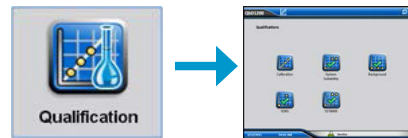


USP System Suitability



Bulk Water

The US Pharmacopeia (USP 36-NF 31, section <643>) provides specific guidance on how to qualify TOC instrumentation for use. When used for Bulk Water (such as purified water and water for injection) a System Suitability must be “periodically demonstrated” using three standard solutions:

- Reagent water, r_w
- Standard solution, r_s (500ppb of carbon as Sucrose)
- System Suitability Solution, r_{ss} (500ppb of carbon as Benzoquinone).

After measuring these solutions, calculate the response efficiency as:

$$\% \text{ Response Efficiency (RE)} = 100 [(r_{ss} - r_w) / (r_s - r_w)]$$

The TOC analyzer system is considered suitable if: $85\% \geq RE \leq 115\%$. USP further defines the Limit Response as:

- Limit Response = $(r_s - r_w)$
- When measuring Bulk Water samples, the water is considered to meet the USP requirements if the value is below the limit response.

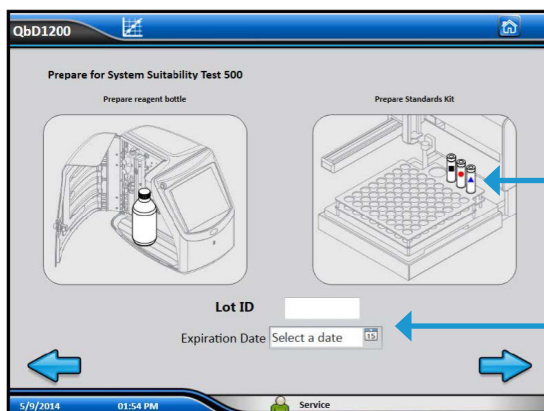
Sterile Water (New!)

When the water being tested is to be used as sterile water for injection, sterile purified water, sterile water for irrigation, or sterile water for inhalation, the System Suitability should be demonstrated in a similar manner as for Bulk Water. However, the standard solutions use different concentrations:

- Reagent water, r_w
- Standard solution, r_s (8000ppb of carbon as Sucrose)
- System Suitability Solution, r_{sS} (8000ppb of carbon as Benzoquinone).

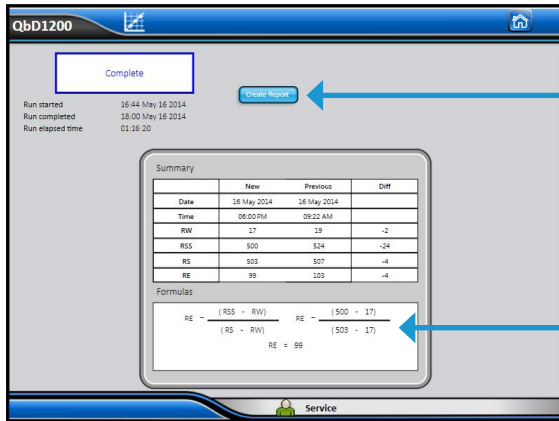
RE calculation and criteria are the same as for Bulk Water. Sterile Water samples are considered to meet USP requirements if the value is below the limit response.

QbD1200 is designed so that System Suitability is very convenient and easy to perform.



Instrument display guides operator where to place standards

Enter standards lot number and expiration date



Option to send report of SST
Paperless over Ethernet (secure FTP)

Calculation Details Shown

Notes:

- USP requires system suitability (SST) to be periodically demonstrated.
- QbD1200 is designed to make this process convenient.
- SST standards use color coded shapes to ensure proper placement in auto sampler rack.
- All standards are measured with 3 replicates and the average is used for the calculations.
- System Suitability procedure takes approximately 50 minutes.
- Paperless reporting allows operator to easily store all important qualification results on central server and maintain 21 CFR 11 compliance.