SOP Title: General Cleaning of Process Equipment
SOP Number: 12149
Revision: 07

TABLE OF CONTENTS

1. PURPOSE 1
2. SCOPE 1
3. RESPONSIBILITIES 1
4. PROCEDURE OR USE 2
5. CLEANING 4
6. DOCUMENTATION AND RECORDS 5
7. REFERENCES AND RELATED DOCUMENTS 6

1. PURPOSE

This SOP describes the general guidance for cleaning production equipment in BDP facilities.

2. SCOPE

This SOP applies to BDP personnel who perform general equipment cleaning. This SOP does not apply to equipment that has a specific cleaning SOP (reference Section 4.2 of this SOP for additional guidance).

3. RESPONSIBILITIES

3.1 The Director, Technical Operations, Late Process Sciences, Biopharmaceutical Development Program (BDP)

- Defines this procedure.

3.2 The Manager, Technical Operations Manufacturing

- Trains personnel on this procedure

3.3 BQA

- Provides quality oversight.

4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
30116	CIP 100 Detergent	☒ YES ☐ NO

5. PROCEDURE

NOTE: Use the concentration recommended by the manufacturer unless otherwise noted.

5.1 Discard liquid waste generated in this process per Environmental Health and Safety Operations Manual, Environmental Compliance, D-1, Waste Management.

5.2 Guidelines

5.2.1 This procedure is designed as a stand-alone cleaning procedure for equipment without a specific cleaning SOP. Document the cleaning using **Form 12149-01**. If the equipment has a specific cleaning SOP, or if the Supervisor or MPR provides specific instructions for cleaning, those instructions supersede the general procedure within this SOP. When cleaning agents are not specified in the specific cleaning SOP, Master Production Record (MPR) or the Supervisor's instructions, use CIP 100, PN 30116 at a concentration of 20 mL/L.

5.2.2 When the cleaning interval is not specified in the specific cleaning SOP, Master Production Record (MPR), or the Supervisor's instructions, the duration of equipment contact with the cleaning solution is 30 minutes minimum.

5.2.3 **Form 12149-01** may be used to capture equipment cleaning performed via other procedures, specifically the use of the Girton Parts Washer via **SOP 19411**. In these cases, capture all relevant data on the form as directed in Section 7.0 of this SOP.

5.3 Recirculation

5.3.1 If the product-contact surfaces of the equipment cannot completely contact cleaning solution via recirculation, proceed to Section 5.4.

5.3.2 Batch the cleaning solution in equipment to be cleaned. If equipment cannot be filled directly (such as pumps), fill a clean container for use in the cleaning of the equipment.

5.3.3 Set up to recirculate the cleaning solution through the equipment to be cleaned by feeding to a pump (if the pump is being cleaned, use this pump only) and return it back to the container or equipment via piping, hose, and/or tubing and spray ball (where applicable), such that all internal surfaces will come in contact with the cleaning solution.

5.3.4 Recirculate the cleaning solution for the interval specified (refer to Step 5.2.2). Use operational settings that closely resemble common production parameters.

5.3.5 After the required elapsed time, shut off the recirculation pump. Dispose of the cleaning solution into a biowaste or pH neutralization drain.

5.3.6 Rinse the equipment with DPRO or WFI water, making sure to flush all ports.

5.3.7 Comprehensively rinse the equipment with WFI until the rinse water conductivity is ≤ 5 µS/cm. Collect rinse water samples for testing per **SOP 12169, Rinse Water Sampling for Production Equipment.**

5.4 Soaking

5.4.1 Completely submerge the equipment in or fill the equipment with cleaning solution (refer to the specific cleaning SOP, Master Production Record (MPR) or the Supervisor's instructions).

5.4.2 Allow the equipment to soak for the interval specified (refer to Step 5.2.2.

5.4.3 To facilitate cleaning of surfaces, a brush or other utensil may be used. Use only non-shedding utensils that will not damage the finish of the equipment.

5.4.4 Collect the cleaning solution in a waste container. Dispose of the cleaning solution into a biowaste or pH neutralization drain.

