



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning, Operation and Calibration of Halogen Moisture Balance (LCGC)	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for cleaning, operation and calibration of Halogen Moisture Balance (LCGC Make and Model MAC 50/NH).

2.0 SCOPE:

This SOP is applicable for cleaning, operation & calibration of Halogen Moisture Balance (LCGC Make and Model MAC 50/NH) in the Production area.

3.0 RESPONSIBILITY:

Operator: Cleaning and Operation

Production and IPQA officer/ executive: Checking cleaning and operation

Head Production Department, Quality assurance Department: SOP Compliance

4.0 DEFINATION (S):

NA

5.0 PROCEDURE:

5.1 Cleaning

5.1.1 Switch 'OFF' the main power supply of the HMB.

5.1.2 Switch 'OFF' the main power supply of the printer.

5.1.3 Open all windows of protective guard and clean with wet cotton cloth and finally clean with lint free cloth.

5.1.4 Take out the weighing stainless steel stand from center of the instrument and clean with wet lint free cloth and finally clean with dry lint free cloth.

5.1.5 Clean the bottom side of the balance and area with tissue paper taking care that no powder should remains inside the narrow opening or edges of the balance.

5.1.6 Clean the external surface of HMB with wet lint free cloth and finally clean with lint free cloth.
Close all the protective guards.

5.1.7 Clean the external surface of printer with wet lint free cloth and finally clean with dry lint free cloth.

5.1.8 Ensure that HMB and printer are visually clean and dry.

5.1.9 **Frequency:** Daily or whenever required.



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5.2 OPERATION AND PARAMETERS SETTING:

Place the balance in area with minimum temperature fluctuation and on a solid support in order to avoid jerks or vibrations.

5.2.1 HMB PARAMETERS SETTING:

5.2.1.1 Ensure the Calibration status of the instrument.

5.2.1.2 Ensure that instrument is clean and free from dust.


5.2.1.3 Ensure that spirit level of balance (bubble position in center) by moving front two screws before using.


5.2.1.4 Switch 'ON' the mains.


5.2.1.5 Press the 'ON/OFF' key to 'ON/OFF' the balance. The balance is now in normal weighing mode, to display 0.000 g on balance screen. The screen displays as follows:





 **Start/Stop** key – switch on/ off process of drying according to chosen program.

 **Esc** key, resignation from introduced changes / exit to one level higher in menu.

 Group of navigation keys – change of parameters value; moving in menu.

 **Print/Enter** key – sending display state to external device (Print) or confirmation of chosen value or function (Enter).

 **TARA** key – zeroing the indications.

 **Setup** key – enter to main menu.

 **Test menu** key – starting choice of drying modes.

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

5.2.1.7 Now balance is ready for operation.




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5.2.2 WORKING MODE PARAMETERS SETTING:


5.2.2.1 For the Working mode parameters setting choose 'SETUP', by pressing the 'SETUP'.

5.2.2.2 All the functions, groups and their contents are chosen P1 to P5 by the keys.


5.2.2.3 To fill the parameters as per the specification using ▲, ►, ▼ & ◀ keys and press  to accept.

5.2.2.4 To save drying parameters, select YES then enter  to accept.

5.2.3 SETTING OF TEMPERATURE IN MOISTURE BALANCE

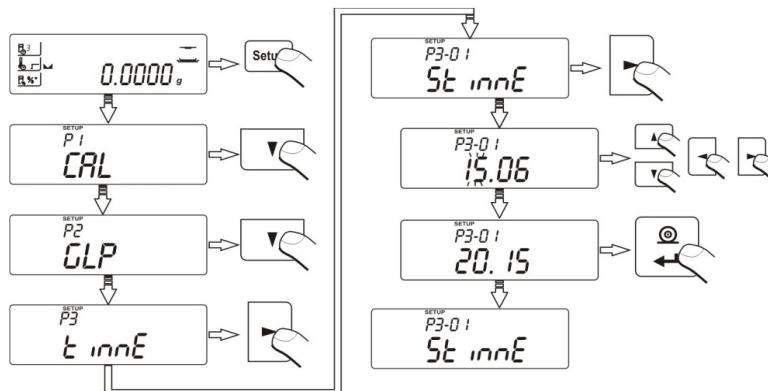
5.2.3.1 To set the temperature for the test press the , left side three programs blinks.


5.2.3.2 Then press the ▼ key then two times ► key.

5.2.3.3 On the screen digits in number blinks. Set the required specified value by keys ▼ & ▲. Then press  key to displays the main screen.

