BIOSPECTRA

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USP/EP WATER FOR INJECTION TESTING METHODS

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1. PURPOSE:

1.1. To provide the Laboratory personnel with a procedure for analyzing water samples from the water generation valves and point of use valves in the laboratory and manufacturing.

2. SCOPE:

2.1. Applies to the USP/EP Purified Water and USP/EP Water for Injection (WFI) produced by the water purification systemslocated at the Bangor, PA facility.

3. RESPONSIBILITES:

3.1. The Laboratory Manager, or other qualified designee, is responsible for the implementation, control, training, and maintenance of this procedure.
3.2. All Laboratory personnel are responsible for complying with the requirements of this procedure.
3.3. Laboratory Analysts are responsible for notifying the appropriate personnel of failure to meet any specifications.

4. REFERENCES:

4.1. BSI-ATM-0005, Water Testing Methods
4.2. BSI-ATM-0097, Analytical Method: Determination of Elemental Impurities in Water for Injection
4.3. BSI-FRM-0383, Bangor Zone E Water for Injection (WFI) Summary Sheet
4.4. BSI-FRM-0492, Zone L Water for Injection (WFI) Phase 3 Summary Sheet
4.5. BSI-FRM-0563, Water for Injection Microbial Alert Checklist
4.6. BSI-FRM-0564, WFI Microbial Alert Checklist Log Book
4.7. BSI-FRM-0706, Zone E Water for Injection Analytical Procedure
4.8. BSI-PRL-0795, Zone E Purified Water System Performance Qualification 2024
4.9. BSI-RPT-0498. USP/EP Water for Injection System Performance Qualification
4.10. BSI-RPT-0916, USP/EP Water for Injection Zone L System Performance Qualification
4.11. BSI-SOP-0069, Preparation of Samples for Outside Testing SOP
4.12. BSI-SOP-0092, Total Organic Carbon Water Analysis
4.13. BSI-SOP-0144, Metrohm 914 pH Conductometer Operation and Calibration
4.14. BSI-SOP-0224, Bangor Zone E USP/EP WFI Purified Water System Maintenance Manual & Procedures
4.15. BSI-SOP-0245, Hach Total Hardness Kit for Water Testing SOP
4.16. BSI-SOP-0249, Hach Pocket Colorimeter II Chlorine Test Kit SOP
4.17. BSI-SOP-0255, XL200 pH/mV/Conductivity Meter SOP
4.18. BSI-SOP-0345, Endosafe NexGen-PTS Endotoxin Reader SOP
4.19. BSI-SOP-0446, Zone L WFI Maintenance Manual
4.20. BSI-SOP-0494, Sievers M9 TOC Analyzer SOP
4.21. BSI-SOP-0608, M40 Metallurgical Reflected Light Microscope SOP
4.22. USP-NF, Purified Water
4.23. USP-NF, Water for Injection
    4.23.1. <1231> Water for Pharmaceutical Purposes
    4.23.2. EP (0008) Water, Purified
    4.23.3. EP (0169) Water for Injections
    4.23.4. EPA Drinking Water Standards

4.24. FDA Bad Bug Book 2nd Edition
4.25. USP/EP Water for Injection System Performance Qualification Protocol No. 6250-PQ-002
4.26. USP/EP Water for Injection System Performance Qualification Protocol No. 6250-PQ-200

5. EQUIPMENT:

5.1. Endosafe NexGen-PTS Endotoxin Reader, or equivalent
5.2. Online Conductivity Meters
5.3. Hach Pocket Colorimeter II Chlorine Test Kit
5.4. Hach Total Hardness Kit
5.5. Online Total Organic Carbon Analyzers
5.6. pH/Conductivity Meter, or equivalent
5.7. Shimadzu Total Organic Carbon Analyzer
5.8. Sievers M9 Total Organic Carbon Analyzer
5.9. Fein Optic M40 Reflected Light Metallurgical Microscope
5.10. NexION 350X ICP-MS

6. REAGENTS:

6.1. **Ammonium chloride buffer solution pH 10.0**: purchased commercially.
6.2. **Ammonium standard solution (1 ppm NH_4):** Immediately before use, dilute ammonium standard solution (2.5 ppm NH_4) to 2.5 times its volume with purified water.
6.3. **Ammonium Standard Solution (2.5 ppm NH_4):** Immediately prior to use, weigh 0.741 g of ammonium chloride and transfer to a 1000 mL volumetric flask. Dissolve and dilute to volume with purified water. Pipette 1 mL of the resulting solution into a 100mL volumetric flask and dilute to volume with purified water.
6.4. **0.75 mg/L 1,4-Benzoquinone RS Reference Standard Solution (500 ppb):** On a micro-balance, weigh 0.75 mg of 1,4-Benzoquinone reference standard into a small weigh boat. Transfer to a 1L volumetric flask, rinsing with Low TOC water. Dilute to volume with low TOC water, cap and mix. Separate prepared solution into TOC vials. Solution stable for 4 weeks when stored in TOC vials at 2-8°C in a closed box. (1, 4-Benzoquinone standard solution is light sensitive and exposure to light must be minimized)
6.5. **Bromothymol Blue Solution R1:** Dissolve 50 mg of bromothymol blue in a mixture of 4mL of 0.02M NaOH and 20 mL of reagent alcohol. Dilute to 100 mL with purified water. Can be purchased commercially.
6.6. **Chloroform:** purchased commercially.
6.7. **Conductivity Standard, 10 µS/cm**: purchased commercially.
6.8. **Conductivity Standard, 100 µS/cm**: purchased commercially.
6.9. **Diphenylamine Solution R:** A 1 g/L solution of diphenylamine R in sulfuric acid.
6.10. **EDTA Titration Cartridge (0.0800M):** purchased commercially.
6.11. **Endotoxin cartridges-FDA Licensed (0.01-1 EU/mL)**: purchased commercially.
6.12. **Free Chlorine Powder Pillow:** purchased commercially.
6.13. **Hardness 1 Buffer Solution:** purchased commercially.
6.14. **Hydrochloric Acid (0.02M):** Slowly add 20 mL of 0.1N HCl to 80 mL of purified water to make a total volume of 100 mL.
6.15. **LAL Reagent Water:** purchased commercially.
6.16. **ManVer2 Hardness Indicator**: purchased commercially.

6.17. **Methyl Red Solution:** Dissolve 50 mg of methyl red in a mixture of 1.86 mL of 0.1M Sodium Hydroxide and 50 mL of reagent alcohol. Dilute to 100 mL with purified water. Can be purchased commercially.

6.18. **Mordant black 11 triturate:** Mix 1 gram of mordant black 11 (Eriochrome Black) with 99 grams of sodium chloride.

6.19. **Nitrate Standard Solution (2 ppm NO_3) R**: Immediately before use, dilute with water to 10 times its volume a solution containing potassium nitrate equivalent to 0.815 g of KNO3 in 500.0 mL (100 ppm NO3). Immediately before use, dilute nitrate standard solution (100 ppm NO3) to 10 times its volume with water (10 ppm NO3). Immediately before use, dilute nitrate standard solution (10 ppm NO3) to 5 times its volume with water R (2 ppm NO_3).

6.20. **Nitric acid, dilute:** Dilute 20 g of nitric acid to 100 mL with purified water.

6.21. **pH Standards: pH 4, pH 7, pH 9, pH 10**: purchased commercially.

