ION Nutritional Labs	Standard Operating Procedure Laboratory Notebook, Equipment Use Logs, Data Handling, and Data Review	SOP Number D-102	Revision 7
		Effective Date 09/01/23	Page Page 1 of 9

Written by/ Date	Reviewed by/ Date	Approved by/ Date
08/31/23	SAS 08/31/23	08/31/23
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1.0 Purpose

This procedure outlines the assignment of laboratory notebooks to both laboratory analysts and laboratory equipment. This procedure also gives guidance on proper documentation of tests and experiments recorded in laboratory notebooks and use logs, and provides guidance on review of that documentation. This procedure is intended to give additional specific guidance for laboratory notebooks in addition to SOP A-106 Documentation Guidelines for cGMP Records.

2.0 Scope

This procedure is applicable only to official, registered laboratory notebooks that are property of Ion Nutritional labs. This procedure applies only to notebook entries and data handling for QC Laboratory Analysts. In the event that there is a conflict between this procedure and SOP A-106 Documentation Guidelines for cGMP Records, the most conservative option of the two will be followed.

3.0 Responsibility

3.1 It is the responsibility of DC to oversee the logging of notebook inventory.

3.2 It is the responsibility of QC Chemists to follow this procedure.

3.3 It is the responsibility of Quality Management to implement this procedure and to ensure that personnel are following this procedure.

3.4 It is the responsibility of QC Laboratory Management to keep this procedure current with latest Ion Nutritional Labs practices.

4.0 Definitions

4.1 **DC** – Document Control

4.2 **QC** – Quality Control

4.3 **OTC** – Over the Counter (Referencing nonprescription drugs)

4.4 **cGMP** – Current Good Manufacturing Practices

4.5 **OOS** – Out of Specification

4.6 **Checklist** – tool to be used by both the analyst and data reviewer to assist in defining required pieces of a data packet needed to complete data packet review.

4.1 **Redzone (RZ)** – a software application used to collect data during the production process; used to track production data, as well as cGMP data

4.2 **Data Sheet** – an RZ component of the RZ Compliance Module, configured to collect data

4.3 **SOP** – Standard Operating Procedure

5.0 References

5.1 A-106, SOP, Documentation Guidelines for cGMP Records

5.2 D-102-F1, form, General Data Review Checklist

5.3 C-111, SOP, Redzone General Use

5.4 C-107, SOP, Redzone Reviewer Activities

6.0 Procedure

6.1 Notebook Assignment

6.1.1 Notebooks are released in sequential order.

6.1.2 Each notebook is assigned to a single individual for individual use only, to a single specific test (i.e. loss on drying, weight variation), or to a specific piece of equipment (i.e. balance).

6.1.2.1 Notebooks assigned to specific tests or equipment will be kept in a centralized location and the department for the assigned notebook will be responsible for the notebook.

6.2 Notebook Inventory Control

6.2.1 DC will oversee the maintenance of a ledger which summarizes the following information:

6.2.1.1 Notebook number

6.2.1.2 Name of person, test, or equipment assigned to notebook.

6.2.1.3 Date when the book is put into service.

6.2.1.4 Date notebook is retired.

6.3 Entries for identifying test and laboratory information in a notebook.

6.3.1 The assigned notebook number (found on the inside front cover) should be filled out at the top of every page on the Book line if applicable.

6.3.2 When documenting a new write up, the first page of the document should read Start/new on the *Continued from page* line. If multiple pages are required to fully document the information the next page should be filled in on the

Continued on page line, the previous page number should be filled in on the *Continued from page* line and end if it's the final page.

6.3.3 The name of the product, raw material, test, or experiment should be listed on the Title line at the top of each notebook page along with any associated batch numbers, R numbers, or sample identifiers.

6.3.4 An analyte, buffer, test abbreviation, OOS designator, protocol designator or other project identifier should be listed on the Project line, if applicable.

6.3.5 On the first line of the first page, list any SOPs, monographs, or other test identification information that references the methods or procedures used to execute testing.

6.4 Components of a Write Up

6.4.1 A hypothesis/purpose statement should be added when applicable at the beginning of the first page to describe/identify the experiment being performed and the expected outcome. A hypothesis statement is not required for finished product and raw material release testing, standard certification, buffer preparation, or if assigned to equipment.

