INSTALLATION QUALIFICATION

S. No	Title	
1	Pre Approval	
2	Objective	
3	Scope	
4	Instrument description	
5	Identification of Major components / accessories	
6	Installation check / review	
7	Inspection check / review	
8	Identification and verification of material of construction	
9	Identification and verification of supporting utilities	
	Identification of standard operating procedure	
1	Abbreviations	
2 1	Post Approval	,

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE **Instrument SN** S200350 EM200 **Instrument Name**

APPROVAL 1.0

I. Approval of the IQ procedure:

Harshit Medical & Research Centre and Transasia are jointly responsible for the installation of the syste ERBA Clinical Chemistry Analyzer, Model: EM200, Serial No. S200350 in the clinical lab of Harshit Medical & Research Centre as per the attached protocol.

Protocol Performed By: Transasia Representative

Name

Sarvesh Singh

Signature: Savesh
Date: 29/7/21

Title Company **INSTALLATION-QUALIFICATION** TRANSASIA BIO-MEDICALS LTD.

Customer Authorizations:

Name Title

Site

Dr.D.C.Kothari

INSTALLATION QUALIFICATION

Jaunpur

Signature: Larnchand

Date: 29/7/21

TRA IQOQP	NSASIA BIOMEDIC Q HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CE	NTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

2.0 OBJECTIVE

The objective of this document is to provide an outline for the inspection of EM 200 (Bio-Chemistry Random Analyzer) and to verify that the following boundaries:

- Each Installed subcomponent complies with the engineering design and instrument data sheet / design specifications & manufacturer's recommendations.
- To ensure that all the safety features are defined before the start up of operational qualification exercise.
- o The system meets the current regulatory requirements.
- o To identify the Standard operating procedures for Operational Qualification.

3.0 SCOPE

The scope of this protocol is to outline procedure for Installation qualification of the subjected instrument within the following boundaries:

- o Identification and verification of its Major components / Accessories
- Identification, Classification and Verification of Process Control Instruments / Gauges / Devices
- o Identification and verification of Material of Construction
- o Identification and verification of Supporting Utilities
- Identification of Standard Operating Procedures
- o Identification and Verification of Documents

TRA	ANSASIA BIOMEDIC	ALS LIMITED AL & RESEARCH CE		TOAL
	Q HARSHIT MEDIC	AL & RESEARCH CE	NTRE	TRAN
Instrument Name	EM200	Instrument SN	S200350	Rio-Med

4.0 INSTRUMENT DESCRIPTION

The Clinical Chemistry Analyzer is an open, full automated, discrete, patient prioritized, random access, computerized analyzer.

Technical Specifications:

System Type	Open, Automated, Discrete, Random Access, Patient Prioritized, 1/2Reageants
Analysis Speed	200 Biochemistry tests per hour 400 tests per hour (with ISE) for a cycle time of 18 seconds
Display resolution	1024 X 768
Analyzer Dimensions	810 (W) x 800 (D) x 600 (H) mm
Number of tests on board	Maximum: 50
Assay Modes	1-point, 2-point, Rate-A and Rate –B, ISE optional
Calibration	Linear (two point and multi point), Factorized and Non-linear multipoint
Sample (Tubes / Cups)	Primary tubes of 5, 7 or 10mL & sample cups
Photometric Optics	Mono and Bi-chromatic measurement using 8 wavelengths
Absorbance Range	0-2.5
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication
Stat Sampling	Total 30 positions

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE

Instrument Name EM200

Instrument SN S200350

TRANSASIA Bio-Medicals Ltd.

Purpose:

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholestrol, Tri-glycerides, Proteins, etc.

The working unit of the analyzer comprises the following:

- Basic operating unit with an intelligentphotometer
- Sophisticated robotics combined with an operating console and a central processing unit(CPU).

Operating Unit:

The operating unit of the analyzer includes the sample and reagent handling systems. The sample handling system consists of a sample tray, sample arm, sample syringe and a wash station for the sample probe.

Photometric System:

The photometric system consists of 45 hard glass cuvettes, multi wavelength diffracting photometer and a halogen lamp.

Operating Console:

The operating console consists of a touch screen (optional) color TFT monitor, a key board and a mouse.