5.4.5 Rinse the equipment with DPRO or WFI water, making sure to flush all ports.

5.4.6 Comprehensively rinse the equipment with WFI until the rinse water conductivity is ≤ 5 µS/cm. Collect rinse water samples for testing per **SOP 12169, Rinse Water Sampling for Production Equipment**.

5.5 Visually inspect the equipment for cleanliness. Additional cleaning followed by reinspection is required if the initial inspection fails.

6. CLEANING

6.1 Procedure

6.1.1 Drain equipment completely and store small equipment and fittings to promote drying. Close all valves on the equipment and cover (if applicable).

6.1.2 Label all equipment per **SOP 12188, Labeling and Storage of CGMP Raw Materials, Samples, and Equipment.**

6.1.3 Document cleaning in the equipment logbook as per **SOP 21531, Equipment/ Facility Logs**, if applicable.

6.2 Frequency

6.2.1 Perform cleaning after every production lot.

6.2.2 Equipment does not need to be recleaned before use if this procedure was performed within two months (for example, if the item was cleaned on May 5, it would be considered clean until July 5). If it has been more than two months, the following procedures are performed prior to use.

6.2.3 If the equipment was cleaned and stored appropriately, the equipment must be re-cleaned.

6.2.4 If the equipment was cleaned, sterilized, and stored in an undamaged, sealed, and sterilized container/enclosure, the equipment need only be re-sterilized.

6.2.5 If the equipment was cleaned, depyrogenated, and stored in an undamaged container/enclosure that prevented exposure from the external environment, the equipment need only be depyrogenated again.

6.2.6 Equipment must be rinsed with WFI water within three days of use. Submit rinse water samples for testing per SOP 12169, Rinse Water Sampling for Production Equipment.

7. DOCUMENTATION AND RECORDS

7.1 Record pertinent information on **Form 12149-01, Equipment Cleaning**.

7.2 Documenting equipment cleaning on **Form 12149-01**.

7.2.1 Section 1: Pre-Operation Information. This section captures information about the last use of the equipment and how it should be cleaned. It also captures the recipe name used if cleaning is performed with the parts washer or CIP skid. A portion of this section should be left blank if using one of these systems because the cleaning agent, concentration, and contact time are all part of the recipe.

7.2.2 Section 2: Operation Information. This section captures the ID's of every piece of equipment cleaned, details about the cleaning agent and the duration of cleaning, whether the parts washer or CIP skid was used, what the run # was if the parts washer was used, and documents the visual inspection. A portion of this section should be left blank if the parts washer is used because the batching of cleaning solution and contact time are automatically performed by the unit as directed by the chosen recipe.

7.2.2.1 Equipment ID's recorded in this section should be any piece of equipment staged/recorded in a BPR. For items that are reusable for multiple applications/projects (i.e., – hoses, carboys, graduates, bottles, etc.) and do not have unique IDs, record the cleaning date on the item after cleaning via tape or label. Fittings and hoses used to connect equipment/skids to the CIP systems need not be labeled if they are exclusively used for CIP purposes.

7.2.3 Section 3: Analysis. This section captures sample submission, QC results, and document review.

7.3 Documenting equipment passivation on **Form 12149-01**

NOTE: Equipment passivation may be performed by an outside contractor and, therefore, sections of the form will need to be marked NA when used to document passivation.

7.3.1 Section 1: Pre-Operation Information. Enter equipment, lot, and project number information. N/A the cleaning agent, SOP, and contact time sections. Note "Passivation" and the method and/or company performing the procedure under special instructions.

7.3.2 Section 2: Operation Information. Capture the IDs of the items passivated. Upon return of the items, verify the IDs and visually inspect the items for damage. N/A all other boxes in this section.

7.3.3 Section 3: Analysis. N/A all boxes except for the Reviewed By/Date in this section.

7.3.4 Passivated items must be cleaned per this SOP prior to use.

7.4 Document equipment cleaning and/or passivation in the equipment logbook per **SOP 21531, Equipment/Facility Logs, if applicable**.

8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
12149-01	Equipment Cleaning
12169	Rinse Water Sampling for Production Equipment
12188	Labeling and Storage of CGMP Raw Materials, Samples, and Equipment
19411	Operation and Maintenance of the Girton Parts Washer
21531	Equipment/Facility Logs