

Application News

No.051

Total Organic Carbon Analysis

TOC System Suitability Test for Sterile Water According to USP

The United States Pharmacopeia (USP) specifies that total organic carbon (TOC) content be used for management of organic impurity values permitted in bulk purified water, water for injection, in addition to sterile purified water and sterile water for injection. According to USP, TOC analyzers to be used for sterile water must satisfy the TOC system suitability test using test water having a carbon content of 8.0 mg/L, and must also be able to detect TOC at 0.1 mg/L or less. Here, we introduce an actual example of TOC system suitability testing using the Shimadzu TOC-L_{CPH} combustion catalytic oxidation type analyzer.

■ USP-Specified TOC System Suitability Test of Sterile Water

The USP's sterile water TOC system suitability test specifies that two USP standard substances (sucrose and 1,4-benzoquinone) be used. Sucrose is used as the test solution reference sample, and 1,4-benzoquinone as the system suitability test solution. Further, it is specified that the TOC analyzer be suitably calibrated. The test procedure is shown in Table 1.

Table 1 USP-Specified TOC System Suitability Test Procedure

TOC System Suitability Test Procedure	
1. Measure TOC of pure (distilled) water -> r_w	
2. Measure TOC of sucrose standard solution (8 mg/L of carbon) -> r_s	
3. Measure TOC (1,4-benzoquinone solution with carbon concentration 8.0 mg/L) according to system suitability test -> r_{ss}	
4. System suitability is satisfied if system suitability recovery rate ($(r_{ss} - r_w) / (r_s - r_w)$) is 85 % to 115 %.	

■ USP TOC System Suitability Test Data

We conducted the TOC system suitability test following the procedure of Table 1, using the Shimadzu TOC-L_{CPH} combustion type TOC analyzer. The instrument was calibrated beforehand using potassium hydrogen phthalate solution at 0 and 8.0 mgC/L. Fig. 1 shows the TOC system suitability test data. The USP specifies that calculation of the recovery rate be evaluated based on the analyzer response values, but here, evaluation was based on the measured concentration values.

The results indicated a recovery rate of 99.0 % using the system suitability test solution (1,4-benzoquinone aqueous solution). (Table 2)

<Measurement Conditions>

Analyzer	: Shimadzu TOC-L _{CPH} Total Organic Carbon Analyzer
Catalyst	: High-sensitivity catalyst
Injection volume	: 51 μ L
Measurement item	: TOC (= NPOC: TOC by acidification sparging)
Calibration curve	: 2-point calibration curve generated using TOC 0 – 8.0 mgC/L potassium hydrogen phthalate aqueous solution

Table 2 Results of TOC System Suitability Test

1. Distilled water TOC value $r_w = 0.063$ mg/L
2. Sucrose standard solution TOC value $r_s = 8.087$ mg/L
3. System suitability test (1,4-benzoquinone aqueous solution) TOC $r_{ss} = 8.007$ mg/L
4. System suitability test recovery rate = $100 (r_{ss} - r_w) / (r_s - r_w)$
 $= 100 (8.007 - 0.063) / (8.087 - 0.063)$
 $= 99 \%$

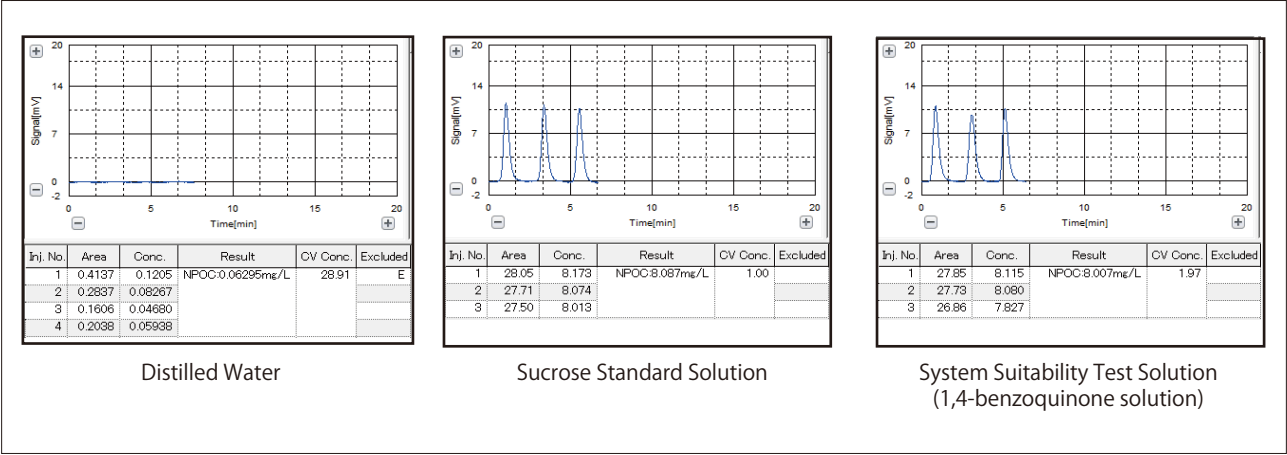


Fig. 1 TOC System Suitability Test Data

■ TOC Measurement Below 0.1 mg/L

The USP specifies the use of an instrument capable of TOC quantitation below 0.10 mg/L. We therefore conducted measurement of a potassium hydrogen phthalate solution with a 0.0987 mgC/L TOC concentration. Those results are shown in Fig. 2 and Table 3. The measurement result was 0.0987 mgC/L, with a 4.31 % coefficient of variation (CV value). As the CV value is within 10 % in the vicinity of the lower limit of quantitation, the requirement of a TOC instrument capable of TOC measurement at or below 0.10 mg/L as specified in the USP is fully satisfied, indicating the applicability of the Shimadzu TOC-L_{CPH} combustion type TOC analyzer.

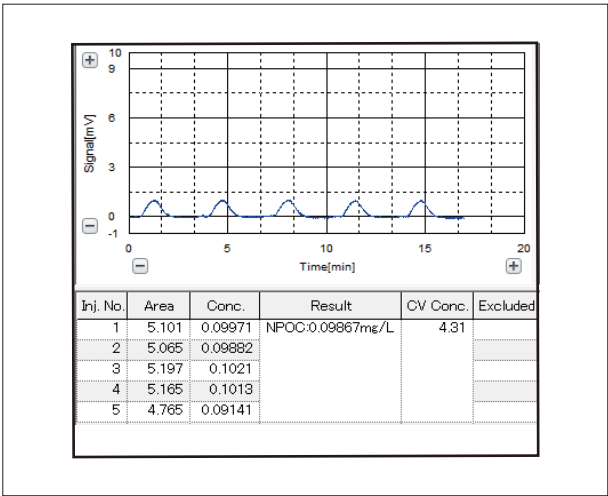


Fig. 2 Measurement Data for TOC Below 0.1 mg/L

<Measurement Conditions>

Analyzer	:Shimadzu TOC-L _{CPH} Total Organic Carbon Analyzer
Catalyst	:High-sensitivity catalyst
Injection volume	:500 μ L
Measurement item	:TOC (= NPOC: TOC by acidification sparging)
Calibration curve	:5-point calibration curve generated using TOC 0 – 0.1 – 0.5 – 1.0 – 2.0 mgC/L potassium hydrogen phthalate aqueous solution

Table 3 Measurement Data for TOC Below 0.1 mg/L

Sample Name	TOC Value (mgC/L)	Coefficient of Variation CV (%)
Potassium hydrogen phthalate	0.0987	4.31 %

Related Products

Some products may be updated to newer models.



> TOC-L Series
Total Organic Carbon Analyzer

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