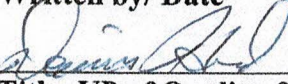
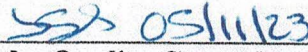

	Standard Operating Procedure Quality Inspection Process		SOP Number B-905	Revision 3
			Effective Date 09/12/23	Page Page 1 of 17
Written by/ Date  05-11-23	Reviewed by/ Date  05/11/23	Approved by/ Date  05/11/23		
Title: VP of Quality & Regulatory Affairs	Title: Quality Control Director	Title: Quality Assurance Director		

1.0 Purpose

The purpose of this procedure is to provide direction for quality inspection of products during the manufacturing/packaging process for products manufactured by Ion Labs, Inc.

2.0 Scope

This procedure is applicable to the inspection of products manufactured and packaged by Ion Labs, Inc. The procedure applies to inspections conducted by the quality department as well as production personnel to ensure and monitor product quality.

3.0 Responsibility

3.1 It is the responsibility of Production personnel to:

3.1.1 Follow this procedure during production inspections, cleaning activities, and startup activities.

3.2 It is the responsibility of QC Inspectors to:

3.2.1 Follow this procedure during QC audits, cleaning activities, and startup activities as applicable.

3.2.2 Report observed risks to Quality Management.

3.3 It is the responsibility of Quality Management to:

3.3.1 Assess risks and distribute quality resources appropriately.

3.3.2 Approve corrective action to Alert Observations.

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3.3.3 Approve AQSD.

3.4 It is the responsibility of Production Management to:

3.4.1 Establish and execute corrective action to Alert Observations.

3.4.2 Approve AQSD.

3.4.3 Ensure that production personnel follow inspection processes identified in manufacturing and packaging batch records.

4.0 Definitions

4.1 **Alert Level Observations** – an observation that meets acceptance limits but is not well centered or would benefit from action in order to maintain acceptable product

4.2 **Action Level Observation** – an observation that is outside of acceptance limits or otherwise requires action before product is acceptable

4.3 **BPR** – Batch Production Record

4.4 **Inspection** – an inspection or check conducted by Production and/or Quality personnel

4.5 **Interval Based Inspection** – inspection or check conducted at specific intervals

4.6 **Inspection/check** – both terms refer to the act of evaluating product quality, adherence to procedure, and/or conformance to established specifications, and are used interchangeably in this procedure

4.7 **AQSD** – Approved Quality Standard Definition; a quality standard defined in writing outside of a batch and approved by signature according to the formatting requirements of this procedure

4.8 **AQL** – Acceptance Quality Limit; the maximum number of defective units, beyond which a batch is rejected

4.9 **QC** – Quality Control

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- 4.10 **PDT** – Product Detail Tag
- 4.11 **Redzone (RZ)** – a software application used to collect data during the production process; used to track production data, as well as cGMP data
- 4.12 **Data Sheet** – an RZ component of the RZ Compliance Module, configured to collect data
- 4.13 **PQC** – Process Quality Check: Details are provided within this procedure
- 4.14 **PQV** – Process Quality Verification: Details are provided within this procedure
- 4.15 **Critical Defect** – Any condition found which poses the possibility of causing injury of harm to, or otherwise endangering the life or safety of, the end user of the product or others in the immediate vicinity of its use.
- 4.16 **Major Defect** – Any condition found adversely affecting the product’s marketability and sale-ability or adversely affecting its required form, fit, or function, and which is likely to result in the end user returning it to the source from which purchased for replacement or refund.
- 4.17 **Minor Defect** – Any condition found which while possibly less than desirable to the end user of the product, does not adversely affect its required marketability, sale-ability, form, fit, or function and is unlikely to result in its return to the source from which purchased.

