ION LABS QUALITY FIRST	Standard Operating Procedure **Laboratory Raw Data Definition and Management**	**SOP Number** **D-114**	**Revision** **1**
		Effective Date 08/11/21	**Page** **Page 1 of 2**
Written by/ Date 06/07/21	**Reviewed by/ Date** 06/07/21	**Approved by/ Date** 06-07-21	
Title: QC Laboratory Director	**Title: Analytical Method Validation Manager**	**Title: VP of Quality & Regulatory Affairs**	

1.0 Purpose

The purpose of this SOP is to describe how raw data is defined and maintained in the QC Laboratory.

2.0 Scope

This procedure applies to all GMP testing performed at Ion Labs for the release of any raw material, finished product or stability batches.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Management to ensure all raw data is stored and maintained according to the standards depicted in this SOP.

3.2 It is the responsibility of IT to secure and archive any electronic data at regular intervals

4.0 Definitions

4.1 **Raw Data** –any laboratory worksheets, records, memorandum, notes that are the result of original observations and activities and are necessary for the reconstruction and evaluation of the report of that study.

4.2 **RM** – Raw Material

4.3 **CofA** – Certificate of Analysis

4.4 **DC** – Document Control

4.5 **QC** – Quality Control

4.6 **SOP** – Standard Operating Procedure

5.0 References

5.1 D-901, SOP, Raw Material Life Cycle

5.2 C-502, SOP, Record Storage, Retention and Destruction

5.3 D-101, SOP, Laboratory Housekeeping

6.0 Raw Data Definition and Archival of Raw Data

6.1 Raw data generated for the release of finished product will be turned into DC with the FPTT (Finished Product Test Ticket) and will be archived with the batch record for that lot.

6.2 Raw data generated for stability testing will be archived with each individual stability study.

6.3 Raw data generated for the release of raw materials will be turned into DC, scanned electronically and stored on the network.

6.4 Raw data created from original observations documented in a laboratory notebook will be archived with the notebook in DC.

6.5 Laboratory data will be archived for a period of time as defined in SOP C-502, Record Storage, Retention, and Destruction.

6.6 Electronic data should also be preserved in accordance with the written documentation associated with the raw material, finished product or stability time point being tested.

7.0 Protection of Raw Data and Archived Raw Data

7.1 Archived raw data should be stored in a location with controlled access to prevent the loss and/or manipulation of data.

7.2 Audit trails will be regularly reviewed for completeness, unreported data and any unexplained data deletion.

7.3 Electronic data should be archived at regular intervals.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	03/22/18	New.	N/A	J. Maignan
1	06/02/21	Clarified raw data in the laboratory	CC-21-0216	J. Sassman