

Guidance Number 058:

**Table I: Purified Water (PW)
Pre-Treatment System Sampling Location, Frequency and Test Type**

Pre-Treatment System Sample Location	Commissioning Tests & Frequency Duration ≈ 1-5 days	Phase 1 Tests & Frequency Duration ≈ 1 month	Phase 2 Tests & Frequency Duration ≈ 1 month	Phase 3 Tests & Frequency Duration ≈ 10 months
Potable Water Supply/ Inlet of Media Filters	1) <u>Potable Water Feed</u> : Semi-annual for Chemical testing & Monthly Micro testing (coliforms & Total Viable Organisms (TVO))			
Outlet of Media Filters/ Inlet of Softener	1) Silt Density Index (SDI)	Not Applicable	Not Applicable	Not Applicable
Outlet of Softener/ Inlet of Dechlorination Unit	1) Hardness	Not Applicable	Not Applicable	Not Applicable
Outlet of Dechlorination Unit/ Inlet of Surge Tank	1) Chlorine Content	Not Applicable	Not Applicable	Not Applicable

**Table 2: Purified Water (PW)
Generation System Sampling Location, Frequency and Test Type**

Generation System Sample Location	Commissioning Tests & Frequency Duration ≈ 1-5 days	Phase 1 Tests & Frequency Duration ≈ 1 month	Phase 2 Tests & Frequency Duration ≈ 1 month	Phase 3 Tests & Frequency Duration ≈ 10 months
Outlet of RO Unit/ Inlet of CEDI Unit	1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity (daily)	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily)	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily)	1) Micro Testing (3x/week**) 2) Micro ID (distinct)* 3) Conductivity (daily)
Outlet of CEDI Unit/ And post-Particulate Filter (if present) [Feed to Loop]	1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests 6) JP Chemical Tests	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/week) 6) JP Chemical Tests (1x/week)	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/2 weeks) 6) JP Chemical Tests (1x/2 weeks)	1) Micro Testing (3x/week**) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/quarter) 6) JP Chemical Tests (1x/quarter)

*Micro ID:

Microbiological identification testing is performed to provide a profile of the resident microflora within the water system and are obtained from the microbiological testing samples. Microbial identification is not required for samples where the microorganisms have been previously identified.

**With at least 1 day between samples.

**Table 3: Purified Water (PW)
Distribution System Sampling Location, Frequency and Test Type**

Distribution System Sample Location	Commissioning Tests & Frequency Duration ≈ 1-5 days	Phase 1 Tests & Frequency Duration ≈ 1 month	Phase 2 Tests & Frequency Duration ≈ 1 month	Phase 3 Tests & Frequency Duration ≈ 10 months
Loop Supply – First & Last Use Point on Loop	1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests 6) JP Chemical Tests	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/week) 6) JP Chemical Tests (1x/week)	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/2 weeks) 6) JP Chemical Tests (1x/2 weeks)	1) Micro Testing (3x/week**) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/quarter) 6) JP Chemical Tests (1x/quarter)
Non-Critical Use Point (Each Non-Critical Use Point tested at least once during Commissioning through Phase 2 Qualification)	1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity 4) TOC			1) Micro Testing (1x/month) 2) Micro ID (distinct)* 3) Conductivity (on-line or 1x/month) 4) TOC (on-line or 1x/month)
Critical Use Point (CUP) (Each Critical Use Point tested at least weekly during Commissioning through Phase 1 Qualification)	1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests 6) JP Chemical Tests	1) Micro Testing (See Note Below) 2) Micro ID (distinct)* 3) Conductivity (See Note Below) 4) TOC (See Note Below) For CUPs which are not the first and last in the Loop: Sample all CUPs at least once per week; Sample at least one CUP per day with at least one day between samplings <i>For EU & JP Testing only:</i> The samples should be distributed over the qualification phase such as there is a minimum of one CUP being tested per day for EU & JP tests.	1) Micro Testing (See Note Below) 2) Micro ID (distinct)* 3) Conductivity(See Note Below) 4) TOC (See Note Below) For CUPs which are not the first and last in the Loop: Sample all CUPs at least once per week; Sample at least one CUP per day with at least one day between samplings;	1) Micro Testing (See Note Below) 2) Micro ID (distinct)* 3) Conductivity(See Note Below) 4) TOC (See Note Below) Sample all CUPs at least every two weeks; Sample three different CUPs weekly with at least one day between samplings.