5.0 References

- 5.1 B-905-F1, Form, QC Audit Form
- 5.2 B-905-F2, Form, AQL – Inspection Form for Critical Defects
- 5.3 B-905-F3, Form, AQL – Inspection Form for Major Defects
- 5.4 B-905-F4, Form, AQL – Inspection Form for Minor Defects

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- 5.5 B-905-F5, Form, AQL – Inspection Form
- 5.6 B-108, SOP, Reprocessing Procedure
- 5.7 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment
- 5.8 E-704, SOP, AQL Statistical Sampling Plan
- 5.9 21 CFR part 111, 114, 117, 210, 211 - as applicable to Dietary Supplements, Cosmetics and OTC (reference FDA CFR - Code of Federal Regulations Title 21 for specific part reference)
- 5.10 C-104, SOP, Master Batch Record and Issuance of Batch Production Record
- 5.11 C-111, SOP, Redzone General Use
- 5.12 C-109, SOP, Redzone Operator Activities
- 5.13 C-110, SOP, Redzone QC Inspector Activities
- 5.14 C-107, SOP, Redzone Reviewer Activities
- 5.15 C-201, SOP, Deviation and Investigation Procedure

6.0 Process Overview

- 6.1 The BPR for each product defines required Quality Inspections. This SOP defines standardized default inspection parameters. The BPR follows these standards unless the customer, or product development / experience dictate other inspection requirements. In either case, the inspection process defined by the BPR takes precedence over the inspection process defined by this procedure.
- 6.2 SOP C-104 Master Batch Record and Issuance of Batch Production Record controls the issuance of the BPR. SOP C-104 defines forms for recording Quality Inspection activities and associated data customized to specific product Master Batch Records.

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Additionally form(s) associated with this procedure provide the mechanism to record Quality Audit activities and associated data.

- 6.3 Forms provided by SOP C-104 Master Batch Record and Issuance of Batch Production Record and B-905 Quality Inspection Process provide detailed instructions for Inspections. These forms may be available in Redzone. The forms provided also serve as a backup documentation option if the Redzone data sheets are not available for use. Use Redzone data sheets as the preferred method for recording inspections / audits if available. When Redzone data sheets are not available, use the associated forms.
- 6.4 NOTE: Redzone is a software application used to collect data during the production process. Redzone is not available for all data collection. The use of Redzone requires verification activities covered by SOP C-107 Redzone Reviewer Activities prior to use in our facility.

7.0 PQC – Process Quality Check

- 7.1 A PQC is a process quality check. PQC activities include but are not limited to:
- Room Startup Checks as defined by the BPR and described later in this SOP
 - Metal detector operational verification.
 - Interval based inspections as defined by the BPR and described later in this SOP
- 7.2 Any qualified individual may complete a PQC. Production operators typically complete PQC activities. QC Inspectors may also complete a PQC; however, QC Inspectors usually perform this function as part of the QC Audit.

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8.0 PQV – Process Quality Verification

8.1 A PQV is a process quality verification. A PQV is necessary for critical activities that require documentation of the completion of an activity (i.e. a PQC) as well as the verification of that activity (i.e. a PQV). Examples of PQV activities include but are not limited to:

- Room startup readiness verification
- Metal detector operational verification
- Verification of cleaning effectiveness

8.2 Production leads, production management, and QC Inspectors complete PQV activities. QC Inspectors may perform a PQV function as part of the QC Audit after a PQC is already completed. Any qualified individual may complete a PQV; however, a different person than the one completing a corresponding PQC for the same activity must complete a PQV.

9.0 QC Audits

9.1 Quality Control conducts regular audits of production activities using form B-905-F1 or Redzone audit forms as applicable. Audits conducted in Redzone are available through the Redzone interface and Power BI reports. DC files audits conducted on form B-905-F1. NOTE: Redzone audit forms will collect all the same information indicated on form B-905-F1, but may collect additional information.