CPU (Central Processing Unit):

CPU consists of Pentium – IV 1.7 GHz processor (or Higher) with a 48 x CD Drive, and minimum 256 MB memory. The application software can be installed on computers with operating systems of Windows XP.

Besides the above mentioned, this analyzer has got the unique Software and Hardware features.

TRA IQOQP	NSASIA BIOMEDIC Q HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CEN	TRE	TRANSASIA
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Lt



IDENTIFICATION OF MAJOR COMPONENTS /ACCESSORIES 5.0

Details of each major component identified in this section, is recorded in a data sheet.

Name of Component / Accessories	Present	Verified by		
	Yes / No	Signature	Observations	
Sample Tray / Disk	Yes	1		
Sample Syringe	Yes			
Sample Probe	Yes			
Wash Station for Sample Probe	Yes		$\mathcal{L}_{\mathcal{A}_{\mathcal{F}}}$	
Reagent Tray / Disk	Yes			
Reagent Bottles	Yes			
Reagent Probe	Yes	- Alla		
Stirrer	Yes	Lavell		
Permanent Reaction Cuvette	Yes			
9 Stage Laundry System	Yes			
Light Source	Yes			
Sample Cups	Yes			
Software of EM 200	Yes			

	TRANSASIA BIOMEDICA		WANNA .	TRANS	
IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE					
Instrument Name	EM200	Instrument SN	S200350	Bio-Medic	



6.0 INSTALLATION CHECK /REVIEW

S. No.	Statement	Yes / No	Verified by Signature
1.	Verify that the "as built' drawings are complete and represent the design concept	Yes	Yes Table
2.	Verify that major components / accessories are securely anchored and shock proof.	Yes	
3.	Verify that there is no observable physical damage.	Yes	
4.	Verify that there is sufficient room of servicing provided	Yes	
5.	Verify that all utilities and electrical connections have been done according to the drawings.	Yes	
6.	Walking access to ground mounted instrument provided.	Yes	Sawarh
7.	Required electric connections are tight, weather proof and earthed.	Yes	
8.	Instrument identification nameplate visible.	Yes	
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.	Yes	
10.	Verify that the instruments installed and leveled properly on the floor.	Yes	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
11.	Verify that the Material of Construction is proper and meeting the requirements.	Yes	

TRA	NSASIA BIOMEDIC	ALS LIMITED	
IQOQP	Q HARSHIT MEDIC	AL & RESEARCH CE	NTRE
Instrument Name	EM200	Instrument SN	S200350

Instrument SN S200350

7.0 **INSPECTION CHECK / REVIEW**

Instructions for completing the check / review

1. For each data sheet, record the required information withpen. Wherever required record "Yes" for acceptance, "No" for non-compliance and "NA" for notapplicable.

"No" replies must be explained / justified.

- 2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.
- 3. When a list of acceptable options is presented, tick () the option that is actually present.
- 4. In the "Method of Verification" column indicate that item is installed and inspected according to manufacturer's specifications, such as by Visual / Physical, SOP, Test Certificate, Manual, etc.

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE

Instrument Name

EM200

Instrument SN

S200350

TRANSASIA" Bio-Medicals Ltd.

Instrument/ Component Name: Sample Tray / Disk

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	OK	Physical/Practical	
Standards / Stat	30 positions	OK	Physical/Practical	a ann_
Blank	Can be put on any position	OK	Physical/Practical	Laura 1
Controls	Can be programmed on any positions	OK	Physical/Practical	

Instrument/ Component Name: Sample Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 μL	OK	Physical/Practical	
Installed Location	Behind the instrument on the right side	OK	Physical/Practical	Cawan
Quantity	01 No.	OK	Physical/Practical	//
Increase in dispensing volume	0.2 μL	OK	Physical/Practical	

TR	ANSASIA BIOMEDIC PQ HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CE	NTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

Instrument/ Component Name: Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	$2-70\mu L$	OK	Physical/Practical	Signature
MOC	Teflon coated	ОК	Physical/Practical	
Quantity	01 No.	OK	Physical/Practical	Garron
Increase in aspiration volume	0.2 μL	OK	Physical/Practical	/ •

