INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

TABLE OF CONTENTS

1.0 Pre-Approval

2.0 Overview

2.1 Purpose
2.2 Scope
2.3 Responsibility
2.4 Re-qualification
2.5 System Description

3.0 Instrument Specification

4.0 Instrument Identification

5.0 Instrument Location

6.0 Installation Qualification Procedure

6.1 Inspection Checklist
6.2 Installation Qualification
6.2.1 Physical verification of the Instrument / Environment
6.2.2 Major Component Verification
6.2.3 Verification of Utility Supply
6.2.4 Standard Operating Procedure (SOPs) Identification
6.2.5 Deficiency (if any) and corrective Action Report

7.0 Acceptance Criteria

8.0 Remarks (if any)

9.0 Summary

9.1 Conclusion
9.2 Post-Approval Signatures

10.0 Appendix

10.1 Abbreviations
10.2 List of Documents

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

1.0 Pre-Approval:

Signing of this Approval page of Installation Qualification Protocol No..... indicates agreement with the Installation Qualification approach described in this document. Should Modifications to the Installation 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		

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is to provide an outline for the Installation Qualification of the instrument for static attributes to verify that:

- Each installed sub component complies with the instrument data sheets / specifications, agreed upon with the manufacturer.
- All supporting utilities are connected.
- The instrument is installed as per the laid down specifications.
- No unauthorized or unrecorded modifications have taken place.
- Required testing reports are available.
- A *draft* Standard Operating Procedures (SOP) have been identified and listed.

2.2 Scope:

This protocol covers the installation qualification of the Analytical Balance (Mettler Toledo).

2.3 Responsibility:

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

- Engineering Department
- Production Department
- Quality Assurance Department

The Engineering Department shall be responsible for the proper utility required for the instrument as per the procedures outlined in this protocol.

The Production Department shall be responsible for the checking proper installation and recording installation data as per the procedures outlined in this protocol.

The Quality Assurance Department shall be responsible for the final review of the qualification documents and its compliance to meet the acceptance criteria of the Installation Qualification protocol.

The summary report shall be reviewed and approved by the head of the Quality Assurance and Plant Head.

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

2.3 Requalification:

Installation Qualification to be requalified on:

- Replacement of major component of the Instrument with a new component.
- Any major modification in the existing Instrument.
- Shifting of the Instrument from one location to another.

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

2.4 System Description:

Weighing is a frequent step in analytical procedures and the balance is a essential piece of Laboratory Equipment in most of the analysis. Weighing is a common source of error that can be difficult to detect in the final analytical results. To avoid these errors weighing Procedure can be separated into three basic steps: planning, checking the balance and weighing the material.

The Mettler Toledo has been tested to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC Rules and the ratio interference of the Canadian Department of Communications.

The Mettler Toledo GmbH, Greifensee, company was examined and evaluated in 1991 by the Swiss Association for Quality Assurance Certificate, SQS and was awarded the ISO 9001 Certificate.

The Mettler Toledo Dual Range AB204-S balance line range from high resolution analytical balance with a readability of 0.1 mg / 0.01 mg.

In addition to the basic weighing operation such as weighing, taring and adjusting (calibration) the functions “Piece counting”, Percent weighing” or “Dynamic weighing” (automatic or manual start) are also available.

Mettler Toledo Dual Range balances have two ranges i.e. it has a fine (semi micro) range from o to 61g. In this fine range the balance shows the results with a higher resolution (with five decimal place)

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

Mettler Toledo Dual Range AB204-S balances are fitted with a glass drift shields in the factory and RS 232C interface as standard.

Mettler Toledo Dual Range AB204-S balances is a **certified balance** and having an internal adjustment weight.

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

3.0 Instrument Specification:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Readability	0.1 mg
Maximum Capacity	220 g
Repeatability (s)	0.1 mg
Linearity - / +	0.2 mg
Sensitivity Drift	2.5 ppm / °C
Typical stabilization time	3.5 s
Adjustment weight / Adjustment weight for certified balances	200 g
External dimensions of the balance (W/D/H)	245 / 321 / 344 mm
Weighing pan	∅ 80 mm
Max. height above weighing pan	237 mm
Net weight	6.4 kg
Power Supply	220 - 240V, 50-60Hz / 100 mA Balance Power input 8-14.5 V, 50 / 60Hz, 6 VA or 9.5 – 20 V DC 6 W

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

4.0 Instrument Identification

The subjected instrument is identified as ***Analytical Balance***

Serial No. : ----------

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

Name of the Supplier : ----------

Purchase Order No. : ---------- Dated ----------

5.0 Instrument Location:

Facility	:	Manufacturing
Area	:	Process Area
Room / Lab. Identification	:	In Process Quality Control

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

6.0 Installation Qualification Procedure:

6.1 Inspection Checklist

Instructions:

6.1.1 Check the Instrument physically for any damage and record the observation in the Data Sheet of section 6.2.

6.1.2 Identify the utility supplies required for instrument operation. Verify that utilities are as per the specification mentioned in the Check Point and record the observation in the Data Sheet of section 6.2.