6.22. **Potassium Chloride Solution R (100 g/L)** – Dissolve 25.00 g of potassium chloride in USP/EP purified water to 250 mL

6.23. **Potassium Chloride Solution, 3.0 M**: purchased commercially.

6.24. **Potassium permanganate(0.02M/0.1N):** purchased commercially or made in house.

6.24.1. Weigh 0.3161 g of potassium permanganate with water to make 100 mL.

6.25. **Potassium tetraiodomercurate solution, alkaline:** Dissolve 11 g of potassium iodide and 15 g of mercuric iodide in water and dilute to 100 mL with the same solvent. Immediately before use, mix 1 volume of this solution with an equal volume of a 250 g/L solution of sodium hydroxide.

6.26. **Reagent Water (Low TOC):** purchased commercially.

6.27. **Silver Nitrate (0.1N):** purchased commercially.

6.28. **Silver Nitrate Solution R2**: A 17 g/L solution of silver nitrate. (See 0.1N Silver Nitrate)

6.29. **Sodium Chloride:** purchased commercially.

6.30. **Sodium Edetate (EDTA Disodium Salt) :** purchased commercially.

6.31. **0.01M Sodium Edetate:** Dissolve 0.37g of sodium edetate in purified water to make 100mL.

6.32. **Sodium Hydroxide (0.02M):** Slowly add 20 mL of 0.1N NaOH to 80 mL of purified water to make a total volume of 100 mL.

6.33. **Sodium Hydroxide (0.1N):** purchased commercially.

6.34. **1.19 mg/L Sucrose RS Standard (500 ppb):** On a micro-balance, weigh 1.19 mg of Sucrose reference standard into a small weigh boat. Transfer to a 1L volumetric flask, rinsing with Low TOC water. Dilute to volume with low TOC water, cap, and mix. Separate prepared solution into TOC vials. Solution stable for 4 weeks when stored in TOC vials at 2-8°C in a closed box.

6.35. **Sulfuric acid, dilute**: Add 5.5 mL of sulfuric acid to 60 mL of purified water, allow to cool and dilute to 100 mL with purified water.

6.36. **Sulfuric Acid R (Nitrogen-Free):** purchased commercially.

6.37. **Total Chlorine Powder Pillow:** purchased commercially.

6.38. **USP/EP Nitrogen-Free Water:** Purchased commercially.

7. REPORTING:

7.1. All water lot numbers will be recorded with the Valve Identification and a dash followed by the date with no dashes or slashes. For example, a sample taken from SV-02 on April 30, 2024 would be labeled SV-02-043024.

7.1.1. While performing system qualification all water lot numbers will be recorded with the Valve Identification, a dash followed by the date with no dashes or slashes, and a dash followed by the PQ phase. For example, a sample taken from SV-100 on April 30, 2024 during the 2nd phase of qualification would be labeled SV-100-043024-PQ2.

7.2. The data will be evaluated and if acceptable, each phase of the PQ will be summarized and closed out with a summary report.

7.2.1. **Phase 3 testing for Zone E was complete on 3/5/20.**

7.2.2. **Phase 1 qualification testing for Zone L/M was completed on 9/25/20.**

7.2.3. **Phase 2 qualification testing for Zone L/M was completed on 10/8/20.**

7.2.4. **Phase 3 qualification for Zone L/M began 10/11/20.**

7.2.5. **Phase 3 qualification for Zone L/M was completed on 2/1/22.**

7.2.6. **Zone E Requalification is scheduled to start 6/2024, in accordance with BCC24-24 and BSI-PRL-0795.**

8. PROCEDURE:

8.1. Note: In-house testing must be performed within 24 hours of logging water samples into the laboratory.

8.2. Documentation of Pre-Sampling Checklists:

8.2.1. Pre-Sampling Checklists are built into each Zone-specific analytical procedure. The purpose of the Pre-Sampling Checklist is to document the status of the water port and surrounding area prior to sampling for microbial testing. Pre-Sampling checklists must be used prior to sampling.

8.2.2. The Pre-Sampling Checklist sections should be utilized in the following manner:

8.2.2.1. Document the date of sampling and the analyst who sampled each valve.

8.2.2.2. Document the status of the manufacturing room at the time of sampling, if applicable. Use the room-specific (Production Equipment Logbook) log book to find this information.

8.2.2.3. Document the date and time of the last port sanitization, if applicable. Use the room-specific (Sanitization Minncare Logbook) log book to find this information.

8.2.2.4. Document the current visual status of the water port. Describe any instance that it is not a clean, dry port with no attachments. Document if extenders or hoses are attached to the port, if a cap is present, or if the port is leaking, dripping, or wet.

8.2.2.5. Document the visual status of the room. Describe any abnormality in the areas nearby the water port. Document if there is product visible on the floors or walls around the port, or if there is a presence of liquid on the floors around the port. Any additional sightings may be documented in the Additional comments section.

8.2.2.6. Document the visual status of the port-specific funnels, or the sampling reservoirs. If there are particulates, or discoloration present, it should be noted.

8.2.2.7. Document the visual status of the sampling tool box or ledge for each port. Describe any particulates or moisture present in these locations.

8.2.2.8. Document if any BioSpectra personnel or outside service providers are working in the immediate vicinity of the water port at the time of sampling.

8.2.2.8.1. NOTE: BioSpectra personnel are allowed to be present in the room at the time of sampling. QA does not need to be notified if they are in the room.

8.2.2.9. Document if any equipment is being stored by or has been left in the water port area.

8.2.2.10. Photos may be taken and attached to the analytical procedures to clearly identify any issues found.

8.2.2.11. If any of the Pre-Sampling Checklist sections have been checked *Yes*, notify Laboratory Management, and Quality Assurance, immediately, to resolve the issues prior to obtaining a sample from the waterport.

8.2.2.11.1. If sampling is occurring on a day with no Laboratory, QA, management available, a sample may be taken and the appropriate personnel notified via email. The issue can be resolved during the next business day.

8.2.3. Documentation of Water for Injection Microbial Alert Checklists:

8.2.3.1. Checklists must be issued using the WFI Microbial Alert Checklist Log Book. For any Microbial OOS occurring in relation to a WFI system, the control number will consist of nine characters. The first three characters will be "WFI". The fourth and fifth characters will be the last two digits of the current year. A dash will be the sixth character. The last three characters will be the digits assigned consecutively beginning with "001" for the first request of the calendar year.

8.2.3.1.1. Example: WFI24-001

8.2.3.2. All fields in the Checklist Initiation Information section must be filled out accordingly.

8.2.3.2.1. The following fields can be filled out using the MPL Report: Sample Identification, Result Obtained, Identifications (if applicable), MPL Lab ID, and Date of Report.

8.2.3.2.2. The Alert/Action Level and Specification sections can be filled out using sections 9 and 10 of this SOP.

8.2.3.3. The General Sampling Information fields can be filled out using the following locations:

8.2.3.3.1. Pre-sampling checklist, FDA Bad Bug Book List, Valve Specific Sanitization Log book, Laboratory Sample Log in Book, Bangor Outside Testing Log book, and this SOP.

8.2.3.3.2. If the room is stated to be In-Process at the time of sampling, the room-specific logbook should be checked to see what lot of materialwas being manufactured at the time of sampling. It will up to management discretion as to whether or not there is risk of microbialcontamination to the product being manufactured at that time.

