Design Qualification

Moisture Balance
Model: AMA110L

Design Qualification

Protocol Number : ASIPL/DQ/

Company Name :

Location :

Instrument : Moisture Analyzer

Model : AMA110L

Instrument Sr. No. :

Protocol Approved By : Analab Scientific Instruments Pvt. Ltd.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

Design Qualification

Design qualification (DQ) defines the functional and operational specifications of the instrument. DQ should ensure that instruments have all the necessary functions and performance criteria that will enable user to be successfully implemented for the intended application and to meet business requirements.

Technical Specification

- Moisture analyzer capacity : 110 Gram
- Resolution : 0.001 g
- Repeatability : ± 1mg
- Pan size : Φ 90
- Temperature Range : 40°C ~ 199°C
- Heating Source : Halogen Lamp
- Time Setting : 1 ~ 99 minutes
- Display : Graphic Display
- Analysis Data Storage : 15 Data
- Power Supply : 220 V, 50 Hz

The supplied Instrument is according to the Purchase Order and as per specification.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

DESIGN QUALIFICATION

The Design Qualification (DQ) final report for the Moisture analyzer has been reviewed and was found acceptable for use.

INSTRUMENT : Moisture Analyzer
MODEL : AMA100L
SR.NO. :
FINAL REPORT :
REVIEWED AND
ACCEPTED BY :
(Name & Designation)
DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

Installation Qualification
&
Operational Qualification

Moisture Balance
Model: AMA110L

Installation & Operational Qualification

Protocol Number	**:**	ASIPL/IQ-OQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Moisture Balance
Model	**:**	AMA110L
Instrument Sr. No.	**:**	
Protocol Approved By	**:**	Analab Scientific Instruments Pvt. Ltd.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

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Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

1 Installation Qualification: -

Installation qualification establishes that the ordered instrument is received as designed and specified, that it is properly installed in the specified environment, and that this environment is suitable for the operation and use of the instrument.

1.1. Instrument Identification & Verification

Customer Purchase Order No. _____ Date_____

Main System Contents.

Sr. No.	Description	PO Qty	Received Qty.	Remark	
				Ok	Not ok
01	Moisture Balance: Model: AMA110L				
02	Wind Cover				
03	The sample pan holder				
04	Tray handle				
05	Power cord				
06	Aluminum sample pan (1set= 50 pcs)				
07	100g standard weight				
08	Operational & Instruction Manual with SOP				
09	Warranty Card				
10	DQ/IQ-OQ/PQ Documents				

The supplied Instrument is according to the Purchase Order and as per specification.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

1.2. Pre-Installation Requisites & Verification

Check the installation place for fulfillment of manufacturer's recommendation. (Utilities such as Power requirement, necessary chemicals and environmental conditions such as Humidity, Temperature, Light and Dust etc. These all factors will affect weight readings. (Please refer Pre-Installation requisites attached with this document.)

Item	Condition	Observation	
		Ok	Not Ok
Instrument & Accessories appearance check	No Damage and Breakage of the instrument & Accessories.		
Installation Table space Leveling & Vibration.	As per requirements.		
Power Requirements • Connections sockets • Supply Voltage • Earth (Earth to Neutral Potential	• 5 Amps. 02 no. • 230 V AC ± 10% • Not more than 3 (Three) Volts.		
Environmental conditions. 1) Sunlight 2) Air Draft 3) Room Temp. 4) Humidity 5) Dust 6) Flammable, Toxic & Corrosive Vapors	 Away from sunlight No direct fan or AC 15 ° ~ 50° C 20 ~ 80 % Free from dust Free from vapor.		

DO NOT install the instrument:

- Next to open windows or doors causing drafts or rapid temperature changes.
- Near air conditioning or heat vents.
- Near vibrating, rotating or reciprocating equipment.
- Near magnetic fields or equipment that generate magnetic fields.
- On an unlevel or unstable work surface.
- In confined areas, allow sufficient space around the instrument for ease of operation
- Keep away from radiating heat sources.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

1.3. Installation Qualification Verifications

1.3.1. Accessories Assembly

Follow the Instruction Manual and Install all parts of the instrument .

1.3.2. Instrument Leveling

Keep balance on the non-vibration table to get repeated results. Adjust the level feet on the bottom of the instrument until the air bubble in the level indicator is centered.

Note : Always adjust the level when balance location changes.

