	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Cleaning, Operation & Calibration of IR Moisture Balance	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0   OBJECTIVE:

To lay down a procedure for Cleaning, Operation and Calibration of IR Moisture Balance.

2.0   SCOPE:

This procedure is applicable to Cleaning, Operation and Calibration of IR Moisture Balance in production department.

3.0   RESPONSIBILITY:

Technical Associate, Officer / Executive: Operation and Calibration

Head Production   : SOP Compliance

IPQA Person   : Calibration

4.0   DEFINITION(S):

NA

5.0   PROCEDURE:

5.1   Cleaning:

5.1.1   Press ↑↓ to open/close the sample chamber.

5.1.2   Switch off the main supply.

5.1.3   Remove the sampling plate, sampling plate support and shield disk.

5.1.4   Clean the IR moisture balance body and dismantled parts with clean dry lint free cloth or tissue paper and assemble the dismantle parts in the reverse order they are dismantled.

5.1.5   Wipe the dismantled parts with 70% V/V IPA once in week.

5.2   Operation:

5.2.1   Setting:

5.2.1.1   Adjust the air bubble in the circle by using leveling feet.

5.2.1.2   Switch "ON" the main power supply. Balance displays 'OFF'.

5.2.1.2   Switch "ON" the main power supply. Balance displays 'OFF'.

5.2.1.3   Press the 'I/O' key to "ON/OFF" the balance. Balance will turn 'ON'

5.2.1.4   Balance will perform self test and display the opening screen as:

Prog.	**Stat.**	**ID**	**Mode**	**Tare**

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5.2.1.5   Press 'Prog' key. Program main screen will open. Press 'ᵛ or ᴧ key to

select program or add a new program.

5.2.1.6   Press '>' key. Program main screen will open and it will display

- Program Name
- Heating Program
- Standby Temperature
- Bar Graph for Weighing-in Sample
- Start Analysis
- End of Analysis
- Weight Resolution for Analysis
- Display Mode
- Print Intermediate Results
- Analysis ID with Auto Numbering
- Analysis W/Former Spl (100 % fot.)
- Identification #
- Factory Settings

5.2.1.7   Select the desired function by pressing 'ᵛ or ᴧ' key. After reaching the desired

function press '>' key.

5.2.2   Heating Program Setting:

5.2.2.1   Select 'Heating Program' and press '>' key. Next screen will display various drying

Options :

- a. Standard drying
- b. Quick drying
- c. Gentle drying
- d. Phase drying
- e. High temp. drying

5.2.2.2   Select the desired drying option by pressing 'ᵛ or ᴧ' key. After reaching the desired

drying option press '>' key.

5.2.2.3   Change the drying temperature as per specifications in respective BMR and press 'ENTER' arrow key for

confirmation.

5.2.2.4   Press '<<' key. Program main screen will open.

5.2.2.5   Press '<<' key to go to Main screen.

5.2.3   Stand by temp setting:

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Select : Off

: On Mode

5.2.4   Target weight and tolerance in percentage:

5.2.4.1   Target weight 2 mg to maximum 90% of maximum capacity can be selected.

5.2.4.2   1 to 50 % of tolerance can be selected.

5.2.5   Start analysis by selecting one of the option:

5.2.5.1   With stability and auto close

5.2.5.2   With stability and Manual close

5.2.5.3   Without stability and auto close

5.2.5.4   Without stability and Manual close

Note   :   Time delay can be selected from 0 to 99 secs for the above stages.

5.2.6   End analysis: End Analysis parameter can be selected depending upon users requirement.

5.2.6.1   **Automatic:** The fully automatic mode can be selected when system shows the result automatically after removal of moisture.

5.2.6.2   **Semi Auto Parameters:** In this case we need to press a stop key to end the analysis.

The weight loss then be calculated and saved as drying parameter.

5.2.6.3   **Semi auto absolute weight loss:** The analysis ends as soon as the weight loss for a selected time limit is less than the defined limit which can be selected in milligrams.

5.2.6.4   **Semiauto weight loss in percentage:** The analysis ends as soon as the weight loss for a selected time limit is less than the defined limit, which can be selected in percentage.

5.2.6.5   **Time :** The analysis ends as soon as the time set for completion of process has elapsed.