Instrument/ Component Name: Wash Station for Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	OK	Physical/Practical	The same
Type of positions	i) Drain	ОК	Physical/Practical	Souver
	ii) Trough	V		13 14 14

TRA IQOQP	NSASIA BIOMEDIC Q HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CEN	NTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

Instrument/ Component Name: Reagent Tray / Disk

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions	OK	Physical/Practical	\ \
Outer Rings	25 positions	OK	Physical/Practical	
Inner Rings	25 positions	OK	Physical/Practical	
Adaptors of 5mL	50 positions	OK	Physical/Practical	
Maintenance of Temperature	8-12°C ± 2°C	OK	Physical/Practical	Land
Rotation of disk	Counter-Clockwise	OK	Physical/Practical	
Time for Rotation of one Cuvette	Every 18 seconds	OK	Physical/Practical	

TRA IQOQP	NSASIA BIOMEDIC Q HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CEN	NTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

Instrument/ Component Name: Reagent Bottles

Description	Specified	Actual	Method of Verification	Verified by Signature
Minimum Capacity	20 mL	OK	Physical/Practical	1-1-1
Maximum Capacity	50 mL	OK	Physical/Practical	
Quantity (Large)	25 Nos'	ОК	Physical/Practical	
Quantity (Smaller)	25 Nos'	OK	Physical/Practical	
Type	Screw Capped	OK	Physical/Practical	
Outer ring position	20 mL bottles & 5ml adaptors	OK	Physical/Practical	
Inner ring position	20 mL & 50 mL bottles & 5ml adaptors	OK	Physical/Practical	Garm
MOC	Plastic	OK	Physical/Practical	9/
Adaptor	50 Nos'	ОК	Physical/Practical	
Adaptor Capacity	5 mL	OK	Physical/Practical	
Identification of Reagents	Barcode labels on the reagent containers	OK	Physical/Practical	

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE Instrument Name EM200 Instrument SN S200350

Instrument/ Component Name: Reagent Probe

Description	Specified	Actual	Method of Verification	Verified by
Aspiration/Dispensing Volume	R1: 50 – 300 µL	OK	Physical/Practical	Signature
	R2: 0 or10 – 300 μL	OK	Physical/Practical	
MOC	Teflon coated	OK	Physical/Practical	Cara
Quantity	02 Nos'.	OK	Physical/Practical	9/
Increase in aspiration/dispensing volume	1 μL	OK	Physical/Practical	

Instrument/ Component Name: Reagent Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 μL	OK	Physical/Practical	Signature
Installed Location	At the back of the instrument on the right side	ОК	Physical/Practical	Laven
Quantity	01 No.	OK	Physical/Practical	
Increase in dispensing volume	IμL	OK	Physical/Practical	

Instrument/ Component Name: Stirrer

Description	Specified	Actual	Method of Verification	Verified by
Туре	Single Stirrer	OK	Physical/Practical	Signature
No. of paddles	O1 No			Laven
rior of paddies	01 No.	OK	Physical/Practical	

TRA	ANSASIA BIOMEDIC PQ HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CEI	NTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

Instrument/ Component Name: Permanent Reaction Cuvette

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos'	OK	Physical/Practical	Digitature
MOC	Hard Glass	OK	Physical/Practical	Samonh
Capacity	770 µL	OK	Physical/Practical	

Instrument/ Component Name: 7 Stage Laundry System

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	OK	Physical/Practical	A
	Nozzle – 2	OK	Physical/Practical	
	Nozzle – 3	ОК	Physical/Practical	-
	Nozzle – 4	OK	Physical/Practical	Canson
	Nozzle – 5	OK	Physical/Practical	7/
	Nozzle – 6	OK	Physical/Practical	
	Nozzle - 7	OK	Physical/Practical	

· T	TRANSASIA BIOMEDIC OPPO HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CE	NTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

Instrument/ Component Name: LightSource

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	OK	Physical/Practical	
Volts	12 V	OK	Physical/Practical	Jamoon
MOC	Halogen	OK	Physical/Practical	
Quantity	01 No	OK	Physical/Practical	

Instrument/ Component Name: SampleCups

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 Nos'	OK	Physical/Practical	
MOC	Plastic	OK	Physical/Practical	Sawari
Capacity	2 mL	OK	Physical/Practical	

