



## Standard Operating Procedure

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**Title:** Rinse Water Sampling for Production Equipment

**SOP Number:** 12169

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### **1.0 Purpose**

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

### **2.0 Scope**

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

### **3.0 Authority and Responsibility**

- 3.1 The Director, Technical Operations, Biopharmaceutical Development Program (BDP), has the authority to define this procedure.
- 3.2 The Director, Technical Operations, BDP is responsible for training personnel in the procedure and for documenting this training to Biopharmaceutical Quality Assurance (BOA).

- 3.3 The Director, Process Analytics/Quality Control (PA/QC) is responsible for ensuring that PA/QC personnel perform tests per **SOP 22002 - Request for Quality Control Testing** and the specific testing procedure.
- 3.4 Technical Operations personnel are responsible for the implementation of this procedure.
- 3.5 BQA is responsible for quality oversight of this procedure.

#### 4.0 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  $\leq 5 \mu\text{S}/\text{cm}$  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  $\leq 5 \text{ ppm}$  as tested per **SOP 22963 - Operation of the Shimadzu TOC Analyzer**.

#### 5.0 Documentation

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

#### 6.0 References and Related Documents

- 6.1 **SOP 22002**      *Request for Quality Control Testing*
- 6.2 **SOP 22138**      *Operation of the Orion Conductivity Meters, Model 150 and 150 USP and Performance of Conductivity Determinations by Current USP <645>*
- 6.3 **SOP 22963**      *Operation of the Shimadzu TOC Analyzer*