

CALIBRATION CERTIFICATE

NAME OF CUSTOMER:

HOSCONS HEALTHCARE INDIA PRIVATE LIMITED
9/830, RANGANADHAN ROAD,
NALLATHAMBI NAGAR
MEDAVAKKAM,
CHENNAI-600100

BIO CHEMISTRY SEMI AUTO CHEMISTRY ANALYZER PHOTOMETER BEARING.

S/NO: 601723038IE

CALIBRATIONS ON: 01.04.2023

CALIBRATION VALUES:

LIGHT INTENSITY TEST

LED	TINT	MAIN	REFERENCE
340	14	955024	211051
405	9	959849	636066
505	28	977728	651266
535	19	984954	543820
560	30	958066	588964
600	16	930117	490573
635	13	968910	527603
670	19	978105	600117

VALUES	CURRENT	NEW
<u>SAMPLE VOLUME</u>	<u>44226</u>	<u>44227</u>
<u>POSITIONING</u>	<u>1500</u>	<u>1800</u>
<u>PUMB DELAY</u>	<u>2</u>	<u>2</u>

PERISTALTIC PUMP ADJUSTMENT TEST

NEXT CALIBRATION DUE ON: 31.03.2024

THIS INSTRUMENT IS CALIBRATED BY USING THE PERFORMANCE OF THE LIQUID CALIBRATOR ONLY

TESTED BY: G DINESH

APPROVED BY: Q.A

NOTE: 1) Calibration Points & due date is given as per customer request 2) This certificate refer only to particular item submitted for certificate 3) The calibration results reported are valid at the time of and under the stated conditions of the measurements 4) Any error in the certificate should be brought to our lab within 45 days from the date of issue of certificate

INTERNAL QUALITY ASSURANCE LOG REGISTER

FORMAT NO: F/HHC/03

REV NO: 01

REV DATE: 01-04-2023

INTERNAL QUALITY ASSURANCE		BIO CHEMISTRY INTERNAL QC						
EQUIPEMENT NAME		SEMI AUTO ANALYZER			SAMPLE TYPE		SERUM	
S.NO	SPECIFIC TESTS/EXAMINATION PERFORMED	UNIT	LIMITS	03-05-2023	10-05-2023	17-05-2023	QA RUN BY	QA MONITOR BY
1.	GLUCOSE	mg/dL	260 (222-300)	244	247	248	Mr. Paramasivam	Mr. Prabaharan
2.	UREA	mg/dL	135 (116-156)	123	124	123	Mr. Paramasivam	Mr. Prabaharan
3.	CREATININE	mg/dL	5.0 (4.0 - 5.7)	5.1	4.9	4.7	Mr. Paramasivam	Mr. Prabaharan
4.	T.BILIRUBIN	mg/dL	5.5 (4.8-6.9)	5.6	5.4	5.1	Mr. Paramasivam	Mr. Prabaharan
5.	T-PROTEIN	g/dL	8.0 (7.0-9.0)	8.4	8.4	8.4	Mr. Paramasivam	Mr. Prabaharan
6.	ALBUMIN	g/dL	4.5 (3.7-5.3)	4.6	4.4	4.4	Mr. Paramasivam	Mr. Prabaharan
7.	URIC ACID	mg/dL	10.1 (8.6-11.6)	10.4	10.4	10.4	Mr. Paramasivam	Mr. Prabaharan
8.	CHOLESTEROL	mg/dL	263 (224-302)	263	260	264	Mr. Paramasivam	Mr. Prabaharan
9.	TRIGLYCERIDE	mg/dL	220 (187-253)	236	246	246	Mr. Paramasivam	Mr. Prabaharan



Medsource Ozone Biomedicals Pvt. Ltd

URA Semi-Automatic Clinical Chemistry Analyzer

IQ-OQ-PQ DOCUMENT

Model	: <i>URA Semi-Automatic Clinical Chemistry Analyzer</i>
Make	: <i>Medsource Ozone Biomedicals Pvt. Ltd</i>
S No	: <i>601723038 IE</i>
Installation No	: <i>1</i>
Purchase Order No	: <i>183/HHI/2022-23</i>

QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer**DESCRIPTION OF SYSTEM/EQUIPMENTS:**

URA Biomedicals' experience and understanding of laboratory needs has led to an innovative product developed with one key objective – provide excellent Chemistry Analyzer, resulting in the ultimate customer satisfaction. URA is a compact, convenient, new generation analyzer most suitable for medium and small sized laboratories, also as a backup for large laboratories.