Instrument/ Component Name: Software of EM 200

Description	Specified	Actual	Method of Verification	Verified by Signature
Version	2019	OK	Physical/Practical	,
CD number		OK	Physical/Practical	Cawah
Product	EM- 200	OK	Physical/Practical	
Make	Erba Transasia	OK	Physical/Practical	

	NSASIA BIOMEDIC		7	TO A LICA CIA®
IQOQP	Q HARSHIT MEDIC	AL & RESEARCH CEN	NTRE	TRANSASIA
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

8.0 IDENTIFICATION AND VERIFICATION OF MATERIAL OF CONSTRUCTION

Identify and list down all components of the equipment for its material of construction.

Method of Test may be Molybdenum Test, Test Certificate, Manual, etc.

Component (s)	Material of Construction	Actual	Method of Verification	Verified by Sign & Date
Sample Probe	Teflon coated	OK	Physical/Practical	1
Reagent Probe	Teflon coated	OK	Physical/Practical	
Permanent Reaction Cuvette	Hard Glass	ОК	Physical/Practical	
Light Source	Halogen	OK	Physical/Practical	Landon
Reagent Bottle	Plastic	OK	Physical/Practical	29/7/21
Sample Cups	Plastic	OK	Physical/Practical	α ''((')'''

9.0 IDENTIFICATION AND VERIFICATION OF SUPPORTINGUTILITIES

List the supporting utilities and record whether or not they are properly connected and identified.

Utilities	Observation / Result	
Power	OK	
Distilled Water	OK	Conven
Wash Solution	OK	
UPS	OK	29/7/21

	NSASIA BIOMEDIC			® 4444 04 1 ®
· IQOQI	Q HARSHIT MEDIC	CAL & RESEARCH CE	VTRE	TRANSASIA
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

10.0 IDENTIFICATION OF STANDARD OPERATINGPROCEDURE

SOP No.	Title
Operation	Operation of Bio-Chemistry Random Analyzer
Calibration	Calibration of Parameters
Controls	Checking of Controls for Parameters
Maintenance	Maintenance / Checking of Distilled water, Waste, Wash solution, Cuvette rinse, Sample probe wash and Water save
Cleaning	Cleaning of Instrument surface

11.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification

	TRANSASIA BIOMEDIC	ALS LIMITED		
IQO	DQPQ HARSHIT MEDIC	AL & RESEARCH CEN	TRE	TRANSASIA
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

12.0 POSTAPPROVAL:

12.1 Checkedby

Name	Designation	Signature	Date
Sarvesh Singh	Service Engineer	Carvert	29/7/21
Dheeraj Gupta	Application Specialist	Dhenor Gum	2917/21
		7	

12.2 CustomerAuthorization:

Name	Designation	Signature	Date
Dr.D.C.Kothari	HOD	tranchand	29/7/21

OPERATIONAL QUALIFICATION

As part of Operational qualification, the following checks shall be done and each test shall be recorded:

Instrument Start-up

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

Functional Checks

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

Interlocks and Alarms Check

To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

Safety / Security Checks

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

Instrument Shut-down

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

	NSASIA BIOMEDIC Q HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CE	NTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

1.0 INSTRUMENT START-UP:

Action	Observation	Verified by	Remarks
Ensure that all the required electrical connections are properly connected.	OK	Sarvesh Singh	NA
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	OK	Sarvesh Singh	NA
Ensure the availability of XL Wash.	OK	Sarvesh Singh	NA
Ensure the availability of Biohazard Waste.	OK	Sarvesh Singh	NA /
Ensure the availability of Normal Waste.	OK	Sarvesh Singh	*NA
Switch ON the rear switch of the analyzer.	OK	Sarvesh Singh	NA
Switch ON the side switch of the analyzer.	OK	Sarvesh Singh	NA
Switch ON the computer and start the analyzer application software.	OK	Sarvesh Singh	NA
Initialization	OK	Sarvesh Singh	NA

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE				
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

2.0 FUNCTIONALCHECKS:

2.1 Maintenance:

Activity	Observation	Verified by	Remarks
Photometer functioning	OK	Sarvesh Singh	NA
Cuvette Rinse	OK	Sarvesh Singh	NA

