



Standard Operating Procedure

Title: System Suitability Procedure for the TOC Analyzers

SOP Number: 22920

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1.0 Purpose

The objective of this system suitability procedure is to demonstrate that the Total Organic Carbon Analyzers are capable of determining low-level carbon in water as defined in USP Method <643> Total Organic Carbon. This is done daily before any samples are analyzed.

2.0 Scope

This procedure applies to the Total Organic Carbon Analyzers that have been calibrated and blanked for low level TOC analysis. The procedure is designed specifically to match the protocol in the USP Method <643> TOC. However, the same logic of analyzing a standard solution and subtracting its reagent water contribution to determine the net response can also be applied to any standard solution in any range or mode to verify the performance of the analyzer at this range

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and mode. Therefore, this part of the procedure can be used in lieu of the Calibration and Verification Procedure (**SOP 22921 - Calibration for the TOC Analyzer**) to verify calibration performance.

3.0 Authority and Responsibility

- 3.1 The Manager, Process Analytics\Quality Control (PA\QC) has the authority to define this procedure.
- 3.2 PA/QC is responsible for training laboratory personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).
- 3.3 PA/QC personnel are responsible for the performance of this procedure.
- 3.4 PA/QC is responsible for reviewing the data and documentation of the results of this procedure.
- 3.5 BQA is responsible for quality oversight of this procedure.

4.0 Materials, Reagents and Equipment

4.1 Reagent Water (W)

The reagent water used must be of the highest quality deionized, distilled, or reverse osmosis water available, containing no more than 0.1 ppmC for low-level analysis.

4.2 Sucrose (S) $C_{12}H_{22}O_{11}$

- 4.2.1 Grade: USP Reference Standard <11> or equivalent
- 4.2.2 Preparation: **SOP 22919 - Standard Preparation for the TOC Analyzer**
- 4.2.3 Concentration 0.5 mg/L C

4.3 1,4-Benzoquinone (SS) $C_6H_4O_2$

- 4.3.1 Grade: USP Reference Standard <11> or equivalent
- 4.3.2 Preparation: **SOP 22919 - Standard Preparation for the TOC Analyzer**
- 4.3.3 Concentration 0.5 mg/L C

4.4 Equipment

- 4.4.1 Phoenix 8000 TOC Analyzer (MEF# 82010)
- 4.4.2 Shimadzu TOC Analyzer (MEF# 85140)

5.0 Procedure

- 5.1 Verify that the TOC Analyzer is turned on and ready to operate by performing the daily maintenance checks, per **SOP 22922 - Preventive Maintenance for the TOC Analyzer**.
- 5.2 For the Phoenix 8000 unit, perform an automatic cleaning of the TOC analyzer's tubing, valves, and glassware by analyzing three sets of replicates, selecting "5" as the number of replicates and blank the Phoenix 8000 TOC Analyzer in TC Blank Range 2, per **SOP 22917 - Operation of the Phoenix 8000 TOC Analyzer**. For sample type choose Blank and confirm 5 as the number of repeats.
- 5.3 Prepare reagent water, standard solution (S), and the system suitability solution (SS) per **SOP 22919 - Standard Preparation for TOC Analysis**.

- 5.4 Calibrate/Ensure calibration of the TOC Analyzers in the TOC mode, per **SOP 22921 - Calibration of the TOC Analyzers**.
- 5.5 Analyze all three of these solutions for TOC content just as you would an unknown sample. Refer to **SOP 22917 - Operation of the Phoenix 8000 TOC Analyzer** or **SOP 22963 - Operation of the Shimadzu TOC Analyzer**.
 - 5.5.1 Analyze reagent water (W).
 - 5.5.2 Analyze system suitability solution (SS).
 - 5.5.3 Analyze standard solution (S).

NOTE: Rinse TOC tube with a standard solution before filling it with the solution.