*Micro ID:

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**With at least 1 day between samples.

**Table 4: Water for Injection (WFI)
Generation System Sampling Location, Frequency and Test Type**

Generation System Sample Location	Commissioning Tests & Frequency Duration ≈ 1-5 days	Phase 1 Tests & Frequency Duration ≈ 1 month	Phase 2 Tests & Frequency Duration ≈ 1 month	Phase 3 Tests & Frequency Duration ≈ 10 months
Feed to the Generator (Still) Note: Water quality should be of a quality beyond potable water (e.g. deionized)	Conductivity of feed water if not measured elsewhere	Conductivity of feed water if not measured elsewhere	Conductivity of feed water if not measured elsewhere	Conductivity of feed water if not measured elsewhere
Outlet of the Generator (Still)	1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests 6) JP Chemical Tests 7) Endotoxin	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/week) 6) JP Chemical Tests (1x/week) 7) Endotoxin (daily)	1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/2 weeks) 6) JP Chemical Tests (1x/2 weeks) 7) Endotoxin (daily)	1) Micro Testing (3x/week**) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/quarter) 6) JP Chemical Tests (1x/quarter) 7) Endotoxin (3x/week)

*Micro ID:

Microbiological identification testing is performed to provide a profile of the resident microflora within the water system and are obtained from the microbiological testing samples. Microbial identification is not required for samples where the microorganisms have been previously identified.

**With at least 1 day between samples.

**Table 5: Water for Injection (WFI)
Distribution System Sampling Location, Frequency and Test Type**

Distribution System Sample Location	Commissioning Tests & Frequency Duration ≈ 1-5 days	Phase 1 Tests & Frequency Duration ≈ 1 month	Phase 2 Tests & Frequency Duration ≈ 1 month	Phase 3 Tests & Frequency Duration ≈ 10 months
<p>Loop Supply - First Use Point on Loop</p> <p>Loop Return- Last Use Point</p>	<p>1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests 6) JP Chemical Tests 7) Endotoxin</p>	<p>1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/week) 6) JP Chemical Tests (1x/week) 7) Endotoxin (daily)</p>	<p>1) Micro Testing (daily) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/2 weeks) 6) JP Chemical Tests (1x/2 weeks) 7) Endotoxin (daily)</p>	<p>1) Micro Testing (3x/week**) 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests (1x/quarter) 6) JP Chemical Tests (1x/quarter) 7) Endotoxin (3x/week)</p>
<p>Critical Use Point (CUP)</p> <p>(Each Critical Use Point tested at least weekly during Commissioning through Phase 1 Qualification)</p>	<p>1) Micro Testing 2) Micro ID (distinct)* 3) Conductivity (daily) 4) TOC (daily) 5) EU Chemical Tests 6) JP Chemical Tests 7) Endotoxin (daily)</p>	<p>1) Micro Testing (See Note Below) 2) Micro ID (distinct)* 3) Conductivity (See Note Below) 4) TOC (See Note Below) 5) Endotoxin (See Note Below)</p> <p>For CUPs which are not the first and last in the Loop: Sample all CUPs at least once per week; Sample at least one CUP per day with at least one day between samplings</p> <p><i>For EU & JP Testing only:</i> The samples should be distributed over the qualification phase such that there is a minimum of one CUP being tested per day for EU & JP tests.</p>	<p>1) Micro Testing (See Note Below) 2) Micro ID (distinct)* 3) Conductivity(See Note Below) 4) TOC (See Note Below) 5) Endotoxin (See Note Below)</p> <p>For CUPs which are not the first and last in the Loop: Sample all CUPs at least once per week; Sample at least one CUP per day with at least one day between samplings.</p>	<p>1) Micro Testing (See Note Below) 2) Micro ID (distinct)* 3) Conductivity(See Note Below) 4) TOC (See Note Below) 5) Endotoxin (See Note Below)</p> <p>Sample all CUPs at least every two weeks; Sample three different CUPs weekly with at least one day between samplings.</p>

*Micro ID:

Microbiological identification testing is performed to provide a profile of the resident microflora within the water system and are obtained from the microbiological testing samples. Microbial identification is not required for samples where the microorganisms have been previously identified.

**With at least 1 day between samples.