TRANSASIA BIOMEDICALS LIMITED IQOOPQ HARSHIT MEDICAL & RESEARCH CENTRE				TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

2.2 Loading of Reagents:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by	Remarks
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	ОК	Sarvesh Singh	NA

2.3 Calibration:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by	Remarks
Blank (Distilled Water)	OK	Dheeraj Gupta	NA
Standard (Multical)	OK	Dheeraj Gupta	NA

3.0 INTERLOCKS AND ALARMS CHECK:

Action	Observation	Verified by	Remarks
Less volume of Distilled Water	OK	Dheeraj Gupta	NA
Less volume of Wash Solution	OK .	Dheeraj Gupta	NA
More volume of Bio- Hazard waste	OK	Dheeraj Gupta	NA
More volume of Normal / General waste	OK	Dheeraj Gupta	NA

TRANSASIA BIOMEDICALS LIMITED				
IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE				TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

4.0 SAFETY / SECURITY CHECKS:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by	Remarks
Password Check for Test Parameters	OK	Dheeraj Gupta	NA
Password Check for QC Mode	OK	Dheeraj Gupta	NA

5.0 INSTRUMENT SHUT-DOWN:

Action	Observation	Verified by	Remarks
Sample Probe Wash	OK	Dheeraj Gupta	NA
Water Save	OK	Dheeraj Gupta	NA
Switch OFF the computer.	OK	Dheeraj Gupta	NA
Switch OFF the side switch of the analyzer.	OK	Dheeraj Gupta	NA
Switch OFF the rear switch of the analyzer.	OK	Dheeraj Gupta	NA

	NSASIA BIOMEDIC			TRANSASIA®			
IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE							
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.			

Protocol Performed By:

Name	Designation	Signature	Date		
Sarvesh Singh	Service Engineer	Saver	29/7/21		
Dheeraj Gupta	Application Specialist	Dheraj Grun	29/7/21		

Customer Authorization:

Name	Designation	Signature	Date		
Dr. D.C.Kothari	HOD	territand	29/7/21		

	NSASIA BIOMEDIC O HARSHIT MEDIC	ALS LIMITED AL & RESEARCH CEN	VTRE	TRANSASIA®
Instrument Name	EM200	Instrument SN	S200350	Bio-Medicals Ltd.

Performance Qualification

S. No	Title
1.0	Pre approval
2.0	Objective
3.0	Scope
4.0	Pre- Requisites
5.0	Test Plan
6.0	Execution of Test Plan
7.0	Post Approval

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE

Instrument Name

EM200

Instrument SN

S200350

Signature:) Levaj (jupta)

Signature: Darmchard



1.0 PRE APPROVAL

L. Approval of the PO procedure

Both Harshit medical & reseach Centre and Transasia are jointly responsible for conducting the Performance Check of the Clinical Chemistry Analyzer, Model: ERBA – EM200, Serial No. S200350 in the clinical lab of Harshit medical & reseach Centre as per the attached protocol.

Protocol Performed By: Transasia Representative

Name

Dheeraj Gupta

Title

PERFORMANCE-QUALIFICATION

Company

TRANSASIA BIO-MEDICALS LTD.

Date:29-7-2021

Customer Authorizations:

Name

: Dr. D.C.Kothari

Title

PERFORMANCE-QUALIFICATION

Site

Jaunpur

Date:

TRANSASIA BIOMEDICALS LIMITED IQOQPQ HARSHIT MEDICAL & RESEARCH CENTRE

Instrument Name El

EM200

Instrument SN

S200350



2.0 OBJECTIVE

The objective of this protocol is to establish documented evidence for the Performance Qualification of EM 200 (Bio-Chemistry Random Analyzer) and to ensure that the results obtained are within the pre-determined Acceptance Criteria.

3.0 SCOPE

The Scope of this protocol is applicable to EM 200 (Bio-Chemistry Random Analyzer).

4.0 PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification prior toPQ.
- Completion of Operational Qualification prior toPQ.

	ANSASIA BIOMEDIC							
IQOQ	PQ HARSHIT MEDIC	AL & RESEARCH CE	NTRE	TR				
Instrument Name EM200 Instrument SN S200350								

5.0 TEST PLAN

The following tests shall be followed, during the Performance Qualification of EM200 (Bio-Chemistry Random Analyzer).