6.0 Calculations and Terminologies

6.1 Terminologies

6.1.1 Reagent water control raw data, r_w

NOTE: If this value is negative number, record the value as 0 on Form 22920-01 for r_w .

NOTE: To calibrate the Phoenix 8000 successfully, refer to **SOP 22921 - Calibration of the TOC Analyzers**.

6.1.1.1 Standard solution raw data, r_s

6.1.1.2 System suitability solution raw data, r_{ss}

6.1.1.3 Actual Sucrose Concentration, C_s

6.1.1.4 Actual 1,4 Benzoquinone Concentration, C_b

6.2 Corrected Standard Solution Response or Limit Response, R_1

6.2.1 Calculate the analyzer's response from the standard solution after the reagent water control has been subtracted. This is also known as the limit response for purposes of the USP Method <643> Total Organic Carbon. This calculation can also be used in lieu of the Calibration Verification Procedure, per **SOP 22921 - Calibration of the TOC Analyzers** to verify calibration performance.

$$6.2.2 \quad R_1 = (r_s - r_w)/C_s$$

6.3 Corrected System Suitability Solution Response, R_2

6.3.1 Calculate the analyzer's response from the system suitability solution after the reagent water control has been subtracted.

$$6.3.2 \quad R_2 = (r_{ss} - r_w)/C_b$$

6.4 Response Efficiency for the System Suitability Solution, E

6.4.1 Calculate the percent recovery or efficiency (E) of the suitability solution compared to the standard solution.

$$6.4.2 \quad E = 100 (R_2 / R_1)$$

6.5 The Total Organic Carbon Analyzer is suitable for TOC analysis per USP Method <643> TOC, if the response efficiency, E , is not less than 85% not more than 115%.

- 6.6 If this range is not met the system is not suitable for use. Check calculations, and/or repeat the procedure, using new aliquot standards.

7.0 Documentation

- 7.1 Record all calculations, results of analyses and decisions on Form 22920-01.

8.0 Definitions

- 8.1 TOC – Total Organic Carbon.
8.2 TOC Analyzer – Total Organic Carbon Analyzer

9.0 References and Related Documents

- 9.1 **BDP SOP 22917** *Operation of the Phoenix 8000 TOC Analyzer*
9.2 **BDP SOP 22919** *Standard Preparation for TOC Analysis*
9.3 **BDP SOP 22921** *Calibration for the TOC Analyzers*
9.4 **BDP SOP 22922** *Preventive Maintenance for the TOC Analyzer*
9.5 **BDP SOP 22963** *Operation of Shimadzu TOC Analyzer*
9.6 Phoenix 8000 User Manual, Part Number 14-7045-074
9.7 USP Method <643>, Total Organic Carbon

10.0 Attachments

- 10.1 **Attachment 1** Form 22920-01, System Suitability for the TOC Analyzer

Attachment 1**Form 22920-01, System Suitability for the TOC Analyzer**

FNLCR, BDP
Form No.: 22920-01
SOP No.: 22920
Revision 05: APR 14 2016

System Suitability for the TOC Analyzer

MEF# of TOC instrument _____

C_s = Actual Sucrose Concentration in ppm C _____

r_s = 0.5 ppm C Sucrose Raw TOC Data _____

r_w = Reagent Water Blank Raw TOC Data _____

C_b = Actual 1,4 Benzoquinone Concentration in ppm C _____

r_{ss} = 0.5 ppm C 1,4 Benzoquinone Raw TOC Data _____

Corrected Standard Solution Response or Limit Response, R_1

$R_1 = (r_s - r_w) / C_s$ _____

Corrected System Suitability Solution Response, R_2

$R_2 = (r_{ss} - r_w) / C_b$ _____

Response Efficiency for the System Suitability Solution, E

$E = 100 * (R_2 / R_1)$ _____

Specification: E : 85% - 115%

☐ Pass ☐ Fail (If this range is not met the system is not suitable for use. Check calculations, and/or repeat the procedure, using new aliquot standards.)

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____