8.2.3.4. A root cause of the Elevated Microbial Result should be stated in the appropriate section. If no root cause can be determined, further investigationmay be required.

8.2.3.5. Further Investigation may be required even if a root cause can be determined. This is up to management discretion.

8.2.3.6. The checklist should be signed and dated by the person completing it and a member of the Laboratory Leadership team.

8.2.3.7. Once completed, a copy of the checklist will be made and attached to that associated analytical procedure. The original copy will be filed in the appropriate binder.

8.3. **ACIDITY OR ALKALINITY** :

8.3.1. Boil and cool NLT 30 mL of sample in a borosilicate glass flask.

8.3.2. To 10 mL of the prepared sample, add 0.05 mL of methyl red solution. The solution should not be colored red to report as Passes Test.

8.3.3. To 10 mL of sample add 0.1 mL of bromothymol blue solution. The solution should not be colored blue to report as Passes Test.

8.4. **APPEARANCE** :

8.4.1. Transfer a suitable amount of sample into a 50mL Nessler Color Comparison Tube.

8.4.2. Utilizing sufficient lighting, view the sample from all angles.

8.4.3. The sample should be clear and colorless with no noticeable odor to report as Clear, Colorless Liquid, no odor.

8.5. **ALUMINUM** :

8.5.1. Refer to BSI-ATM-0097, Analytical Method: Determination of Elemental Impurities in Water for Injection for sample preparation and analysis.

8.6. AMMONIUM :

8.6.1. Pipette 20 mL of sample into a Nessler Color Comparison Tube and add 1 mL of alkaline potassium tetraiodomercurate solution.

8.6.2. Prepare a standard by pipetting 1 mL of Alkaline Potassium Tetraiodomercurate Solution into a Nessler Color Comparison tube containing 4 mL of 1 ppm Ammonium Standard Solution and 16 mL of purified water.

8.6.3. After 5 min, examine the solution down the vertical axis of the tube.

8.6.4. The sample solution is not more intensely colored than the standard in order to report as ≤0.2ppm.

8.7. **CALCIUM AND MAGNESIUM** :

8.7.1. Transfer 100 mL of sample solution to suitable vessel.

8.7.2. To the sample solution, add the following:

8.7.2.1. 2 mL of ammonium chloride buffer solution pH 10.0

8.7.2.2. 50 mg of mordant black 11 triturate

8.7.2.3. 0.5 mL of 0.01 M sodium edetate.

8.7.3. A pure blue color must be produced in order to report as Passes Test.

8.8. **CHLORIDES** :

8.8.1. Transfer 10 mL of sample solution to a suitable vessel.

8.8.2. To the sample solution, add 1 mL of dilute nitric acid, and 0.2 mL of silver nitrate solution R2.

8.8.3. Set a calibrated timer for 15 minutes.

8.8.4. After 15 minutes, the sample solution shows no change in appearance in order to report as passes test.

8.9. **CONDUCTIVITY** :

8.9.1. **STAGE 1:**

8.9.1.1. **Zone E:** Conductivity results will be reported in µS/cm with the water temperature value, as recorded from the appropriate online meter. See below for the specific online meter tobe used to record the results for a specific valve.

8.9.1.1.1. *Online Meter AIT-66B (Channel 2): SV-27 and distribution loop*

8.9.1.1.2. *Online Meter AIT-55A: SV-12*

8.9.1.1.3. *Online Meter AIT-66A (Channel 1): SV-18*

8.9.1.2. **Zone L:** Conductivity results will be reported in µS/cm with the water temperature value, as recorded from the appropriate online meter. See below for the specific online meter to be used to record the results for a specific valve.

8.9.1.2.1. *Online Meter AI-219: SV-230*

8.9.1.2.2. *Online Meter AI-229: SV-242*

8.9.1.2.3. *Online Meter AI-308: SV-305, SV-322 and distribution loop*

8.9.1.3. Using Stage 1 Temperature and Conductivity requirements table, find the temperature value that is NMT the measured temperature, i.e., the next lower temperature. The corresponding conductivity value on this table is the limit. For example, if the measured temperature is 24°C, the corresponding specification for the Water sample is 1.1 µS/cm at 20°C for Stage 1. The table provided below is only a portion of the USP table provided, if further numbers are required, refer to USP <645>.

8.9.1.4. If the measured conductivity is NMT the table value determined in step 2, the water meets the requirements of the test for conductivity. If the conductivity is higher than the table value, proceed with *Stage 2.*

8.9.1.4.1. For valves with a specification of For Information Only, Stage 2 and 3 Conductivity analyses are not required. Document the result of Stage 1 as the official conductivity result.

8.9.1.5. Drop Sample Conductivity:

8.9.1.5.1. NOTE: During routine analysis, SV-02 and SV-100 Conductivity is to only be performed for monthly analysis.

8.9.1.6. The sample will be analyzed by transferring approximately 100 mL of water sample into a pre-rinsed sterile cup (samples obtained in a sterile cup may be analyzed directly from these containers). Determine the conductivity and temperature (°C) of the water, using a calibrated conductivity probe. Using the Stage 1 Temperature and Conductivity requirements table, find the temperature value that is NMT the measured temperature. The corresponding conductivity value on this table is the limit. Record the result, the data is for information only.

8.9.1.6.1. For valves with a specification of For Information Only, Stage 2 and 3 Conductivity analyses are not required. Document the result of Stage 1 as the official conductivity result.

8.9.2. **STAGE 1 -- TEMPERATURE AND CONDUCTIVITY REQUIREMENTS**

8.9.2.1. For non-temperature-compensated conductivity measurements only.

Table 1: Temperature and Conductivity Requirements

Temperature(°C)	Conductivity(µS/cm)
0	0.6
5	0.8
10	0.9
15	1.0
20	1.1
25	1.3
30	1.4
35	1.5
40	1.7
45	1.8

8.9.3. **STAGE 2:**

8.9.3.1. **Sample must be taken for analysis only if stage 1 online measurement is OOS and a specification is available. Immediately notify appropriate personnel if online measurement is OOS for stage 1.**

8.9.3.2. Conductivity should be measured as soon as samples are logged into the lab in order to obtain the most accurate results.

8.9.3.3. At the Stroudsburg facility, calibrate the 0.11 cm^{-1} conductivity probe prior to sample measurement and refer to Metrohm 914 pH/Conductometer Operation and Calibration. Utilize the 100 µS/cm Conductivity Standard Solution for calibrating.

8.9.3.4. At the Bangor facility, calibrate the 0.1cm^{-1} conductivity probe prior to sample measurement and refer to XL200 pH/mV/Conductivity Meter SOP. Utilize the 10 µS/cmConductivity Standard Solution for calibrating.

8.9.3.5. Transfer approximately 100 mL of water sample into a pre-rinsed sterile cup.

8.9.3.5.1. Samples obtained in sterile cups may be analyzed directly from these containers.

8.9.3.6. Stir the test specimen from Stage 1. Adjust the temperature, if necessary, to 25°C ±1°C and begin vigorously agitating the test specimen, while periodically observing the conductivity. When the change in conductivity (due to uptake of atmospheric carbon dioxide) is less than a net of 0.1 µS/cm per 5 minutes, record the conductivity and temperature.

8.9.3.6.1. If the conductivity is not greater than 2.1 µS/cm, the water meets requirements and no further conductivity testing is required. If the conductivity is greater than 2.1 µS/cm, proceed with Stage 3.

8.9.4. **STAGE 3:**

8.9.4.1. Perform this test within approximately 5 minutes of the conductivity determination in Stage 2 above, while maintaining the sample temperature at 25 °C ± 1 °C.

8.9.4.2. Standardize the pH meter according to the appropriate SOP.

8.9.4.3. Add 0.3 mL of 3.0 M saturated Potassium Chloride solution (3.0 M Potassium Chloride in water reagent solution) per 100 mL of the test specimen.

8.9.4.4. Determine the pH to the nearest 0.1 pH unit, as directed under pH <791>.

8.9.4.5. Referring to the Stage 3 - pH and Conductivity Requirements table, determine the conductivity limit at the measured pH value. If the measured conductivity from Stage 2 is not greater than the conductivity requirements for the pH determined in Stage 3, the water meets the requirements of the test for conductivity. If either the measured conductivity is greater than this value or the pH is outside of the range of 5.0 to 7.0, the water does not meet the requirements of the test for conductivity.

8.9.5. **STAGE 3 -- pH AND CONDUCTIVITY REQUIREMENTS**

8.9.5.1. For atmosphere and temperature equilibrated samples only.

Table 2: Stage 3 pH and Conductivity Requirements

pH	Conductivity (µS/cm)
5.0	4.7
5.1	4.1
5.2	3.6
5.3	3.3
5.4	3.0
5.5	2.8
5.6	2.6
5.7	2.5
5.8	2.4
5.9	2.4
6.0	2.4
6.1	2.4
6.2	2.5
6.3	2.4
6.4	2.3
6.5	2.2
6.6	2.1
6.7	2.6
6.8	3.1
6.9	3.8
7.0	4.6

8.9.5.2. After measurement is completed, the conductivity electrode should be rinsed with, and stored in purified water.

8.9.5.3. After measurement is completed, the pH electrode should be rinsed with purified water and stored in the appropriate solution.

8.10. ELEMENTAL IMPURITIES :

8.10.1. For Routine Analysis: Perform quarterly point of use sample valves for Zone E and Zone L. Refer to BSI-ATM-0097, Analytical Method: Determination of Elemental Impurities in Water for Injection

8.10.1.1. This analysis will be implemented in May 2024 for Zone L and in June 2024 for Zone E for the established sample valves below:

8.10.1.1.1. Zone E: SV-18, SV-27, E06, E05, E04, E03, E02, D10

8.10.1.1.2. Zone L: SV-242, SV-305, SV-322, L05, L09, L08, L01, M07, M03

8.10.2. Record results in the appropriate laboratory documentation and create an Elemental Impurity Result Profile in Master Control.

8.11. **ENDOTOXIN :**

8.11.1. Perform analysis according to Endosafe NexGen-PTS Endotoxin Reader SOP or equivalent.

8.11.2. Record results in the appropriate laboratory documentation.

8.12. **FREE AND TOTAL CHLORINE** :

8.12.1. Refer to the Hach Pocket Colorimeter II Chlorine Test Kit SOP.

8.12.2. NPDWR recommended maximum is 4.0 mg/L. Free Chlorine results should be lower than those obtained for Total Chlorine at the valves analyzed. Record results in the appropriate laboratory documentation.

8.12.2.1. If Total Chlorine result is >0.1mg/L, please notify Water Systems Supervisor to be compliant with BSI-SOP-0224 step 5.2.2. for replacement of Rechargeable Activated Carbon Canister for Zone E.

8.12.2.2. If Total Chlorine result is >0.1mg/L, please notify Water Systems Supervisor to be compliant with BSI-SOP-0446 step 5.2.2. for replacement of Rechargeable Activated Carbon Canister.

8.13. **NITRATES** :

8.13.1. Sample Preparation:

8.13.1.1. Transfer 5 mL of sample into a test tube.

8.13.2. Reference Standard Preparation:

8.13.2.1. Prepare a mixture of 4.5 mL of USP/EP nitrate-free Water R and 0.5 mL of Nitrate Standard Solution (2 ppm NO_3) R.

8.13.3. Procedure:

8.13.3.1. Immerse test tubes in iced water. To each tube, add 0.4 mL of a 100 g/L Potassium Chloride Solution R and 0.1 mL of Diphenylamine Solution R. Add dropwise with gentle shaking, 5 mL of Nitrogen-Free Sulfuric Acid R. Transfer the tubes to a water bath at 50 °C.

8.13.3.1.1. After the final addition of reagents, thoroughly mix the standard and sample solution.

8.13.3.2. After 15 minutes, any blue color in the sample solution is not more than that in the reference solution in order to be reported as ≤ 0.2 ppm.

8.13.3.3. Record results in appropriate laboratory documentation.

8.14. **OXIDIZABLE SUBSTANCES** :

8.14.1. Transfer 100 mL of sample to a suitable beaker.

8.14.2. To the sample, add 10 mL of dilute sulfuric acid and 0.1 mL of 0.02M potassium permanganate.

8.14.3. Boil the sample solution for 5 min.

8.14.4. The solution must remain faintly pink in order to report as Passes Test.

8.15. **PARTICULATE MATTER** :

8.15.1. Use a suitable binocular microscope, a filter assembly for retaining particulate matter, and a membrane filter for examination.

8.15.2. The filter assembly for retaining particulate matter consists of a filter holder made of glass or other suitable material, and is equipped with a vacuum source and a suitable gridded or non-gridded membrane filter that is 1.0 µm or finer in nominal pore size.

8.15.3. The test should be carried out under conditions limiting particulate matter.

8.15.4. Very carefully wash the glassware and filter assembly used, except for the membrane filter with abundant amounts of water to remove all traces of possible detergent and dust.

8.15.5. Immediately before use, rinse both sides of the membrane filter and the equipment from top to bottom, outside and then inside, with particle-free water.

8.15.6. Observe the particulate matter of a 50 mL volume of particle-free water. If more than twenty individual particles that are 10 µm or larger in size or five particulates that are greater than 25 µm or larger in size are observed within the filtration area, then enough precaution was not taken and all glassware must be washed again and reperformed until this is met.

8.15.7. Method:

8.15.7.1. Mix the contents of water samples by slowly inverting the container twenty times up and down.

8.15.7.2. Clean the outer surface of the container, including the opening, using particle-free water and avoiding any contamination of the overall contents of the container.

8.15.7.3. Pre-wet the membrane filter with a little portion of particle-free water then transfer contents of sample to filtration set-up and apply vacuum.

8.15.7.4. Continue adding contents step-wise until all of the volume of the sample has been added. After the sample has been adding, carefully wash the walls with particle-free water while maintaining vacuum and until the membrane filter is free from any liquid.

8.15.7.5. Place the membrane filter in a Petri dish and allow to air-dry with the cover slightly ajar.

8.15.7.6. After the filter has been dried, place the Petri dish on the microscope. Scan the entire membrane filter under the reflected light and count the number of particles that are equal to or greater than 10 µm and the number of particles that are equal to or greater than 25 µm.

8.15.7.6.1. Alternatively, partial membrane filter count and determination of the total filter count by calculation is allowed. Calculate the mean number of particles for the preparation to be examined.

8.15.7.7. The particle sizing process, with the use of the circular diameter graticule, is carried out by estimating the equivalent diameter of the particle in comparison with the 10 µm and 25 µm reference circles on the graticule.

