



**PERFORMANCE QUALIFICATION PROTOCOL FOR ANALYTICAL BALANCE**

**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 |             |                    |                  |             |



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**1.0 Objective:**

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Analytical Balance.
- To determine that the Analytical Balance 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>Analytical Balance</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. Refer Performance Verification Checklist as per Annexure - I.

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

Refer Annexure – II.

**5.0 Recommendations and Conclusions:**

.....  
.....  
.....  
.....  
.....



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**6.0 References:**

- Installation Qualification
- Operational Qualification
- Standard Operating Procedure

**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 |             |                    |                  |             |



**PERFORMANCE QUALIFICATION PROTOCOL FOR ANALYTICAL BALANCE**

**Annexure - I**  
**Checklist for Performance Verification**

**(A) Measurement Uncertainty Test:**

| Standard Weight: _____                |                | Standard Weight: _____          |                |
|---------------------------------------|----------------|---------------------------------|----------------|
| Standard Weight: _____                |                | Standard Weight: _____          |                |
| S.No.                                 | Observed Value | S.No.                           | Observed Value |
| 1.                                    |                | 1.                              |                |
| 2.                                    |                | 2.                              |                |
| 3.                                    |                | 3.                              |                |
| 4.                                    |                | 4.                              |                |
| 5.                                    |                | 5.                              |                |
| 6.                                    |                | 6.                              |                |
| 7.                                    |                | 7.                              |                |
| 8.                                    |                | 8.                              |                |
| 9.                                    |                | 9.                              |                |
| 10.                                   |                | 10.                             |                |
| Average                               |                | Average                         |                |
| Standard Deviation                    |                | Standard Deviation              |                |
| % RSD                                 |                | % RSD                           |                |
| <b>Random Error:</b>                  |                | <b>Random Error:</b>            |                |
| <b>Systematic Error:</b>              |                | <b>Systematic Error:</b>        |                |
| <b>Measurement Uncertainty:</b>       |                | <b>Measurement Uncertainty:</b> |                |
| <b>Acceptance Criteria: NMT 0.1 %</b> |                |                                 |                |



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**(B) Uncertainty Test:**

| Standard Weight | Certified Value | Observed Value | % Difference | Acceptance Criteria | Remarks |
|-----------------|-----------------|----------------|--------------|---------------------|---------|
| 100 mg          |                 |                |              | ± 0.1 %             |         |
| 200 mg          |                 |                |              | ± 0.1 %             |         |
| 500 mg          |                 |                |              | ± 0.1 %             |         |
| 1 gm            |                 |                |              | ± 0.1 %             |         |
| 2 gm            |                 |                |              | ± 0.1 %             |         |
| 5 gm            |                 |                |              | ± 0.1 %             |         |

**(B) Eccentricity / off Center Accuracy Test:**

| Position      | Certified Value | Observed Value | % Difference | Acceptance Criteria | Remarks |
|---------------|-----------------|----------------|--------------|---------------------|---------|
| Center        |                 |                |              | ± 0.1 %             |         |
| Right Corner  |                 |                |              | ± 0.1 %             |         |
| Left Corner   |                 |                |              | ± 0.1 %             |         |
| Top Corner    |                 |                |              | ± 0.1 %             |         |
| Bottom Corner |                 |                |              | ± 0.1 %             |         |

**Note:**

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

**Verification Done By:**



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**Annexure - II**

**List of Changes / Deviations**

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

**Verified By:**

**Approved By:**