



PHARMA DEVILS

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 Calibration 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 H2O, 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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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