

For example, clean steam that is strictly used for the production of ophthalmic products or non-sterile products would typically not have defined bacterial endotoxin specification requirements.

The testing of clean steam systems includes the Generation System and associated Distribution System piping starting with commissioning activities through the three phases of qualification studies that is synonymous with high-purity water systems. ^{1,2,3,4}

Commissioning

Commissioning is defined in the ISPE Good Practice Guide as “a well planned, documented, and managed engineering approach to the start-up and turnover of facilities, systems, and equipment to the end-user that results in a safe functional environment that meets established design requirements and stakeholder expectations”. Sampling and monitoring of the Generation and Distribution Systems for Clean Steam Systems during commissioning are considered Good Engineering Practice. These activities help to define operational and maintenance practices and procedures that will be challenged later during qualification. ³ The sampling and testing activities include chemical testing as appropriate for the unit operation with the maximum acceptable chemical levels of the condensate meeting the applicable WFI compendial limits as determined by the associated compendial methods.

In addition, bacterial endotoxin testing, as needed, to identify bacterial endotoxin levels (if any) within the system based on the intended use of the system. Finally, the quality of the feedwater should be verified both microbiologically and chemically to ensure that the clean steam condensate will meet USP and international WFI specifications as required.⁴

Typically, the duration of commissioning activities may vary depending upon the complexity and size of the system. Once the entire system is operating, each unit of operation should be tested at least once during the commissioning phase. It is the ability to complete this testing of use test points at least once during this phase, which determines the total time necessary to complete commissioning sampling.

Qualification (3 Phase Approach)

Qualification is an adjunct to commissioning and serves to provide documented evidence with oversight by Quality Assurance personnel that a clean steam system will consistently produce the appropriate quality of steam to end users in accordance with regulatory expectations.

Furthermore, it is important to note that activities performed as part of qualification do not necessarily have to repeat work that was already conducted during commissioning of the clean steam system if the commissioning documentation is prepared according to established site quality documentation practices. Depending upon the quality of the initial commissioning plan, the subsequent qualification can simply serve as verification that the system will consistently produce quality product (*i.e.* steam). The data collected as part of the commissioning sampling phase can be used to directly justify the sampling plan