and testing for Phase 1 activities. The Phase 1 activities are performed to demonstrate that the production and delivery of water consistently meets the specified compendial requirements. It is also very important during Phase 1 activities to finalize appropriate operating ranges for critical process parameters as well as to finalize Standard Operating Procedures (SOPs) for routine system operation, cleaning and maintenance.

Phase 2 Qualification (approximately 1 month)
The Phase 2 activities typically last the same duration as Phase 1, which is one month. The sampling and testing frequency are nearly identical to the activities in Phase 1. The purpose of Phase 2 is to further demonstrate consistent production and delivery of water of the required quality within the established ranges when using SOPs. There are some equipment systems which require on-line measurement (e.g., measurement of conductivity when utilizing Reverse Osmosis (RO). It is an acceptable practice to utilize only on-line measurement testing results for the routine release testing. Data resulting from the on-line measurement testing must be treated as primary data.

Phase 3 Qualification (approximately 10 months)
The Phase 3 portion of the water system qualification activities continue for the remaining balance of the year (approximately 10 months). Collectively, the entire Qualification process consisting of Phase 1, Phase 2, and Phase 3 is an extended study of the system for a period of one year. A one year time frame allows for the system to be challenged by evaluating its effectiveness of delivering water of acceptable quality despite seasonal variations in the raw water feed to the system.

Typically, the Phase 3 sampling plan is reduced in frequency from the Phase 1 and Phase 2 schedule with the sampling and testing activities being consistent with the routine monitoring program post-validation. At a minimum the sample schedule for Phase 3 testing must be consistent with any specified sampling requirements indicated within Guidance 078 *Water Purification, Storage, and Distribution for Pharmaceutical Production.*

Risk Based Approach:
A risk based approach to commissioning and qualification may be utilized to develop the sampling strategy. For example, impact assessments may be utilized to determine what components or functions of the PW or WFI System are considered critical.

A water quality attribute may be defined as critical based on the need to meet a specific compendia specification and is not further affected by additional downstream operating steps. For example, conductivity is a critical attribute that is measured at the outlet of a PW Generation System (e.g., outlet of the Continuous Electrodeionization (CEDI) or Reverse Osmosis (RO)) for verifying the results satisfactorily meet compendia limits. Sampling the conductivity at this point would occur during commissioning and qualification activities.

Non-critical quality attributes (e.g., outlet of the media filters,) are tested only during commissioning. Thus they may become part of an on-going routine monitoring program subject to Good Engineering Practices (GEP) which may include routine monitoring tests to assure proper maintenance and operation of the System (e.g., regeneration of resin beds, sanitization of equipment, etc.). This on-going monitoring on non-critical attributes is not to be a part of the qualification studies.

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 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.

