TITLE: PROCEDURE FOR TEMPERATURE MAPPING OF TRAY DRIERS AND VACUUM TRAY DRIERS

1.0 PURPOSE:

To lay down the Procedure for Temperature mapping of uniform temperature distribution in tray driers and vacuum tray driers.

2.0 SCOPE:

This Procedure is applicable to provide a documented procedure for Temperature mapping of uniform temperature distribution in tray drier and vacuum driers, which are using in the manufacturing facility of Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 **Engineering Department:**

It is the responsibility in coordination with External agency Hired to do the driers mapping) to follow the procedure given in this SOP and compile the reports after completion of the validation of the tray and vacuum Driers.

3.2 **User Department:**

It is the responsibility of production personnel to coordinate during the temperature mapping of tray and vacuum driers.

3.3 **Quality Assurance (QA) Department:**

It is the responsibility of Q.A. department personnel to approve the temperature mapping reports after review.

4.0 DEFINITIONS: NIL

5.0 PROCEDURE :

5.1 **PROBES ARRANGEMENT PLAN**

5.1.1 Ensure that the drier, trays and all accessories are cleaned thoroughly and ready for use.

5.1.2 Keep the empty trays in their position.

5.1.3 Ensure that the identification tags are arranged for all the probes.

5.1.4 All the probes shall be inserted from air inlet provision in uniform manner.

5.1.5 Keep the probe in tray in its specified place as shown in figure all the trays.

5.1.6 Connect all the probes to data logger.

5.2 **ARRANGEMENT OF DATA LOGGER:**

5.2.1 Ensure that all the probes and the printer are connected to data logger.

5.2.2 Ensure that the logger is electrically connected.

5.2.3 Program the data logger as per the manual and as per the temperature and time intervals Required

5.2.4 Start the data logger and record the temperature for two intervals in idle condition in the drier.

5.2.5 Ensure that the temperatures are recorded for all the probes.

5.2.6 Proceed for the heating operation.

5.3 **TEMPERATURE DISTRIBUTION MAPPING PROCEDURE :**

5.3.1 Close the drier door.

5.3.2 Switch on the drier fan.

5.3.3 Air dry for about 30 minutes.

5.3.4 Set the data logger to record the temperature for every at every set point for all the probes.

5.3.5 Set the temp. apply steam to the dryer and after raising of the temperature to the near of the set temperature stop steam and wait for the stabilization of the temperature and ensure that the temperature is constant and does not change any more (in digital thermometer) then take print out of the temperature readings at each sensor point/ points.

5.3.6 Again apply steam and raise the temperature about 30ºC, 60ºC, 90ºC, similarly take print out at the regular intervals as mentioned in point 6.3.5.

5.3.7 After completion close the steam supply to the drier and stop the data logger.

5.3.8 Cool the temperature to room temperature.

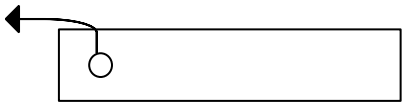
5.3.9 Open the drier doors and remove the probes from the trays.

5.3.10 Clean the trays by using lint free cloth and keep the trays in its position.

5.3.11 Use minimum 16 probes.

5.4 **LEGEND:**

PROBE



5.4.1 Similarly for 96 trays capacity tray dryers adjust the probes on four front corners, two at back side and other two at the middle of the trays.

5.5 **DATA TO BE COMPILED :**

Attach data logger temperature sheets and compile the minimum and maximum temperature.

5.6 **ACCEPTANCE CRITERIA :**

±5ºC tolerance is applicable for the set value.

Temperature mapping should be carried out for every three years.

5.7 **REVIEW OF DOCUMENTS :**

Preventive Maintenance records.

Calibration records of probes and data logger, temperature record map for uniformity of distribution.

5.8 **STEPS TO BE FOLLOWED IN CASE OF FAILURE :**

In case of failure, identify the problem and investigation to be carried for failure. The investigation to be done in co-ordination with production and quality assurance. Based on the investigation take necessary corrective action, upon rectification proceed for revalidation of temperature distribution. In the investigation, if it is found that the equipment is not functioning well then the report to be reviewed and further investigation to be carried out.

5.9 **CONCLUSION :**

Conclusion shall be drawn based on the data compiled.

6.0 FORMATS / ANNEXURE(S): NIL

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.	Remarks
00	01.01.2017	New SOP	ED-CRF-006/16	---
01	17.08.2017	1. SOP format changed in line with SOP-QA-001-05.	CCF/GEN/17007	--