OURVITA	Standard Operating Procedure Document Control	SOP Number C-501	Revision 10
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Written by/ Date	Reviewed by/ Date	Approved by/ Date
Diana S. 01/29/26	Jessica Lugo 02/04/26	M. M 02/04/26
Title: Senior QA Specialist	Title: QA Compliance Supervisor	Title: Quality Director

1.0 Purpose

This procedure establishes a process that ensures consistent document lifecycles. This includes identification, format, preparation, approval, implementation, distribution, filing, copying, access, document tracking, and scheduled reviews.

2.0 Scope

This procedure applies to all controlled documents related to the manufacturing, packaging, labeling, testing, and holding of products manufactured at HBI Ion Labs, including but not limited to SOPs, batch records, specifications, forms, and logs.

3.0 Responsibility

3.1 It is the responsibility of Quality (Document Control) to ensure that all official documents are implemented and made available for use according to this procedure.

3.2 It is the responsibility of all employees to follow this procedure and to ensure that the most current revision of a document is being utilized.

3.3 Each department is responsible for reviewing and revising procedures that are applicable to their department when revisions are needed or when the procedure is due for review.

4.0 Definitions

4.1 **Controlled Document** – a document of quality system/cGMP importance that is subject to approval of content, review, and revision

4.2 **cGMP** – Current Good Manufacturing Practice

4.3 **SOP** – Standard Operating Procedure

4.4 **SOP Table of Contents** – a list of all current, effective procedures maintained by Document Control

4.5 **Form Table of Contents** – a list of all current, effective forms maintained by Document Control

4.6 **Training Matrix** – a list of all training required/completed for all job descriptions and employees

4.7 **QC** – Quality Control

4.8 **QA** – Quality Assurance

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

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

5.0 References

5.1 C-101, SOP, Format of SOPs and Forms

5.2 C-105, SOP, Protocol and Report Documentation Requirements

5.3 C-403, SOP, Change Control Procedure

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

5.5 QS-112, SOP, Core Quality Systems and Quality Events

5.6 C-501-F1, Form, SOP Review Form

5.7 C-501-F2, Form, SOP Distribution Log

5.8 C-111, SOP, Redzone General Use

6.0 Procedure

6.1 Identification and Format of Documents

6.1.1 Refer to SOP C-101 Format of SOPs and Forms for current SOP and form format and documentation preferences.

6.1.2 Refer to SOP C-105 Protocol and Report Documentation Requirements for current format and documentation preferences for reports and protocols.

6.1.3 Document templates are available for use here: *U:\+Docs\Templates*. Copies of these templates are to be utilized. Do not make any changes to the templates provided in the above referenced folder.

6.1.4 Document templates are to be used whenever creating a new document. At no time should an existing document be used to create a new document.

6.2 Preparation of Documents

6.2.1 New Document Creation

6.2.1.1 The initiator will prepare the document using the appropriate template and request a document number from Document Control.

6.2.1.2 The initiator will initiate a change control per SOP C-403 Change Control Procedure and submit to Document Control.

6.2.1.3 The initiator will forward the completed document to Document Control for formatting and review.

6.2.2 Revision of Existing Documents

6.2.2.1 The initiator will initiate a change control per SOP C-403 Change Control Procedure and submit to Document Control.

6.2.2.2 Document Control will evaluate the request and ensure that the document is not currently in a state of revision.

- If the document is already in revision, the initiator will be informed. If possible, the requested change will be added to the existing in-process document revision and rerouted for additional approvals with the new changes.

- If the document is not currently being revised, the initiator will revise the document and follow SOP C-403 Change Control Procedure for approval and implementation of the revised document.

6.3 Review and Approval of Documents

6.3.1 Documents are reviewed and approved following SOP C-403 Change Control Procedure. Authors/initiators, reviewers, and approvers are responsible for signing and dating any documents where a signature is required (SOPs, product profiles, etc.).

6.3.2 All documents must be approved by Quality.

6.4 Implementation and Obsoletion of SOPs and Forms

6.4.1 A SOP is considered to be "Effective" when all required reviews and approvals have been obtained and training for all required personnel has been performed.