6.1.3 Identify the critical accessories supplied with the instrument or installed on the utility supply line. Verify that instruments are as per the desired specifications.

6.1.4 Check the installation of instrument:

- To verify the proper assembly of the components as per the instrument manual. Record the installation location and verification of assembly in Test Data section 6.2.

6.1.5 Identify the SOP's and assign SOP Numbers, record the SOP Title and Number in Section No. 6.2.

6.1.6 Record the deficiency (if any) in section number 6.2 and report the details of action taken.

Note:

1. *Record all the observations against the respective specifications, mentioned in the specific checkpoints, under section 6.2 (The specifications are extracted from the Purchase order / Manual / Manufacturer's Recommendations).*
2. *Incase of non-compliance, give the explanation / justification in the deficiency and corrective action report format under section 6.2.*
3. *When more than one unit of the same type exist, replicate the corresponding data sheet to match and uniquely identify each page.*
4. *Incase of multiple options; clearly identify the one, which has been supplied.*
5. *The calibration certificates of the instruments shall be traceable to National / International standards.*
6. *Define all technical terms and abbreviations in the appendix under section 10.0.*

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

6.2 Installation Qualification:

6.2.1 Physical verification of the instrument / Environment

Objective: To verify that any physical damage of the instrument and Environmental condition for the operation of the Instrument.

S.No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
Physical Verification				
1.	Check the Instrument for any damages.	There should not be any damages.		
Environmental Conditions				
1.	Room Temperature	10° C to 30°C		
2.	Relative Humidity	15% to 80%		
3.	Away from the Sunlight	-		
4.	Away from Air Draft	-		
5.	Away from Vibrations	-		
6.	Disturbance due to magnetic field	-		
7.	No corrosive Gases	-		
8.	Free from dust	-		

Checked by (Engineering)

Name	Sign.	Date

Verified by (Quality Assurance)

Name	Sign.	Date

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

6.2.2 Major Component Verification:

Objective: To verify that major components as identified below are complying as per the desired specifications.

S.No.	Name	No.	Observations	Acceptance Yes/No
1	Mettler Toledo Balance [AB204-S]	1 No.		
2	Mettler Printer [LC-P45]	1 No.		
3.	AC Adopter (Output 12V –2.08A)	1 No.		
4.	Printer Roll	2 No.		
5.	RS 232 Cable (9P D type)	1 No.		
14.	Spare Fuse – 2A / 230 VAC	2 Nos.		
15	Operator's Instruction Manuals (for Mettler Balance and Printer)	1 No.		

Checked by (Engineering) _____ Name _____ Sign. _____ Date

Verified by (Quality Assurance) _____ Name _____ Sign. _____ Date

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

6.2.3 Verification of Utility Supply:

Objective: To verify that necessary utility supplies required for instrument operation are as per the desired specification and connected properly.

S.No.	Utility	Specifications	Observations	Connected and Identified (Yes / No)
1.	Power	Single Phase, 230V ± 10% 50 Hz		
		12V DC from power adapter		

Note: *Power Supply to be checked with a Multimeter.*

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

6.2.4 Standard Operating Procedures (SOP's) Identification:

SOP's	Number	Title
Operating, Calibration and cleaning	.....	Analytical balance Make: Mettler Toledo Model: .....

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

6.2.5 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 : _____

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

7.0 Acceptance Criteria:

Installation Qualification shall be considered acceptable when all the conditions specified in various forms under section 6.0 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.

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

8.0 Remarks (if any) :

_____

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_____

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

9.0 Summary:

Checks	Observations	Remarks
Whether acceptance criteria of the protocol and Specific check points are met.	Yes/No	

9.1 Conclusion:

Mettler Toledo Analytical balances bearing Instrument No..... **is / is not** qualifying the Installation Qualification tests as per Protocol No....., hence the instrument **can / cannot** be tested for its Operational Qualification as per Protocol No.....

9.2 Post-Approval Signatures:

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

10.0 Appendix:

10.1 Abbreviations and Definitions:

IQ	- Installation Qualification
mm	- Millimeter
Min	- Minutes
V	- Volt
Hz	- Hertz
cm	- Centimeter
N.A.	- Not Applicable
S. No.	- Serial Number
Sr.	- Senior
mV	- milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
g	- Gram
RH	- Relative Humidity

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

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.
Installation qualification	:	The documented verification that all aspects of a facility, utility or equipment that can affect product quality adhere to approved specifications (e.g., construction, materials) and are correctly installed?
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.

INSTALLATION QUALIFICATION OF ANALYTICAL BALANCE

10.2 List of Documents:

1. Instrument manuals

2. Purchase Order Attached (Yes / No). If no, state Location.
   Purchase Order No. _____ Dated _____
   attached. (Yes /No) If no, state Location _____

3. Calibration Certificates

4. _____

5. _____