8.15.7.7.1. The inner diameter of the transparent graticule reference circles is used to size white and transparent particles, while dark particles are sized by using the outer diameter of the black opaque graticule reference circles.

8.15.7.8. While counting the particle, do not count amorphous, semiliquid, or otherwise morphologically indistinct materials that have the appearance of a stain or discoloration on the membrane filter as these will show little or no surface relief and look gelatinous in appearance.

8.15.7.9. The preparation complies with the test if the average number of particles present in sample does not exceed 3000 per container equal to or greater than 10 µm and does not exceed 300 per container equal to or greater than 25 µm.

8.16. **pH** :

8.16.1. Transfer 100 mL of sample into a suitable beaker.

8.16.2. Add 0.3 mL of 3.0 M saturated Potassium Chloride solution.

8.16.3. Follow the appropriate instrument SOP to measure and record the pH of the sample at 25°C ± 2°C.

8.16.4. Specification is 5.0 – 7.0.

8.17. **RESIDUE ON EVAPORATION** :

8.17.1. Dry a suitable crucible or vessel in an oven at 100-105°C for 1 hour. Cool the crucible in a desiccator prior to use for 15 minutes.

8.17.2. Accurately transfer 100 mL of sample solution to an appropriate vessel (crucible, beaker, vial...)

8.17.3. Evaporate the sample to dryness in a water bath, or equivalent. Transfer the beaker to an oven and dry at 100-105 °C for 1 hour. Cool in a desiccator for 15 minutes and weigh.

8.17.4. Return the sample to the oven and dry at 100-105°C for an additional hour. Cool in desiccator for 15 minutes and weigh.

8.17.5. Reweigh and repeat the drying/weighing process, if necessary, to obtain a constant weight.

8.17.6. Maximum 3 mg (0.003%) for containers with a nominal volume greater than 10 mL.

8.17.7. Calculate the residue on evaporation as follows:

$$Residue\ on\ Evaporation = \frac{Residue\ Weight\ (g)}{Crucible\ Weight\ (g)}\ x\ 100\%$$

8.18. **TOC** :

8.18.1. Online Meter:

8.18.1.1. Zone E: For the appropriate valves, record the result readout from online meter AI-120 in the appropriate laboratory documentation.

8.18.1.1.1. Distribution loop valves: SV-27, D10, E02, E03, E04, E05, E06.

8.18.1.2. Zone L: For the appropriate valves, record the result readout from online meter AI-307 in the appropriate laboratory documentation.

8.18.1.2.1. Distribution loop valves: SV-305, L01, L05, L08, L09, M07, M03, SV-322.

8.18.2. Manual TOC Analysis:

8.18.2.1. Zone E: The following valves require drop samples to analyze for TOC. Referto the tables in section 9.6 for testing frequency.

8.18.2.1.1. SV-02, SV-05, SV-06, SV-12, SV-18

8.18.2.2. Zone L: The following valves require drop samples to analyze for TOC. Referto the tables in section 10.7 for testing frequency.

8.18.2.2.1. Zone L: SV-100, SV-113, SV-230, SV-242

8.19. Analyze the sample in accordance with BSI-SOP-0092, Total Organic Carbon Water Analysis or BSI-SOP-0494, Sievers M9 TOC Analyzer SOP.

8.19.1.1. For valves with a TOC specification, if the result does not meet requirements, the valve will be resampled due to residual IPA in the sample. Document the resample in the appropriate laboratory documentation. All required analyses will need to be performed on the resampled material.

8.19.1.2. For manual analysis reporting, the sample is evaluated against the Limit Response (R_L) that is the corrected Standard Solution response.

8.20. **TOTAL HARDNESS AS CALCIUM CARBONATE** :

8.20.1. Refer to the Hach Total Hardness Kit for Water Testing SOP.

8.20.2. Record results in the appropriate laboratory documentation.

8.21. **TOTAL VIABLE BACTERIA AND TOTAL COLIFORMS** :

8.21.1. Send sample to approved laboratory for microbial testing using the appropriate size sanitary sample container. Microbial samples must be sent within 24 hours of sampling.

8.21.1.1. If the microbial sample is damaged while in transit to the approved outside testing facility, the affected valve will be resampled for microbial testing only.

8.21.2. The following valves requires a sample bottle containing a sodium thiosulfate tablet to reduce disinfecting agent which is present in the city water supply for Total Viable Bacterial and Coliform analysis:
8.21.2.1. Zone E: SV-02 and SV-03
8.21.2.2. Zone L: SV-100, SV-103, and SV-110
8.21.3. The samples must meet the requirements stated in sections 9 and 10 for each specific valve at the Bangor, PA facility. The samples must also be free from the detection of any of the FDA Bad Bugs as seen in section 8.20.4.
8.21.4. Pathogenic Bacteria
8.21.4.1. Gram-negative bacteria
8.21.4.1.1. *Salmonella* spp.
8.21.4.1.2. *Campylobacter jejuni*
8.21.4.1.3. *Yersinia enterocolitica*
8.21.4.1.4. *Shigella* spp.
8.21.4.1.5. *Vibrio parahaemolyticus*
8.21.4.1.6. *Coxiella burnetii*
8.21.4.1.7. *Brucella* spp.
8.21.4.1.8. *Vibrio cholerae* Serogroups O1 and O139
8.21.4.1.9. *Vibrio cholerae* Serogroups non-O1 and non-O139
8.21.4.1.10. *Vibrio vulnificus*
8.21.4.1.11. *Cronobacter* (*Enterobacter sakazakii*) spp.
8.21.4.1.12. *Aeromonas* spp.
8.21.4.1.13. *Plesiomonas shigelloides*
8.21.4.1.14. *Miscellaneous* bacterial enterics
8.21.4.1.14.1. E.g. *Klebsiella, Enterobacter, Proteus, Citrobacter, Aerobacter, Providencia, Serratia*
8.21.4.1.15. *Francisella tularensis*
8.21.4.1.16. *Pathogenic* Escherichia coli Group
8.21.4.1.16.1. Enterotoxigenic *Escherichia coli* (ETEC)
8.21.4.1.16.2. Enteropathogenic *Escherichia coli* (EPEC)
8.21.4.1.16.3. Enterohemorrhagic *Escherichia coli* (EHEC
8.21.4.1.16.4. Enteroinvasive *Escherichia coli* (EIEC)
8.21.4.2. Gram-positive bacteria
8.21.4.2.1. *Clostridium perfringens*
8.21.4.2.2. *Staphylococcus aureus*
8.21.4.2.3. *Bacillus cereus* and other *Bacillus* spp.
8.21.4.2.4. *Streptococcus* spp.
8.21.4.2.5. *Listeria monocytogenes*
8.21.4.2.6. *Mycobacterium bovis*
8.21.4.2.7. *Clostridium botulinum*
8.21.4.2.8. *Enterococcus*

9. TESTING REQUIRED: ZONE E:

Note: A Performance Qualification is being executed in accordance with BSI-PRL-0795 in June 2024 for the Zone E Purified Water System. The testing methods will include the USP/EP Water for Injection and USP/EP Purified Water Specifications for evaluation. At minimum, the Purified Water System will be released as USP/EP Purified Water.

9.1. Generation System Sample Locations & Analysis

9.1.1. Note: How to Handle a Generation System result that exceeds the Alert/Action Level or Specification for TVB or Coliform: If a result is received that exceeds the alert/action level or specification, a WFI Microbial Alert Checklist must be issued and completed to document the occurrence.

