



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and calibration of Moisture Analyzer	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for operation and calibration of Sartorius Moisture Analyzer.

2.0 SCOPE:

This procedure is applicable to operation and calibration of Sartorius Moisture Analyzer in the quality control department.

3.0 RESPONSIBILITY:

Officer, Executive, Sr.Executive- Quality control Department.
Head- Quality Control Department

4.0 PROCEDURE:

4.1 Balance setting:

4.1.1 Adjust the level by using four adjustable leveling feet.

4.1.2 Switch "ON" the main power supply and select the menu key.

4.1.3 Select the 'Method management' key and then select the 'standard' key then parameter screen will appear.

4.1.4 Set the required parameters as per BMR like heating temperature and set the process in 'Fully automatic' mode in the parameter screen.

4.1.5 Save the above process and back into the home screen.

4.2 Operation:

4.2.1 Ensure the machine is cleaned before start of operation.

4.2.2 Select the 'START' key and then screen displays as 'open hood'.

4.2.3 Open the hood of the analyzer and the screen displays 'place pan, close hood for tare the weight.

4.2.4 Place the pan on the pan support and then close the hood for tare the weight and wait for some times to stable and screen displays 'Open hood'.

4.2.5 Open the hood of the analyzer and add 2.0 to 3.0 gm of sample spread over the pan and screen displays 'close hood to start'.



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4.2.6 Close the hood and the analyzer starts automatically. The current measurement value and progress are shown on the display during the moisture analysis. When the moisture analysis is finished, the moisture content of the sample is shown on the display and collects the printout and attach on the respective BMR.

4.2.7 Cool the Moisture Analyzer to ambient temperature before next determination.

4.2.8 If the analyzer is not in operation then keep the analyzer in 'Standby' mode.

4.4 Calibration:

4.4.1 Make sure that the pan support is empty before starting the calibration operation.

4.4.2 Select the 'MENU' key on the main screen.

4.4.3 Select the 'SETUP' key and then settings screen will appear.

4.4.4 Select the 'Calibration/Adjustment' key in the settings screen.

4.4.5 Select 'Weighing system adjustment' key and select the 'weighing only' key and then place the standard weights one by one on the pan and records as per Annexure-I.

4.4.6 Select the standard weights as mentioned below.

Standard Weights to be used for calibration			
1.000 gm	20.000 gm	50.000 gm	100.000 gm

4.4.7 The balance is considered satisfactory for use if the readings are found within acceptance limits.

4.4.8 If the readings are exceeding the acceptable limit then inform the head of the department and Engineering Department for necessary action and record the same in Balance Calibration Record.

4.4.9 Do not use a balance till the problem is rectified.

4.4.10 After rectification, re-calibrate the balance before use and enter the same in the Annexure-I.

4.4.11 Check for the zero error and enter the reading in the Annexure-I for the balance.

4.4.12 Use the Standard weights duly certified by the Weights and Measures Department.

4.4.13 Frequency: Daily

Note: Clean the Moisture analyzer balance after every use by using dry lint free duster/tissue paper.

4.5 Error messages during operation

4.5.1 "Value is too small" : When an entered value is too low for the parameter.

4.5.2 "Value is too large" : When an entered value is too high for the parameter.



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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4.5.3 “Error 46” : When the maximum heating temperature has been briefly exceeded

4.5.4 “Error 401 to 407” : Faulty heating element and contact the manufacturer.

5.0 ANNEXURE (S):

Annexure –I: Balance Calibration Record for Moisture Analyzer.

6.0 REFERENCE (S):

SOP: Preparation, Approval, Distribution control, revision and destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S) :

Gm: gram

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---

ANNEXURE I

BALANCE CALIBRATION RECORD FOR MOISTURE ANALYZER

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BALANCE CALIBRATION RECORD FOR MOISTURE ANALYZER			
			Reference SOP No.:
Location		Model No.	
Manufacturer		Capacity	
Instrument ID No.		Least Count	
Month & Year			

Calibrated weight box Certificate No.: _____ **Validity:** _____

Tolerance: + 0.10 % of actual weight

Standard Weight	1.00 g	20.0g	50.0g	100.0 g	Done by	Checked by
Actual Weight						
Limits (mg)						
Date	*Balance Level	Observed Weight (mg)				

Note: *Record the balance level (Bubble position in centre) and zero display as OK/Not OK.