9.2 Ideally, QC conducts audits of each area actively in production three times per shift. This frequency may vary depending upon:

- The risk of the production activity
- The risks imposed by the product under production
- The length of time activity is underway during that shift

9.3 QC Audits provide the following functionality:

- Inspection of the quality of product produced.
- Accountability for those conducting PQC and PQV functions.
- Direction to Production personnel for corrective actions to observed defects

10.0 Interval Based Inspections

10.1 The BPR defines inspection actions (i.e. PQC and PQV activities) and intervals for those inspections.

10.2 The table below lists default inspections. The default time interval for inspections is 60 minutes.

Inspection
Tableting (e.g. weight, thickness, hardness, etc.)
Encapsulation (e.g. weight, capsules locked, etc.)
Liquid Fills
Powder Fills
Gummy (e.g. weight)
Bottling (e.g. product quality, space filler, desiccant, cap seal integrity, neckband, etc.)
Labeling (e.g. batch # legible and correct, shelf life legible and correct, Julian lot legible and correct, bottle label present and correctly oriented, etc.)
Cartoning (e.g. batch # legible and correct, shelf life legible and correct, Julian lot legible and correct, bottle label present and correctly oriented, etc.)
Metal Detection

11.0 Interval Based Inspection Documentation

11.1 When using Redzone datasheets to record interval based checks, Redzone may be programed to interpret intervals as the amount of time the line is running. This allows Redzone to automatically account for down time due to breaks or stoppage of the line. Rezone may also be configured to initiate checks based on elapsed time. The

appropriate configuration of Redzone occurs during the development and verification of the datasheet as covered by SOP C-107.

11.2 When using paper forms to record interval based checks, interpret the intervals as elapsed time unless there is documented down time as described later in this section.

11.3 Where a time/date entry is required for an inspection, the following list defines parameters for documenting those inspections.

11.3.1 Enter the date/time that represents the date and time the inspection was completed.

11.3.2 Complete the inspection entry immediately after the completion of the inspection.

11.3.3 Interval based inspections are on time if the inspection is within the allowed interval (table below) from the previous inspection time, excluding production downtime. More frequent inspections (i.e. shorter time intervals than required) are allowed. SOPs and / BPRs may dictate specific allowances other than those listed here.

Interval	Allowed Interval
Less than or equal to 30minutes	+ 10 minutes
More than 30 minutes	+ 15 minutes

11.3.4 In the event that an interval based inspection is performed outside of the required time allowance, a deviation must be initiated as per SOP C-201 Deviation and Investigation Procedure.

11.3.5 When using paper forms to document an inspection, follow these documentation practices.

11.3.5.1 Unless specific values are required (i.e. length, thickness, hardness, weight, use a check mark (✓) entry to indicate that an inspection was completed and that the subject of the inspection met all expectations.

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11.3.5.2 Use a check mark with a comment (✓①) entry to indicate that the inspection was completed and that an action observation occurred. The “①” above is a note or footnote to document the action observation in the BPR.

11.3.5.3 Document production downtime if it is longer than 15 minutes. Use a comment on the time entry following the downtime or write across one column of inspection boxes with an indication of the down time reason. Examples of downtime include:

- Lunch
- Break
- Maintenance/Repair (add detail as applicable)

11.3.6 Example paper form based inspection documentation is available as attachments in Section 15.0.

12.0 Room/Equipment Cleaning Inspections

12.1 SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment provides details for cleaning equipment and production areas.

12.2 SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment also provides details for inspection and verification of those processes.

12.3 This provides a summary here only for references. Details provided in SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment supersede any details provided herein.

12.4 Production personnel are responsible for completing cleaning activities and PQC /

12.5 Production leads, production management, and QC Inspectors complete PQV activities as described in section 8.0 of this SOP.

12.6 Quality Inspectors are responsible for auditing cleaning activities.

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12.7 In general, PQC / PQV activities include:

12.7.1 Ensure that the room / line / equipment is clean and suitable for use.

12.7.2 Ensure that required room / line / equipment tags correctly identify the cleaning status.

12.7.3 Ensure that cleaning documentation has been completed properly and reflect the status of the room / line / equipment.

13.0 Startup Inspections

13.1 In addition to any specific startup checklist / instructions listed in the batch record, production personnel must complete and confirm completion of the following list:

13.1.1 Ensure that the room and equipment is clean and suitable for use.

13.1.2 Ensure that cleaning documentation is appropriate for the intended use of the current production activity.

13.1.3 Ensure that required room / line / equipment tags have the correct PDT, which identifies the intended activity.

13.1.4 Ensure that the materials / components intended for use are released or approved by the QC Laboratory to be used at risk, and that ID codes match those called out in the BPR.

