

SOP Title: **Glassware Cleaning for Trace TOC Analysis**

SOP Number: **22918**

Revision: **03**

TABLE OF CONTENTS

1.	PURPOSE	1
2.	SCOPE	1
3.	RESPONSIBILITIES	1
4.	DEFINITIONS	2
5.	MATERIALS AND REAGENTS	2
6.	PROCEDURE	2
7.	REFERENCES AND RELATED DOCUMENTS.....	3

1. **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. **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. **RESPONSIBILITIES**

3.1 Director / Process Analytics (PA)

- Defines this procedure.

3.2 Personnel / PA

- Performs this procedure.
- Trains personnel.

3.3 Quality Assurance (QA)

- Provides quality oversight.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Glassware Cleaning for Trace TOC Analysis

SOP Number: 22918

Revision: 03

4. DEFINITIONS

- 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, it should contain no more than 0.1 ppmC for low level analysis.

5. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
30601	Nitric Acid, (HNO ₃): ACS Reagent Grade (70%)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
20442	TOC Sampling Containers	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
30783	Contrex	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

6. PROCEDURE

6.1 For new use of dedicated equipment only, wash all glassware, containers, and closures with hot tap water and Contrex.

NOTE: For glassware that has been previously used for TOC analysis (excluding sample vials), proceed to 6.3.

6.2 Rinse (5 times) with Reagent water.

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

6.3.1 Dilute 1-part Nitric Acid 70% to 139 parts Reagent water.

Example: add 1mL of Nitric acid to 139 mL of Reagent water.

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

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

6.4 Rinse 5 times with reagent water.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Glassware Cleaning for Trace TOC Analysis

SOP Number: 22918

Revision: 03

- 6.5 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.

7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22963	Operation of the Shimadzu TOC Analyzer
USP Method <643>	Total Organic Carbon
USP Method <1051>	Cleaning Glass Apparatus
ASTM D1193	Standard Specification for Reagent Water