- 1. Glucose
- 2. Chol
- 3. SGOT
 - Data Analysis of PQ attachedseparately.

Conclusion:-

The study data has been determined, The system describes all Criteria outlined in its protocol The system is ready for specific uses

6.0 ABBREVIATIONS

SOP	Standard Operating Procedure
мос	Material of Construction
PQ	Performance Qualification

TRANSASIA BIOMEDICALS LIMITED TRANSASIA BIOMEDICAL & RESEARCH CENTRE IQOQPQ HARSHIT MEDICAL & RESEARCH SN S200350 Instrument Name EM200 Instrument SN S200350
--

7.0 POSTAPPROVAL

7.1 Protocol doneby

Name	Designation	Signature The endum 2	Date
Dheeraj Gupta	Application Specialist	Dia d	4(7)

7.2 Customer Authorization:

Name	Designation	Signature	Date - 29/7/21
Dr.D.C.Kothari	HOD	Harricland	24//





Date:29/07/2021

CALIBRATION REPORT

Customer Name: HARSHIT MEDICAL AND RESEARCH CENTRE, JAUNPUR

Model: Fully Automated Bio-Chemistry Analyzer EM-200

Serial No.: S200350

Calibration done date: 29/07/2021

Next Calibration due Date: 29/07/2022

<u>Lab In charge:</u> Dr.D.C.KOTHARI

This is to certify that above mentioned product has been verified of calibration

Ву

Checking Lamp Voltage 11.8V

Checking gain of Photo meter for all wavelength values obtained are as under:

Filter	340	405	505	546	578	600	660	700
Gain	788	722	644	629	566	587	551	513

Checked calibration of probe on all locations.

Checked temperature at Reagent tray at 8.0 degree (Range 4 to 11 degree) and reaction tray 37.2 degree (Range 36.5 to 37.5 Degree)

Followed by QC run with satisfactory values of QC

Calibration at site performed by Mr.Sarvesh Singh

Authorized Signatory (Mr.Sarvesh Singh)

Service Engineer

For Transasia Bio-Medicals Ltd.

2 ones

Result Reprint

17	16	15	14	13	12	<u> </u>	10	9	œ	7	6	σı	4	ω	2	۵	Sr#	
S052024A	Lot#	Report Type																
ERBA NORM	Consumable	: Controls																
UREA	PHOS	ALPU	PRO	ALBD	CA	UA	HDLC	CHOL	TRIG	GLUR	CRENZ	BTDCA	BIDD	ALPU	SGOTD	SGPTD	Test	29-Jul-2021
32.4 mg/dl	4.00 mg/dl	154 U/L	5.32 g/dl	3.65 g/dl	8.8 mg/dl	6.4 mg/dl	40.0 mg/dl	147.7 mg/dl	117.5 mg/dl	87.7 mg/dl	1.05 mg/dl	1.59 mg/dl	0.60 mg/dl	111 U/L	42.8 U/L	40.4 U/L	Result Unit	
-2SD	-2SD	+2SD	-1SD		+1SD		-2SD		+1SD					-2SD		-1SD	Flag	
33329	33322	33315	33303	33302	33301	33300	33299	33298	33297	33296	33295	33293	33292	33290	33289	33288	Curve #	
29-Jul-2021 11:42:28	29-Jul-2021 11:40:22	29-Jul-2021 11:38:15	29-Jul-2021 10:43:52	29-Jul-2021 10:43:34	29-Jul-2021 10:43:16	29-Jul-2021 10:42:58	29-Jul-2021 10:42:40	29-Jul-2021 10:42:22	29-Jul-2021 10:42:04	29-Jul-2021 10:41:46	29-Jul-2021 10:41:28	29-Jul-2021 10:40:52	29-Jul-2021 10:40:34	29-Jul-2021 10:39:57	29-Jul-2021 10:39:39	29-Jul-2021 10:39:22	Result Date	
36.780	4.510		5.900		8.190	6.120	46.750	140.730	109.190	85.960	1.100	1.520	0.590	135.590	44.750	43.400	Mean	
1.840	0.230	9.040	0.300	0.180	0.410	0.310	3.120	7.040	5.460	4.300	0.060	0.130	0.050	9.040	2.980	2.890	SD	
31.26 - 42.3	3.82 - 5.2	108.47 - 162.71	5 - 5. X	2.98 - 4.06	6.96 - 9.42	5.19 - 7.05	37.39 - 56.11	119.61 - 161.85	92.81 - 125.57	73.06 - 98.86	0.92 - 1.28	1.13 - 1.91	0.44 - 0.74	108.47 - 162.71	35.81 - 53.69	34.73 - 52.07	Interval (3SD)	