14.0 Defect Categorization

14.1 This section defines common potential defects as Critical, Major, or Minor based on the definitions provided at the beginning of this SOP and repeated herein. Interpretation of these definitions is required in classifying defects, and as there are potentially other less common defects, the BPR may define other classifications and/or AQL assignments. Defect categorization and AQL levels defined in the BPR supersede those defined in this SOP.

14.2 In general, AQL categories are set as follows:

AQL Category	Definition	AQL
Critical	Any condition found which poses the possibility of causing injury of harm to, or otherwise endangering the life or safety of, the end user of the product or others in the immediate vicinity of its use.	0.10
Major	Any condition found adversely affecting the product's marketability and sale-ability or adversely affecting its required form, fit, or function, and which is likely to result in the end user returning it to the source from which purchased for replacement or refund.	0.65
Minor	Any condition found which while possibly less than desirable to the end user of the product, does not adversely affect its required marketability, sale-ability, form, fit, or function and is unlikely to result in its return to the source from which purchased.	2.5

Product / Process	Defect	AQL Category
Any	Foreign Materials on the inside of a container that is in contact with product	Critical
Packaging	Any labels that are missing, illegible, ripped, or torn	Critical
Packaging	Any container that has missing, burnt, or not fully adhered inner induction seal	Critical
Packaging	Any product with missing, incorrect, illegible, or overlapping traceability marks (e.g. expiration dates, lot numbers)	Critical
Any	Foreign Materials on the outside of a container and not in product contact	Major
Packaging	Any labels that are wrinkled, folded, doubled, or misaligned, but that are still legible	Major
Packaging	Any container that has missing, loose, detached, or broken outer neckband or seal	Major
Packaging	Any scuffed, smudged, or ink spot marks on the container. Any dented or damaged primary packaging components (bottles / caps)	Major
Packaging	Any product with quantities short of specification ranges	Major
Capsules	Product Quality- folding, dimpling, tears, completely locked with consistent size, color and shape	Minor
Tablets	Surface Erosion, Edge Erosion, Breakage, Film Cracking, Orange Peel Roughness, Color Variation, Black Specs, Logo Bridging, Twinning, Peeling, Spray Drying, Picking and Sticking, Tablet to Tablet Color Variation, Other	Minor
Packaging	Any product with quantities that exceed specification ranges	Minor
Packaging	Any missing components such as desiccant or scoop	Minor

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15.0 Final Step AQL Inspections

- 15.1 The “Final Step” inspection applies to product after the final step of the applicable production operation is complete. It is acceptable to pull final step samples earlier in the operation to avoid unnecessary destructive testing. For example, it is acceptable to pull bottle samples after filling but before capping to avoid the destructive operation of re-opening the bottle and destroying induction seals or labels.
- 15.2 Final Step AQL Inspections are part of QC Audits. The use of AQL inspections may provide supporting data for responses to operational issues and/or observed defects outside of QC Audit observations.
- 15.3 SOP E-704 AQL Statistical Sampling Plan provides instructions for conducting AQL inspections. QC Inspectors may provide direction for Production execution of AQL inspections in response to a QC Audit finding.
- 15.4 In general, AQL categories and levels apply to an entire batch. Base sampling plans and acceptance criteria on the full batch size. When conducting in-process inspections and/or evaluating a portion of a batch, choose a sampling plan based on the sub-set quantity understanding that this represents a worst-case scenario.
- 15.5 Failure of an AQL inspection does not necessarily result in rejection of product, but may point to activities or steps to correct identified defects.

16.0 Final Step General Inspections

- 16.1 The “Final Step” inspection applies to product after the final step of the applicable production operation is complete. It is acceptable to pull final step samples earlier in the operation to avoid unnecessary destructive testing. For example, it is acceptable to pull bottle samples after filling but before capping to avoid the destructive operation of re-opening the bottle and destroying induction seals or labels.

