

STANDARD OPERATING PROCEDURE					
SOP No.:	SOP-QC-016-05	Effective Date:	01.01.2017		
Supersedes:	SOP-QC-016-04	Next Review Date:	31.12.2019		
Department: Quality Control Page: 1 of 3					

TITLE: OPERATION AND CALIBRATION OF VACUUM OVEN

1.0 PURPOSE:

To describe the procedure for Operation and calibration of Vacuum Oven.

2.0 SCOPE:

The procedure applies to the Vacuum Oven in laboratory.

MAKE: Biotech

ID No : DIPL/QC/INS/VO/001

3.0 RESPONSIBILITY:

- 3.1 Analyst-QC is responsible to follow this SOP.
- 3.2 Head-QC/Designee is responsible for ensuring implementation of this SOP.
- 3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.

4.0 **DEFINITIONS:**

Nil

5.0 PROCEDURE:

5.1 **Operation:**

- 5.1.1 Ensure that the Vacuum Oven is clean.
- 5.1.2 Check the gasket before and after usage.
- 5.1.3 Check calibration of vacuum gauge within the due date.
- 5.1.4 Insert a previously calibrated thermometer or Digital temperature indicator in the socket provided.
- 5.1.5 Place the sample which is to be dried under vacuum.
- 5.1.6 Close the lid tightly with the help of screw knobs provided.
- 5.1.7 Attach the vacuum valve to attain the required vacuum.
- 5.1.8 Close the vacuum valve and detach the vacuum line and ensure that there is no vacuum Decrease due to leakage .If the vacuum indicator shows already reading, star heating up to the required temperature.

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Sign & Date			
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- 5.1.9 After completing the drying release the vacuum valve slowly and allow the oven to come to the room temperature.
- 5.1.10 Switch off the instrument.

5.2 Calibration:

- 5.2.1 Set the required temperature with the help of thermostat.
- 5.2.2 Insert the calibrated thermometer in to the thermometer socket of the oven.
- 5.2.3 Allow the temperature to attain constant value.
- 5.2.4 Note down the oven temperature and cross-check with the calibrated thermometer or Digital temperature indicator with Accuracy of $\pm 2^{\circ}$ C
- 5.2.5 Set the following temperatures: 50°C, 100°C, 150°C and 200°C
- 5.2.6 Record the readings in Digital temperature indicator (Vacuum oven) calibration.
- 5.2.7 The acceptance criteria for observed temperatures is as follows $\pm 2^{\circ}$ C.
- 5.2.8 Calibration frequency: Once in a 3 Months (±3 Days)

6.0 FORMATS / ANNEXURE(S):

6.1 Instrument Usage log book : QC048-FM086

6.2 Digital temperature indicator (vacuum oven) calibration : QC016-FM052

7.0 CHANGE HISTORY:

Revision No.	Effective Date		Details of Revision		Ref CCF No.
00	01.06.2007	introduc	New SOP calibration of equipments is introduced across all the API manufacturing facilities of Discovery.		
01	01.08.2009	Formats	Formats changed with clear and clarity		
02	29.10.2011	The SOP has been revised due to incorporate the some more instructions in the operating procedure of Vacuum oven.			
03	01.06.2014	Calibration Acceptance criteria change			
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Revision No.	Effective Date	Details of Revision	Ref CCF No.
		$\pm 4^{\circ}$ C to $\pm 2^{\circ}$ C	
		2. Formats are the part of SOP. So prepared	
		separately.	
04	01.01.2017	SOP format changed make to line with SOP-	QC-CRF-
01.01.2017		QA-001-04.	025/16

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