USER REQUIREMENT SPECIFICATION (URS) FOR ONLINE TOTAL ORGANIC CARBON (TOC) ANALYZER

Department :

URS no.

Supersede :

USER REQUIREMENT SPECIFICATION

Name of Item: Online Total Organic Carbon Analyzer	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 9

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Issued to mfg / supplier by purchase department _____

USER REQUIREMENT SPECIFICATION

Name of Item: Online Total Organic Carbon Analyzer	**Protocol No.:**.....
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1. Approval:

ACTIVITY DETAIL	NAME OF PERSON	DESIGNATION	SIGNATURE	DATE
Prepared By				
Reviewed By				
Approved By				

2. Change History:

REVISION NUMBER	REVISION DETAILS	DATE OF REVISION

3. Purpose:

The purpose of the user requirement for Online Total Organic Carbon (TOC) Analyzer is:
To define the instruction for selection of Online Total Organic Carbon (TOC) Analyzer for intended use
To provide a specification to the vendors for their submission of quotation.
To ease the selection process of vendors

4. Scope:

4.1 This document is applicable for Online Total Organic Carbon (TOC) Analyzer intended to use at manufacturing plant at Nalagarh.

4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

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5. Specifications:

5.1 Description of equipment / system:

The Online Total Organic Carbon (TOC) Analyzer shall have following components.

- Pressure control valve
- conductivity sensor
- UV oxidation
- flow meter
- flow control valve
- Resistivity sensor
- flow orifice
- analog output terminal

The detail description of the components is as follows;

5.1.1 Gas flow rate controller:

- Must have excellent temperature control and fast cool down time for maximum productivity.
- Must be software controlled.
- Must be capable for analyzing the samples in the range 30 °C to 400 °C.
- Oven temperature must be programmable.
- Headspace Auto sampler
- It shall have built in syringe auto sampler for maximum sample capabilities.
- All control parameters shall be controlled through software.
- Sample vial must return to same position after the analysis is over.

- It shall have minimum 10 or more vial overlapping thermo stated facility to reduce the analysis time.
- Built-in leak test facility should be available.
- It shall have built-in analyte trapping capability to maximize the extraction and transfer of headspace of vapor into the Online Total Organic Carbon (TOC) Analyzer column for enhanced sensitivity
- It should have built in method storage facility.

5.1.2 TC injection port

- Injector must have provision for attaching packed and capillary column.
- There should be no trapping of nonvolatile residues.
- Required temperature range: 50 to 450°C.
- Split/Split less capillary injector shall have facility for programming and shall have pneumatic controls.
- Split ratio must be easily adjustable in split/Split less capillary injector.
- It should have a facility to prevent contamination of split valve and lab air.

5.1.3 IC reaction vessel method storage facility

- Gas chromatograph shall be provided with Flame Ionization Detector (FID) and Thermal Ionization Detector (TCD) for analysis of nitrogen and Carbon Dioxide gas.
- Detector control parameters shall be pneumatically controlled.
- FID shall have auto ignition facility and in case of Flame out it must give warning and hydrogen and airflow shall be pneumatically controlled.
- TCD shall be compatible with capillary column.
- TCD should give constant current and reference gas shall be pneumatically controlled.
- FID range: 80°C to 450°C
- TCD range:100° to 450°C

5.1.4 Dehumidifier/gas pretreatment unit

- Should have complete control of Online Total Organic Carbon (TOC) Analyzer.
- Software should have streamlined series of operations like acquiring, processing, reporting, reviewing and approving data.
- It should be able to control simultaneous operations of all channels.
- Calibration curves with multi-standards can be plotted and viewed.

- Data integrity should be maintained.

