



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Preventative Maintenance for the TOC Analyzers

SOP Number: 22922

Revision: 06

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1. PURPOSE

The objective of this preventative maintenance procedure is to provide guidelines for optimal, long-term performance of the Shimadzu Total Organic Carbon Analyzer. This includes procedures for daily, weekly, and monthly maintenance and cleaning items. Also, all parts with relatively short operational lives are listed and their frequency of replacement is defined.

2. SCOPE

This procedure applies to the entire Shimadzu Operating System, including all reagents and chemicals used during the analysis, and all components in product contact that are used by the Process Analytics/Quality Control (PA/QC) Laboratory.

3. RESPONSIBILITIES

3.1 Director / PA/QC

- Defines procedure
- Performs ABC
- Records XXX

3.2 PA/QC Personnel

- Trains laboratory personnel
- Performs procedure

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4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
30134	Sodium Persulfate $\text{Na}_2 \text{S}_2\text{O}_8$ Grade: ACS Reagent Grade $\geq 95\%$ Use: 10% in reagent	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
30536	Phosphoric Acid H_3PO_4 Grade: ACS Reagent Grade $\geq 85\%$ Use: 5% (by weight) in persulfate reagent and 21% (by weight) in acid reagent	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
N/A	Reagent Water - The reagent water used must be of the highest quality deionized, distilled, or reverse osmosis water available that contains the least amount of carbon in the water. At a minimum, the water must meet the USP <643> specification of ≤ 0.1 ppmC. It is recommended Type 1 water or equivalent be used to obtain this quality of water.	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO

5. PROCEDURE

5.1 Daily Preventative Maintenance (Prior to Operation of the TOC Analyzer)

5.1.1 Replace the reagent water supply with fresh reagent water. See **SOP 22918 - Glassware Cleaning for Trace TOC Analysis**, for the definition of reagent water quality.

5.1.2 Check the persulfate reagent supply for ample volume for the day's analysis. A minimum of 150 mL is required for 70 samples.

5.1.3 Check the acid reagent supply for ample volume for the day's analysis. A minimum of 150 mL is required for 70 samples.

5.1.4 Verify that the gas/liquid separator water level is filled to the waste outlet.

While in Ready Mode, verify that the gas in the internal tube of the gas/liquid separator does not escape into the outer tube water.

Visually inspect the chlorine scrubber for signs of moisture or discoloration. If inspection were to fail, replace the chlorine scrubber. (See the **Shimadzu User Manual**).

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5.2 Weekly Preventative Maintenance

5.2.1 Perform all daily preventive maintenance items listed above in Section 5.1.

5.2.2 Replace the persulfate reagent supply with a freshly made solution, per SOP 22919 – Solutions and Standard Preparation for TOC Analyzer. Make the reagent at least one day in advance of use.

5.2.3 Rinse the UV reactor, IC sparger, and gas-liquid separator with reagent H₂O.

5.3 Monthly Preventative Maintenance

5.3.1 Perform all daily and weekly preventive maintenance items listed above in Sections 5.1 and 5.2.

5.3.2 Replace the acid reagent supply with a freshly made solution if needed (if low or expired), per SOP 22919 – Solutions and Standard Preparation for TOC Analyzer.

5.3.3 Inspect the permeation tube for damage such as a twisted inner tube, discoloration, obvious restriction(s) in flow, and/or excessive water accumulation.

5.4 Procedures to Minimize Contamination and High Blanks

5.4.1 Rinse the reservoirs with reagent water before filling them up.

5.4.2 Rinse the reagent tubes with water before putting them back in the reagent bottle.

5.4.3 Soak the reagent bottles in a dilute nitric acid solution overnight once every two months if needed for cleaning of glassware.

6. DOCUMENTATION AND RECORDS

Record maintenance performed on the in the corresponding TOC instrument logbook.



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7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22918	Glassware Cleaning for Trace TOC Analysis
22919	Solutions and Standard Preparation for TOC Analyzer
22963	Operation of Shimadzu TOC Analyzer
	Shimadzu User Manual