairs and other pertinent information in the equipment logbook.

9.2 Documentation of this procedure must be made on production records where requested.

10. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
12169	Rinse Water Sampling for Production Equipment
21529	Equipment Interproduct Cleaning and Clearance
NA	Equipment manual, Panda Instruction for Use & Maintenance – Spare Parts List.