6.4.1.1 In the event that a current employee is unable to be trained due to a leave of absence or like event, the SOP will be made effective without the missing employee's training record. The training will be completed upon the employee's return.

Note: Training is not required for QC Laboratory test methods (SOP Numbering Series D-700 and D-1000) and can be made effective once all approvals have been obtained.

6.4.2 The following steps will be completed when an SOP is ready to be made effective:

6.4.2.1 The Training Matrix will be updated with the new revision and all training will be documented.

6.4.2.2 The Effective Date will be added to the front page of the SOP.

6.4.2.3 All employees will be informed via email of the newly effective revisions. Employees will be responsible for ensuring that they are referencing/using this newly effective revision.

6.4.2.4 A scanned copy of the newly effective procedure will be secured so that the document cannot be printed and placed here for reference: *U:\+Docs\Standard Operating Procedures*. The previous revision will be removed.

- If an employee requests a hard copy of a procedure, Document Control will complete form C-501-F2 SOP Distribution Log and prepare a "For Reference Only" copy of the requested procedure. The requestor will initial and date on

form C-501-F2 SOP Distribution Log that a copy of the SOP was received.

- Once signed, the SOP Distribution Log will be filed behind the original SOP in the books located in Document Control.
- When a new revision of the SOP is effective, the previous revision's distribution log will be pulled and any copies that were distributed must then be returned. Document Control will initial and date the form once the file has been received. The form will be scanned and filed with the obsolete version of the SOP.

6.4.2.5 The previous revision of the SOP will be removed from the SOP binders (located in Document Control) and the new revision will be added. The previous revision will be made obsolete, then scanned, and filed electronically here: *F:\Doc Control Only\SOPs\SOPs*. The hard copy will be discarded.

6.4.2.6 The SOP Table of Contents and/or Form Table of Contents will be updated and distributed as needed.

6.5 Implementation and Obsoletion of Product Profiles/Test Tickets/Test Details, Packaging Profiles, and Raw Material Profiles

6.5.1 When a new or revised version of the document has been approved, the following steps will be taken:

6.5.1.1 Product Profiles will be scanned and placed here for easy reference to all employees: U:\+Docs\Product Profiles

6.5.1.2 Packaging Profiles will scanned and placed here for easy reference to all employees: U:\+Docs\Packaging Profiles

6.5.1.3 Raw Material Profiles will be scanned and placed here for easy reference to all employees: U:\+Docs\Raw Material Profiles

6.5.1.4 Finished Product Test Details will be scanned and placed here for easy reference to all employees: U:\+Docs\Finished Product Test Details

6.5.1.5 For revised Product Profiles, Packaging Profiles, Finished Product Test Tickets, and Finished Product Test Details, the original copy will be

filed with the Master Batch Record for the specified product. The previous revision will be removed and scanned into the obsolete folder located in each product's specific product folder in the Document Control Only file on the U Drive. When possible, the hard copy will be attached to the change control and filed in the back of the master batch record to preserve MBR change history.

6.5.1.6 For revised Raw Material Profiles, the previous revision will be removed from the file referenced in 6.5.1.3 and replaced with the newly effective revision. The previous revision will be filed here: U:\Doc Control Only\Raw Material Profiles Folder

6.6 Document House – Current Forms

6.6.1 Certain forms will be secured and made available electronically for use. If a form is needed, an employee will find the necessary form here: *U:\+Docs\Document House - Current Forms*

6.6.2 Only certain types of forms will be made available in the Document House. These types are as follows:

6.6.2.1 Forms related to Safety or Human Resources

6.6.2.2 Training forms

6.6.2.3 Request and Initiation Forms, such as:

- Change Control Request Forms
- Deviation Initiation and Closure Forms
- Protocol Initiation and Closure Forms
- New Product Approval Forms
- OOS Forms
- General Data Review Checklists
- NCR Initiation and Closure Forms
- Return and Waste Forms

- Equipment Profiles and IOQ Checklists
- Continuous Improvement Forms (CAPA, RCA, EC, etc.)

6.6.2.4 These forms will be printed and used as needed. No extra copies will be printed and filed. Forms will always be printed from this file and no other. These files are not to be moved or copied, only printed when required.

