



**INSTALLATION QUALIFICATION PROTOCOL FOR WATER BATH**

**Pre - Execution Approval**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



## INSTALLATION QUALIFICATION PROTOCOL FOR WATER BATH

### 1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Water Bath.
- To determine that the Water Bath performs as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets predefined specifications under normal conditions and where appropriate for worst case situations.

### 2.0 Scope:

Scope is limited to the following

<b>Equipment / System Name</b>	<b>Water Bath</b>
<b>ID Number</b>	.....
<b>Location</b>	<b>Media Preparation Room</b>

### 3.0 Performance Verification Checklist:

Verify the performance of all the critical process/functions as per their respective procedure defined in SOP and ensure the reproducibility. Record the raw data as per Annexure - I.

### 4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II.

### 5.0 Recommendations and Conclusions:

### 6.0 References:

Installation Qualification  
Operational Qualification  
Standard Operating Procedure



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**7.0 Annexure**

Annexure - I : Performance Verification Checklist

Annexure - II : List of Changes / Deviation.

Annexure - III : Performance Qualification Report.

**8.0 Abbreviations:**

SOP : Standard Operating Procedure

**Post execution approval:**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



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**Annexure - I**

**Checklist for Performance Verification**

<b>Temperature Mapping of Water Bath</b>				
<b>Controller Set Point (Temperature)</b>	<b>Acceptance Criteria</b>	<b>Temperature Mapping Result</b>	<b>Remarks</b>	<b>Verification Done By</b>
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**Note:**

**Remarks:** - Performance Verification of Water Bath - Complies / Does not comply.



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**Annexure - II**

**List of Changes / Deviations**

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

**Verified By:**

**Approved By:**