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:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Analytical Balance is installed as per design.
- To ensure that the Analytical Balance installed confirms to purchase specifications and manufacturer literature, and to document the information that the Analytical Balance meets the specification.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**Analytical Balance**
ID Number	**……..**
Location	**Media Preparation Room**

3.0 Equipment / System Description:

Pharmacopeial test, assays and preparation of media etc for different testing purpose require balance that varies in capacity, sensitivity and reproducibility. When substances are to be accurately weighed for assay, the weighing is to be performed with a weighing device whose measurement uncertainty does not exceed 0.1 % of the reading. Measurement uncertainty satisfactory if three times the standard deviation of not less than ten replicate weighing divided by the amount weighed, does not exceed 0.001.

A weight class is chosen so that the tolerance of the weights used does not exceed 0.1 % of the amount weighed. Generally class 2 may be used for quantities greater than 20 mg, class 3 for quantities of greater than 50 mg and class 4 for quantities of greater than 100 mg. Weights should be calibrated periodically against an absolute standard weight.

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4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

5.0 Checklist for Installation verification:

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

8.0 References:

Copy of Purchase order

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification

Annexure - VII : Copy of Purchase order

10.0 Abbreviations:

IQ	:	Installation Qualification
%	:	Percentage
mg	:	Milligram

Post execution approval:

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

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Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.	……..		
2.	Vendor's Name	Mettler - Toledo India Pvt. Ltd. Amar Hill, Saki Vihar Road, Mumbai		
3.	Instrument Make	Mettler Toledo		
4.	Instrument Model No.	……..		
5.	Instrument Manual	Instrument Manual submitted by the vendor		

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Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
1.	Analytical Balance	Mettler Toledo		
B.	**Location suitability**			
1.	Placement	Should be place In Media Preparation Room		
2.	Temperature	Ambient		
3.	Relative Humidity	Not More than 55 %		
4.	Bench Surface	Non Vibrating		
5.	Static Electricity	Negligible		
6.	Area	Free from strong magnetic field		
7.	Location	A location that minimizes the chance of water entering the underside		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
C.	**Utilities**			
1.	Electrical power supply	A Stable source of 100 - 220 VAC ± 10 – 15 %, 50 - 60 Hz, should be provided		
D.	**Safety**			
1.	Safety	Balance should connect to a correctly installed line power outlet having protective conductor (Earth / ground)		
		Should not make internal adjustment except as directed in the manual		
		Should not operate the balance with any covers or parts removed		
		If the balance is not horizontal from the beginning, it will have to leveled during initial operation		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
D.	**Safety**			
1.	Safety	Should not connect the balance or AC adaptor to the power supply if local power supply voltage is not in range i.e. 100 - 220 VAC ± 10 – 15 %, at 50 - 60 Hz.		
E.	**MOC Certificates**	Not Applicable		
F.	**Calibration Certificates**			
1.	Certificates of Weights	Certificates of Weights should be provided		
G.	**Testing Certificates**	Not Applicable		
H.	**Drawing Details**	**Drawing No.**		
1.	Not Applicable	Not Applicable		

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Annexure - III

List of changes / Deviations

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

Verified By:

Approved By:

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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

_____

_____

_____

_____

_____

_____

Summary Report Prepared By:

Date & Sign