9.1.2. The particular valve can be re-sampled 2 times to see if results are replicated. The valve must have three consecutive exceeding results before action is required. If three consecutive replicates are received, a discrepancy may be issued to further evaluate, at the discretion of management.

9.1.3. **Establishing a System Baseline:** The samples collected from the Sample Valves: SV-18, SV-27, E02, E03, E04, E05, E06 and D10 on the ***1st day of Phase 1 Performance Qualification*** will be analyzed for Elemental Impurities to establish baseline values to be used for system maintenance frequencies. ***After initial baseline testing***, samples will be taken ***quarterly*** for elemental impurity analysis for the duration of the Performance Qualification and for routine sampling after completion of the Performance Qualification. The results will be documented in an EI result report in Master Control.

Table 3 Zone E Testing Requirements

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Raw Municipal Feed Water, SV-02	Total Viable Bacteria (TVB)	Method of Analysis[1]	Total Viable Bacteria, Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	EPA Drinking Water Standards
		Alert/Action Level	≥ 200 CFU/mL	
		Specification	< 500 CFU/mL	
	Coliform	Method of Analysis[1]	Total Coliform Bacteria media, 100 ml sample per EPA methods	EPA Drinking Water Standards
		Specification	< 1 CFU/100 mL	
	Total Chlorine	Specification	For Information Only	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
	Free Chlorine	Specification	For Information Only	
	Total Hardness as Calcium Carbonate	Specification	For Information Only	
	Total Organic Carbon (TOC)	Specification	For Information Only	
	Conductivity	Specification	For Information Only	
	Bacterial Endotoxin	Specification	For Information Only	

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Prefilter Product Water SV-03	Total Viable Bacteria (TVB)	Method of Analysis[1]	Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48- 72 hour 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Alert/Action Level	≥ 200 CFU/mL	
	Coliform	Method of Analysis[1]	Total Coliform Bacteria media, 100 ml sample per EPA methods	
		Specification	For Information Only	
Rechargeable Activated Carbon Canister Product Water SV-05	Total Viable Bacteria (TVB)	Method of Analysis	Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Specification	For Information Only	
	Coliform	Method of analysis	Total Coliform Bacteria media, 100 ml sample per EPA methods	
		Specification	For Information Only	
	Total Chlorine	Specification	For Information Only	
	Free Chlorine	Specification	For Information Only	
	Total Organic Carbon (TOC)	Specification	For Information Only	
Post-Rechargeable Activated Carbon Ultraviolet Unit Product Water SV-06	Total Viable Bacteria (TVB)	Method of Analysis	Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Alert/Action Level	≥ 200 CFU/mL	
	Coliform	Method of Analysis	Total Coliform Bacteria media, 100 ml sample per EPA methods	
		Specification	For Information Only	
	Total Chlorine	Specification	For Information Only	
	Free Chlorine	Specification	For Information Only	
	Total Organic Carbon(TOC)	Specification	For Information Only	

[1]Total Viable Bacteria and Coliform samples shall use a sample bottle/container containing a sodium thiosulfatetablet to reduce disinfecting agent which is present in the city water supply

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Reverse Osmosis System Product Water SV-12	Total Viable Bacteria (TVB)	Method of Analysis	Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Alert/Action Level	≥ 100 CFU/mL	
	Coliform	Method of Analysis	Total Coliform Bacteria media, 100 mL sample per EPA methods	
		Specification	For Information Only	
	Total Organic Carbon (TOC)	Specification	For Information Only	
	Conductivity	Specification	For Information Only	
Product Water from Second Rechargeable Mixed Bed Canister in Series SV-14	Total Viable Bacteria (TVB)	Method of Analysis	Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Alert/Action Level	> 100 CFU/mL	
Product Water from Post Rechargeable Mixed Bed Canister Ultraviolet Unit SV-16	Total Viable Bacteria (TVB)	Method of Analysis	Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Alert/Action Level	> 100 CFU/mL	
USP/EP Water for Injection Specifications				
Product Water from Hollow Fiber Ultrafiltration Unit SV-18	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	[1] Meets the requirements	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	

[1] The Limit Response (R_L) of ≤500ppb of Carbon will be equal to this corrected Standard Solution response.

9.2. Storage & Distribution System Sample Locations & Analysis: ***USP/EP Water for Injection Specifications***

9.2.1. Note: How to Handle a Storage and Distribution System result that exceeds the Alert/Action Level for TVB: If a result is received that exceeds the alert/action level or specification, a WFI Microbial Alert Checklist must be issued and completed to document the occurrence.

Table 4: Storage and Distribution Systems Location and Analysis USP/EP Water for Injection

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Water Purification Area – Room E07 SV-27	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
	Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
	Conductivity	Specification	Meets the requirements	USP-NF Water for Injection
	Nitrates	Specification	≤ 0.2 ppm	EP Water for Injections (0169)
API Suite – Room E06 E06DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
	Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
	Conductivity	Specification	Meets the requirements	USP-NF Water for Injection
	Nitrates	Specification	≤ 0.2 ppm	EP Water for Injections (0169)

Sample Location	Analysis	Designation	Requirement	Justification of Specification
API Suite – Room E05 E05DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
	Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
	Conductivity	Specification	Meets the requirements	USP-NF Water for Injection
	Nitrates	Specification	≤ 0.2 ppm	EP Water for Injections (0169)
API Suite – Room E04 E04DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
	Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
	Conductivity	Specification	Meets the requirements	USP-NF Water for Injection
	Nitrates	Specification	≤ 0.2 ppm	EP Water for Injections (0169)

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Excipient Cell 2 – Room E03 E03DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
	Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
	Conductivity	Specification	Meets the requirements	USP-NF Water for Injection
	Nitrates	Specification	≤ 0.2 ppm	EP Water for Injections (0169)
Excipient Cell 1 – Room E02 E02DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
	Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
	Conductivity	Specification	Meets the requirements	USP-NF Water for Injection
	Nitrates	Specification	≤ 0.2 ppm	EP Water for Injections (0169)

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Zone D Laboratory – Room D10 D10DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 5 CFU/100 mL	
		Specification	< 10 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
	Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
	Conductivity	Specification	Meets the requirements	USP-NF Water for Injection
	Nitrates	Specification	≤ 0.2 ppm	EP Water for Injections (0169)

9.3 Generation System Sample Locations & Analysis: ***USP/EP Purified Water Specifications***

9.3.1 Note: How to Handle a Generation System result that exceeds the Alert/Action Level or Specification for TVB or Coliform: If a result is received that exceeds the alert/action level or specification, a Microbial Alert Checklist must be issued and completed todocument the occurrence.

9.3.2 The particular valve can be re-sampled 2 times to see if results are replicated. The valve must have three consecutive exceeding results before action is required. If three consecutive replicates are received, a discrepancy may be issued to further evaluate, at the discretion of management.

Table 5: Generation System Sample Locations and Analysis USP/EP Purifies Water Secifications

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Product Water from Hollow Fiber Ultrafiltration Unit SV-18	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	Water Systems service provider recommendation for system monitoring and maintenance frequency establishment
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	[1] Meets the requirements	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	

[1] The Limit Response (R_L) of ≤500ppb of Carbon will be equal to this corrected Standard Solution response.

9.4 Storage & Distribution System Sample Locations & Analysis: ***USP/EP Purified Water Specifications.***

9.4.1 Note: How to Handle a Storage and Distribution System result that exceeds the Alert/Action Level for TVB: If a result is received that exceeds the alert/action level or specification, a Microbial Alert Checklist must be issued and completed to document the occurrence.

Table 6: Storage and Distribution System Sample Locations and Analysis USP/EP Purified Water Specifications

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Water Purification Area – Room E07 SV-27	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	≤500 ppb	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	EP Water, Purified (0008)
API Suite – Room E06 E06DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	≤500 ppb	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	EP Water, Purified (0008)

Sample Location	Analysis	Designation	Requirement	Justification of Specification
API Suite – Room E05 E05DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	≤500 ppb	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	EP Water, Purified (0008)
API Suite – Room E04 E04DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	≤500 ppb	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	EP Water, Purified (0008)

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Excipient Cell 2 – Room E03 E03DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	≤500 ppb	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	EP Water, Purified (0008)
Excipient Cell 1 – Room E02 E02DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	≤500 ppb	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	EP Water, Purified (0008)

Sample Location	Analysis	Designation	Requirement	Justification of Specification
Zone D Laboratory – Room D10 D10DI01	Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
		Alert/Action Level	≥ 100 CFU/100 mL	
		Specification	< 200 CFU/100 mL	
	Bacterial Endotoxin	Specification	< 0.25 EU/mL	
	Total Organic Carbon (TOC)	Specification	≤500 ppb	
	Conductivity	Specification	Meets the requirements	
	Nitrates	Specification	≤ 0.2 ppm	EP Water, Purified (0008)

9.5 Frequency of Performance Qualification sampling and testing for both Zone E and L is detailed in the applicable Performance Qualification Protocol.

9.6 Frequency of Routine Testing:

9.6.1 Refer to the tables below for testing frequency. For weekly testing, each valve is to be sampled once per week with sampling occurring from the Storage & Distribution system a minimum of three days per week. A week is considered 7 calendar days in this context, therefore there should be no longer than 4 days of a period without sampling. Quarterly data when requested will be obtained from the combined monthly data of the quarter.

Table 7: Example Weekly Schedule - Zone E

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	E02DI01 E03DI01	E04DI01 E05DI01 E06DI01	SV-27 D10DI01 SV-18			

Table 8: Weekly Water Testing Valve Reference

Weekly Water Testing Valve Reference Table	
Valve Identifications	Testing Required
E02DI01	Total Viable Bacteria, Bacterial Endotoxin, TOC, Conductivity, Nitrates
E03DI01	
E04DI01	
E05DI01	
E06DI01	
D10DI01	
SV-27	
SV-18	

Table 9: Bangor Monthly Testing Valve Reference

Bangor Monthly Testing Valve Reference Table	
Sample Location	Testing Required
SV-02	Coliform, Conductivity, Total Viable Bacteria, Total Chlorine, Free Chlorine, Total Hardness as Calcium Carbonate, TOC, Bacterial Endotoxin
SV-03	Coliform, Total Viable Bacteria
SV-05	Coliform, Total Viable Bacteria, Total Chlorine, Free Chlorine, TOC
SV-06	Coliform, Total Viable Bacteria, Total Chlorine, Free Chlorine, TOC
SV-12	Coliform, Total Viable Bacteria, TOC, Conductivity
SV-14	Total Viable Bacteria
SV-16	Total Viable Bacteria

Table 10: Quarterly Water Testing Valve Reference

Quarterly Water Testing Valve Reference Table	
Valve Identifications	Testing Required
E02DI01	Elemental Impurities, BSI-ATM-0097
E03DI01	
E04DI01	
E05DI01	
E06DI01	
D10DI01	
SV-27	
SV-18	

Table 11: Example Monthly Schedule:

Note: This serves as an example schedule only.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	E02DI01 E03DI01	E04DI01 E05DI01 E06DI01	SV-27 D10DI01 SV-18			
Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
	E02DI01 E03DI01	E04DI01 E05DI01 E06DI01	SV-18 SV-27 D10DI01			
Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
	E02DI01 E03DI01	E04DI01 E05DI01 E06DI01	SV-27 D10DI01 SV-18			
Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
	E02DI01 E03DI01	E04DI01 E05DI01 E06DI01	SV-18 SV-27 D10DI01	SV-02 SV-03 SV-05 SV-06 SV-12 SV-14 SV-16		

10 TESTING REQUIRED: ZONE L:

10.3 Note: How to Handle a Generation System result that exceeds the Alert/Action Level or Specification for TVB or Coliform: If a result is received that exceeds the alert/action level or specification, a WFI Microbial Alert Checklist must be issued and completed to document the occurrence.

10.4 The particular valve can be re-sampled 2 times to see if results are replicated. The valve must have three consecutive exceeding results before action is required. If three consecutive replicates are received, a discrepancy may be issued to further evaluate, at the discretion of management.

10.5 **Establishing a System Baseline:** The samples collected from the Storage and Distribution System Sample Valves: SV-242, SV-305, SV-322, L05, L09, L08, L01, M07 and M03 will be analyzed for Elemental Impurities to establish baseline values to be used for system maintenance frequencies. ***After initial baseline testing (target start date May 2024)***, samples will be taken ***quarterly*** for elemental impurity analysis for routine sampling. The results will be documented in an EI result report in Master Control.

Table 12: Raw Municipal Feed Water, SV-100

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis[1]	Total Viable Bacteria (TBV), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	EPA Drinking Water Standards
	Specification	< 500 CFU/mL	
Coliform	Method of Analysis[1]	Total Coliform Bacteria media, 100 ml sample per EPA methods	EPA Drinking Water Standards
	Specification	< 1 CFU/100 mL	
Total Chlorine	Specification	For Information Only	Water Systems Provider Recommendation for system monitoring and maintenance frequency establishment
Free Chlorine	Specification	For Information Only	
Total Hardness as Calcium Carbonate	Specification	For Information Only	
Total OrganicCarbon (TOC)	Specification	For Information Only	
Conductivity	Specification	For Information Only	
Bacterial Endotoxin	Specification	For Information Only	

[1] Total Viable Bacteria and coliform samples shall use a sample bottle/container containing a sodium thiosulfate tablet to reduce disinfecting agent which is present in the city water supply

Table 13: Prefilter Product Water SV-103

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis[1]	Total Viable Bacteria (TBV), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems service provider Recommendation for system monitoring and maintenance frequency establishment
	Alert/Action Level	> 500 CFU/mL	
Coliform	Method of Analysis[1]	Total Coliform Bacteria media, 100 mL sample per EPA methods	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment
	Specification	For Information Only	

[1] Total Viable Bacteria and coliform samples shall use a sample bottle/container containing a sodium thiosulfate tablet to reduce disinfecting agent which is present in the city water supply.

Table 14: Water Softener Product Water SV-110

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis[1]	Total Viable Bacteria (TVB), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment
	Alert/Action Level	≥ 500 CFU/mL	
Coliform	Method of Analysis[1]	Total Coliform Bacteria media, 100 mL sample per EPA methods	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment
	Specification	For Information Only	
Total Hardness as Calcium Carbonate	Specification	For Information Only	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment

[1] Total Viable Bacteria and coliform samples shall use a sample bottle/container containing a sodium thiosulfate tablet to reduce disinfecting agent which is present in the city water supply.

