SOP Title: **Rinse Water Sampling for Production Equipment**
SOP Number: **12169**
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1. PURPOSE

This procedure describes how to collect and submit rinse water samples taken from production equipment.

2. SCOPE

This procedure applies to persons collecting and submitting rinse water samples in GMP production areas.

3. RESPONSIBILITIES

3.1 Director, Technical Operations, BDP

- Defines this procedure.
- Trains personnel.
- Ensures that PA/QC personnel perform tests per SOP 22002 - Request for Quality Control Testing and the specific testing procedure.

3.2 Technical Operations personnel

- Implements the procedure.

3.3 BQA

- Provides Quality oversight of this procedure.

4. PROCEDURE

4.1 Collect rinse sample(s) from equipment as per the appropriate SOP or Batch Production Record (BPR).

NOTE: It is recommended to collect redundant or reserve samples in the event of container failure or the need for a PA retest.

4.1.1 Wear gloves during sampling operations.

4.1.2 Place samples for Total Organic Carbon (TOC) analysis in TOC vials PN 20442 or equivalent. The minimum sample size for TOC analysis is 40 mL. Fill the sample container completely.

4.1.3 Place samples for conductivity testing in PETG or polystyrene containers. The minimum sample size for conductivity testing is 300 mL.

4.1.4 Check the conductivity of the discharged rinse water with online or offline probe to verify sufficient rinsing. Continue rinsing as required.

4.1.5 Collect TOC, conductivity, and any samples required specifically for product changeover directly into the compatible sample container as the rinse water is discharged.

4.2 Submit samples to PA for analysis per **SOP 22002 - Request for Quality Control Testing.**

4.3 Assay results for rinse water samples are reviewed and deemed acceptable or unacceptable according to the following criteria.

4.3.1 Conductivity: Must be ≤ 5 µS/cm as tested per **SOP 22138 - Operation of the Orion Conductivity Meters, Model 150 and 150 USP and Performance of Conductivity Determinations by Current USP <645>.**

4.3.2 TOC: Must be ≤ 5 ppm as tested per **SOP 22963 - Operation of the Shimadzu TOC Analyzer.**

5. DOCUMENTATION AND RECORDS

Perform documentation of this procedure in accordance with SOP 22002 - Request for Quality Control Testing.

6. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22002	Request for Quality Control Testing
22138	Operation of the Orion Conductivity Meters, Model 150 and 150 USP and Performance of Conductivity Determinations by Current USP <645>
22963	Operation of the Shimadzu TOC Analyzer