OPERATION QUALIFICATION

FOR

MOISTURE ANALYZER

	PHARMA DEVILS	
	QUALITY CONTROL DEPARTMENT	

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

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1.0   Pre-Approval:

Signing of this Approval page of Operational Qualification Protocol 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.

Written By	Signature	Date
Quality Control		

Checked By	Signature	Date
Production		
Quality Assurance		

Approved By	Signature	Date
Quality Assurance		
Plant Head		

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

2.0 Overview

2.1 Purpose:

The purpose of this protocol is:

- To verify the operational attributes of *Sartorius MA 50 Moisture analyzer*, critical to serve the intended purpose.
- To establish the suitability of the draft SOP prepared for the operation of the instrument.
- To document the observations for future reference.

2.2 Scope:

This protocol covers the Operational Qualifications of Moisture Analyzer MA 50.

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

♦ Quality Control Department

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

Quality Control 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 Head Quality Assurance and plant Head.

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.

2.5   **Instrument Identification:**
The Instrument is identified as   **Moisture Analyzer MA 50**

Serial No.   _____

In-house Instrument No.   **........................**

Name of the Supplier   _____

Purchase Order No.   _____ **Dated** _____

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 Sartorius MA 50 Moisture analyzer.

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) **: _____**

Date **: _____**

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3.2. **Key Functionality & Safety Features:**

A. **Purpose:**

The purpose of this procedure is to demonstrate that the control panel and other manual operations (if any) of Moisture Analyzer function as specified by the manufacturer.

B. **Testing:**

1. Turn on the power from the electrical panel.
2. Verify functionality of each component against its Specified functions.
3. Observe and record the responses in the Test Data Sheet, under section 3.2.1.

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3.2.1 TEST DATA SHEET:

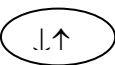| S.No	Test Particulars	Specified Functions	Observations	Ckd By
1	Switch 'ON' the mains	Display will show 'OFF'		
2	Press (I / O) button	Display will show 0.000 g		
3	Press Prog. Key. Display will show the list of programme names	Select the required program by using '∧' '∨' keys		
4	Load the selected program by pressing the 'LOAD' soft key	Display will show NO and YES options		
5	Press YES soft key	Selected program will get loaded		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Functions	Observations	Ckd By
6	Press 'ID' key	Display will show ID1, ID2, ID3, ID4		
7	Enter product name, batch no. and lot	Use ⬭ABC Key and 0….9 numerical keys		
8	Entring the ID	Press ↵ key to entre ID		
9	Exit from ID	Press << to exit from ID		
10	Press ⬭↓↑ key	The sample chamber should open		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

S.No	Test Particulars	Specified Functions	Observations	Ckd By
11	Press 'TARE' Key	Display will show 'WEIGH-IN : Load sample'		
12	Distribute approximately 2.0 g of sample evenly on the disc surface to cover the entire disc,	Display will show 'WEIGH IN: Start analysis'		
13	Press 'Start' Key	Display will show 'Analysis Begin' and the rate of drying.		
14	Completion of analysis	Alarm sound is produced and display shows the result and message 'Analysis End'		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

S.No	Test Particulars	Specified Functions	Observations	Ckd By
15	Press 'Next' key	The instrument will exit from the analysis		
16	Setting the new Program	Press 'PROG' soft key and set the program by using '∧' '∨' keys		
17	Press '>' key	The set programm will get confirmed and display will show 'Entre Password'		
18	Entre the password	Use (ABC) Key and 0….9 numerical keys		
19	Press ↵ Key	Display will show program menu		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

S.No	Test Particulars	Specified Functions	Observations	Ckd By
20	Select 'PROGRAM NAME'	Press '∧' '∨' Keys to select 'Program Manu'		
21	Press > key	The program menu will get confirmed		
22	Entre the program name	Use (ABC) Key and 0….9 numerical keys		
23	Press ↵ key	The program name will get entred		
24	Press < key	Exit from the program name		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

S.No	Test Particulars	Specified Functions	Observations	Ckd By
25	Select 'Heating Program'	Use '∧' '∨ ' Keys		
26	Press > key	The "Heating program' will get confirmed and display will show 'Heating Program Menu' • Standard Drying • Quick drying • High Temperature drying		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

S.No	Test Particulars	Specified Functions	Observations	Ckd By
27	Select 'Standard Drying'	Use '∧' '∨ ' Keys		
28	Press > key	The standard drying will get confirmed and display will show 'TEMPERATURE: ____°C Entre the required temperature by using 0....9 numerical keys		
29	Press ⏎ key	The fed temperature will be entred		
30	Press < key	Exit from the temperature menu		
31	Press < key again	Exit from standard drying		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

| S.No	Test Particulars	Specified Functions	Observations	Ckd By
32	Select 'standby temperature'	Use '∧' '∨ ' Keys		
33	Press > key	Confirm the standby temperature and display will show - OFF -ON		
34	Enter OFF	Press ⏎ key		
35	Press < key	Exit from standby temperature menu		

Verified By:

Name: _____ Signature: _____ Date: _____

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| S.No	Test Particulars	Specified Functions	Observations	Ckd By
36	Select ' Bar Graph for weighing in sample'	Use '∧' '∨ ' Keys		
37	Press > key	Confirm the 'Bar graph for weighing in sample' Display shows: - Inactivated - Minimum and maximum initial weight - Target weight, tolerance in %		
38	Select 'Inactivated'	Use '∧' '∨ ' Keys		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

