OPERATIONAL QUALIFICATION OF ANALYTICAL BALANCE

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

OPERATIONAL QUALIFICATION OF ANALYTICAL BALANCE

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1.0 Pre-Approval:

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

Compiled By	Signature	Date
Manager - Engineering		

Checked By	Signature	Date
Manager - Production		
Manager - Quality Assurance		

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

OPERATIONAL QUALIFICATION OF ANALYTICAL BALANCE

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the operational attributes of *Mettler Toledo Analytical Balance*, critical to serve the intended purpose.
- To establish the suitability of the draft SOP prepared for the operation of System.
- To document the observations for future reference.

2.2 Scope:

This Protocol covers the operational qualification of Analytical Balance.

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2.3 Responsibility:

The validation 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
- Engineering Department

The Production and Engineering shall be responsible for checking the operations and recording data as per the procedures outlined in this protocol.

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

The Reports shall be checked by Production and Quality Assurance.

The post approval of the Qualification shall be done by the Engineering, Quality Assurance and the Plant Head.

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2.4 Requalification:

Operational 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 .....***

Serial No. : _____

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

Name of the Supplier : _____

Purchase Order No. : _____ Dated _____

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3.0 Operational Qualification Procedure:

1) A draft SOP shall be prepared on the basis of manufacturer guide / instrument manual for operation before the Qualification testing.

2) Prior to the Qualification test, the Personnel shall be trained by the Engineer from the Manufacturer / supplier on the operational features of the instrument. This training shall be recorded in Section 3.1.

3) The trained personnel shall carry out the Operational Qualification along with the Service Engineer, following the Procedures mentioned under Section 3.2.1 through 3.2.4 for Key Functionality and Safety Features. Record the observations of Qualification Test in Test Data Sheet of Section 3.2.1 through 3.2.4 Checkpoints designed for the purpose of OQ are also aimed at verification of these draft SOP's.

4) Operate the instrument as per the draft SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.3.

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

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3.1 Training **Date:**

Title : Operation of *Mettler Toledo AB204-S Analytical Balance*

Name of the Trainer(s): ……

S.No.	Name of the Trainee	Employee Number	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Signature of Trainer(s) : _____

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3.2. Key Functionality & Safety Features:

The critical components of the *Analytical Balance* shall be checked to ensure that these are operating to meet the desired design specification, as given by the supplier.

The following attributes are considered as critical:

3.2.1 TEST DATA SHEET (Confirmation of Services Connection):

S.No.	Test Particulars	Specified Function	Observations	Checked By
1.	Switch 'ON' the power supply and close the side windows	The balance will display 'OFF'		
2	Press 'ON/ OFF' key	The balance will perform self test and '0.0000 g' will be displayed		
3.	Switch 'ON' the printer	Switch is provided at the backside of the printer		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
4	Stability of the balance	Balance shall show '0.0000 g' on the display		
5	Unstability of the balance	Balance shall show a small circle at the left bottom of the display		
6.	To take weight	Open the side glass window		
7.	After indication of the stable weight press 'O/T' key	The weight will be tarred.		

Verified By:

Name : _____ Signature : _____ Date : _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
8.	Actual weighing	Place the specimen to be weighed on the butter paper, weight taken shall be the weight of the specimen		
9.	After completion of the activity switch ‘OFF’ the balance by pressing the ‘O/T’ key	Message ‘OFF’ appears on the display after sometime.		

Verified By:

Name : _____ Signature : _____ Date : _____

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3.3 SOP Verification:

Draft 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) : _____

_____NO_____

_____

SOP to be revised (Yes/No) : NO

If yes, Review No. _____

Remarks : SOP Confirmed / Not Confirmed

Verified By:

Name: _____ Signature: _____ Date: _____

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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: _____

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4.0 Acceptance Criteria:

Operational 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 Operational Qualification tests as per the Protocol No. ..... The Instrument **can / cannot be** tested for its Performance Qualification as per Protocol No.....

5.2 Post-Approval:

Name	Signature	Date
Manager - Engineering		
Manager - Quality Assurance		
General Manager - Works		

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6.0 Appendix:

6.1 Abbreviations and Definitions

OQ	- Operation Qualification
mm	- Millimeter
Min	- Minutes
V	- Volt
Hz	- Hertz
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.
Operational qualification	The documented verification that all aspects of a facility, utility, or equipment that can affect product quality operate as intended throughout all anticipated ranges.
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