



INSTALLATION QUALIFICATION PROTOCOL FOR ANALYTICAL BALANCE

Pre - Execution Approval

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



INSTALLATION QUALIFICATION PROTOCOL FOR ANALYTICAL BALANCE

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 | Analytical Balance |
| ID Number | |
| Location | Media Preparation Room |

3.0 Checklist for Operational verification:

Operation of Analytical Balance 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 operation, cleaning and calibration of Analytical Balance 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.

S. No. SOP Title SOP Number

1. Operation, cleaning and calibration
Of Analytical Balance



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6.0 Training

The List of QC (Microbiology) person trained during the operation qualification of Analytical Balance 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

Post execution approval:

| | Name | Designation | Signature | Date |
|-------------|-------------|--------------------|------------------|-------------|
| Compiled By | | | | |
| Reviewed By | | | | |
| Reviewed By | | | | |
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| Approved By | | | | |



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Annexure - I

Checklist for Operational Verification

| S.No. | Operating Parameters | Function | Observation | Remarks |
|-------|--|---------------------------------|-------------|---------|
| A. | Operating parameter of analytical balance | | | |
| 1. | ON / OFF | To ON / OFF the balance | | |
| 2. | → O / T ← | For Tare | | |
| 3. | C | To Zero | | |
| 4. | F | To change mode gm / mg | | |
| 5. | Cal / Menu | For internal calibration / menu | | |



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Annexure - II

List of Changes / Deviations

| S.No. | Description of Change / Deviations | Justification based on impact analysis |
|-------|------------------------------------|--|
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Verified By:

Approved By:



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Annexure - III

Training Detail

| S.No. | Name of Trainee | Name of Trainer |
|-------|-----------------|-----------------|
| | | |
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| | | |
| | | |
| | | |

Verified By:

Approved By: