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1.0 Purpose

This procedure describes the method for the cleaning of the Millipore Pellicon™ - 2, the Millipore Pellicon™ -2 Mini Holder, and/or the Pall Centrasette™ Tangential-Flow Filtration (TFF) Hardware.

2.0 Scope

This procedure is to be performed by manufacturing personnel at the Advanced Technology Research Facility (ATRF).

3.0 Authority and Responsibility

- 3.1 The Manager of Purification, Late Process Sciences, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.
- 3.2 BDP personnel are responsible for the implementation of this procedure.
- 3.3 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Materials and Supplies

- Millipore Pellicon™-2 Tangential Flow Filtration Hardware, Millipore Pellicon™-2 Mini Holder Tangential Flow Filtration Hardware, and/or Pall Centrasette™ Tangential Flow Filtration Hardware.
- 0.5N NaOH, BDP PN 46109.
- Water for Injection (WFI).
- 15 mL conical tubes, BDP PN 20006, or BDP approved equivalent.
- Swabs, BDP PN 20876, or BDP approved equivalent.
- Storage bin.
- Aluminum foil, BDP PN 20012, or BDP approved equivalent.
- 1X PBS for SDS-Page testing.



5.0 Procedure

- 5.1 Obtain the Millipore Pellicon™-2, the Millipore Pellicon™-2 Mini Holder, and/or the Pall Centrasette™ TFF Hardware.
- 5.2 Disassemble all hardware. Remove and dispose of all used filters from the Millipore Pellicon™-2, the Millipore Pellicon™-2 Mini Holder, and/or the Pall Centrasette™ hardware.
- 5.3 Rinse all parts of the hardware with WFI.
- 5.4 Place all parts in a storage bin filled with 0.5N NaOH. Ensure that all parts are completely submerged. Cover with aluminum foil. Label as "Cassette Filter Holder stored in 0.5N NaOH, initials and date."
- 5.5 Allow parts to soak in 0.5N NaOH for ≥ 60 minutes.
- 5.6 Thoroughly rinse all parts with WFI until a pH 5-7 of the rinse is achieved.
- 5.7 Take swab samples of the permeate, retentate, and feed ports. If performing an Interbatch cleaning, submit samples to PA for silver stain SDS-Page testing. If performing Interproduct Cleaning, take and submit samples as per **SOP 21529, *Equipment Interproduct Cleaning and Clearance***.
- 5.8 Place all parts in a clean, dry storage bin and cover with aluminum foil. Label the container with a Yellow "Cleaned: Quarantined (Not Released for Use)" tag.
- 5.9 If the Pellicon™ 2, the Pell0000033333icon™ 2 Mini Holder, and/or the Pall Centrasette™ do not meet specifications, repeat Steps 5.1 to 5.8.
- 5.10 Upon receipt of passing PA results, label the container with a Green "Cleaned: Released for Use" tag.

6.0 Documentation

- 6.1 Document procedure on Form 14101-01, "Cleaning of TFF Cassette Holder Hardware," Attachment 1.

7.0 References and Related Documents

- 7.1 **SOP 21529** *Equipment Interproduct Cleaning and Clearance*
- 7.2 **Form 14101-01** *Cleaning of TFF Cassette Holder Hardware*

8.0 Change Summary