1.3.3. Instrument Identification & Verification

Sr. No.	Description	Result	
		Yes	No
A	Items received as per Purchase Order		

1.3.4. Pre-Requisites Inspection

Sr. No.	Descriptions	Result	
		Yes	No
A	Instruments & Accessories Checked for Damages		
B	Table Space & Leveling		
C	Power Supply Availability		
D	Environmental Requirements		

1.3.5. Standard & Optional Accessories (as ordered)

Sr. No.	Descriptions	Result	
		Yes	No
A	Wind Cover		
B	The sample pan holder		
C	Tray handle		
D	Power cord		
E	Aluminum sample pan (1set= 50 pcs)		
F	100g standard weight		
G	Operational & Instruction Manual with SOP		
H	Warranty Card		
I	DQ/IQ-OQ/PQ Documents		

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

2 Operational Qualification

Operational Qualification (OQ) is the process of demonstrating that an instrument will function according to its operational specifications in the selected environment.

2.1. Customer Orientation & Training

Orientation for the end user/s will be performed as per the Instruction Manual.

Sr. No.	Orientation Topic	Status	Verified	
			Yes	No
1	Instrument Setup/Connectivity with Accessories, Peripherals and Mains etc.	Explained / Shown		
2	Instrument Front Panel – Key Function	Explained / Shown		
3	Instrument Back Panel – Connection	Explained / Shown		
4	Instrument's Modes: • Calibration • Analysis • Temperature • Icon Description	Explained / Shown		
5	Instrument & Accessories Maintenance	Explained / Shown		

The Training on the above topics is given to following personnel

Personnel Trained	Designation	Location	Verified

The Instrument orientation and training were carried out in accordance with the Instruction Manual and found satisfactory.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

2.2. Operational Checking & Verification

Ensure connection of DC Power adaptor with the instrument. (Pl. refer instruction manual)

2.2.1. Power on Check

Requirement Condition & Observation	Remark	
	Pass	Fail
➢ Internal calibration starts and shows 0000		

2.2.2. Calibration

- Use certified weights to calbibrate he instrument
- Carefully follow the instructions given in the instruction manual

2.2.3. Repeatability Test

Procedure to check the repeatability of the instrument.

1 Zero the instrument
2 Place test mass which is near to the capacity of the instrument at the center of the platform.
3 Record the readings
4 Remove test mass from the platform, reading should return to 0 Gram.
5 Repeat the above steps five times and calculate standard deviation.

Sr. No.	Standard Weight (Gram)	Display Weight (Gram)	Deviation	Standard Deviation
1				
2				
3				
4				
5				

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

2.2.4. Temperature Test

Use calibrated thermometer/Sensor to verify temperature. (Place thermometer/sensor near to instrument sensor)

Set Temperature	Temperature Display on Instrument (ºC)	Temperature display on Calibrated Thermometer (ºC)	Temperature Deviation ± 1.0 (°C)

2.2.5. OFF Center Test

The off-center load test is used to determine whether displayed weight values are affected by putting weights in different areas of the balance platform. (see figure 1)

1 Zero the instrument
2 Place a weight equal to ½ of the full-scale capacity of balance in the center of the platform.
3 Press Zero to return the reading to Zero.
4 Move the weight hallway between the center and left edge of the platform and record the reading.
5 Move the weight halfway between the center and Right edge of the platform and record the reading.
6 Move the weight hallway between the center and Front edge of the platform and record the reading.
7 Calculate the differences in the displayed weight reading at all positions.
8 Move back to center and zero the balance after each reading if necessary.

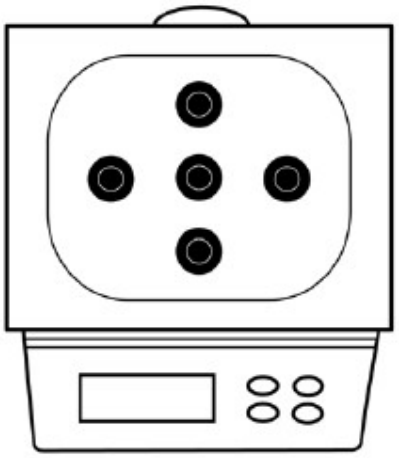

Figure: 1

Reading on center: _____
Reading on Back : _____
Reading on Front : _____
Reading on Right : _____
Reading on left : _____
Maximum Reading: _____

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

2.3. Summary of Operational Checking & Verification

Sr No.	Description	Result	
		Pass	Fail
01	Power ON Check		
02	Calibration check		
03	Repeatability Test		
04	Temperature Test		
05	Off Center Test		

All system components and functions are operating satisfactorily.

The Operational check and the verification were carried out in accordance with the operating Manual and found satisfactory.

