PERFORMANCE QUALIFICATION OF ANALYTICAL BALANCE

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

PERFORMANCE QUALIFICATION OF ANALYTICAL BALANCE

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1.0 Pre-Approval:

Signing of this Approval page of Performance Qualification Protocol No..... indicates agreement with the Performance Qualification approach described in this document. Should Modifications to the Performance Qualification become necessary, an addendum will be prepared and approved.

Written By	Signature	Date
Officer – Production		

Checked By	Signature	Date
Manager – Production		
Manager – Quality Assurance		

Approved By	Signature	Date
Manager - Quality Assurance		
General Manager - Works		

PERFORMANCE QUALIFICATION OF ANALYTICAL BALANCE

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the performance attributes of the *Mettler Toledo AB204-S Analytical Balance*, critical to serve the intended purpose.
- To document the observations for future reference.
- To provide documented evidence that the *Mettler Toledo AB204-S Analytical Balance* is operated and performed s per the Standard Operating Procedure.

2.2 Scope:

This protocol covers the performance Qualification of Analytical Balance (Mettler Toledo – AB204 – S)

2.3 Responsibility:

The group comprising of representatives from each of the following departments shall be responsible for the overall compliance with this protocol:

- Production Department
- Quality Assurance Department

The Production and In Process Quality Control shall be responsible for Performing as well as the checking of the Performance Qualification along with the Quality Assurance and recording data as per the procedures outlined in this protocol.

Manager Quality Assurance shall collect all the test data and shall compile the results to make the reports of qualification studies.

The Reports shall be checked by Manager Quality Assurance.

The Manager-Quality Assurance and Plant Head shall finally approve the Qualification report.

2.4 Requalification:

Performance Qualification to be repeated incase of

- Replacement of any major component.
- Major modification in the existing instrument.
- During monitoring if instrument. is found to be malfunctioning.
- Shifting of the instrument from one location to another.

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2.5 Instrument Identification

The Instrument is identified as ***Analytical Balance, Model AB204-S***

Serial No. : _____

In-house Instrument No. : .....

Name of the Supplier : _____

Purchase Order No. : _____ Dated _____

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3.0 Performance Qualification

3.1 Performance Qualification Procedure

Perform the Qualification as per the following procedure.

3.1.1 Operate the instrument as per the SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.2.

3.1.2 Perform the Internal Calibration (Adjustment) and Calibration (Adjustment) with the External weights and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.3 Perform the Calibration of the Instrument Calibrated Weights for the full range and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.4 Check repeatability ten times with 0.5 g weight and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.5 Check off-center error with 0.5 g weight and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.6 Report the deficiency from the specified function, if any in the section 3.4

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3.2 SOP Verification:

SOP No. :

Title :

Operate the instrument. as per the draft SOP and record the details given below:

Operated By : ……

Checked By : ……...

The operating personnel understand and follow the SOP description (Yes/No) : YES

Changes required in draft SOP (If any) :

_____

_____

_____

SOP to be revised (Yes/No) : NO

If yes, Review No. _____

Remarks : SOP Confirmed / Not Confirmed

Verified By :

Name : _____ Signature : _____ Date : _____

3.3 Performance Qualification Test Data Sheet:

3.3.1 Internal Calibration (Adjustment) and Calibration (Adjustment) with External weights:

Type of the Calibration	Observations	Checked By (Sign / Date)
Internal Calibration (Adjustment)		
Calibration (Adjustment) with External weights		

Verified By :

Name : _____ Signature : _____ Date : _____

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3.3.2 Calibration by External Weights

Details of the weight box …….

S.No.	Standard Weights	Actual Weight	Tolerance Limits	Observed Weights	Remarks	Done By
1.	200 g		± g			
2.	100 g		± g			
3.	50 g		± g			
4.	20 g		± g			
5.	10 g		± g			
6.	5 g		± g			
7.	2 g		± g			
8.	1 g		± g			
9.	0.5 g		± g			
10.	0.2 g		± g			
11.	0.1 g		± g			
12.	0.05 g		± g			
13.	0.02 g		± g			
14.	0.01 g		± g			

Verified By :

Name : _____ Signature : _____ Date : _____

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3.3.3 Uncertainty measurement of 0.2g weight

Details of the weight box ……

S.No.	Observed Weights	Remarks	Done By
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
Avg.			
SD			

Calculation for uncertainty = $\frac{3 \times \text{S.D.}}{\text{Reported standard mass weight (g) (as per certificate)}}$

= ---------- =

Verified By :

Name : _____ Signature : _____ Date : _____

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3.3.4 Uncertainty measurement of 0.5 g weight

Details of the weight box ……

S.No.	Observed Weights	Remarks	Done By
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
Average			
SD			

Calculation for uncertainty = $\frac{3 \times \text{S.D.}}{\text{Reported standard mass weight (g) (as per certificate)}}$

= ---------- =

Verified By:

Name : _____ Signature : _____ Date : _____

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3.3.5 Uncertainty measurement of 1.0 g weight

Details of the weight box ……

S.No.	Observed Weights	Remarks	Done By
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
Average			
SD			

Calculation for uncertainty = $\frac{3 \times \text{S.D.}}{\text{Reported standard mass weight (g) (as per certificate)}}$

= ---------- =

Verified By :

Name : _____ Signature : _____ Date : _____

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3.3.6 Off Centre Error by 0.5 g weight

Details of the weight box …….

S.No.	Observed Weights	Remarks	Done By
Centre			
Corner -1			
Corner –2			
Corner -3			
Mean			

Verified By:

Name : _____ Signature : _____ Date : _____

3.4 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA.

Description of deficiency and date observed:

_____
_____
_____
_____
_____

Person, responsible for corrective action and date assigned:

_____
_____
_____
_____

Corrective actions taken and date conducted:

_____
_____
_____
_____
_____
_____

Conducted By : _____ Approved By : _____

Date : _____ Date : _____

Comments (if any):

_____

_____

Verified By:

Name: _____ Signature: _____ Date: _____

4.0 Acceptance Criteria:

Performance Qualification shall be considered acceptable when all the conditions specified in various data sheets under section 3.0 have been met.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the instrument / component.

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5.0 Summary:

Checks	Observations Yes / No	Remarks(if any)
Whether the acceptance criteria of the protocol and specific checkpoints are met.		

5.1 Conclusion:

The Mettler Toledo AB204-S Analytical Balance (Instrument No..... **is / is not** qualifying the Performance Qualification tests as per the Protocol No. The Instrument **can / cannot** be used for the routine analysis.

5.2 Post-Approval:

Name	Signature	Date
Manager – Quality Assurance		
Manager – Quality Assurance		
General Manager – Works		

6.0 Appendix:

6.1 Abbreviations and Definitions:

PQ - Performance Qualification
mm - Millimeter
Min - Minutes
V - Volt
Hz - Hertz
Kg. - Kilogram
cm - Centimeter
N.A. - Not Applicable
Sr. - Senior
mV - milli Volt
°C - Degree Centigrade
AC - Alternate Current
DC - Direct Current
g - Gram
RH - Relative Humidity
s. No. - Serial Number

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Acceptance criteria	:	The product, instrument., and / or process specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject.
Performance Qualification	:	The documented verification that all aspects of a facility, utility, or equipment that can affect product quality perform as intended meeting predetermined acceptance criteria ?
Validation	:	Establishing documented evidence that a system does what it purports to do .
Revalidation	:	Repetition of the validation process or a specific portion of it