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NEUATION

Microplate Shaker iShak BL UNO VT

IQ-OQ-PQ DOCUMENT

QUALIFICATION OF Shaker iShak BL UNO VT

MAKE : Neuation, India

MODEL NO : Microplate Shaker iShak BL UNO VT

SERIAL NO : 03049427

INSTALLATION NO : 02

PURCHASE ORDER NO : MPUH/10/2021/PUR/29

DESCRIPTION OF SYSTEM / EQUIPMENTS:

Microplate Shaker iShak BL UNO VT is a laboratory equipment used to mix, blend, or to agitate substances in microplate by shaking them, which is mainly used in the fields of chemistry and biology. For further detail kindly refer User manual.

SAFETY REQUIREMENT:

- ✓ Ensure that only trained staff work with the appliance.
- ✓ Socket must be earthed (protective ground contact).

QUALIFICATION OF Shaker iShak BL UNO VT

- ✓ Set up the appliance in a spacious area on an even, stable, clean, non-slip, dry and fireproof surface.

QUALIFICATION OF Shaker iShak BL UNO VT

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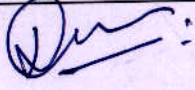
QUALIFICATION OF Shaker iShak BL UNO VT

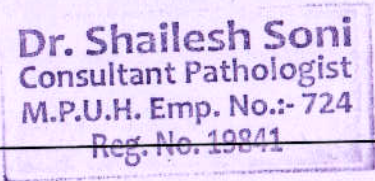
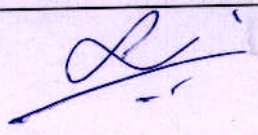
CHECKLIST FOR INSPECTION OF Microplate Shaker iShak BL UNO VT (To be checked on receipt of the equipment)

SL. NO.	ITEM	QTY	ACCEPTANCE CRITERIA	OBSERVATION
1.	Shaker - iShak BL UNO VT	1 No	Available along with Package	Yes
2.	Standard Attachment	1 No	Available along with Package	Yes
3.	Operating Manual	1 No	Available along with Package	Yes
4.	Warranty Registration Card	1 No	Available along with Package	Yes

QUALIFICATION OF Shaker iShak BL UNO VT

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Padhyas	 28/12/2021

Name of the Department Head	Signature/Date
 Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.: 724 Reg. No. 19841	 28/12/2021

INSTALLATION QUALIFICATION

QUALIFICATION OF Shaker iShak BL UNO VT

1. Purpose: The purpose of Installation Qualification is to establish that the Microplate Shaker and its Components are as per the specifications and are installed as per the approved procedure.

2. Scope: Installation 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 Location suitability:		
1.1 Size & Location of Shaker	The instruments should not be exposed to direct sunlight and placed rigid table	OK
1.2 Weight & Structural suitability	The civil structure should be suitable to accommodate the Platform Shaker	OK
1.3 Utilities		
<u>Electrical supply:</u>	Should be 230 VAC, 50-60 Hz.	OK
<u>Safety provisions:</u>	Proper Earthing should be provided.	
<u>Environmental conditions:</u>	Temperature 25°C ±5°C	
2.0 Installation as per manufacturers instruction	Personing/Production/ Quality Assurance To certify.	OK
3.0 Safety		

QUALIFICATION OF Shaker iShak BL UNO VT


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	04

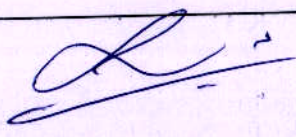
TECHNICAL DETAILS

DEVICE	Microplate Shaker iShak BL UNO VT
Type of Motor	BLDC motor
Speed range	300 - 1800 rpm
Run Time	1 min to 99 mins & infinite mode
Maximum Volume	384x60 μ l
LED Indicator	Power on LED indicator
Output Voltage	9VDC, 1.5A
Ambient Temperature	5 - 40°C
Power Consumption	15 W
Dimensions(L x W x H)	127 x 85 x 86 (mm)
Noise Level	<60 dB

QUALIFICATION OF Shaker iShak BL UNO VT

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Padhiyar	 28/12/2021

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

OPERATIONAL QUALIFICATION

1. **Purpose:** The purpose of Operation Qualification is to establish that the Microplate Shaker and its Components are as per the specifications and are installed as per the approved procedure.

2. **Scope:** Operation Qualification to be performed at the time of Operation.