- Wide Analytical Mode
- Open System
- Online Graphics
- Collated Patients Reports
- L-J Chart For Quality Control

SAFETY REQUIREMENT

- Ensure that only trained staff work with the appliance
- Set up the appliances in a spacious area on an even, stable, clean, non-slip, dry and fireproof surface.

QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer**TABLE OF CONTENT**

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8	Installation Qualification Report	
9	Operation Qualification Report	
10	Performance Qualification Report	

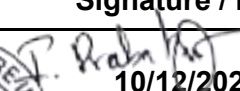
QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

**CHECKLIST FOR INSPECTION OF URA Semi-Automatic Clinical Chemistry Analyzer
(To be checked on receipt of the equipment)**

TABLE OF CONTENT

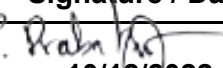
S No	Item	Qty	Acceptance Criteria	Observation
1	URA Semi-Automatic Clinical Chemistry Analyzer	1 No	Available along with Package	Available
2	Standard Attachment	1 No	Available along with Package	Available
3	Operating Manual	1 No	Available along with Package	Available
4	Warranty Registration Card	1 No	Available along with Package	Available

Checking Sign Off:

Name of the Person	Signature / Date
Mr. Prabakaran	 10/12/2022

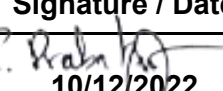


QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer		
INSTALLATION QUALIFICATION		
<p>1. Purpose: The purpose of Installation Qualification is to establish that the URA Semi-Automatic Clinical Chemistry Analyzer and its Components are as per the specifications and are installed as per the approved procedure</p> <p>2. Scope: Installation Qualification to be performed at the time of installation</p> <p>3. Responsibility: R&D, Personing, Safety and Quality Assurance</p> <p>4. Critical Variables to be met:</p>		
Critical Variables	Acceptance Criteria	Observation
1.0 Location Suitability		
1.1 Size & Location of URA Semi-Automatic Clinical Chemistry Analyzer	The instruments should not be exposed to direct sunlight and placed rigid table	Yes
1.2. Weight & Structural suitability	The civil structure should be suitable to accommodate the URA Semi-Automatic Clinical Chemistry Analyzer	Yes
1.3 Utilities	Should be 100 - 240V AC $\pm 10\%$, 50/60 Hz	Yes
Electrical Supply:		
Safety provisions:	Proper Earthing should be provided	
Environmental condition:	Temperature: 15°C to 40°C, Relative Humidity : up to 85%	
2.0 Installation as per manufacturers instruction	Personing / Production / Quality Assurance to certify.	Yes
3.0 Safety		
3.1 Earthing	Should be provided with Electric supply	Yes
4.0 Documentation		
4.1 Manuals	Manufacturer's manual	Yes
4.2 Training	No. of personnel to be trained <u>One Person</u>	Yes

Checking Sign Off:	
Name of the Person	Signature / Date
Mr. Prabakaran	 10/12/2022



QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer	
TECHNICAL DETAILS	
Assay types	Absorbance, Endpoint, Kinetic, Fixed Time, Coagulation
Wavelengths	Wide spectrum of 340nm -700 nm i.e 340, 405, 500, 546, 578,620nm plus two vacant positions for additional / optional filters
Photometer range	-0.1-3.000Abs
Aspiration Volume	0.2mL to 1.0mL
Cuvette Volume	500µL
Flow Cell	30 µL
Storage Capacity	up to 60 Test Programs and has a huge memory to store 2000 tests results.
Light Source	6V/10W, Tungsten Halogen Lamp
Temperature Control	25°C, 30°C & 37°C.
Display	On-line graphs for all assays in real-time mode on a large LCD display
Printer	on-board high speed thermal printer
Interface	External Keyboard/ Mouse
External Dimensions	360 x 318 x 160mm
Weight	7 Kg

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Mr. Prabakaran	 10/12/2022



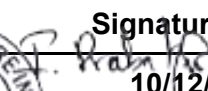
QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

OPERATIONAL QUALIFICATION

1. **Purpose:** The purpose of Operational Qualification is to establish that the URA Semi-Automatic Clinical Chemistry Analyzer and its Components are as per the specifications and are installed as per the approved procedure
2. **Scope:** Operational Qualification to be performed at the time of installation
3. **Responsibility:** R&D, Personing, Safety and Quality Assurance
4. **Critical Variables to be met:**

