 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QC-021-04	Effective Date:	01.01.2017
	Supersedes:	SOP-QC-021-03	Next Review Date:	31.12.2019
	Department:	Quality Control	Page:	1 of 3
TITLE: PROCEDURE FOR TEMPERATURE & HUMIDITY MONITORING				

1.0 PURPOSE:

To lay down a procedure on monitoring of temperature and humidity in quality control department using suitable temperature and relative humidity sensing devices.

2.0 SCOPE:

This procedure applies to temperature and humidity monitoring by using digital hygrometer, for quality control department in Discovery.

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 Ensure that the hygrometer is within calibration period (Frequency: Once in a year)
- 5.2 The calibrated hygrometer having unique identification number shall be used in the laboratories for measurement of temperature and relative humidity.
- 5.3 Ensure that the digital temperature meter/ digital Temperature and Humidity meter is clean and dust free.
- 5.4 The QC areas like reserve sample room, wet area shall be monitored.
- 5.5 Record the minimum and maximum values of temperature and humidity as displayed in hygrometer afternoon hours in all working days.
- 5.6 The afternoon recording is considered keeping in the view of highest probable temperature in any season
- 5.7 The same shall be verified/checked on regular basis.
- 5.8 The relative humidity monitoring shall be for information only.

	Prepared by	Reviewed by	Approved by
Sign & Date			
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Department	Quality Control	Quality Control	Quality Assurance

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- 5.9 The tolerance limit of maintaining temperature below 25°C excursions permitted 15°C-30°C for wet lab.
- 5.10 The temperature monitoring for control sample room would be the ambient temperature. The products which are not stable at room temperature are to be stored as per their recommended storage conditions and monitored.
- 5.11 QC personal shall record the Temperature and Humidity as per format no QC021-FM054.
- 5.12 The same shall be verified/checked by section in charge/second chemist and put his checked by signature.
- 5.13 Review the temperature and humidity for each quarter (1st quarter-January to March, 2nd quarter-April to June, 3rd quarter July to September and 4th quarter October to December) by recording the minimum and maximum values of temperature and humidity in temperature and humidity record as per format number QC021-FM055.
- 5.14 Annual review of temperature and humidity in temperature and humidity record shall be done by QA at the end of the year.

6.0 FORMATS / ANNEXURE(S):

- 6.1 Temperature and humidity record : QC021-FM054
- 6.2 Annual review of temperature and humidity data : QC021-FM055

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.08.2009	New SOP is introduced	--
01	07.11.2012	Incorporate Temperature & Humidity monitoring in instrumentation lab.	--
02	01.06.2014	Formats are the part of SOP. So prepared Separately.	--
03	01.01.2017	1. SOP format changed make to line with SOP-	QC-CRF-
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Revision No.	Effective Date	Details of Revision	Ref CCF No.
		QA-001-04. 2. Temperature And Relative Humidity Quarterly Review Record included. 3. Daily Temperature & Relative Humidity Monitoring record modified.	025/16

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