6.4.2 If samples are being analyzed, the product or material names and associated lot numbers should be listed. For stability testing, testing time points should be included.

6.4.3 If prepared solutions are being used, the solution's name, notebook/ page identifier and expiration date should be listed.

6.4.4 If chemicals are being used, the manufacturer, lot number and expiration date should be listed for each chemical. For each standard used, the unique identifier, purity, and expiration date should be documented.

6.4.5 If equipment is utilized during testing, the special ID or Ion# and/or calibration due date should be documented in notebooks (this includes balances, pH meter, HPLC, ICP, FTIR, HPLC Column, etc.).

6.4.6 Testing performed on different days should include different write-ups. Referencing a previous write-up is not allowed.

6.4.7 All documentation will be signed by the analyst on the day it occurred. If a write-up occurs over the course of multiple days then the analyst should write "end of day" and sign/ date after each days entries.

6.4.8 If following a procedure or a monograph and a deviation from the referenced procedure is used, cite the procedure being used and describe in detail any deviations from referenced procedure. If an undocumented procedure is being used such as in a method's development, list in detail each step and measurement used while conducting the experiment and document in a notebook.

6.4.9 Hard copy data such as weigh tapes should be permanently affixed to the page and signed and dated across tape or edge.

6.4.10 Where applicable, for procedures where a result is reported, a section labeled 'results' should be included. In the results section document or reference all calculations associated with the generation of final result as required.

6.5 Raw Data Handling

6.5.1 When digital raw data is generated, a raw data report needs to be printed in hard copy to include all digital data associated with the test. Examples of sources are: HPLC, UV/VIS Spectroscopy, and ICP. FTIR does not require a write up or test ticket and the scans are archived electronically.

6.5.2 All electronic data generated will be assessed for system suitability acceptance

criteria prior to submitting for data review, if applicable.

6.5.3 A hardcopy of a spreadsheet including the data summary and result(s) or a photocopy of the associated notebook page(s) can be attached to the front of the data packet.

6.5.4 If a spreadsheet is used the spreadsheet must reference the laboratory notebook and page number(s) associated with the data when not accompanied by the photocopies of the notebook pages.

6.5.5 The data packet will be submitted with the associated finished product and/ or raw material and then scanned in by DC.

6.5.6 Stability data packets are maintained by the QC Laboratory.

6.6 Data Review

6.6.1 Analysts will review their write up to verify completion of the documentation then sign and date before review. The analyst will submit all supporting documents for each write-up to the reviewer including, but not limited to: copies of standard preparations, electronic reports generated from analytical runs, and checklists, if applicable.

6.6.2 If a portion or an entire page was not used, a single line will be drawn across the unused portion of the page. The line will be initialed and dated in the middle.

6.6.3 Data review includes but is not limited to:

6.6.3.1 Review documentation against all current practices, testing methods, and procedures. Ensure that procedures were followed as written.

6.6.3.2 All equipment used was within calibration.

6.6.3.3 All system suitability acceptance criteria met.

6.6.3.4 Results are within specification and reported correctly as per rounding rules.

6.6.3.5 Handwritten or manual calculations shall be verified for correctness.

6.6.3.6 All documents needed are present in data packet.

6.6.4 The originating analyst is responsible for correcting, signing and dating any changes made as a result of the review.

6.6.5 When the procedure has been reviewed and all corrections made, the reviewer will sign and date the page(s) associated with the write up on the *Disclosed and Understood by* line.

6.6.6 Where applicable, notebook review must be signed off within three business days of the primary Analyst's sign-off or the date of last correction, whichever is most recent.

6.7 Checklist

6.7.1 Each data packet should include a checklist that is used by both the analyst and data reviewer to ensure the packet contains all required documentation.

6.7.2 Additionally, the checklist should be used to show assessment of all method suitability requirements by both the analyst and data reviewer.

6.7.3 As applicable, testing specific checklist are included as an official controlled form associated with each testing process. Form D-102-F1 General Data Review Checklist can also be used if a test specific checklist is not available.