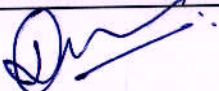
QUALIFICATION OF Shaker iShak BL UNO VT


3. Responsibility: R&D, Personing, Safety and Quality Assurance.

4. Critical Variables to be met:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION
Operate the instrument as per manufacturer's manual	Should function as desired	OK
Press the ON/OFF key to switch on the unit	Display glowing indication	OK
To select Rotor	As directed in manual	OK
To set the timing in mins(i.e.5,10,15)	As directed in manual	OK
To set the RPM	As directed in manual	OK
3.0 Maintenance and cleaning.	As per given in the manual.	OK
4.0 Training.	No. of personnel to be trained	04

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Pachiyas	 28/12/2021

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

QUALIFICATION OF Shaker iShak BL UNO VT

PERFORMANCE QUALIFICATION

1. **Purpose:** The purpose of Performance Qualification is to establish that the Microplate Shaker 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 Operation.



3. **Responsibility:** R&D, Personing, Safety and Quality Assurance.

4. **RPM Verification:**

(i) Measure with Calibrated Tachometer.


(ii) The set RPM showed match with the measured RPM.

FOLLOWING PARAMETERS ARE CHECKED FOR ITS PERFORMANCE:

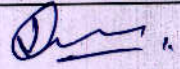
Set in RPM	Observed in RPM	Acceptable in RPM	Deviation in RPM	APPROVED BY
500	510	± 50	± 10	
1100	1075	± 50	-25	

5. **Time Verification:**


(i) Measured with Digital Stopwatch.

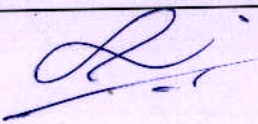
Set in Time	Observed in Time	Acceptable in Time	Deviation in Time	APPROVED BY
01:00	01:00	± 2	00:00	

QUALIFICATION OF Shaker iShak BL UNO VT

05:00	05:00	$\pm 2\%$	00:00	
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Checking sign off:

Name of the Person	Signature/Date
Kamlesh Padhiyar	 28/12/2021

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

TRAINING CERTIFICATE

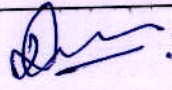
This is to certify that the following personal of M/S. Reshamu Patel are trained how to use the Microplate Shaker as per manual.


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QUALIFICATION OF Shaker iShak BL UNO VT

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Checking sign off:

Name of the Person	Signature/Date
Kamlesh Padhiyar	 28/12/2021


Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

EQUIPMENT HANDOVER CERTIFICATE


QUALIFICATION OF Shaker iShak BL UNO VT

This is to certify that the Microplate Shaker iShak BL UNO VT Make Neuation Technologies, India has been qualified and is here with approved for regular R & D experiments.

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Padhiyas	 : 28/12/2021

QUALIFICATION OF Shaker iShak BL UNO VT

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021

INSTALLATION QUALIFICATION REPORT

This is to certify that the Microplate Shaker iShak BL UNO VT Make Neuation, India has been installed successfully as per user requirement.

MAKE : Neuation, India

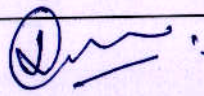
MODEL NO : Microplate Shaker iShak BL UNO VT

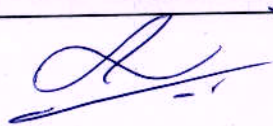
SERIAL NO : QJ049427

INSTRUMENT ID : MPUH/LAB/CLIA/EQUIP/11

QUALIFICATION OF Shaker iShak BL UNO VT

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Pachiyar	 28/12/2021

Name of the Department Head	Signature/Date
<p>Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841</p>	 28/12/2021

QUALIFICATION OF Shaker iShak BL UNO VT

OPERATION QUALIFICATION REPORT

This is to certify that the Microplate Shaker iShak BL UNO VT Make Neuation, India has been installed and is operating as per user manual.

MAKE : Neuation, India


MODEL NO : Microplate Shaker iShak BL UNO VT

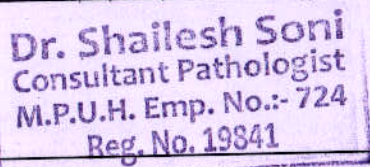

SERIAL NO : Q70 49427

INSTRUMENT ID : MPUH / LAB / CLIA / EQUIP / 11

QUALIFICATION OF Shaker iShak BL UNO VT

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Padriyas	 28/12/2021

Name of the Department Head	Signature/Date
	 28/12/2021

PERFORMANCE QUALIFICATION REPORT

This is to certify that the Microplate Shaker iShak BL UNO VT Make Neuation, India has been installed and is performing as per specifications.

MAKE : Neuation, India

MODEL NO : Microplate Shaker iShak BL UNO VT

QUALIFICATION OF Shaker iShak BL UNO VT

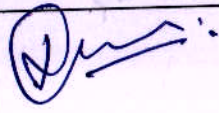
SERIAL NO


: QJ0 49427

INSTRUMENT ID

: MPDH / LAB / CLIA / EQUIP / 11

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Paudyal	 28/12/2021

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2021