6.6.2.5 Writable forms will be created per request, if determined to be acceptable for electronic population.

6.6.2.6 When a new revision of a form becomes effective, the document will be updated in the file and the previous revision will be archived here: *U:\Quality\Private\Doc Control\SOPs\SOPs*.

6.7 Control of Forms not assigned to the Document House

6.7.1 Certain forms will not be accessible to employees outside of Document Control. The following types of forms will not be made available in the Document House as outlined in section 6.6.

6.7.1.1 QC Laboratory Test Tickets

6.7.1.2 QC Laboratory Logbooks

6.7.1.3 Production Logbooks

6.7.1.4 Warehouse Logbooks

6.7.1.5 Facility Logbooks

6.7.1.6 Employee Registers

6.7.1.7 Cleaning Forms and Logs

6.7.1.8 Batch Record Forms

6.7.2 The above forms can be controlled in the following manners.

6.7.2.1 Forms that pertain to the testing of a specific lot of finished product or raw material may be issued with the record by Document Control. These forms will have the initials of the issuing Document Control

employee and the date of issuance. Only one form for each required test will be supplied. Should an additional form be needed, it must be requested from Document Control and valid reason provided for the need of an additional form.

6.7.2.2 Forms may be issued in a secured book. These forms will be assigned a unique identifier for reconciliation purposes. In the event that this method is used to collect data pertaining to a lot of finished product or raw material, a copy must be made to retain with the lot's release packet.

- Unique identifiers will be assigned using the following format: Form Number-Book Number-Date-Number of Pages
    - Form number: the number referenced in the header of the form the book is issued for
    - Book number: a sequential number starting at 1 for the form the book is issued for
    - Date: the date that the book is being issued by Document Control
    - Number of Pages: the number of form copies provided in the book

      Example: The first book of fifty pages of form D-703-F1 issued on 08/24/23 by Document Control would have the following unique identifier: D-703-F1-B1-082423-50.

6.7.2.3 Forms issued as a book will have a cover sheet which outlines the unique identifier, form description, number of pages issued, and the start and end dates of the book. The start date will be added once the first entry has been made into the book. Once all pages have been used, the end date will be added on the cover sheet and the book will be submitted to Document Control for reconciliation and archiving. A new book will be provided at that time following the same guidelines. If a book is submitted for archiving prior to all pages being used, the unused pages will be marked as N/A and filed with the rest of the logbook. No pages are to be removed and destroyed.

6.7.3 Redzone data sheets may be used if available. If a datasheet has been created and validated in Redzone for a form, this method is preferred and should be used. Paper forms will still be maintained and serve as a backup documentation option if the Redzone data sheet is not available for use. When Redzone data sheets are not available, use the associated paper forms, to be distributed in the manner outlined in either section 6.7.1 or 6.7.2.

6.8 Review of Procedures and Forms

6.8.1 Review is applicable to all procedures and Forms. This review should occur every three years, one month prior to the month it was made effective last.

6.8.2 During the last week of each month, Document Control will identify all procedures that are due for review and send notification to the departments..

6.8.2.1 Document Control will complete the SOP information section of form C-501-F1 SOP Review Form, assign a due date for review completion, and initial/date. The form will then be submitted to the SOP reviewer with a copy of the SOP to be reviewed.

6.8.2.2 Review due dates should be one month from the issuance of form C-501-F1 SOP Review Form.

6.8.2.3 The reviewer will complete the remainder of form C-501-F1 once the SOP review has been executed.

- If changes are required, the reviewer will follow section 6.2.2 of this procedure. The change control number will be recorded on form C-501-F1 SOP Review Form and submitted with the change control and revised SOP.

- If no changes are needed, the reviewer will notate this on form C-501-F1 SOP Review Form and return the packet to Document Control. Document Control will create a change control which states that no changes are needed. The SOP revision history will be updated to the next revision number, documenting that no changes were made. The SOP and change control will follow normal review processes through the change control system. This will ensure that the procedure is still routinely trained on even when changes have not been made.