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- 16.2 Final Step General Inspections are part of QC Audits. These general inspections are similar to an AQL inspection; however, this general inspection does not apply AQL statistics to determine sample size or accept / reject levels.
- 16.3 General Inspections assume a zero tolerance for Critical and Major defects. Acceptance of minor defects is based on the discretion of the QC Inspector. Ultimately, the goal of the inspection is to ensure that the finished product would meet all applicable AQL limits if an AQL inspection were applied to the complete batch.
- 16.4 Failure of an AQL inspection does not necessarily result in rejection of product, but may point to activities or steps to correct identified defects.

17.0 Action Observations

- 17.1 Action observations are observations that are outside of acceptance limits and otherwise require action before the product is acceptable. Document action observations in the BPR with a comment for the inspection documentation.

18.0 Alert Observations

- 18.1 Alert observations are observations that meet acceptance limits but are not centered or would benefit from action in order to maintain acceptable product. It is not necessary to add a comment on alert observations in the BPR.

19.0 Correction of Action Observations

- 19.1 Quality Management and Production Management must collaborate to determine how to correct observations of product that is outside of acceptance limits or that otherwise requires action to meet quality standards. Identify the cause of the observation and then the scope of the product impacted by that observation (see further discussion in Section 19.2 below). If there is no correction plan identified, then reject or mark as waste any product that fails to meet acceptable standards. If there is a correction plan identified (see further discussion in Section 19.3 below), then execute that plan and disposition product accordingly.

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19.2 Determine Observation Scope

19.2.1 Based on the identified cause of the observation, it may be possible to limit the product evaluation and/or correction plan to a portion of the batch or a period of production activity. Conduct additional inspection as applicable to determine the scope of the observation. The following are typical inspection practices:

19.2.1.1 Inspection of a pallet (i.e. layer by layer)

19.2.1.2 Inspection back to the last good check

19.2.1.3 Inspection of a subpart of a batch (i.e. one pan, barrel, bucket)

19.2.2 Consider using AQL sampling (covered in SOP E-704 AQL Statistical Sampling Plan) or other statistical approaches to evaluate the observation.

19.3 Correction Plan

19.3.1 Document the correction plan in a protocol as directed by SOP B-108 Reprocessing Procedure unless the plan meets the following criteria:

19.3.1.1 The correction activity does not require inspection or processing other than that already defined by the applicable BPR.

19.3.1.2 The BPR that contains the correction steps is still open and the product is still in the same room or stationed next to the same line used to process those steps in the BPR.

20.0 Quality Standards

20.1 Where possible, establish quality standards in the BPR for each specific product. Numerical standards (i.e. weight, thickness, hardness, torque) are easy to describe within the record. Descriptive standards (i.e. cosmetic defects like wrinkles, spots, legible coding) benefit from examples to describe what is and is not acceptable. Some standards may differ from product to product based on customer expectations –

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especially those standards associated with product and / or packaging elegance. Where possible, define descriptive quality standards as clearly as possible using an AQSD.

20.2 AQSD Document Format

20.2.1 Format an ASQD as needed such that the definition of the standard is clearly communicated. If pictures are included, color printouts may be necessary. If physical standards are necessary, use an ASQD document as described here to reference those physical standards.

20.2.2 An AQSD document must have at minimum the following pieces of information:

20.2.2.1 Indication of the scope the standard applies to (for example):

- General production – default standard for all similar production activities
- Specific product – a standard established for a specific product
- Specific campaign – a standard established for a specific period of time
- Specific batch – a standard that only applies to a specific batch or listed batches

20.2.2.2 Description of the standard that is defined

20.2.2.3 Definition of the standard

20.2.2.4 Required signatures and signature dates

- Quality Management
- Production Management

20.2.2.5 If applicable, an AQSD document should address the following:

- The reason for tightening or loosening a current AQSD.
- AQL Inspection Level and Limit used if an AQL inspection is required and is associated with the AQSD.
- Reference to customer approval of the AQSD.
- Customer approval Signature and/or Ion Account Manager Signature, representing customer approval of the AQSD.

