

Application News

No. 082

Total Organic Carbon Analysis

TOC System Suitability Test Using TOC-1000e According to USP 643

For water used in pharmaceuticals, the US Pharmacopoeia (USP) specifies that total organic carbon (TOC) should be used for management of organic impurities. According to USP 643 TOC, TOC analyzers to be used for analysis of bulk purified water and water for injection must satisfy the TOC system suitability test using test water with a carbon content of 0.500 mg/L.

This article introduces an actual example of TOC system suitability testing using the online total organic carbon analyzer TOC-1000e and optional sampler.

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Fig. 1 TOC-1000e + Sampler

■ Summary of USP 643 TOC System Suitability Test

The USP 643 TOC system suitability test for bulk purified water and water for injection specifies the use of two USP reference standards (sucrose and 1,4-benzoquinone) with a carbon content of 0.500 mgC/L. Sucrose is used as the standard solution, and 1,4-benzoquinone as the system suitability solution. The test procedure is shown in Table 1.

Table 1 TOC System Suitability Test Procedure in Accordance with USP 643

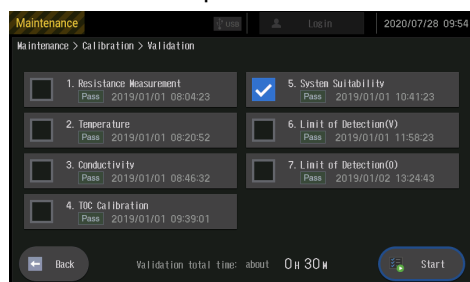
- (1) Measure TOC of reagent water (pure water used for preparation of the standard solution) → r_w .
- (2) Measure TOC of sucrose standard solution (0.500 mg/L of carbon) → r_s .
- (3) Measure TOC of system suitability solution (1,4-benzoquinone solution with a carbon content of 0.500 mg/L) → r_{ss} .
- (4) System suitability is satisfied if $100 (r_{ss} - r_w) / (r_s - r_w)$ is 85% - 115%.

Test Procedure

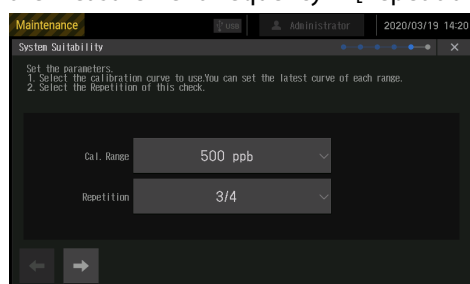
TOC-1000e is equipped with the USP's TOC system suitability test software.

The test procedure is as follows:

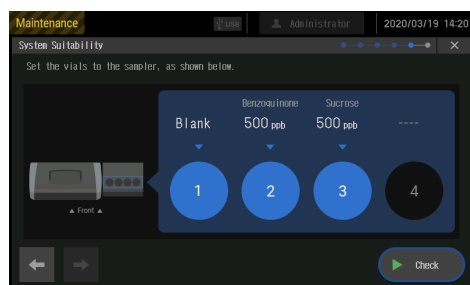
1. On [Validation] screen, Check [5. SYSTEM SUITABILITY] and press [Start] button.



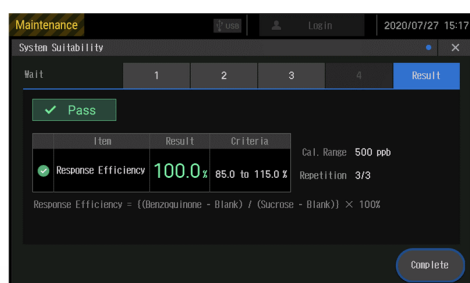
2. Set the range to 500 ppb in [Cal Range], and set the measurement frequency in [Repetition].



3. Follow the on-screen instructions to set the reagent for USP testing using TOC-1000e, including reagent water, benzoquinone solution and sucrose solution to the sampler, and press [Check] button.



4. When the measurement is completed, the results are shown in [Result]. If the results satisfy the standard values, [Pass] is displayed.

**Test Results**

Using TOC-1000e, a TOC system suitability test was conducted. The measurement conditions are shown in Table 2. Table 3 shows the measurement results and Fig. 2 shows an example of printed results. The results of tests repeated three times satisfied the specified values (85 – 115%).

Table 2 Measurement Conditions

Analyzer	: Shimadzu TOC-1000e online total organic carbon analyzer
Calibration curve	: 0-250-500 ppb
Reagents	: USP 643 system suitability test set, confirmed (USP standard) 500 ppb sucrose 500 ppb 1,4-benzoquinone reagent water

Table 3 Results of TOC System Sustainability Test

	Blank [ppb]	Sucrose [ppb]	Benzoquinone [ppb]	Result
1	23.0	509	526	103.5 %
2	21.3	516	509	98.6 %
3	20.9	514	514	100.0 %

Serial No: 1/1

Printed by: System 2020/06/18 10:52:09

***** TOC-1000e Validation: System Suitability *****

Date: 2020/06/16 13:31:10

User Name:

Options: Vial Sampler

Cal.Conditions: Range: 500ppb
Cal.Point: 0-250-500
(Created at: 2020/06/15 13:36:34)

Criteria: Response Efficiency, 85.0 to 115.0%
(Response Efficiency = {(Benzoquinone - Blank)/(Sucrose - Blank)})

Result: Passed

Meas Data: Response Efficiency: 100.0%

Vial	Standard	Rejection	Result	RMK	Statistics	Date Time
1	Blank	1. 23.9 ppb 2. 19.0 ppb 3. 19.7 ppb			AVG:20.9 SD:2.65 CV:12.7%	2020/06/16 13:31:10
2	Benzoquinone 500ppb	1. 500 ppb 2. 516 ppb 3. 525 ppb			AVG:514 SD:12.7 CV:2.5%	2020/06/16 13:38:56
3	Sucrose 500ppb	1. 516 ppb 2. 517 ppb 3. 509 ppb			AVG:514 SD:4.36 CV:0.8%	2020/06/16 13:46:42

Fig. 2 Results of TOC System Sustainability Test**Conclusion**

A TOC system suitability test can be conducted easily by TOC-1000e using the optional sampler and following the instructions on the software screen.

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TOC-1000e On-Line TOC Analyzer for Pure Water

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Pharmaceutical

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➤ Product Inquiry

➤ Technical Service /
Support Inquiry

➤ Other Inquiry