

Summary - Purified Water and Water for Injection System Commissioning and Qualification Sampling Plans

Sampling and monitoring of the Pre-treatment, Generation and Distribution Systems for PW and WFI 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. The sampling and testing activities include chemical testing as appropriate for unit operation and microbial testing to identify the indigenous microbial bioburden of the system. 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.

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.

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