20.2.3 AQSD Document Filing/Use

20.2.3.1 DC files and maintains all official AQSD documents. Make copies of AQSD documents that apply to general use available to Production and Quality personnel (i.e. in binders near applicable activities). Make copies of AQSD documents that are specific to products, campaigns, or specific batches available with the applicable BPRs.

21.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/17/19	New procedure.	N/A	K. Burris
1	08/10/21	Added reference to CFR. Added Gummy to interval based inspection table.	CC-21-0319	C. Mitchell
2	05/26/22	Removed incremental inspections for QC inspectors. Removed attachment 3. Removed section 8.12. Clarified procedure throughout. Updated logo and format. Removed portions of risk-based inspection activities.	CC-22-0248	K. Burris
3	01/09/23	Re-write of procedure to define Process Quality Check (PQC) and Process Quality Verifications (PQV) and clearly define the QC Inspectors' responsibilities for production audits.	CC-23-0009	D. Herd

22.0 Attachments

22.1 Attachment 1 – Interval Based Inspection Documentation Example


Attachment 1 – Interval Based Inspection Example

Interval Based Inspection

	6:00 AM	7:10 AM	8:05 AM	8:55 AM	10:10 ^① AM	Comment About This Example
Activity 1	✓	✓	✓	✓	✓	N/A
Activity 2	✓	✓ ^②	✓	✓	✓	N/A
Activity 3	✓	✓	✓	✓	✓	N/A

① Comment explaining late interval with initials and date.

② Comment explaining action observation during inspection with initials and date.

	QC Audit Form		
	Form: B-905-F1	CCR No. CC-23-0009	Revision: 0

Audit Information

Location		Date / Time	
Lot #		Product Name	

QC Audit Activities Summary

Activity	Comment	Result																				
Final Step AQL Inspection	<input type="checkbox"/> N/A <input type="checkbox"/> See Below <ul style="list-style-type: none"> Document AQL Inspection(s) on forms B-905 AQL Inspection forms as applicable. Summarize those inspections here. 	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A																				
Final Step General Inspection	<input type="checkbox"/> N/A <input type="checkbox"/> See Below <ul style="list-style-type: none"> Unit inspected (e.g. case, bottle, tablet, etc.) _____ # of units inspected: _____ # of units that fail _____ 	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A																				
GMP Fundamentals	<input type="checkbox"/> N/A <input type="checkbox"/> See Below <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:10%;">Pass</th> <th style="width:10%;">Fail</th> <th style="width:10%;">N/A</th> <th style="width:70%;">GMP Fundamental</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Labels / Signs</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Temporary Fixes</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td>GMP Gowning</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Cross contamination requirements followed (e.g. doors closed)</td> </tr> </tbody> </table>	Pass	Fail	N/A	GMP Fundamental	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Labels / Signs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Temporary Fixes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	GMP Gowning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cross contamination requirements followed (e.g. doors closed)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A
	Pass	Fail	N/A	GMP Fundamental																		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Labels / Signs																		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Temporary Fixes																		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	GMP Gowning																		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cross contamination requirements followed (e.g. doors closed)																			
PQC / PQV Re-check	<input type="checkbox"/> N/A <input type="checkbox"/> See Below details about PQC(s) that were re-checked.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A																				
Other	<input type="checkbox"/> N/A <input type="checkbox"/> See Below	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A																				
Other	<input type="checkbox"/> N/A <input type="checkbox"/> See Below	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A																				

Note: N/A indicates that the activity does not apply or was not completed in this audit.

Audit Supporting Information (notes, comments, references)

<input type="checkbox"/> N/A <input type="checkbox"/> See Below

Audit Actions (none or all actions that apply)

<input type="checkbox"/> None	<input type="checkbox"/> Initiate Product Inspection <input type="checkbox"/> Other – as described in supporting information
-------------------------------	---

Name	Title	Signature	Date
Completed By:			

**AQL – Inspection Form for Critical Defects**

Form: B-905-F2

CCR No. CC-23-0009

Revision: 0

AQL Inspection Subject

Lot #		Product Name	
Unit Type		# of Units	
Location		Date / Time	

Critical Level Inspection Parameters

AQL	0.10	Sample Size		Ac Limit		Re Limit	
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Based on the number of “units” contained in the batch or portion of the batch under inspection, determine and record the inspection parameters for this AQL. NOTE: “Ac Limit” = Accept Limit and Re Limit = “Reject Limit.”