5.1.5 TC furnace

- Gas Purification system shall be provided with (but not limited to) molecular Sieve, Silica Gel, Activated Charcoal, Pressure Regulator, and filter gel for all gases, De-oxy trap in case of carrier line with suitable housing.
- Regulators – Double Stage Pressure Regulator with Metal Diaphragm
- IC reagent
- TC combustion tube
- Non-dispersive infrared detector
- Data processor

5.2 Identification number and location:

Equipment Name	**Identification Number**	**Location**
Online Total Organic Carbon (TOC) Analyzer		Instrument room

5.3 Intended use:

Operation of equipment depends upon the production output; the equipment should be designed to work continuously for 3 shifts per day.

5.4 Intended type of material to be handled:

The equipment is intended for carrying out water for injection, purified water and Highly Purified water at plant.

- Solid & Liquid pharmaceutical raw materials
- Ophthalmic dosage forms
- Liquid injectable
- Nitrogen and Carbon Dioxide gas

5.5 Construction:

Not Applicable

5.6 Capacity:

The Online Total Organic Carbon (TOC) Analyzer must be capable for routine laboratory analyses as well as those involved in research and development.

5.7 Electrical construction:

Control panel includes all control equipment and switch cabinet will contain all high voltage equipment, the cabinet will provide the sterilizer with either 440 VAC, 50 Hz, 3Phase.
Cabinet enclosure- Protection category will be IP/54, IP/55.

5.8 Control parameters:

Pressure control valve, conductivity sensor, UV oxidation, flow meter, flow control valve, Resistivity sensor, flow orifice and analog output terminal.

5.9 Acceptable tolerance for control parameters:

Parameter	Criteria
Mode	Online
Alarms	With high/low set point
Port	Two isolated 4-20mA port
TOC Range	0.1-1000 ppb
TOC Resolution	0.01 ppb
TOC Accuracy/repeatability	0.1± 0.05
Conductivity-Range	0.055-20µs
Conductivity-Resolution	Resistivity-0.01mOhm
Sample temp. Range	5-90 deg. C
System Suitability Kit	Provided
Calibration Kit	Resistor set for PCB calibration
Alarms displayed	UV lamp replacement Alarm

5.10 Type of control System:

The equipment must have a limit of detection specified by the manufacture of 0.05 mg. or less of carbon per liter.
System suitability: The response efficiency is not less than 85% and not more than 115% of the theoretical response.

It should have Programmable Pneumatic control system.
Software for complete control on Online Total Organic Carbon (TOC) Analyzer.

5.11 Feasible parameters to be set:

Not Applicable

5.12 Parameters to be indicated by control systems:

Continuously displays TOC value in ppb, Resistivity/conductivity, temperature, Current operating mode, and location of the active sensor, analysis details during its run.

5.13 Available utilities:

1) 230 VAC for the meter
2) Instrument air for the actuated valve
3) A small tapping will be required on the return UPW/WFI line.
4) All other sensors will require suitable Tees/Triclover connections.
5) Utilities required for electric connection can be provided.
6) Solvents can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

1. Equipment must be complaint with internationally valid EN standards and the Pharmaceutical ICH guidelines Q1A and Q1B.
2. Software must be complying with 21 CFR part 11 regulation of USFDA.
3. Software employed for having a control on Online Total Organic Carbon (TOC) Analyzer.

5.16 Delivery Address:

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6 Safety:

Electric connection must be connecting with UPS system.
Proper equipment earthing shall be provided.

7 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

- Consumable wear parts
- Parts that are easily broken
- Parts that can wear out, and are long lead time availability.
- Electronic components those are not readily available from a local source to the user.
- The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.2 Support:

- Start-up Support

  Start-up support shall consist of full time assistance on the User's site for installation, start-up and commissioning.

- Training

  User training shall consist of equipment training by a qualified trainer.

  Certificates of training shall be provided for each person completing the training program.

- Post Start-up Support

  Post start-up support shall consist of User site visits for a period of 1 year after the completion of commissioning activities as and when required.

- Technical Support

  Technical support shall be available via telephone for a period of 5 years following the completion of commissioning.

8 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Design specification	Paper
4.	Qualification documents	Paper
5.	Spare parts list	Paper

9 References:

Control components shall be identified with a tag number consistent with the documentation.