6.8 Laboratory Equipment Use Logs

6.8.1 Laboratory equipment used in or supporting the manufacture or testing of GMP materials that requires a record of traceability shall have a use log. Exceptions

to this requirement are listed below.

6.8.1.1 Laboratory equipment that uses an electronic software to collect data and presents the ability to create reports that summarizes all samples tested during a specific time period.

6.8.1.2 Equipment used exclusively for R&D purposes (non-GMP).

6.8.2 Use log requirements

6.8.2.1 Laboratory equipment use logs may be manually captured in a laboratory notebook or electronically captured, i.e. using RedZone.

6.8.2.1.1 If applicable and available, RedZone may be used to capture equipment use using RedZone datasheets.

6.8.2.1.2 The appropriate configuration of Redzone occurs during the development and verification of the datasheet as covered by SOP C-107 RedZone Reviewer Activities.

6.8.2.2 Use logs entries should be in chronological order.

6.8.2.2.1 If an entry is mistakenly omitted, it can be added at a later date with justification as a footnote. The use entry should be verified against other supporting documentation as applicable.

6.8.2.3 The following must be documented at time of use as applicable

6.8.2.3.1 Date

6.8.2.3.2 Product Details

6.8.2.3.3 Lot Number or other sample traceability details

6.9 Data Review Audits

6.9.1 Periodically, the data reviewer shall check entries in logbooks of instruments and equipment used for analysis and shall verify the calibrations/ qualifications at random. This check can be captured by the data reviewer signature of audit in the logbook.

6.9.2 Periodically, Laboratory management should audit data that has been previously reviewed by the data reviewer. This check can be captured by using a "checkmark" and initials/ date next to the data reviewers' original approval.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	New	-	-
1	01/24/12	Made SOP more detailed.	-	-
2	01/30/13	Generalized procedure for documenting in a laboratory notebook. Instituted a section breakdown of a procedure. Updated SOP format.	13-030	B. Johns
3	01/20/15	Update format. Expanded responsibilities. Use of cGMP and cGLP notebooks. Added handling of raw data not entered into notebook. Increased detail to improve clarity. Changed SOP title. Biennial Review.	15-0038	B. Johns
4	03/04/16	Updated SOP to reflect current practices.	16-0213	D. Thompson
5	01/13/19	Updated SOP to reflect current practices. Add responsibilities for the R&D Department. Updated format to include OTC testing. Changed SOP title to obsolete D-113 "QC Laboratory Notebook and Data Handling	19-0132	I. Garrett
6	11/22/22	Defined review process in more detail. Added additional requirements for laboratory write-up. Added data review audits. Included Data Review in SOP title. Added data checklists. Removed R&D from scope. Created Form D-102-F1.	CC-22-0447	J. Sassman
7	08/30/23	Added Equipment Use Log Requirements. Added RedZone to scope of SOP. Changed logo on form and SOP.	CC-23-0439	J. Sassman

ION Nutritional Labs	General Review Checklist		
	Form: D-102-F1	CCR No. CC-23-0439	Revision: 1

Notebook/ Page (s) #:_____ Method Reference/ Rev#:_____

Testing Description: _____ Batch/Lot#:_____

Check	Analyst Check	Reviewer Check	N/A	Comments
General Clerical Review				
1) All required documents are attached and write-up is complete. Including:				
a) Notebook write-up complete/ signed				
b) Standard (s) are prepared as directed in method				
c) Sample (s) are prepared as directed in method				
d) All solutions used are appropriately captured/ documented/ within expiry				
e) All equipment used is within calibration				
2) All blocks are filled out properly, affixed items are signed and dated. N/A lines used properly.				
3) Sample numbers are consistent across all required page.				
Analysis Report				
4) Sample weight matches the weigh tape on sample prep documents.				
5) Final volume, dilution multiplier and unit of measure are aligned with product documentation				
6) Product profile referenced to ensure all reported values meet acceptance criteria.				
7) Measurement of Uncertainty is evaluated for acceptance if applicable.				
Sample & Standard Preparation Documents				
8) All data recorded is legible and accurate. (Calibration dates, lot numbers, units of measure, etc.)				
9) All required copies are present in packet.				
10) All data recorded is verifiable through other pages attached to packet.				
Other				
11) Other:				
12) Other:				

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____