



OPERATIONAL QUALIFICATION PROTOCOL FOR WATER BATH

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



OPERATIONAL QUALIFICATION PROTOCOL FOR WATER BATH

1.0 Objective:

- To determine that the equipment operates according to specifications, and to record all relevant information's and data to demonstrate its functions as intended for.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Water Bath
ID Number
Location	Media Preparation Room

3.0 Checklist for Operational verification:

Operation of Water bath is verified for the compliance with the critical parameters mentioned in the Functional Specification. Sequentially prepare the list of operating checks specifying critical parameters, perform them as per operating procedure as mentioned in the vender operating manual & document the same in the attached check list (Annexure - I).

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II

5.0 Identification & preparation of Standard Operating Procedures:

Prepared the SOP for cleaning, calibration and operation of Water bath using the actual feedback from the operation checks and vendor-operating manual. The preventive maintenance procedure and schedule shall be applicable as per Annual Maintenance Contract of QC Instrument.

<u>S. No.</u>	<u>SOP Title</u>	<u>SOP Number</u>
1.	Cleaning, Calibration and Operation of Serological Water bath



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6.0 Training

The List of QC (Microbiology) person trained during the operation qualification of Water Bath is listed as per Annexure - III.

7.0 Recommendations and Conclusions:

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8.0 References:

- Installation Qualification
- Operating Manual submitted by the Vendor.

9.0 Annexure

- Annexure - I : Checklist for Operational Verification.
- Annexure - II : List of Changes / Deviation.
- Annexure - III : Training Detail

10.0 Abbreviations:

- SOP : Standard Operating Procedure
- QC : Quality Control



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Annexure - I

Checklist for Operational Verification

S.No.	Operating Parameters	Function	Observation	Remarks
A.	Control Panel Testing			
1.	Mains key	To start the machine		
2.	MAINS button	To start the instrument (LCD Display)		
3.	SET Button	For Setting of Temperature		
4.	Coarse Button (Fine tuning pot)	Setting of desired temperature by turning clock wise or anti clock wise		
3.	RESET Button	For resetting the desired temperature		



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Annexure - II

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

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Annexure - III

Training Detail

S.No.	Name of Trainee	Name of Trainer

Verified By:

Approved By: