TABLE OF CONTENTS

TRANSASIA BIO-MEDICALS LTD. CHANDIGARH

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Siddharth Pandey	Sr. Application Specialist		

1.2 Checked By

Name	Designation	Signature	Date
Kuldeep	Manager		

1.3 Approved By

Name	Designation	Signature	Date
Manjit	Manager		

Note: After the Pre-Approval, this document is effective for the execution.

4.0 EXECUTION TEAM

Name	Department	Designation	Signature

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.
- The system meets the current regulatory requirements.
- 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:

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

TRANSASIA BIO-MEDICALS LTD. CHANDIGARH

5.0 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, 1/2 Reageants
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

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 intelligent photometer
- 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.

6.0 IDENTIFICATION OF MAJOR COMPONENTS / ACCESSORIES

Details of each major component identified in this section, is recorded in a data sheet under the section **08.0.**

Name of Component / Accessories	Present	Verified by Signature	Observations
	Yes / No		
Sample Tray / Disk	Yes		
Sample Syringe			
Sample Probe			
Wash Station for Sample Probe			
Reagent Tray / Disk			NIL
Reagent Bottles			
Reagent Probe			
Stirrer			
Permanent Reaction Cuvette			
9 Stage Laundry System			
Light Source			
Sample Cups			
Software of EM 200	Yes		

TRANSASIA BIO-MEDICAL LTD. CHANDIGARH

7.0 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	
2.	Verify that major components / accessories are securely anchored and shock proof.		
3.	Verify that there is no observable physical damage.		
4.	Verify that there is sufficient room of servicing provided		
5.	Verify that all utilities and electrical connections have been done according to the drawings.		
6.	Walking access to ground mounted instrument provided.		
7.	Required electric connections are tight, weather proof and earthed.		
8.	Instrument identification nameplate visible.		
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.		
10.	Verify that the instruments installed and leveled properly on the floor.		
11.	Verify that the Material of Construction is proper and meeting the requirements.	Yes	

TRANSASIA BIO-MEDICALS LTD. CHANDIGARH

8.0 INSPECTION CHECK / REVIEW

Instructions for completing the check / review

1. For each **data sheet,** record the required information with pen. Wherever required record "Yes" for acceptance, "No" for non-compliance and "NA" for not applicable.

   "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.

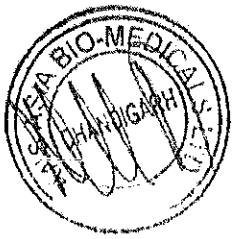
Instrument/ Component Name: Sample Tray / Disk

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions			
Standards / Stat	30 positions			
Blank	Can be put on any position			
ISE positions (Optional)	Can be programmed on any positions			
Controls	Can be programmed on any positions			

TRANSASIA BIO-MEDICALS LTD. BADDI (H.P.)

Instrument/ Component Name: Sample Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 µL	60 uL	OK	
Installed Location	Behind the instrument on the right side	—	OK	
Quantity	01 No.	01	OK	
Increase in dispensing volume	0.2 µL	0.2 uL	OK	



Instrument/ Component Name: Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 – 70 µL	Complies	OK	
MOC	Teflon coated	Complies	OK	
Quantity	01 No.	Complies	OK	
Increase in aspiration volume	0.2 µL	Complies	OK	

Instrument/ Component Name: Wash Station for Sample Probe

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	✓	✓	✓
Type of positions	i) Drain ii) Trough	✓	✓	

Instrument/ Component Name: Reagent Tray / Disk

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

Instrument/ Component Name: Reagent Bottles

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

Instrument/ Component Name: Reagent Probe

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

Instrument/ Component Name: Reagent Syringe

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 µL	✓	✓	
Installed Location	At the back of the instrument on the right side	✓	✓	
Quantity	01 No.	✓	✓	
Increase in dispensing volume	1 µL	✓	✓	

Instrument/ Component Name: Stirrer

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	✓	✓	
No. of paddles	01 No.	✓	✓	

TRANSASIA BIO-MEDICALS LTD. CHANDIGARH

Instrument/ Component Name: Permanent Reaction Cuvette

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 Nos	✓	✓	
MOC	Hard Glass	✓	✓	
Capacity	770 µL	✓	✓	

Instrument/ Component Name: 7 Stage Laundry System

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1	✓	✓	
	Nozzle – 2	✓	✓	
	Nozzle – 3	✓	✓	
	Nozzle – 4	✓	✓	
	Nozzle – 5	✓	✓	
	Nozzle – 6	✓	✓	
	Nozzle - 7	✓	✓	

TRANSASIA BIO-MEDICALS LTD.

Instrument/ Component Name: Light Source

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W	✓	✓	
Volts	12 V	✓	✓	
MOC	Halogen	✓	✓	
Quantity	01 No	✓	✓	

TRANSASIA BIO-MEDICALS LTD CHANDIGARH

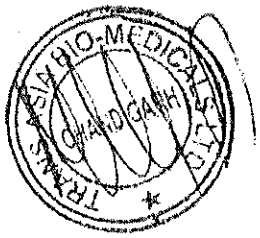
Instrument/ Component Name: Sample Cups

Date :

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 Nos'	✓	✓	
MOC	Plastic	✓	✓	✓
Capacity	2 mL	✓	✓	

Instrument/ Component Name: Software of EM 360

Description	Specified	Actual	Method of Verification	Verified by Signature
Version		✓	✓	✓
CD number		✓	✓	
Product	EM- 200	✓	✓	
Make	Erba Transasia	✓	✓	



