



QbD1200+ Analyzer

Japanese Pharmacopeia SDBS Validation

JP 16, section 2.59 Test for Total Organic Carbon

JP 16 specifies that when measuring a 500 ppb standard of sodium dodecylbenzenesulfonate (SDBS), a TOC analyzer should recover a value of at least 450 ppb (90% recovery). As SDBS is known to be a compound considered hard to oxidize, successful measurement would indicate that the TOC analyzer has been validated to be functioning properly.

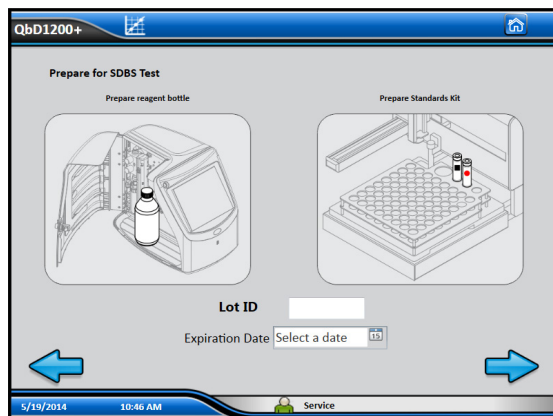


The QbD1200+ analyzer has a built-in qualification routine, “SDBS”, which makes performing a JP 16 compliant validation convenient. Two standard solutions are used:

- Blank water
- 500 ppb SDBS

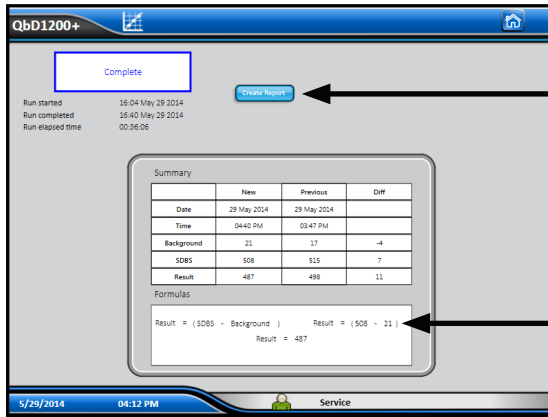
After three replicate measurements are taken of each solution, the average value of the blank water is subtracted from the average value of the SDBS measurements and the result is displayed.

The QbD1200+ analyzer is designed so that SDBS validation 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
Paperless over Ethernet
(secure FTP)

Results Clearly Shown

Notes:

- JP requires that a TOC Analyzer be validated to recover ≥ 450 ppb carbon from a 500 ppb SDBS standard.

The QbD1200+ analyzer is designed to make this process convenient.

Standards use color-coded shapes to ensure proper placement in auto sampler rack.

All standards are measured with 3 replicates.

SDBS validation procedure takes approximately 35 minutes.

Paperless reporting allows operator to easily store all important qualification results on central server and enable 21 CFR Part 11 compliance.