Table 15: Pretreatment UV Product Water SV-113

Analysis	Designation	Requirement	Justification ofSpecification
Total Viable Bacteria (TVB)	Method of Analysis	Total Viable Bacteria (TVB), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment
	Alert/Action Level	> 500 CFU/mL	
Coliform	Method of Analysis	Total Coliform Bacteria media, 100 mL sample per EPA methods	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment
	Specification	For Information Only	
Total Chlorine	Specification	For Information Only	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment
Free Chlorine	Specification	For Information Only	
Total OrganicCarbon (TOC)	Specification	For Information Only	

Table 16: 5-micron Prefilter Product Water SV-119

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Total Viable Bacteria (TVB), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	Water Systems provider recommendation for system monitoring and maintenance frequency establishment
	Alert/Action Level	> 500 CFU/mL	
Coliform	Method of Analysis	Total Coliform Bacteria media, 100 mL sample per EPA methods	Water Systems provider recommendation for system monitoring and maintenance frequency establishment
	Specification	For Information Only	

Table 17: Break Tank Water SV-202

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Total Viable Bacteria (TVB), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°Cincubation	Water Systems Provider recommendation for system monitoring and maintenance frequency establishment
	Alert/Action Level	> 500 CFU/mL	
Coliform	Method of Analysis	Total Coliform Bacteria media, 100 ml sample per EPA methods	Water Systems provider recommendation for system monitoring and maintenance frequency establishment
	Specification	For Information Only	

Table 18: RO Product Water SV-230

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Total Viable Bacteria (TVB), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	EPA Drinking Water Standards
	Alert/Action Level	> 100 CFU/mL	
Coliform	Method of Analysis	Total Coliform Bacteria media, 100 mL sample perEPA methods	EPA Drinking Water Standards
	Specification	For Information Only	
Total OrganicCarbon (TOC)	Specification	For Information Only	Water Systems provider Recommendation for system monitoring and maintenance frequency establishment
Conductivity	Specification	For Information Only	
Bacterial Endotoxin	Specification	For Information Only	

Table 19: CEDI Product Water SV-234

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Total Viable Bacteria (TVB), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	EPA Drinking Water Standards
	Alert/Action Level	> 100 CFU/mL	

Table 20: RO/CEDI Loop UV Product Water SV-237

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Total Viable Bacteria (TVB), Heterotrophic Plate Count (HPC), 1 mL, PCA culture media, 48-72 hour, 30-35°C incubation	EPA Drinking Water Standards
	Alert/Action Level	> 100 CFU/mL	

Table 21: Ultrafilter Product Water SV-242

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	[1] Meets the Requirements	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)
[1] The Limit Response (R_L) of ≤500ppb of Carbon will be equal to this corrected Standard Solution response.			

10.6 Storage & Distribution System Sample Locations & Analysis

10.6.1 Note: How to Handle a Storage and Distribution System result that exceeds the Alert/Action Level for TVB: If a result is received that exceeds the alert/action level or specification, a WFI Microbial Alert Checklist must be issued and completed to document the occurrence.

Table 22: WFI Loop Supply, SV-305

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 ml, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

Table 23: WFI Point-of-Use, L05DI01

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

Table 24: WFI Point-of-Use, L09DI01

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

Table 25: WFI Point-of-Use, L08DI01

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

Table 26: WFI Point-of-Use, L01DI01

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total Organic Carbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

Table 27: WFI Point-of-Use, M07DI01

Note: **Sample Valve marked out of Use until further notice, Reference: BDI23-245. M07DI01 will only be sampled for EI quarterly analysis**

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

Table 28: WFI Point-of-Use, M03DI01

Note: **Sample Valve marked out of Use until further notice, Reference: BDI23-245. M03DI01 will only be sampled for EI quarterly analysis.**

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

Table 29: WFI Loop Return Sample Valve, SV-322

Analysis	Designation	Requirement	Justification of Specification
Total Viable Bacteria (TVB)	Method of Analysis	Membrane Filtration of 100 mL, R2A culture media, ≥ 5 days, 30-35°C incubation	USP <1231> Water for Pharmaceutical Purposes
	Alert/Action Level	≥ 5 CFU/100 mL	
	Specification	< 10 CFU/100 mL	
Bacterial Endotoxin	Specification	< 0.25 EU/mL	USP-NF Water for Injection
Total OrganicCarbon (TOC)	Specification	≤500 ppb	USP-NF Water for Injection
Conductivity	Specification	Meets the Requirements	USP-NF Water for Injection
Nitrates	Specification	≤ 0.2 ppm	EP Water for Injection (0169)

10.7 Frequency of Testing:

10.7.1 Refer to the tables below for testing frequency. For weekly testing, each valve is to be sampled once per week with sampling occurring from the Storage & Distribution system a minimum of three days per week. A week is considered 7 calendar days in this context, therefore there should be no longer than 4 days of a period without sampling. Quarterly data when requested will be obtained from the combined monthly data of the quarter.

Table 30: Example Weekly Schedule-for Testing frequency

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	L01DI01 SV-305 SV-322	L05DI01 SV-242 L09DI01 L08DI01	M07DI01 M03DI01			

Table 31: Weekly Water Testing Valve Reference

Weekly Water Testing Valve Reference Table	
Valve Identifications	Testing Required
SV-242	Total Viable Bacteria, Bacterial Endotoxin, TOC, Conductivity, Nitrates
SV-305	
SV-322	
L05DI01	
L09DI01	
L08DI01	
L01DI01	
M07DI01	
M03DI01	

Table 32: Bangor Monthly Testing Valve Reference

Bangor Monthly Testing Valve Reference Table	
Sample Location	Testing Required
SV-100	Total Viable Bacteria, Coliform, Total Chlorine, Free Chlorine, Total Hardness as Calcium Carbonate, TOC, Conductivity, Bacterial Endotoxin
SV-103	Coliform, Total Viable Bacteria
SV-110	Coliform, Total Viable Bacteria, Total Hardness as Calcium Carbonate
SV-113	Total Viable Bacteria, Coliform, Total Chlorine, Free Chlorine, TOC
SV-119	Coliform, Total Viable Bacteria
SV-202	Coliform, Total Viable Bacteria
SV-230	Total Viable Bacteria, Coliform, TOC, Conductivity, Bacterial Endotoxin
SV-234	Total Viable Bacteria
SV-237	Total Viable Bacteria

Table 33: Quarterly Water Testing Valve Reference

Quarterly Water Testing Valve Reference Table	
Valve Identifications	Testing Required
SV-242	Elemental Impurities, BSI-ATM-0097
SV-305	
SV-322	
L05DI01	
L09DI01	
L08DI01	
L01DI01	
M07DI01	
M03DI01	

Table 34: Example Monthly Schedule – Zone L

Note: This serves as an example schedule only.

Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
	L01DI01 SV-305 SV-322	L05DI01 SV-242 L09DI01 L08DI01	M07DI01 M03DI01			
Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
	L01DI01 SV-305 SV-322	L05DI01 SV-242 L09DI01 L08DI01	M07DI01 M03DI01			
Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
	L01DI01 SV-305 SV-322	L05DI01 SV-242 L09DI01 L08DI01	M07DI01 M03DI01			
Sunday	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
	L01DI01 SV-305 SV-322	SV-242 L09DI01 L08DI01 M07DI01 M03DI01	L05DI01 SV-100 SV-103 SV-110 SV-113 SV-119 SV-202 SV-230 SV-234 SV-237			