



Discovery Labs

STANDARD OPERATING PROCEDURE

SOP No.:	SOP-QC-041-02	Effective Date:	03.06.2017
Supersedes:	SOP-QC-041-01	Next Review Date:	02.06.2020
Department:	Quality Control	Page:	1 of 3

TITLE: PROCEDURE FOR BACKUP / RESTORE ANALYTICAL DATA IN ELECTRONIC FORM

1.0 PURPOSE:

To describe the procedure for ensuring Backup/Restore Analytical Data from computer associated with laboratory instruments

2.0 SCOPE:

The Procedure outlined in this SOP is applicable for Backup/Restore Analytical Data from computer associated with laboratory instruments at Discovery.

3.0 RESPONSIBILITY:

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

4.0 DEFINITIONS:

A backup process must be implemented to allow for recovery of the system following any failure which compromises its integrity.

5.0 PROCEDURE:

5.1 Backup/Restore Analytical data :

- 5.1.1 The computer system associated with laboratory instruments are standalone system with high risk.
- 5.1.2 Copy the required data from the source computer to the destination CD writer which contains the CD to be written.
- 5.1.3 Write the copied data from hard disk to CD
- 5.1.4 Each electronic data should be copied in duplicate CD's
- 5.1.5 Before removing the CD ensure that the required data is copied or not.
- 5.1.6 One CD shall be kept at QA while the 2nd CD shall be kept at head office management cabin.

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5.2 Frequency of Data backup

5.2.1 Take the data backup First week of every month, for previous month data.

5.2.2 Regular testing of backup data (restore data) should be carried out once in every six months to verify the proper integrity and accuracy of data.

5.3 Precautions :

5.3.1 Store the copied CD's protected from heat and dust

5.3.2 During the file copying the source computer should not be switched off.

5.3.3 While copying the files do not perform any other precautions on target computer.

5.4 Numbering System of CD:

Electronic data stored in CD's shall have numbering system for easy traceability:

Numbering should be as XXX-ZZ-MM-YY

Where

XXX : Instrument Name (i.e.: HPLC, GC, IR etc.)

ZZ : No. of particular instrument

MM : month of the data

YY : Last two digits year of the data

Eg.: HPLC-002/01-16

GC-001/01-16

6.0 FORMATS / ANNEXURE(S):

Nil.

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	02.07.2016	New SOP introduced	--
01	01.01.2017	SOP format changed make to in line with SOP-QA-001-04.	QC-CRF-025/16

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Revision No.	Effective Date	Details of Revision	Ref CCF No.
02	03.06.2017	1.0 SOP format changed make to inline with SOP-QA-001-05 2.0 Storage of CD's are redefined 3.0 Precautions of Handling CD's are incorporated 4.0 Altogether procedure has been rephrased for better clarity	CCF/GEN/17018

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