Standard Operating Procedure

Biopharmaceutical Development Program

Title: Preventative Maintenance for the	ne TOC Analyzers
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1.0 Purpose

The objective of this preventative maintenance procedure is to provide guidelines for optimal, long-term performance of the Phoenix 8000 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.

2.0 Scope

This procedure applies to the entire Phoenix 8000 Operating System, including the STS 8000 Autosampler, 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.

3.0 Authority and Responsibility

- 3.1 The Director, Process Analytics/Quality Control 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 (BOA).
- 3.3 PA/QC personnel are responsible for the performance of this procedure.

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4.0 Materials and Reagents

- 4.1 Sodium Persulfate Na₂ S₂O₈
 - 4.1.1 Grade: ACS Reagent Grade ≥95%
 - 4.1.2 Use: 10% in reagent
 - 4.1.3 Part Number: 30134
- 4.2 Phosphoric Acid H₃PO₄
 - 4.2.1 Grade: ACS Reagent Grade ≥85%
 - 4.2.2 Use: 5% (by weight) in persulfate reagent and 21% (by weight) in acid reagent
 - 4.2.3 Part Number: 30536
- 4.3 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.

5.0 Procedure

- 5.1 Daily Preventative Maintenance
 - 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 carrier gas supply contains \geq 500 psi in the tank, if using a tank. Replace the tank if it drops below this pressure.
 - 5.1.5 Verify that the gas flow rate is 200 cc/minutes ± 10%. If the flow rate exceeds these specifications, manually dial the flow rate using the regulator found on the gas tank.
 - 5.1.6 Verify that the NDIR detector baseline is less than 50 milli-volts for the Phoenix 8000 analyzer.
 - 5.1.7 Verify that the gas/liquid separator water level is filled to the waste outlet.
 - 5.1.7.1 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.
 - 5.1.8 Empty the mist trap on the Phoenix 8000 analyzer.
 - 5.1.9 Visually inspect the chlorine scrubber for signs of moisture or discoloration. If inspection were to fail, replace the chlorine scrubber. (See the *Phoenix 8000 User Manual or Shimadzu User Manual*).
 - 5.1.10 Verify that the 8-port valve thumbscrews are hand tightened on the Phoenix 8000 analyzer.

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- 5.1.11 Perform an automatic cleaning on the Phoenix 8000 analyzer of the analyzer's tubing, valves, and glassware by analyzing 3 sets of the cleaning procedure method, each consisting of 5 replicates per *SOP* 22917 *Operation of the Phoenix 8000 TOC Analyzer*.
- 5.2 Weekly Preventative Maintenance
 - 5.2.1 Perform all daily preventive maintenance items listed above in 5.1.
 - 5.2.2 Replace the persulfate reagent supply with a freshly-made solution. Make the reagent at least one day in advance of use.
 - 5.2.2.1 Weigh 25 g of sodium persulfate and put it in the bottle labeled sodium persulfate.
 - 5.2.2.2 Add 9 mL of phosphoric acid and add it to the persulfate.
 - 5.2.2.3 Add 213 mL of reagent water and cap and mix thoroughly.
 - 5.2.2.4 Sonicate for 10 minutes.
 - 5.2.2.5 Record preparation in the reagent logbook, Form 22702-01.
 - 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.
 - 5.3.2.1 Measure 74 mL of phosphoric acid.
 - 5.3.2.2 Add 376 mL of reagent water and mix.
 - 5.3.2.3 Record preparation in the reagent logbook, Form 22702-01.
 - 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.
 - **NOTE:** If high background or blank, >100,000, are observed on Phoenix 8000 analyzer, clean the system. This involves cleaning of the IC chamber, UV reactor, gas-liquid separator, changing reagent water, etc.

6.0 Documentation

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

7.0 References and Related Documents

- 7.1 SOP 22917 Operation of the Phoenix 8000 TOC Analyzer
- 7.2 **SOP 22918** *Glassware Cleaning for Trace TOC Analysis*

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7.3 Phoenix 8000 User Manual.

7.4 Shimadzu User Manual.

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