PHARMA DEVILS

PRODUCTION DEPARTMENT

| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Production | **SOP No.:** |
| **Title:** Operation and Calibration of Moisture Analyzer | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

**1.0 OBJECTIVE:**

To lay down a procedure for operation and calibration of Sartorius Moisture Analyzer model MA 160.

**2.0 SCOPE:**

This procedure is applicable to operation and calibration of Sartorius Moisture Analyzer model MA 160 in granulation.

**3.0 RESPONSIBILITY:**

Production: Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

**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'.

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.

| Balance Capacity | Operating Range | Standard Weights to be used for calibration | | | |
|---|---|---|---|---|---|
| 150gm | 1.000 to 140.000gm | 1.000gm | 40.000gm | 100.000gm | 140.000gm |

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: At the starting of first shift.

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.

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 (Sartorius)

**6.0 REFERENCE (S):**

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

**7.0 ABBREVIATION (S) /DEFINITION (S) :**

QA : Quality Assurance

BMR : Batch Manufacturing Record

Gm : gram

**REVISION CARD**

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