6.8.3 After review and approval of the updated document, training must be completed and the document made effective within one month. This can be extended following SOP QS-112 Core Quality Systems and Quality Events if a large number of employees require training.

6.8.4 Form C-501-F1 SOP Review Form will be filed with the SOP hard copy and will follow the SOP's maintenance and retention requirements.

Note: The revised document cannot be made effective until all necessary training has been completed by active employees. The only exception to this requirement is if an employee is out on leave, then the document will be made effective and the training will be completed upon their return, prior to performing the affected job functions.

Note: For analytical method SOPs, a review of the associated validation will take place during the review of the procedure. A quality event amendment request will be created if the validation is not reflective of the current procedure. Refer to SOP QS-112 Core Quality Systems and Quality Events.

6.9 Confidentiality of Documents

6.9.1 As a general rule, all company documents are confidential and proprietary to HBI Ion Labs.

6.9.2 Only Executive Company management will determine which documents can be disclosed to the public or any third party organization. These documents will be identified, at a minimum, with a confidential stamp.

6.9.3 All records must be readily available for authorized regulatory inspections and internal/external audits.

6.10 Timeliness of Documents

6.10.1 Quality System documents shall follow SOP QS-112 Core Quality Systems and Quality Events to ensure that documents are moving through the system in a timely fashion. Documents may be amended, extended, or cancelled under this SOP.

6.11 Electronic Filing of Scanned Documents

6.11.1 Documents may be scanned and filed electronically for ease of searchability.

6.11.2 Each document must be checked for accuracy, completeness, and quality after scanning to ensure data integrity.

6.11.3 The scanned file must be an exact representation of the paper copy.

6.12 Documents of External Origin

6.12.1 Document Control maintains documents of external origin electronically (if available), such as standard test methods, regulatory standards, industry standards, management system standards (such as ISO), equipment and instrument and information management systems manuals, etc.

6.12.2 These documents of external origin are controlled by their location and are not distributed further unless approved by Document Control. Identified documents represent the most current controlled versions. However, older revisions may be maintained for historical references.

6.12.3 When the Documents of external origin are needed for use, personnel will research on the internet if this is the most current version available. The correct version of the above document is verified with their originators or standards distributors.

6.12.3.1 If a newer version is available, personnel will contact their management for the purchase of the new versions or approval to continue to use the version indicated in test methods, test requests, etc.

6.13 Batch Record Flow:

6.13.1 The Batch Record will be placed into the designated cabinet for use in the manufacturing process.

6.13.2 Warehouse personnel will remove the batch record from the cabinet when needed and deliver to the Belcher location for batch building. Once this process has completed, the batch will travel back to the Main facility with the weighed batch materials and be staged for blending.

6.13.3 Tableting/Encapsulation personnel will retrieve the batch record from operation management when needed. At the completion of the tableting/encapsulation process, the batch record will be placed in the cabinet to await further processing.

6.13.4 If product is to be coated, the Coating personnel will retrieve the batch record from operations management when needed. At the completion of the coating

process, the batch record will be placed in the cabinet to await further processing.

6.13.5 Packaging personnel will retrieve the batch record from operation management when needed. At the completion of the packaging process, the batch record will be forwarded to Production management for review, then to Quality Assurance for review, reconciliation, and release if record is complete and conforms to all release criteria.

6.13.6 The batch record will be forwarded to Document Control to be filed and retained following SOP C-502 Record Storage, Retention, and Destruction.

6.13.7 Should remaining stock be present, the batch record will be forwarded to Document Control once the completed portion of the batch has been released. The batch record is held in Document Control for future production requirements.

6.13.8 The batch record will remain open as long as product is available and within the given shelf life. The records will be monitored by Production Control to ensure batch records are present or have been removed appropriately.

7.0 Revision History

Revision	Date	CCR #
1	03/25/13	13-193
2	04/15/16	15-0929
3	06/21/16	16-0484
4	03/20/17	17-0304
5	08/23/17	17-1199
6	08/17/20	CC-20-0586
7	10/01/21	CC-21-0417
8	05/11/23	CC-23-0215
9	09/16/25	CC-25-0383
10	01/29/26	CC-26-0045