5.2.4 TIME SETTING IN HMB:

5.2.4.1 Setting of time of the HMB is display below:



5.2.4.2 To fill the parameters as per the specification using ▲, ►, ▼ & ◀ keys and press  to accept.

5.2.5 DATE SETTING IN HMB

5.2.5.1 Setting of date of the HMB is display below:

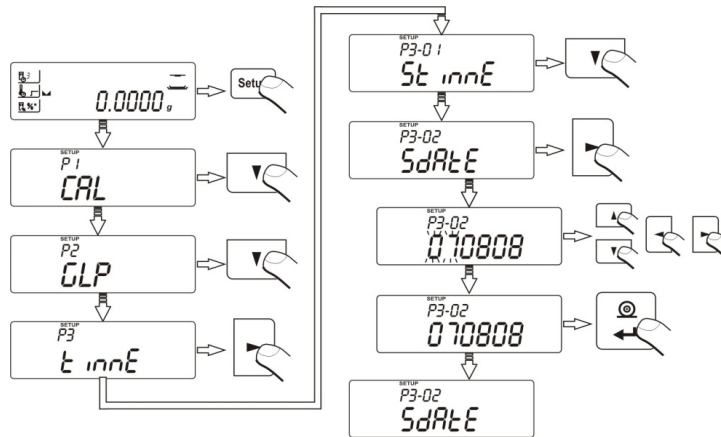


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5.2.5.2


To fill the parameters as per the specification using ▲, ►, ▼ & ◀ keys and press  to accept.

5.3 START OF ANALYSIS:

5.3.1

To start the LOD checking process press  keys to display the reading **0.000 g**, then press the key .

5.3.2

On the right-hand side top of the display blinks. Then press the key , display again blinks.

5.3.3

Then open the drying chamber and using the panhandle & place the single use pan.


5.3.4

Then place the required specified sample on the pan and close the drying chamber.

5.3.5

Process starts automatically after closing the drying chamber as per set parameters.

5.3.6

If you want to STOP the process press the key . Process is Stop.

5.3.7

After completion of the test stops automatically and generate the print report of the above test.

5.4 Calibration

5.4.1 Daily Calibration Record

5.4.1.1

Daily Calibration of balance should be performed at start of operation.

5.4.1.2

After completion the internal calibration press tare to zero display.

5.4.1.3

Place 1 gm standard weight on the pan with help of forceps.

5.4.1.4

Note the displayed weight after the display is stable.

5.4.1.5

Repeat operation with 2 g, 5 g, 10 g, 20 g and 50 g standard weights. Note the displayed weight after the display is stable & record in Annexure- I.



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- 5.4.1.6 Tolerance of Daily Calibration Record of balance ± 0.1 % of actual weight.
- 5.4.1.7 Frequency of Daily Calibration Record is - Daily
- 5.4.1.8 If instrument is out of calibration, affix "OUT of CALIBRATION" and call for service engineer.
- 5.4.1.9 Fill the calibration status on metallic calibration label of the instrument, record the calibration results in **Annexure-I**.

5.4.2 Calibration of Temperature

- 5.4.2.1 Calibration of temperature is to be done by Engineering Department and approved external laboratory / party.
- 5.4.2.2 Frequency - Yearly

5.5 Precaution

- 5.5.1 Balance should be placed on stable, vibration free and leveled support.
- 5.5.2 Balance should not be placed in hazardous area.
- 5.5.3 Clean the pan properly before and after use.
- 5.5.4 Always keep the glass doors of the balance closed.
Authorized person can carry out change of halogen.

6.0 ABBREVIATION (S):

- HMB : Halogen Moisture Balance
- gm : Grams
- SOP : Standard Operating Procedure
- NA : Not Applicable

7.0 REFERENCE (S):

- SOP: Status labeling

8.0 ANNEXURE (S):

- Annexure-I: Daily Calibration Record

9.0 DISTRIBUTION:

- 9.1 **Master copy** : Quality Assurance
- 9.2 **Controlled copy (s)** : Production department; Quality assurance
- 9.3 **Reference copy (s)** : Production department



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ANNEXURE I

Daily Calibration Record: Halogen Moisture Balance (LCGC Make)

Theoretical Wt	1.0 g	2.0 g	5.0 g	10.0 g	20.0 g	50.0 g	Done by	Remark	
Mass/Actual Wt									
Limit (mg/g)									
Date	Spirit level	(Observed Weight (in g))							

Note: *Record the spirit level as Ok/Not Ok (Bubble position in center)