Critical Variables	Acceptance Criteria	Observation
1.0 Operate the instrument as per manufacturer's manual	Should function as desired	Yes
2.0 Press the ON / OFF key to switch on the unit	Display glowing indication	Yes
3.0 Maintenance and cleaning	As per given in the manual	Yes
4.0 Training	No. of personnel to be trained One Person	Yes

Checking Sign Off:

Name of the Person	Signature / Date
Mr. Prabakaran	 10/12/2022

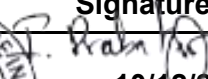


QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

PERFORMANCE QUALIFICATION

1. **Purpose:** The purpose of Performance Qualification is to establish that the URA Semi-Automatic Clinical Chemistry Analyzer and its Components are as per the specifications and are installed as per the approved procedure
2. **Scope:** Performance Qualification to be performed at the time of installation
3. **Responsibility:** R&D, Personing, Safety and Quality Assurance
4. **Calibration:** The Absorbance Factor according to the Factory sec calibration.
The Read Cell Temperature according 10 the Factory sec calibration.

Checking Sign Off:

Name of the Person	Signature / Date
Mr. Prabakaran	 10/12/2022



QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

TRAINING CERTIFICATE

This is to certify that the following personal of **M/s. HOSCONS HEALTHCARE INDIA PRIVATE LIMITED** are trained how to use the URA Semi-Automatic Clinical Chemistry Analyzer as per manual.

Checking Sign Off:

Name of the Person	Signature / Date
Mr. Prabakaran	 10/12/2022

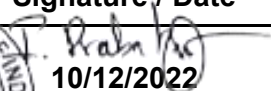


QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

EQUIPMENT HANDOVER CERTIFICATE

This is to certify that the URA Semi-Automatic Clinical Chemistry Analyzer Make Medsource Ozone Biomedicals Pvt. Ltd, India has been qualified and is here with approved for regular R&D experiments.

Model	: <i>URA Semi-Automatic Clinical Chemistry Analyzer</i>
Make	: <i>Medsource Ozone Biomedicals Pvt. Ltd</i>
S No	: <i>601723038 IE</i>

Checking Sign Off:	
Name of the Person	Signature / Date
Mr. Prabakaran	 10/12/2022

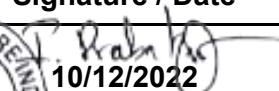


QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

INSTALLATION QUALIFICATION REPORT

This is to certify that the URA Semi-Automatic Clinical Chemistry Analyzer Make Medsource Ozone Biomedicals Pvt. Ltd, India has been installed successfully as per user requirement

Model	: <i>URA Semi-Automatic Clinical Chemistry Analyzer</i>
Make	: <i>Medsource Ozone Biomedicals Pvt. Ltd</i>
S No	: <i>601723038 IE</i>

Checking Sign Off:	
Name of the Person	Signature / Date
Mr. Prabakaran	 10/12/2022



QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

OPERATION QUALIFICATION REPORT

This is to certify that the URA Semi-Automatic Clinical Chemistry Analyzer Make Medsource Ozone Biomedicals Pvt. Ltd, India has been installed and its operating as per user manual.

Model	: <i>URA Semi-Automatic Clinical Chemistry Analyzer</i>
Make	: <i>Medsource Ozone Biomedicals Pvt. Ltd</i>
S No	: <i>601723038 IE</i>

Checking Sign Off:	
Name of the Person	Signature / Date
Mr. Prabakaran	<i>Mr. Prabakaran</i> 10/12/2022

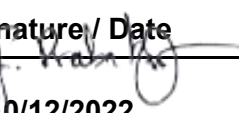


QUALIFICATION OF URA Semi-Automatic Clinical Chemistry Analyzer

PERFORMANCE QUALIFICATION REPORT

This is to certify that the URA Semi-Automatic Clinical Chemistry Analyzer Make Medsource Ozone Biomedicals Pvt. Ltd, India has been installed and performing as per specifications.

Model	: <i>URA Semi-Automatic Clinical Chemistry Analyzer</i>
Make	: <i>Medsource Ozone Biomedicals Pvt. Ltd</i>
S No	: <i>601723038 IE</i>

Checking Sign Off:	
Name of the Person	Signature / Date
Mr. Prabakaran	 0/12/2022

