

Equipment Specification Data Sheet

Equipment Name: TOC Analyser

Document No.: DS-USB 01

Revision: 02

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin QA&QC	Q1-TOC 01,02	0.05 to 10000 µg/ ml	2

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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Prepared by

Ms. Niharika Ruhela	Engineer - Process	<i>for Niharika</i>	8/6/15
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Mr. Yogesha M J	Engineer - Process	<i>yogesha m j</i>	8/6/15
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Mr. Vikas Katial	GM - Projects(SME) & Head COC Vaccines	<i>V. Katial</i>	9/6/15
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HLL Biotech Limited

Name	Designation	Signature	Date
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Authorized by

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HLL Biotech Limited, Chennai		
	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	TOC Analyzer
	Document No.	DS-TOC 01
	Revision No.	02
		
1	Process requirements	
1.1	TOC is the amount of carbon in an inorganic compound indicative of water quality, TOC analyzer is an analytical equipment for monitoring carbon content in the given sample.	
2	Equipment ID	
2.1	Q1-TOC-01,02	
3	Technical Specification	
3.1	Measuring range	0.05 to 10000 µg/ ml
3.2	Detection Limit	0.05 mg/IC
3.3	Precision	<2%
3.4	Accuracy	± 2%
3.5	Sensitivity	0.01 µg/ ml
3.6	Measurement modes	TC, TOC, TIC, NPOC (Non Purgeable Organic Carbon)
3.7	Analysis time	~5 minutes
3.8	Sample-to-sample Carryover (from 500ppb to blank)	< 0.2%
3.9	Detector	Digital NDIR
3.10	Injection Volume	up to 1000µl
3.11	Carrier Gas options	Co ₂ free Air, O ₂ , or N ₂
3.12	Operating temperature	10 °C to 40 °C, Sample temperature
3.13	Sample temperature	1 °C to 95 °C
3.14	Temperature accuracy	0.25 °C
3.15	Humidity	5 to 80 %, non-condensing
3.16	Inorganic Carbon Handling	Dynamic Endpoint Detection to assure complete Inorganic Carbon removal
3.17	Power Requirement	To be compatible with standard Indian power supply socket

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4	Material of Construction	
4.1	Enclosure material	Poly carbonate plastic, flame retardant, UV and chemical resistant
5	Specific Equipment Requirements	
5.1	Equipment should be provided with suitable detector to measure absolute mass amount of carbon di oxide resulting from sample combustion.	
5.2	The system shall display TOC temperature and conductivity.	
5.3	Equipment shall be compatible for cleaning with all standard disinfectants.	
6	Other Requirements	
6.1	Automatic power off after electric furnace cools down.	
6.2	Should be able to store backup for previous calibrations.	
6.3	UV lamp/ LED lights and sensor status for local indicators	
6.4	Shall have measurement reliability for real time analysis of sample by eliminating sensitivity to pressure change	
6.5	Training/Demo for users on operation and cleaning to be provided.	
7	Regulatory Guidelines / Standards	
7.1	CE compliant.	
7.2	21 CFR, part 11 all measurements recorded to encrypted database.	
7.3	Should meet ASTM standard test methods for online monitoring of carbon compounds in water by UV light oxidation.	
7.4	A comprehensive training programme for the operator should be provided.	
8	Safety Requirements	
	Following facilities must be provided to protect personnel and equipment:	
8.1	Appropriate closure of all parts.	
8.2	Proper Earthing is necessary.	
8.3	Emergency stop function on accessible area.	
8.4	Alarming sensors should be provided.	
8.5	The heat given off by the unit must be stated.	
8.6	Arrangement of alternative power supply (UPS) to control and monitoring system.	

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HLL Biotech Limited, Chennai			
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED <small>(A Subsidiary of HLL Lifescare Limited) (A Government of India Enterprise)</small>
	Equipment Name	TOC Analyzer	
	Document No.	DS-TOC 01	
	Revision No.	02	
9	Documents		
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file:		
9.1	IOQ Documents.		
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.		
9.3	Warranty for 1 year from the date of supply.		
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their procedure.		
10	Timelines		
10.1	NA		
11	Preferred list of Makes		
11.1	G E , Ana tel, Hach, Analytic jena, Schimadzu.		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.		

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Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-TOC-01,02	Admin QA&QC	Chemistry Lab/ Biochemistry	Q1S022	4642x 7369	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
11-03-2014	Niharika Ruhela	00	-	New document.	
27-10-2014	Niharika Ruhela	01	All	Updated as per comments received from HBL dated 10-10-2014.	
05-05-2015	Niharika Ruhela	02	All	Updated as per comments received from HBL dated 02-05-2015.	
Table-3: Annexure					
Not applicable					