9.0 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	✓	✓	
Reagent Probe	Teflon coated	✓	✓	
Permanent Reaction Cuvette	Hard Glass	✓	✓	
Light Source	Halogen	✓	✓	
Reagent Bottle	Plastic	✓	✓	
Sample Cups	Plastic	✓	✓	

10.0 IDENTIFICATION AND VERIFICATION OF SUPPORTING UTILITIES

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

Utilities	Observation / Result	Verified by Sign & Date
Power	✓	
Distilled Water	✓	
Wash Solution	✓	
UPS	✓	

11.0 IDENTIFICATION OF STANDARD OPERATING PROCEDURE

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

12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing		

12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
General		
Purchase Order No.		
Warranty Certificate		
Invoice		
Test Certificates		
Material of Construction		
Electrical Motor		

13.0 DEFICIENCIES / DEVIATIONS:

N/C

Reviewed by:

Name	Signature	Date
Kalcy	✓	✓

14.0 SUMMARY AND EVALUATION:

Reviewed by:

Name	Signature	Date
Kuldeep		

15.0 ABBREVIATIONS

SOP	**Standard Operating Procedure**
MOC	Material of Construction
IQ	Installation Qualification

16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date
Kuldeep	Manager		

16.2 Approved by

Name	Designation	Signature	Date
Manik	Manager		

Note: This report is effective from the date of approval.

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

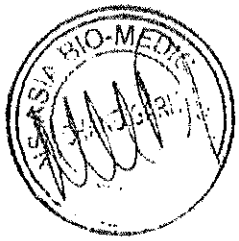
To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

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.



TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Clinical Chemistry Analyzer**	**Instrument ID**	**v200403**	

1.0 INSTRUMENT START-UP:

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

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

2.0 FUNCTIONAL CHECKS:

2.1 Maintenance:

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

Activity	Observation	Verified by (Sign & Date)	Remarks
Photometer functioning	✓	B	✓
Cuvette Rinse	✓	B	✓

2.2 Loading of Reagents:

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

Action	Observation	Verified by (Sign & Date)	Remarks
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	✓	6	—

2.3 Calibration:

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

Action	Observation	Verified by (Sign & Date)	Remarks
Blank (Distilled Water)	✓	✓	—
Standard (Multical)	✓	✓	✓

3.0 INTERLOCKS AND ALARMS CHECK:

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

Action	Observation	Verified by (Sign & Date)	Remarks
Less volume of Distilled Water	✓	✓	—
Less volume of Wash Solution	✓	✓	—
More volume of Bio-Hazard waste	✓	✓	—
More volume of Normal / General waste	✓	✓	✓

4.0 SAFETY / SECURITY CHECKS:

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

Action	Observation	Verified by (Sign & Date)	Remarks
Password Check for Test Parameters	✓	✓	✓
Password Check for QC Mode	✓	✓	✓

5.0 INSTRUMENT SHUT-DOWN:

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

Action	Observation	Verified by (Sign & Date)	Remarks
Sample Probe Wash	✓	✓	—
Water Save	✓	✓	—
Switch OFF the computer.	✓	✓	—
Switch OFF the side switch of the analyzer.	✓	✓	—
Switch OFF the rear switch of the analyzer.	✓	✓	—

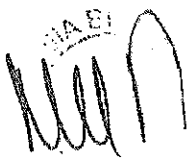


TABLE OF CONTENTS

1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
Siddharth Pandey	Sr. Application Specialist		1/2/2023

1.2 Checked By

Name	Designation	Signature	Date
Kuldeep	Manager	Kuldeep	7/2/2023

1.3 Approved By

Name	Designation	Signature	Date
MANIT	MANAGER		7/02/2023

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 to PQ.
- Completion of Operational Qualification prior to PQ.

5.0 EXECUTION TEAM

Name	Department	Designation	Signature

6.0 TEST PLAN

The following tests shall be followed, during the Performance Qualification of EM 200 (Bio-Chemistry Random Analyzer).

Test Parameter	Acceptance Criteria	Test Procedure / Reference
SGOT	CV% less than 5%	As Manufacturer Guidelines
Chol	CV% less than 5%	As Manufacturer Guidelines
BIT	CV% less than 5%	As Manufacturer Guidelines

8.0 DEFICIENCIES / DEVIATIONS:

Reviewed by:

Name	Signature	Date
Kuldeep		20/02/2023 21/02/2023

7.0 EXECUTION OF TEST PLAN

Reviewed by:

Name	Signature	Date

Reviewed by:

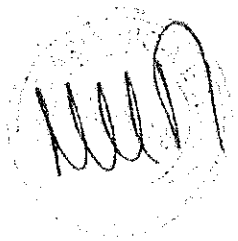
Name	Signature	Date
Kuldeep		01/02/2023

10.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
PQ	Performance Qualification

9.0 SUMMARY AND EVALUATION:

S.NO	SGOT	Chol	BIT
1	139.0	252	4.96
2	141.4	250	4.95
3	142.3	249	4.98
4	142.3	231	4.96
5	141.4	250	4.96
6	145.7	248	4.93
7	144.1	252	4.96
8	139.9	247	4.93
9	141.7	247	4.90
10	140.5	249	4.94
SD	**1.96**	**6.06**	**0.02**
CV%	**1.38**	**2.45**	**0.46**
Acceptable	**Less than 5%**	**Less than 5%**	**Less Than 5%**



11.0 POST APPROVAL

11.1 Checked by

Name	Designation	Signature	Date
Kuldeep	Mangr		6/07/2023

11.2 Approved by

Name	Designation	Signature	Date
Manit	Manager		6/07/2023

Note: This report is effective from the date of approval.