	Standard Operating Procedure	SOP Number C-101	Revision 9
	Format of SOPs and Forms	Effective Date 01/21/26	Page Page 1 of 10
Written by/ Date JLK 01/21/26	Reviewed by/ Date MSM 01-21-26	Approved by/ Date M. W. 01/21/26	
Title: QA	Title: QA	Title: Quality Director	

1.0 Purpose

The purpose of this procedure is to provide guidelines for the preferred format of SOPs and the forms attached.

2.0 Scope

This procedure is applicable to controlled documents intended to meet quality and regulatory requirements located in HBI Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of Quality and DC to implement and maintain this procedure.
- 3.2 It is the responsibility of all employees to follow this procedure when creating or revising an SOP, Job Aide, or form.

4.0 Definitions

- 4.1 CC – Change Control
- 4.2 DC – Document Control
- 4.3 SOP – Standard Operating Procedure
- 4.4 WI – Work Instruction
- 4.5 JA – Job Aide
- 4.6 BPR – Batch Production Record

4.7 TOC – Table of Contents

5.0 References

5.1 C-501, SOP, Document Control Procedure

6.0 SOP Identification System

6.1 The SOP identification system is made up of two fields:

6.1.1 Field one consists of a capital letter(s), which denotes the department that the SOP pertains to.

6.1.1.1 A – General and Personnel: Applies to all departments/personnel at Ion Labs, Inc.

6.1.1.2 B – Manufacturing: Pertains to the manufacturing of products from compounding through packaging/labeling, including equipment procedures.

6.1.1.3 C – Record Management

6.1.1.4 D – Laboratory Operations and Specifications, including equipment procedures

6.1.1.5 E – Material Management

6.1.1.6 F – Facilities

6.1.1.7 G – Equipment

6.1.1.8 H – Audits

6.1.1.9 QS – Quality System

6.1.2 Field two consists of three or four numbers based upon functions within departments and are numbered sequentially by category/units of 100.

Example: C-100 General

C-200 Investigations

D-1000 Methods

6.1.2.1 Individual SOPs are given a sequential number in their appropriate department and category.

Note: SOPs specific to drug products will be identified with a decimal followed by a zero at the end of field 2.

Example: C-100.0 General

C-200.0 Investigations

6.2 Forms are numbered by the SOP number, followed by the capital letter F, and a consecutive number depending upon the number of forms attached to the SOP (e.g. C-101-F1, C-101-F2, C-101-F3, etc.).

Note: Additional step-by-step instructions (i.e. job aides) may be created and reviewed/approved by departmental Supervisors/Managers to supplement SOPs and will be controlled by Document Control. These job aides will not replace existing SOPs.

6.3 Job Aides are numbered by the SOP number, followed by capital JA and a consecutive number, depending upon the number of job aides attached to the SOP (e.g. C-101-JA1, C-101-JA2, C-101-JA3, etc.)

6.4 Documents will be evaluated and assigned by Quality.

6.5 DC will maintain a Table of Contents for SOPs, Job Aides and a Table of Contents for Forms. These TOC will reference all current effective revisions of SOPs, job aides, and forms, along with the effective/review date and associated change control number.

6.5.1 The TOCs will be updated each time an SOP, job aide, or form has been revised and has been made effective.

7.0 Preferred Formatting of SOPs

- 7.1 The document header will contain the following information:
 - 7.1.1 HBI Ion Labs Logo
 - 7.1.2 Document Title
 - 7.1.3 Document Type (SOP, Method, etc.)
 - 7.1.4 Document Identification Number
 - 7.1.5 Revision Level
 - 7.1.6 Effective Date
 - 7.1.7 Page Number
- 7.2 Times New Roman font is to be used, 10pt or larger. Headers are to be 14pt bold (excluding "Standard Operating Procedure") or larger.
- 7.3 There is to be 1.5pt spacing after paragraphs.
- 7.4 The page layout has .7 margins on each side with the footer and header at .5, unless the document is intended to be hole-punched, which should have at least a .75 left-hand margin.
- 7.5 The footer will contain a Confidential and/or Proprietary information statement in Times New Roman 10 Bold.
- 7.6 Additional sections may be added as needed to define process requirements.
- 7.7 Test methods may include sections for materials to include tooling, consumables, or items required to perform the work, as well as process parameters.