5.2.6.6   **Manual :** To end analysis stop key needs to be pressed .

5.2.7   Weight resolution for analysis: Selected no. of decimal places can be displayed on weight Resolution.

5.2.8   Print intermediate results: Intermediate results can get available by setting the time or by pressing ⊙ print button in between the analysis.

5.2.9   Analysis with auto numbering: Total number of analysis can be counted for all analysis performed in a sequence.

5.2.10   Analysis with Former Sample: The sample weight of the last analysis is calculated as 100% for the next analysis.

5.2.11   Identification#: Different identification codes can be given for each drying program.

5.3   Operation procedure

5.3.1   Ensure cleanliness of the instrument and calibration status before operation.

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5.3.2   Press the '↑↓'arrow key to select TARE function and zeroes the weight by pressing

'TARE' key. Load sample massage will be displayed on screen.

5.3.3   Press the '↑↓'arrow key. Safety cover over the weighing platform will slide inside.

5.3.4   Load the powder sample (approximately 2 g), evenly distributed on the weighing plate.

5.3.5   Press the '↑↓'arrow key. Safety cover over the weighing platform will slide out. 'Start Analysis' message will

display on the screen.

5.3.6   Press 'START' key. Analysis will start and 'Begin' message will display on screen.

5.3.7   'Analysis End' message will display on completion of analysis.

5.3.8   Press the '↑↓'arrow key. Safety cover over the weighing platform will slide inside.

5.3.9   Remove the sample plate and empty it in SS container labeled as 'Disposal Bin'.

NOTE: Before analysis of powder sample observe the moisture content of some paper pieces to

avoid the interference of moisture present in the drying chamber.

5.4   Calibration:

5.4.1   Turn 'OFF' the IR moisture balance. Turn 'ON' the IR moisture balance.

5.4.2   Press the '↑↓'arrow key to open the sample chamber.

5.4.3   Press 'TARE' key. Balance will display 0.000 g.

5.4.4   Place standard weights one by one in the center of sample plate as per table given below and record the

observations in the annexure-I.

Balance Capacity	Operating Range	Standard Weights to be used for Calibration			
100 g	1.000 to 95.000 g	1.000 g	20.000g	50.000 g	95.000 g

5.4.5   A balance is considered satisfactory for use if the readings are found to be within acceptance limit of the

balance.

5.4.6   f the readings are exceeding the acceptable limit, put an 'UNDER MAINTENANCE' tag, and Inform to utility

department for necessary action and record the same in Balance Calibration Record.

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

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

5.4.9   Check for the zero error as per the specific operation procedure of the balance and enter the reading in the

respective annexure for the balance.

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

NOTE: 1) Ensure zero reading before placing any standard weight for calibration.

2) Reading observed on balance should not vary more than 0.1 % of the standard weight

used for calibration. In case, if 0.1 % tolerance is not practically readable on balance,

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least count X 2 of that particular balance shall be considered as tolerance limit for the

respective standard weight or nearest possible readable weight w. r. t. 0.1 % tolerance

shall be considered as tolerance for respective standard weight.

5.4.11 **Frequency:** Daily

6.0   ABBREVIATION(S):

SOP   :   Standard operating procedure

g   :   Grams

w r t   :   With Respect To

no.   :   number

7.0   REFERENCE(S):

SOP: Status Labeling

8.0   ANNEXURE(S):

Annexure – I: IR Balance 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

IR BALANCE CALIBRATION RECORD

Department		Month / Year		Least count	0.001g
IR Balance Code No.				Capacity	100 g

Calibrated weight Certificate No.:

Standard weight Box ID No.	Calibration Done On	Calibration Due On

Standard Weights		Tolerance	Acceptance Limit
Lower	1.000 g	± 0.001g	0. 999 g –1.001g
Middle (1)	20.000 g	±0.02 g	19.98 g – 20.02 g
Middle (2)	50.000 g	± 0.05 g	49.95 g – 50.05 g
Upper	95.000 g	± 0.095 g	94.905 g – 95.095 g

Theoretical Wt.		1.000 g	20.000 g	50.000 g	95.000 g	Done By	Checked By
Measured Value/Actual Wt. (g)							
Date	**Spirit level**	Observed Wt. (g)					

Note: Record Spirit Level as OK / Not OK

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