USER REQUIREMENT SPECIFICATION FOR TOTAL ORGANIC CARBON ANALYZER

LOCATION	**QUALITY CONTROL**
SUPERSEDES	**NIL**

PHARMA DEVILS

USER REQUIREMENT SPECIFICATION FOR TOTAL ORGANIC CARBON ANALYZER

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1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (USER DEPARTMENT)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE :

- This URS has been initiated and pertains to procurement of **Total organic carbon analyzer** for **Quality Control.**
- The User Requirements Specification (URS) is provided to aid the user through the critical aspects of Fabrication, Facility for Installation of Required Instruments, Cleaning / Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional total organic carbon analyzer that meets the user's needs in the most cost-effective method possible.
- The URS is then provided to Vendor to submit a Price Quote for procurement of total **organic carbon analyzer.**
- The URS shall help Vendor in understanding the end user requirement in details. This document shall help vendor for developing the Design Specification, will become a Contractual Agreement between Vendor and Customer.
- This URS Shall be recognized as an integral part of the procurement agreement with the vendor. The vendor will abide by the information and conditions set forth by this document as well as the Standard Purchase Terms and Conditions of the Customer.

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of **Total Organic Carbon Analyzer** for **Quality control** of Customer.
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Laboratory Practices (cGLP) and Safety.

4.0 RESPONSIBILITY:

The Team, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation and Approval of User Requirement Specification. • Co-ordination with User Department to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS.
User Department	• Review of User Requirement Specification for compliance with the Product Requirement.

5.0 GMP/REGULATORY REQUIREMENTS :

- The Purpose of procuring **Total Organic Carbon Analyzer** is to provide analytical instrument for evaluating the total organic carbon content in various types of solvents such as - potable water, borewell water, purified water, water for injection in the **Quality Control**.
- **Total Organic Carbon Analyzer** should comply with the "Current Good Manufacturing Practices".
- WHO GMP "Good Manufacturing Practices for Pharmaceutical Products".
- Schedule–M "Good Manufacturing Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products".

6.0 SYSTEM OVERVIEW:

A **Total Organic Carbon Analyzer** is an analytical instrument used for evaluating the total organic carbon content in various types of solvents such as – purified water, bore well water, water for injection purposes.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.	Model	----	As per purchase order
	Measurement Method	----	680°C combustion catalytic oxidation – non-dispersive infrared detection (NDIR) method.
	Measured Items	----	As per your specification
	Applicable Samples	----	Aqueous (optional solid/gas samples)
	Measurement Range	----	• TC: 0 to 30,000 mg/L • IC: 0 to 35,000 mg/L • TN: 0 to 10,000 mg/L • POC: 0 to 500 mg/L
	Detection Limit	----	TC, IC: 4 μg/L, TN: 5 μg/L
	Reproducibility	-----	TC, IC, NPOC: CV 1.5 % max. or ±4 μg/L max (Optional TN: CV 3.0 % max. or ±5 μg/L max)
	Measuring Time	----	TC: approx. 3 min, IC: approx. 3 min (Optional TN: approx. 4 min)
	Sample Injection	-----	Automatic sample injection using a syringe pump and slide type injection mechanism
	Sample Injection Volume	-----	10 to 2,000 μL variable
	IC Removal	-----	Automatic addition of acid and sparging
	Sample Dilution	----	Dilution rate of 2× to 50× (automatic sample dilution by syringe pump), dilution accuracy: ±2 % max. (2× to 20×), ±5 % max. (21× to 50×)
	Display and Operations	----	Operated by PC
	External Memory (Standalone Type)	----	USB flash memory used
	Printer (Standalone Type)	----	Portable thermal printer and PC USB printer can be used
	Carrier Gas	-----	• High-purity air (CO, CO2, HC content: Each 1 ppm max., dew point: -50 °C max.) • Supply pressure: 200±10 kPa (Additional use of optional carrier gas regulator: 300 to 600 kPa) • Optional use of nitrogen gas (not possible in the TN measurement). With the standard model, optional use of pressurized gas.

S.No.	Name of the Component	MOC	Technical Specification
	Gas Consumption	----	150 mL/min (230 to 250 mL/min during sparging) (Variable flow rate)
	Power Supply	----	100 to 240 V AC, 600 VA (Permitted range: 90 to 264 V AC)
	Ambient Temperature Range	----	5 to 35 °C
	Dimensions	----	W340 × D660 × H480 mm (Excluding protrusions. For details, see the External Dimensions Diagram.)
	Weight	---	Approx. 35 kg
2.	**Auto sampler**		
	Vial Types	---	Select from three types: 9 mL, 24 mL, 40 mL
	Number of Vials	---	9 mL: 93, 24 mL: 93, 40 mL: 68
	Vial Septum	---	With dedicated septum (excluding 9 mL vials)
	Sample Sparging	---	Possible (The optional external sparging kit is required.)
	Dimensions	----	W370 × D540 × H490 mm (excluding protrusions)
	Weight	---	Approx. 14 kg

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

➢ FUCTIONAL REQUIREMENTS:

- **Total Organic Carbon Analyzer** shall comply as per cGLP Guideline.

➢ RELIABILITY AND AVAILABILITY:

- The system shall be available for continuous operation.
- The material of construction used shall be suitable for the intended service so as to withstand the working stress without frequent break down.

➢ MAINTENANCE:

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- The supplier shall replace the parts found to be damaged/ broken.
- The supplier shall be available at the site when asked in case of major breakdown.

8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

- The supplier shall follow cGMP in design, development, construction and Installation of the **Total Organic Carbon Analyzer**.

8.2 TESTING:

- The system shall be Factory tested by the supplier with approval witness.
- The system shall be commissioned and qualified at site for Installation and Operation by the supplier with approval witness.

8.3 SUPPORT:

- Supplier shall provide support for Preventive maintenance plan development, cleaning procedure for Total Organic Carbon Analyzer and Operator training.
- Supplier shall provide Safety Manuals during Installation, Operation.

8.4 DELIVERY:

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification (MOC & Calibration Certificates) and Operation Manual in Soft as well as Hard Copy.

9.0 DOCUMENTS TO BE PROVIDED :

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer’s calibration certificate.
- Electrical unit Diagram.
- P&ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.
- Warranty Certificate of machine

Note: The whole URS is a tentative document. Manufacturer or Vendor will be solely responsible for performance of machine specified in the catalogue or during discussion at the time of finalization of purchase order. Specifications and details mentioned in the DQ, dually signed by Vendor/ Manufacturer and dually signed by Head QA will be treated as final specifications of the machine.

The said DQ will be treated as an integral part of purchase order.

10.0 REVIEW COMMENTS:

- The supplier should make/design the **Total Organic Carbon Analyzer** as per technical specification mentioned in the URS.
- For any changes in the design/make of the **Total Organic Carbon Analyzer** if not as per the URS, prior intimation/approval should be taken by the supplier.
- All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.

Approved By:_____
(Head QA)
(Sign/Date)

11.0 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practices
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
SS	:	Stainless Steel
WHO	:	World Health Organization
mm	:	Millimeter
WG	:	Water Gauge
Hz	:	Hertz