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

Installation & Operational Qualification

The Installation Qualification (IQ) & Operational Qualification (OQ) final reports for the Moisture Balance has been reviewed and was found acceptable for use.

INSTRUMENT : Moisture Balance
MODEL : AMA110L
SR.NO. :
FINAL REPORT REVIEWED AND ACCEPTED BY (Name & Designation) :
DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

Date :

Signature :

Analab Representative	Checked by End User	Approved by Head of Department

Performance Qualification

Moisture Balance
Model: AMA110L

PERFORMANCE QUALIFICATION DOCUMENT

Protocol Number	**:**	ASIPL/PQ/
Company Name	**:**	
Location	**:**	
Instrument	**:**	Moisture Balance
Model Number	**:**	AMA110L
Instrument Serial Number	**:**	
Protocol Prepared By	**:**	Analab Scientific Inst. Pvt. Ltd. Vadodara

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department

PERFORMANCE QUALIFICATION

Performance Qualification (PQ) is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its use.

Note: PQ should always be performed under conditions that are like routine sample analyses.

1. Aim

To ensure that the moisture balance is properly calibrated with traceable Weight and chemical. The test will check and confirm that the correct moisture values of different solutions are achieved.

2. Scope

Performance Qualification must be performed in the case of new installation of an instrument or change in the location and / or as per FDA requirements.

3. Responsibility

The responsibility for the Performance Qualification lies with the system user.

4. Preparation for the Test

4.1. Apparatus Required:

1	Moisture Balance Model: AMA110L	3	Dry Di sodium Titrate (DST) - 250 Gms
2	Reference Weight		

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department

5. Linearity Test

The linearity test is used to determine the linearity of the scale throughout its operating range.

NOTE: *The scale must pass the Off-Center Load test and Repeatability Test* ***before*** *the Linearity Test is performed.*

5.1. Place the reference mass on the center of the platform and record the exact value (all decimal places) displayed.
5.2. Remove the reference mass and verify that the display returns to zero. If it does not, disregard the reading, press ZERO to rezero the display, and take the reading again.
5.3. Place a mass equal to ¼ of the full scale capacity on the center of the platform and record the exact value displayed.
5.4. Remove the reference mass and verify that the display returns to zero. If it does not, disregard the reading, press ZERO to rezero the display, and take the reading again.
5.5. Place a mass equal to ½ of the full scale capacity on the center of the platform and record the exact value displayed
5.6. Remove the reference mass and verify that the display returns to zero. If it does not, disregard the reading, press ZERO to rezero the display, and take the reading again.
5.7. Place a mass equal to 3/4 of the full scale capacity on the center of the platform and record the exact value displayed
5.8. Remove the reference mass and verify that the display returns to zero. If it does not, disregard the reading, press ZERO to rezero the display, and take the reading again.
5.9. Place a mass equal to full scale capacity on the center of the platform and record the exact value displayed
5.10. Remove the reference mass and verify that the display returns to zero. If it does not disregard the reading, press ZERO to rezero the display, and take the reading again.
5.11. Compare the reference weight readings. They should agree within the specifications

- Reading at ¼ full scale capacity _____
- Reading at ½ full scale capacity _____
- Reading at ¾ full scale capacity _____
- Reading at Full scale capacity _____

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department

6. Determination of Moisture in unknown Sample:

Di sodium Tartarated is used as an unknown sample as it has fixed percentage of water content (15.67% ± 1 or as per mention by manufacturer). It does not decompose and is not hygroscopic.

6.1. Take approximately 2 gram of DST (fine powdered)

6.2. Set 110 °C on balance through menu.

6.3. Temperature starts increasing.

6.4. After getting END point, long buzzer will hear, and instrument cooled down

6.5. Instrument gives % moisture result on display

6.6. Press Print key, to take print out of result. (If printer is connected)

7. Record of Standards used:

Di sodium Tartarated	
Manufacturer	
Batch No / Quality	
Date of Opening	

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department

PERFORMANCE QUALIFICATION

The instrument has been validated using traceable solutions. The test protocols have been filled in correctly and test results are documented. The system can be released for appropriate use.

INSTRUMENT : Moisture Balance
MODEL : AMA110L
SERIAL NO. :
FINAL REPORT REVIEWED AND ACCEPTED BY (Name & Designation) :
DATE :

Customer	
Department	
Head of Dept.	
End User	
Date	
Signature	
Seal of the Company	

Analab Representative	
Date	
Signature	

Date :

Signature :

Name :

Analab Representative	Checked by End User	Approved by Head of Department