Result Reprint

									00000	-
31.26 - 42.3	1.840	36.780	29-Jul-2021 12:18:49	33343	-1SD	33.2 mg/dl	UREA	ERBA NORM	S052024A	10
108.47 - 162.7	9.040	135.590	29-Jul-2021 12:16:43	33336	+2SD	160 U/L	ALPU	ERBA NORM	S052024A	18
Illicival (200)	Ę	Mean	Result Date	Curve #	Flag	Result Unit Flag	Test	Consumable	Sr# Lot#	Sr#
Internal /3	3						29-Jul-2021	: Controls	Report Type	

Result Reprint

	Report Type	: Controls	29-Jul-2021							
Sr#	Lot#	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
ا د	S052024A	ERBA NORM	SGPTD	40.4 U/L	-1SD	33288	29-Jul-2021 10:39:22	43.400	2.890	34.73 - 52.07
ν .	S052024A	ERBA NORM	SGOTD	42.8 U/L		33289	29-Jul-2021 10:39:39	44.750	2.980	35.81 - 53.69
ω 1	S052024A	ERBA NORM	ALPU	111 U/L	-2SD	33290	29-Jul-2021 10:39:57	135.590	9.040	108.47 - 162.71
4	S052024A	ERBA NORM	BIDD	0.60 mg/dl		33292	29-Jul-2021 10:40:34	0.590	0.050	0.44 - 0.74
ഗ്വ	S052024A	ERBA NORM	BTDCA	1.59 mg/dl		33293	29-Jul-2021 10:40:52	1.520	0.130	1.13 - 1.91
ი	S052024A	ERBA NORM	CRENZ	1.05 mg/dl		33295	29-Jul-2021 10:41:28	1.100	0.060	0.92 - 1.28
7	S052024A	ERBA NORM	GLUR	87.7 mg/dl		33296	29-Jul-2021 10:41:46	85.960	4.300	73.06 - 98.86
œ	S052024A	ERBA NORM	TRIG	117.5 mg/dl	+1SD	33297	29-Jul-2021 10:42:04	109.190	5.460	92.81 - 125.57
9	S052024A	ERBA NORM	CHOL	147.7 mg/dl	*	33298	29-Jul-2021 10:42:22	140.730	7.040	119.61 - 161.85
10	S052024A	ERBA NORM	HDLC	40.0 mg/dl	-2SD	33299	29-Jul-2021 10:42:40	46.750	3.120	37.39 - 56.11
1	S052024A	ERBA NORM	UA	6.4 mg/dl		33300	29-Jul-2021 10:42:58	6.120	0.310	5.19 - 7.05
12	S052024A	ERBA NORM	CA	8.8 mg/dl	+1SD	33301	29-Jul-2021 10:43:16	8.190	0.410	6.96 - 9.42
13	S052024A	ERBA NORM	ALBD	3.65 g/dl		33302	29-Jul-2021 10:43:34	3.520	0.180	2.98 - 4.06
14	S052024A	ERBA NORM	PRO	5.32 g/dl	-1SD	33303	29-Jul-2021 10:43:52	5.900	0.300	5-6.8
15	S052024A	ERBA NORM	ALPU	154 U/L	+2SD	33315	29-Jul-2021 11:38:15	135.590	9.040	108.47 - 162.71
16	S052024A	ERBA NORM	PHOS	4.00 mg/dl	-2SD	33322	29-Jul-2021 11:40:22	4.510	0.230	3.82 - 5.2
17	S052024A	ERBA NORM	UREA	32.4 mg/dl	-2SD	33329	29-Jul-2021 11:42:28	36.780	1.840	31.26 - 42.3