



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning, Operation and Calibration of Infra-Red Moisture Analyzer	Effective Date:
Supersedes: Nil	Review Date:
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Operation and Calibration of IR Moisture Analyzer (MA150).

2.0 SCOPE:

2.1 This procedure is applicable for IR Moisture Analyzer (MA150) in manufacturing area.

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Officer and Executive : Operation

Head Production : SOP compliance

IPQA Person : Operation

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 BALANCE SETTING:

5.1.1 Set the moisture analyzer on a stable, even surface that is not exposed to vibration and level the device using the four leveling feet.

5.1.2 Switch "ON" the main power supply. Balance displays:

OFF

5.1.3 Press the I/O key to "ON/OFF" the balance.

5.1.4 Balance will perform self-test and display –

0.000 g

5.1.5 Press the → or ← arrow key to select TARE function and Zeroes the weight by pressing ENTER Key to get Zero on the display.

5.1.6 To open the door lifts the hinged cover with heating element.

5.1.7 If the Moisture Analyzer shows "OFF" the display it means balance is 'ON'.

OFF



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5.1.8 If the Moisture Analyzer shows “STAND BY” the display it means balance is in ‘STAND BY’ mode.

STAND BY

5.1.9 If the Moisture Analyzer shows “■...■...■” the display it means balance is ‘BUSY’.

■

5.1.10 If the Moisture Analyzer shows “0.000g the display it means balance is ‘STABLE’.

0.000 g

5.2 Operation:

5.2.1 Ensure the machine is cleaned before start of operation.

5.2.2 Load particular program. To load program → or ← key to select PROGRAM option. Then list of programs is displayed in display unit. Ensure the instrument is ready to run in ‘Auto’ mode.

5.2.3 Select program no. by → or ← soft key. To load program press ‘ENTER’ soft key then press ‘CF’ soft key twice and then press → for tarring.

5.2.4 Moisture Analyzer will display the graphic symbol for tarring. Open the doors hinged cover with heating element and then place the sample dish on weighing pan. Take the sample dish by pressing ‘ENTER’ soft key.

5.2.5 Graphic symbol of ‘LOADING THE SAMPLE’ appears on the display. Then load the sample approx. 2-3 gm. evenly (Note: lumps of the granules are loosened before placing of granules.) on dish. Close the hinged cover with heating element, then press ‘ENTER’ soft key to start the analysis.

Note: - Crushing of tablets/pellets in mortar and pastel before performing the LOD of compressed, coated tablets and pellets.

5.2.6 After the end of analysis beep comes for three times and then take printout from the printer for result of analysis and note down the % LOD value displayed in BMR.

5.2.7 Cool the I.R. Moisture Analyzer to ambient temperature before next determination.

5.3 Printing of Result

5.3.1 Connect the Sartorius printer to I.R. Moisture Analyzer with interface cable.

5.3.2 Switch on Sartorius I.R. Moisture Analyzer and printer.

5.3.3 For operation of balance follow the procedure from step 4.1.1 to 4.2.6

5.3.4 Replace the paper roll from paper roll compartment.



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5.3.5 Press the LF key several times or keep it pressed for continuous line feed if required.

5.3.6 To print the date and time press the Dat key.

5.3.7 To print data, press the ~ key.

5.3.8 To reset the numbering function, if necessary, press the ↓N/N key

5.3.9 To turn off the numbering function, press ↑CN Key.

5.3.10 After completion of in process test take the print and review the print to verify the Mode of in process test, it should be perform in Auto mode, and the test shall not be stop in between. If the test is stop in between the print shows the alphabet 'B' on print slip.

5.3.11 If the print slip shows the alphabet 'B' then the in-process test shall be considered as aborted and handled through the Deviation procedure as per SOP (Event Management). Again, carry out the in-process test and sample shall be reconciled.

5.3.12 Attach the print out to the BMR.

5.4 Calibration:

5.4.1 Calibrate the I.R Moisture Analyzer with the standard weights as per Annexure-I (Calibration Record of IR moisture balance,).

5.4.2 Select the standard weights as mentioned below.

Balance Capacity	Operating Range	Standard Weights to be used for Calibration			
150 g	1.000 to 140.000 g	1.000 g	30.000 g	75.000 g	140.000 g

5.4.3 Check the level of the balance with the help of calibrated spirit level and record the observation in Annexure - I (Calibration Record of IR moisture balance).

5.4.4 Place the standard weights one by one on the weighing platform/ pans and check the readings. Record the readings in the Annexure-I (Calibration Record of IR moisture balance).



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5.4.5 Moisture Analyzer is considered satisfactory for use if the readings are found to be within acceptance limit of the Moisture Analyzer.

5.4.6 If the readings are exceeding the acceptable limit, put an "UNDER MAINTENANCE" tag, and inform the head of the department and Engineering Department for necessary action and record the same in Moisture Analyzer Calibration Record.

5.4.7 Do not use a Moisture Analyzer till the problem is rectified.

5.4.8 After rectification, re-calibrate the Moisture Analyzer before use and enter the same in the Annexure – I (Calibration Record of IR moisture balance).

5.4.9 Check for the zero error and enter the reading in the Annexure - I (Calibration Record of IR moisture balance) for the Moisture Analyzer.

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

5.4.11 Frequency: Start of working day, after maintenance work and shift the location of balance.

5.5 TEMPERATURE CALIBRATION:

5.5.1 Calibration of Temperature is to be done by Engineering Department and approved external laboratory / party.

5.5.2 **Frequency - Yearly**

5.6 CLEANING

5.6.1 Clean the instrument with the clean dry lint free cloth daily. Occasionally use wet cloth immediately followed by lint free dry cloth.

5.6.2 Before and after every test clean the sample pan and other accessories used for test. Inner sample compartment should be cleaned using non shredding brush.

5.6.3 Clean mortar and pastel with dry lint free cloth followed by wet lint free cloth.

5.7 PRECAUTION

5.7.1 Instrument should be placed on stable, vibration free and leveled support.

5.7.2 Instrument should not be placed in hazardous area.

5.7.3 Clean the Instrument properly before and after use.

5.7.4 Instrument shall be operated in Auto Mode.

5.7.5 After start of operation doesn't abort or stop Moisture analyzer, till the test completed.



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5.7.6 If test aborted or stop in between it shall be handle through Deviation procedure as per SOP – Event Management

6.0 ABBREVIATION (S):

IR -Infra red

SOP - Standard Operating Procedure.

NA – Not Applicable

7.0 REFERENCE(S):

Event Management.

8.0 ANNEXURE(S):

Annexure No.	Title of Annexure	Format No.	Mode of Execution
Annexure- I	Calibration Record of IR moisture balance		Log book

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (s):** Production department (02), Quality Assurance (01)

9.3 **Reference copy (s) :** Production department (02)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details of Revision	Effective Date
1.	00	NA	New SOP	NA	