S.No	Test Particulars	Specified Functions	Observations	Ckd By
39	Press ⏎ key	'Inactivated Menu' will get confirmed		
40	Press < key	Exit the Bar Graph for weighing in sample menu		
41	Select 'Start Analysis'	Use '∧' '∨ ' Keys		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

S.No	Test Particulars	Specified Functions	Observations	Ckd By
42	Press > key	Confirms the 'Start Analysis' and the display shows 'Start Analysis Menu' • With stability + Autoclose • With stability + Manual close • Without stability + Autoclose • Without stability + Manual close • Fully Automatic with stability • Fully Automatic without stability		
43	Select 'fully automatic with stability '	Use '∧' '∨ ' Keys		
44	Press ⏎ key	'fully automatic with stability' will get confirmed		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

| S.No	Test Particulars	Specified Functions	Observations	Ckd By
45	Press < key	Exit from 'Start Analysis Menu'		
46	Select End of Analysis	Use '∧' '∨ ' Keys		
47	Press > key	Confirm the 'End of Analysis' and display will show 'End of analysis menu' • Automatic • Asap: determine semiautomatic parameters • Semi auto : babsolute weight loss • Semi auto : weight loss in percent • Time • Manual		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Specified Functions	Observations	Ckd By
48.	Select Automatic	Use '∧' '∨ ' Keys		
49.	Press ⏎ key	Automatic Mode will get confirmed		
50.	Press < key	Exit from End of Analysis Menu		
51.	Select 'Display Mode'	Use '∧' '∨ ' Keys		
52.	Press > key	Confirm the Display Mode and the display shows 'Display mode Menu' • Moisture (% L) • Dry Weight (%R) • Ratio (%LR) • Weight Loss (mg) • Residue (g) • Residue (g/kg)		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Specified Functions	Observations	Ckd By
53	Select 'Moisture' (%L)	Use '∧' '∨ ' Keys and Press ←⏎ key		
54	Press > key	The Moisture(%L) menu will get confirmed and display shows: 1 Decimal Place 2 decimal places		
55	Select the 2 decimal places	Use '∧' '∨ ' Keys and Press ←⏎ key		
56	Press < key	Exit from 'Moisture Menu'		
57	Press < key again	Exit from 'Display Mode Menu'		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

| S.No	Test Particulars	Specified Functions	Observations	Ckd By
58	Select Print Intermediate Results	Use '∧' '∨ ' Keys		
59	Press > key	Confirm the Print Intermediate results		
60	Select OFF or ON	Use '∧' '∨ ' Keys and Press ⏎ key		
61	Press < key	Exit from Print Intermediate results		
62	Select Analysis ID# with auto numbering	Use '∧' '∨ ' Keys		
63	Press > key	Confirm the Analysis ID # with auto numbering		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

| S.No	Test Particulars	Specified Functions	Observations	Ckd By
64	Select NO or YES	Use '∧' '∨ ' Keys		
65	Press ⏎ key	Entry will get confirmed		
66	Press < key	Exit from Analysis ID# with auto numbering		
67	Select Analysis w/former spl (100% fct)	Use '∧' '∨ ' Keys		
68	Press > key	The Analysis w/former spl (100% fct) will get confirmed		
69	Select NO or YES	Use '∧' '∨ ' Keys		
70	Press ⏎ key	Confirm your entry		

Verified By:

Name: _____ Signature: _____ Date: _____

PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

| S.No	Test Particulars	Specified Functions	Observations	Ckd By
71	Press < key	Exit from Analysis w/former spl (100% fct)		
72	Select identifiction	Use '∧' '∨ ' Keys		
73	Press > key	Confirms the Identification and display shows Identification menu • ID1: ID1 • ID2: ID2 • ID3: ID3 • ID4: ID4		
74	Select any ID	Use '∧' '∨ ' Keys		

Verified By:

Name: _____ Signature: _____ Date: _____

PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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S.No	Test Particulars	Specified Functions	Observations	Ckd By
75	Enter the ID name	Use ABC and 0…..9 numerical keys		
76	Press ⏎ key	Confirm your entry		
77	Press < key	Exit from identification Menu		
78	Select factory Settings	Use '∧' '∨ ' Keys		
79	Press > key	Confirm the Factory Settings		
80	Select NO or YES	Use '∧' '∨ ' Keys		
81	Press ⏎ key	Confirm your entry		
82	Press < key	Exit from Factory Settings		

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

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) :

Changes required in draft SOP (If any) : _____

_____

_____

SOP to be revised (Yes/No):

If yes, Review No. _____

Remarks: SOP Confirmed / Not Confirmed

Verified By:

Name: _____ Signature: _____ Date: _____

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

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:

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 **MA 50 Moisture analyzer** bearing Equipment 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
Quality Control		
Quality Assurance		
Plant Head		

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
S. No.	- Serial Number
Sr.	- Senior
mV	- Milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
DC	- Direct Current
g	- Gram
RH	- Relative Humidity

OPERATION QUALIFICATION FOR MOISTURE ANALYZER

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