

Done

NEUATION

LABORATORY CENTRIFUGE

I FUGE L400P

IQ-OQ-PQ DOCUMENT

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

MAKE : Neuation, India
MODEL NO : Laboratory Centrifuge - I Fuge L400p
SERIAL NO : QE038534
INSTALLATION NO : 01
PURCHASE ORDER NO : MPUH/10/2021/PUR/29

DESCRIPTION OF SYSTEM / EQUIPMENTS:

Laboratory Centrifuge - I Fuge L400p is used for separation of fluids, gas or liquid based on density. Separation is achieved by spinning a vessel containing material at high speed; the centrifugal force pushes the materials with higher density to the bottom of the tube and lighter density material floats on the top. 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 CENTRIFUGE - I Fuge L400p

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

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

CONTENTS

SL. NO.	DESCRIPTION	PAGE NO.
1.	CHECKLIST FOR CHECKING THE EQUIPMENT ON RECEIPT	04
2.	INSTALLATION QUALIFICATION	05
3.	TECHNICAL DETAILS	06
4.	OPERATION QUALIFICATION	07
5.	PERFORMANCE QUALIFICATION	08
6.	TRAINING CERTIFICATE	09
7.	HAND OVER CERTIFICATE	10


QUALIFICATION OF CENTRIFUGE - I Fuge L400p


CHECKLIST FOR INSPECTION OF LABORATORY CENTRIFUGE - I Fuge L400p (To be checked on receipt of the equipment)

SL. NO.	ITEM	QTY	ACCEPTANCE CRITERIA	OBSERVATION
1.	CENTRIFUGE - I Fuge L400p	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 CENTRIFUGE - I Fuge L400p

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Padhiya	 28/12/2022

Name of the Department Head	Signature/Date
Dr. Shailesh Soni Consultant Pathologist M.P.U.H. Emp. No.:- 724 Reg. No. 19841	 28/12/2022

INSTALLATION QUALIFICATION

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

1. **Purpose:** The purpose of Installation Qualification is to establish that the Laboratory Centrifuge 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 Centrifuge	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 Laboratory Centrifuge	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

QUALIFICATION OF CENTRIFUGE - I Fuge L400p


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	04


TECHNICAL DETAILS

DEVICE	LABORATORY CENTRIFUGE - I Fuge L400p
Type of Motor	(BLDC) Brushless DC motor
Speed range	500- 4500 rpm
Speed display	DIGITAL Display
Speed min (adjustable)	500 rpm
Timer	1 to 999 Mins & infinite mode
Weight	23 kg (without rotor)
Power consumption	460W
Size (L x B x H)	475 x 585 x 325 mm

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Pachhija	 : 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

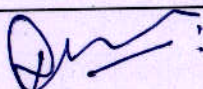
OPERATIONAL QUALIFICATION

QUALIFICATION OF CENTRIFUGE - I Fuge L400p


1. **Purpose:** The purpose of Operation Qualification is to establish that the Laboratory Centrifuge 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.
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	Working Properly
Press the ON/OFF key to switch on the unit	Display glowing indication	Working Properly
To select Rotor	As directed in manual	Working Properly
To set the timing in mins(i.e.5,10,15)	As directed in manual	Working Properly
To set the RPM	As directed in manual	Working Properly
3.0 Maintenance and cleaning.	As per given in the manual.	Working Properly
4.0 Training.	No. of personnel to be trained _____	4

Checking sign off:

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

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

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

PERFORMANCE QUALIFICATION

1. **Purpose:** The purpose of Performance Qualification is to establish that the Laboratory Centrifuge 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.

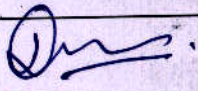

3. **Responsibility:** R&D, Personing, Safety and Quality Assurance.

4. RPM Verification:


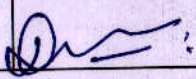
(i) Measure with Calibrated Tachometer.

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


FOLLOWING PARAMETERS ARE CHECKED FOR ITS PERFORMANCE:

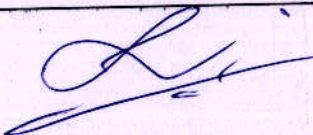
Set in RPM	Observed in RPM	Acceptable in RPM	Deviation in RPM	APPROVED BY
1500	1483	± 100	- 17	
2500	2497	± 100	- 3	

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

Set in Time	Observed in Time	Acceptable in Time	Deviation in Time	APPROVED BY
01:00	01:00	$\pm 2\%$	00:00	
05:00	05:00	$\pm 2\%$	00:00	

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Paethiyas	 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. ELIZABETH ROLAND THAKOR are trained how to use the Laboratory Centrifuge as per manual.

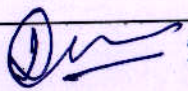
➤

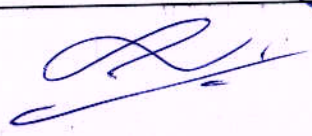
➤

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

-
-
-
-
-

Checking sign off:

Name of the Person	Signature/Date
Kamlesh Paethiyas	 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 CENTRIFUGE - I Fuge L400p


EQUIPMENT HANDOVER CERTIFICATE

This is to certify that the Laboratory Centrifuge I Fuge L400p Make Neuation Technologies, India has been qualified and is here with approved for regular R & D experiments.

QUALIFICATION OF CENTRIFUGE - I Fuge L400p

Checking sign off:

Name of the Person	Signature/Date
Kumlesh Pachriya	 : 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

S