Biopharmaceutical Development Program

Standard Operating Procedure

Title: Glassware Cleaning for Trace TOC Analysis

SOP Number: 22918 **Revision Number: 02**

Supersedes: Revision 01 **Effective Date: APR 5 2011**

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

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1.0 Purpose

The objective of the Glassware Cleaning Procedure is to minimize carbon contamination on glassware and closures used to collect, transfer, or store reagents and standards for trace TOC determination. This procedure uses a dilute nitric acid soaking to clean the containers.

2.0 Scope

This procedure applies to glassware, containers and closures that come in contact with standards, or reagents used during Total Organic Carbon analyses only. This includes reagent and calibration standard solution bottles, volumetric glassware used to make standards and all closures for these containers.

3.0 Authority and Responsibility

3.1 The Director, Process Analytics (PA) has the authority to define this procedure.

3.2 PA personnel are responsible for implementation and performing this procedure. This includes training of personnel in performing this testing.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

3.3 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this operation.

4.0 Materials and Reagents

4.1 Reagent Water

RODI water shall be used in the preparation of the nitric acid solution, but reagent water shall be used in all final rinse of glassware being cleaned.

Note: If using packaged sterile WFI, ensure that a Certificate of Analysis is provided and is kept on record in the appropriate files.

4.2 Nitric Acid (BDP PN 30601), HNO_3

4.2.1	Grade	ACS Reagent Grade
4.2.2	Stock Concentration	70%
4.2.3	Working Concentration	0.5%

4.3 TOC Sampling Containers (BDP PN 20442)

5.0 Procedure

5.1 For new use of dedicated equipment only, wash all glassware, containers, and closures with hot tap water and Contrex (BDP PN 30783).

Note: For glassware that has been previously used for TOC analysis (excluding sample vials), proceed to paragraph 5.3.

5.2 Rinse profusely (5 times) with RODI water.

5.3 Soak all glassware, containers, and closures in dilute (0.5%) nitric acid solution for a minimum of 8 hours or overnight. Glassware maybe stored in this solution until ready for use.

5.3.1 Dilute 1 part Nitric Acid 70% to 139 parts Reagent water. Example: add 1mL of Nitric acid to 139 mL of reagent water.

5.3.2 Fill the glassware and containers completely with the dilute acid to soak.

5.3.3 Place the closures and septa on their respective glassware/containers and leave to soak in this state for required time.

5.4 Rinse profusely (4 times) with RODI water and final rinse with reagent water for a minimum of 5 rinses.

5.5 Once the glassware is clean store it in a clean dry area that is labeled “Cleaned glassware for TOC analysis only.” Be sure that glassware is covered to help ensure that the glassware stays clean.

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6.0 Definitions

6.1 **Reagent Water –** 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. See **SOP 22917, *Operation of the Phoenix 8000 TOC Analyzer***, for a list of sources that provide water of this quality.

7.0 References and Related Documents

7.1 **SOP 22917** *Operation of the Phoenix 8000 TOC Analyzer*

7.2 *Phoenix 8000 User Manual*, Part Number 14-7045-074

7.3 USP Method <643>, Total Organic Carbon

7.4 USP Method <1051>, Cleaning Glass Apparatus

7.5 ASTM D1193, Standard Specification for Reagent Water

7.6 Eagle Pitcher Industries, Miami, OK, 800-331-7425

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