SOP Title: System Suitability Procedure for the Shimadzu TOC Analyzer
SOP Number: 22920
Revision: 07

TABLE OF CONTENTS

1. 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. 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 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. RESPONSIBILITIES

3.1 Manager / Process Analytics\Quality Control (PA/QC)

- Defines procedure.

3.2 PA/QC personnel

- Trains laboratory personnel

- Performs procedure
- Reviews data

3.3 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight

4. DEFINITIONS

- **TOC** – Total Organic Carbon.
- **TOC Analyzer –** Total Organic Carbon Analyzer

5. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
N/A	Reagent Water (W) - The reagent water or lab 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.	☒ YES ☐ NO
30005	1,4-Benzoquinone (SS) C6H4O2 Concentration 0.5 mg/L C, USP Reference Standard <11> or equivalent	☒ YES ☐ NO
30430	Sucrose (S) C12H22O11 Concentration 0.5 mg/L C, USP Reference Standard <11> or equivalent	☒ YES ☐ NO

6. EQUIPMENT

- Shimadzu TOC Analyzer (MEF #85140 and MEF #86600)

7. PROCEDURE

7.1 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**.

7.2 Prepare two reagent water or lab water samples, standard solution (S), and the system suitability solution (SS) per **SOP 22919 Standard Preparation for TOC Analysis**.

7.3 Calibrate/Ensure calibration of the TOC Analyzers in the TOC mode, per **SOP 22921 Calibration of the TOC Analyzers**.

7.4 Analyze all three of these solutions for TOC content just as you would an unknown sample. Refer to **SOP 22963 Operation of the Shimadzu TOC Analyzer**.

7.4.1 Analyze reagent water (W).

7.4.2 Analyze system suitability solution (SS).

7.4.3 Analyze standard solution (S).

8. CALCULATIONS AND TERMINOLOGIES

8.1 Terminologies

8.1.1 Reagent water control raw data, r_w

NOTE: Refer to the second reagent water measurement and if negative, record the value as 0 on Form 22920-01 for r_w.

8.1.1.1 Standard solution raw data, r_s

8.1.1.2 System suitability solution raw data, r_{ss}

8.1.1.3 Actual Sucrose Concentration, C_s

8.1.1.4 Actual 1,4 Benzoquinone Concentration, C_b

8.2 Corrected Standard Solution Response or Limit Response, $\mathbf{R_1}$

8.2.1 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.

8.2.2 $R_1 = (r_s - r_w)/C_s$

8.3 Corrected System Suitability Solution Response, $\mathbf{R_2}$

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

8.3.2 $R_2 = (r_{ss} - r_w)/C_b$

8.4 Response Efficiency for the System Suitability Solution, **E**

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

8.4.2 $E = 100 (R_2 / R_1)$

8.5 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%.

8.6 If this range is not met the system is not suitable for use. Check calculations, repour standards and reagent water

9. DOCUMENTATION AND RECORDS

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

10. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22919	Standard Preparation for TOC Analysis
22920-01	System Suitability for the Phoenix 8000 TOC Analyzer
22921	Calibration for the TOC Analyzers
22922	Preventive Maintenance for the TOC Analyzer
22963	Operation of Shimadzu TOC Analyzer
N/A	USP Method <643>, Total Organic Carbon