

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE		
Department: Quality Control SOP No.:		
Title: Operation, Cleaning and Calibration of TOC (Off-line)	Effective Date:	
Supersedes: Nil	Review Date:	
Issue Date: Page No.:		

1.0 OBJECTIVE:

To lay down procedure for operation, cleaning and calibration of TOC (Off line).

2.0 SCOPE:

This SOP is applicable for operation of Total Organic carbon Analyser, Pharma TOC From Analytik Jena, Germany to Instrument lab Quality Control.

- 3.0 RESPONSIBILITY Execution- Executive QC Checking -Assistant Manager QC
- **4.0 ACCOUNTABILITY** Manager Quality Control
- **5.0 PROCEDURE:**
- 5.1 Switch "ON" the instrument (Pharma TOC). Wait for 5 V, 24 V & Lockin LED to glow.
- 5.2 Wait for one hour warm up period.
- 5.3 Switch "**ON**" the computer, monitor & printer
- 5.4 Double click on Multiwin icon, log on by giving the password.
- 5.5 During the warm up period the systems will be stabilized for Temp, Flow & NDIR values.
- 5.6 Observe these values by Systems State window.
- 5.7 After you get NDIR: OK

Flow: O K.

- 5.8 Now the system is ready for analysis. But still start the real analysis after one hour.
- 5.1.1 SAMPLE ANALYSIS (Method Creation): -
- 5.1.1.1 Click on the Method Select New Give File Name Select the method of analysis (NPOC)
 Select REPLECATES Min 4 Max 5 Click on Standard Deviation 0.015 select Rinse Cycle 3 1 1 1 1.
- 5.1.1.2 Click on Process Parameter Sample volume 2000 Rinse Volume 2000 Purge time 1-10 sec Purge time 2-10 sec –Flow 90 –Max integration time 240 sec Start -0.12 Base line approximation 1-0.20 Base line approximation 2-0.20 Block 10.
- 5.1.1.3 Save the method & follow the instruction of software.
 i.e Adopt calibration data of current method. In this case if want to take the data of previous method, then click on Yes otherwise Click on NO.
- 5.1.1.4 Adopt newly created method as current method. Click on YES.



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5.2 CALLIBRATION PROCEDURE:

Frequency: Once in 3 months

5.2.1 Single Point Calibration By 500 ppb Sucrose:-

- 5.2.1.1 Use blank water below 100 ppb.Prepare the 500 ppb sucrose solution as per USP (Preparation of 500 ppb sucrose solution: take 23.8 mg sucrose in 100 ml water →1 ml→200ml with water i.e. 1.19 ppm sucrose ≈ 500ppb Carbon in sucrose)
- 5.2.1.2 Click on Calibration Select the Method for the calibration
- 5.2.1.3 In Calibartion window select Calibration with Constant Volume No of Samples -1 Analytical Parameter -NPOC Constant Sample Volume 2000 micro liter Preparation Blank Measure feed the concentration in NPOC table 0.500 mg/l Click on Measurement & follow the software instruction.
- 5.2.1.4 At the end of calibration Click on LINK WITH THE METHOD Accept Values.
- 5.2.1.5 Now the calibration values are included in the method.

5.2.2 System Suitability Measurement: -

- 5.2.2.1 Use blank water below 100 ppb. Prepare the 500 ppb sucrose & P -benzoquinone solution as per USP.
 (Preparation of 500 ppb Para benzoquinone solution: take 15 mg Para benzoquinone in 100 ml water →1 ml→200ml with water i.e. 0.75 ppm Para benzoquinone ≈ 500ppb Carbon in Para benzoquinone)
- 5.2.2.2 Use the same water to prepare 500 ppb sucrose & P benzoquinone.
- 5.2.2.3 Click on SST Click on F2-Follow the software instructions –At the end of SST you will get the SST report Print .
- 5.2.2.4 In the same report double click on H20, sucrose, P- benzoquinone to get the analysis reports print all the reports.
- 5.2.2.5 Result: If the SST results are in between 0.85 To 1.15, then go for sample measurement.

5.2.3 SAMPLE ANALYSIS:

- 5.2.3.1 Load the calibrated method Click on Start Measurement Give the sample ID- Press F2 to start analysis.
- 5.2.3.2 At the end of analysis take the printout.



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5.3 CLEANING PROCEDURE:

Frequency: Daily

- 5.3.1 Switch 'OFF' the instrument.
- 5.3.2 Switch 'OFF' the mains.
- 5.3.3 Clean the outer surface of the instrument with a clean and dry cotton cloth.
- 5.3.4 Rinse twice the purging needle as well as sample needle after analysis with Milli Q water after completion of analysis.
- 5.3.5 Record the details of cleaning in the instrument log card.

6.0 SAFETY & PRECAUTIONS:

- 6.1 Use only 4.5 & above grade oxygen. It should be 99.995 % pure & CO2 content should be nil in this oxygen.
- 6.2 Check & ensure that the Oxygen cylinder is opened & the out put pressure is set to 4 bar.
- Also check the pressure on the Oxygen Purification system, it should be set to 4 bar (out put which is going to instrument)
- 6.4 All the glassware should be properly cleaned to avoid the water contamination. (Glassware cleaning as per USP)
- 6.5 Incase of NPOC method fill the Phosphoric Acid bottle with pure water.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date

8.0 DISTRIBUTION:

Сору	Issuance Record			Withdrawal Record		Destruction Record		
No.	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	Ву	Sign/ Date	Ву	Sign/ Date



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9.0 **REFERENCES**:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

QC : Quality Control

TOC : Total Organic Carbon

TC : Total Carbon

NPOC: Non Purge able Organic Carbon

USP : United State Pharmacopeias

SST : System Suitability

NDIR : Non Dispersible Infra Red

Annexures : Not Applicable