



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Calibration of Infra Red Moisture Balance (//*AXIS* LCGC Make)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Operation and Calibration of IR Moisture Balance (//*AXIS* LCGC Make).

2.0 SCOPE:

2.1 This procedure is applicable for IR Moisture Balance Make- //*AXIS* LCGC Model-AGN100M in manufacturing area.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation of balance
- 3.2 Officer and Executive : Operation of balance
- 3.3 Head Production : SOP compliance
- 3.4 IPQA Person : Operation

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 OPERATION:

5.1.1 BALANCE SETTING:

5.1.1.1 Adjust the Spirit Level in the Center Position using Leveling Screws.

5.1.1.2 Switch "ON" the main power supply. Press the I/O keys to "ON/OFF" the balance. Balance starts **INITIALIZATION** (Moisture analyzer proceeds with self tests)

Model	INITIALIZATION	Program version
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✓ PROCESSOR
✓ EEPROM

5.1.1.3 After completing self tests, the analyzer is tared and the dryer begins initial heating necessary to create thermal conditions suitable for measurements.



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5.1.1.4 After initial heating is completed the device displays –

m0 –m/m0*100%		Ts=120°C	ts= 0:10:00s	
T =32.23 °C		0.00 %		
m = 0.000g				
t = 0: 00: 00s				
m0 = 0.000g				
START	SET	STAT	MEM	STOP

Where:

$m0-m/m0*100%$: formula used to calculate the moisture

Ts : defined drying temperature

ts : defined drying time

T : current temperature in the drying chamber

m : current weight

t : current drying time

m0 : initial weight

5.1.2 WORKING MODE PARAMETERS SETTING:

5.1.2.1 For the Working mode parameters setting choose Setting option (SET) pressing F2 key it shows following moisture analyser parameters...

MOISTURE ANALYSER PARAMETERS	
1. Mode	: m0 –m/m0*100%
2. Drying temp.	: 105°C
3. Qualified qty.	: 2 samples
4. Sampling interval	: 10s
5. Drying time	: 0:00:10s
6. Setting storing	:
7. Exit	:

5.1.2.2 To Fill all the parameters as per the specification using ▲ or ▼, < and > keys and press **ENTER** to accept.

5.1.2.3 To save drying parameters, Select Save parameter option using ▲ or ▼ and press **ENTER** to accept.

5.1.2.4 After selecting Save parameter option choose a reference number for specific setting using < and > keys and press **ENTER** to accept.

5.1.2.5 To save settings choose **YES** and press **ENTER** to accept.



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5.1.2.6 To display drying chart choose STAT option with F3 key, select *Drying chart* and press *ENTER*.

DRYING REPORT	
1. Drying chart	: OFF
2. Product Name.	:
3. Operator	:
4. Notes	:
5. Transmission	:
6. Exit	:

5.1.2.7 To Fill all the drying parameters as per the specification using ▲ or ▼, < and > keys and press *ENTER* to accept.

5.1.3 START OF ANALYSIS:

5.1.3.1 Load particular program. To load program Press “MEM” option using F4 key. Then Select a number of desired settings using navigation keys < and >. Press *ENTER* to accept.

5.1.3.2 After loading program, place an empty single-use pan and tare the balance with →T← key.

5.1.3.3 Than open the drying chamber and using the pan handle place the single-use pan with the sample on the pan support. Close the chamber.

5.1.3.4 Start the measurement choosing *START* option (F1 Key).

5.1.3.5 Drying in progress is signaled with alternating **SAMPLE / DRYING** communicate.

5.1.3.6 Wait until *STOP* communicate appears. Now read the result and give the print with the help of 7 no. key.

5.2 CALIBRATION:

5.2.1 EXTERNAL CALIBRATION:

5.2.1.1 For Calibration procedure press ‘Menu’ key.

5.2.1.2 Than Select calibration and press *ENTER key* and feed the correct value of used calibration weight using *External weight* option.

5.2.1.3 Select *External calibration* option and *ENTER* to start calibration.

5.2.1.4 Wait until tare process is finished, than place proper calibration weight on the pan when the message on the display shows..

CALIBRATION External calibration: Put on calib. Weight 100g
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5.2.1.5 Than remove the calibration weight from the pan.....

CALIBRATION
External calibration:
remove the calib. weight

5.2.1.6 After completing calibration process the balance is in the weighing mode.

Max.... Min... e= D=
0.000 g
0% 00%

To print a calibration report, use *Report printout* option.

5.2.1.7 Load the pan with the standard 100 g weight and note down the display reading in Annexure- I.

5.2.1.8 Similarly load the pan with weight 1 g , 2 g , 5 g , 10 g , 20 g, 50 g and note down the display reading in Annexure I(Calibration Record of IR moisture balance).

5.2.1.9 Acceptance criteria : The difference in the observed and actual values shall not be more than 0.1% from the actual value (refer to the calibration certificate of the weight box).

5.2.1.10 **Frequency – Monthly**

5.2.2 MEASUREMENT OF UNCERTAINTY:

5.2.2.1 Use **1 g** standard calibrated weight for measurement of uncertainty.

5.2.2.2 Place **1 g** standard calibrated weight on the pan.

5.2.2.3 Remove the weight and again place the weight on the pan.

5.2.2.4 Take 10 consecutive readings for the same weight.

5.2.2.5 Calculate the standard deviation of above 10 readings.

5.2.2.6 Calculate the uncertainty as follows:

$$= \frac{3 \times SD}{\text{Actual weight in grams}}$$

5.2.2.7 Acceptance criteria: Measurement of uncertainty should be less than or equal to 0.001.

5.2.2.8 **Frequency – Monthly**

5.2.2.9 Record the same in Annexure I(Calibration Record of IR moisture balance).



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5.2.3 TEMPERATURE CALIBRATION:

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

5.2.3.2 **Frequency** - Yearly

5.2.4 Fill the calibration status on metallic calibration label of the instrument, record the calibration results in Annexure-I (Calibration Record of IR moisture balance).

5.2.5 If instrument is fails in calibration, affix "UNDER MAINTENANCE" label and call for service engineer.

5.2.6 Note down the Calibration Activity in Instrument logbook.

5.3 CLEANING:

5.3.1 Before cleaning the instrument ensure all power connections of the instruments are removed.

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

5.3.3 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.

5.4 PRECAUTION:

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

5.4.2 Instrument should not be placed in hazardous area.

5.4.3 Clean the Instrument properly before and after use.

6.0 ABBREVIATION (S):

6.1 IR - Infra red

6.2 SOP - Standard Operating Procedure.

6.3 NA - Not Applicable

7.0 REFERENCE(S):

7.1 NA



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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 : Production department (02), Quality Assurance (01)
- 9.3 Reference copy : Production department (01)

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	NA



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ANNEXURE I

Calibration Record of IR Moisture Balance (Monthly)

Balance level: _____

Calibrated weight box Certificate No.: _____

S.No.	Theoretical weight (in gm)	Actual weight (in gm)	Observed weight (in gm)	Tolerance	Remarks
1.	1.0				
2.	2.0				
3.	5.0				
4.	10.0				
5.	20.0				
6.	50.0				

Acceptance Criteria: $\pm 0.1\%$ of Actual Wt

Remarks: The Instrument Calibration **Complies/Not Comply.**

Done By :

Checked By :

Date :

Date :