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8.0 Preferred Content for Procedures (refer to Attachment 1 – SOP Template)

8.1 Purpose: What is the purpose of the procedure? What regulation or upper-level procedures do the requirements satisfy?

Example: To define the requirements for hygienic practices to meet 21 CFR Part 111.10.

8.2 Scope: What department or process does the procedure cover?

Example: All procedures

8.3 Responsibility: Who is responsible for the maintenance of the procedure? Who is responsible for the performance of the procedure?

Example: Document initiators are responsible for ensuring that the document is clear, concise, and complete using the standard format.

8.4 References: Documents that explain more about the work, or forms to record the work.

Example: C-403-F1, Change Control Request Form

8.5 Definitions: Clarify terms such as acronyms, technical terminology, or regulatory definitions.

8.6 Procedure: Requirements to be followed to accomplish an operation or task, in the order the steps are performed, when applicable. Flow diagrams should be used whenever possible.

8.7 Records: Requirements for record maintenance location and retention times when applicable, or a procedural reference.

8.8 Document Revision History: Includes revision level, date, change control number, and name of the person making the change.

8.9 Attachments: If applicable, any related documents.

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9.0 Preferred Content for Forms (refer to Attachment 2 – Form Template)

9.1 The header will contain the following information:

9.1.1 HBI Ion Labs logo

9.1.2 Name of Form

9.1.3 Change Control Number

9.1.4 Revision Level

9.2 The body will contain tables and borders. Use the Forms toolbar when possible, to allow for electronic entry.

9.3 Font size will be sufficient for accurate interpretation by the user.

9.4 Fields for recording data will be large enough to accommodate data entry as well as room for correcting errors.

9.5 The footer will contain a Confidential and/or Proprietary information statement in Times New Roman 10 Bold.

9.6 The footer will contain a Page Number entry box or number of pages attached to the specific form (i.e. page 1 of 2).

Note: Page numbering may also be placed in the header of forms if the content and formatting requirements justify this.

Note: Forms may be created in Portrait or Landscape mode as needed to provide adequate space for recording information.

10.0 Attachments

10.1 Attachment 1 – SOP Template


10.2 Attachment 2 – Form Template

10.3 Attachment 3 – Job Aide Template

11.0 Revision History

Revision	Date	CCR #	By
0	02/10/10	-	-
1	08/17/10	-	-
2	03/01/12	-	-
3	04/02/13	-	-
4	01/24/14	14-0099	L. Derrick
5	08/29/14	14-0607	D. Popp
6	03/19/15	15-0296	D. Popp
7	01/04/19	19-0018	K. Burris
8	04/18/22	CC-22-0198	K. Burris
9	11/12/25	CC-25-0459	J. Kiger

ATTACHMENT 1 – SOP TEMPLATE

	Standard Operating Procedure	SOP Number	Revision
	Title	Effective Date	Page Page 1 of 1
Written by/ Date	Reviewed by/ Date	Approved by/ Date	
Title: Title Here	Title: Title Here	Title: Title Here	

1.0 Purpose

2.0 Scope

3.0 Responsibility

4.0 Definitions

5.0 References


6.0 Procedure

7.0 Revision History

Revision	Date	CCR #	By


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ATTACHMENT 2 – FORM TEMPLATE

			
	Name:	CCP No:	Revision:

	Name	Title	Date
Written By:			
Approved By:			

ATTACHMENT 2 – JOB AIDE TEMPLATE

			
	Job Aide:	CCR No.:	Revision:

	Name	Title	Date
Written By:			
Approved By:			

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