Defect	Defect Count	Pass – Inspected and no defects found	Pass – Inspected and defects found that meet the accept limits	Fail – Inspected and defects found the exceed or equal the reject limits	N/A – Not applicable or not inspected.
Any: Foreign Materials on the inside of a container that is in contact with product		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Labels that are missing, illegible, ripped, or torn		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Container that have missing, burnt, or not fully adhered inner induction seal		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Product with missing, incorrect, illegible, or overlapping traceability marks (e.g. expiration dates, lot numbers)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Inspection Supporting Information (notes, comments, references)

N/A See Below

Inspection Actions (none or all actions that apply)

None
 Initiate Additional Product Inspection
 Initiate Re-work of product. Reference re-work protocol or describe in supporting information
 Reject product. Reference or provide details in supporting information
 Other – as described in supporting information

Name	Title	Signature	Date
Completed By:			

**AQL – Inspection Form for Major Defects**

Form: B-905-F3

CCR No. CC-23-0009

Revision: 0

AQL Inspection Subject

Lot #		Product Name	
Unit Type		# of Units	
Location		Date / Time	

Major Level Inspection Parameters

AQL	0.65	Sample Size		Ac Limit		Re Limit	
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Based on the number of “units” contained in the batch or portion of the batch under inspection, determine and record the inspection parameters for this AQL. NOTE: “Ac Limit” = Accept Limit and Re Limit = “Reject Limit.”

Defect	Defect Count	Pass – Inspected and no defects found	Pass – Inspected and defects found that meet the accept limits	Fail – Inspected and defects found the exceed or equal the reject limits	N/A – Not applicable or not inspected.
Any: Foreign Materials on the outside of a container and not in product contact		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Labels that are wrinkled, folded, doubled, or misaligned, but that are still legible		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Container that has missing, loose, detached, or broken outer neckband or seal		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Scuffed, smudged, or ink spot marks on the container. Any dented or damaged primary packaging components (bottles / caps)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Product with quantities short of labeled claims		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Inspection Supporting Information (notes, comments, references) N/A See Below**Inspection Actions** (none or all actions that apply)

- None
 Initiate Additional Product Inspection
 Initiate Re-work of product. Reference re-work protocol or describe in supporting information
 Reject product. Reference or provide details in supporting information
 Other – as described in supporting information

Name	Title	Signature	Date
Completed By:			

**AQL – Inspection Form for Minor Defects**

Form: B-905-F4

CCR No. CC-23-0009

Revision: 0

AQL Inspection Subject

Lot #		Product Name	
Unit Type		# of Units	
Location		Date / Time	

Minor Level Inspection Parameters

AQL	2.5	Sample Size		Ac Limit		Re Limit	
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Based on the number of “units” contained in the batch or portion of the batch under inspection, determine and record the inspection parameters for this AQL. NOTE: “Ac Limit” = Accept Limit and Re Limit = “Reject Limit.”

Defect	Defect Count	Pass – Inspected and no defects found	Pass – Inspected and defects found that meet the accept limits	Fail – Inspected and defects found the exceed or equal the reject limits	N/A – Not applicable or not inspected.
Capsules: Product Quality- folding, dimpling, tears, completely locked with consistent size, color and shape		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tablets: Surface Erosion, Edge Erosion, Breakage, Film Cracking, Orange Peel Roughness, Color Variation, Black Specs, Logo Bridging, Twinning, Peeling, Spray Drying, Picking and Sticking, Tablet to Tablet Color Variation, Other		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Any product with quantities that exceed label claims		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packaging: Any missing components such as desiccant or scoop		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Inspection Supporting Information (notes, comments, references)
 N/A See Below
Inspection Actions (none or all actions that apply)

- | | |
|-------------------------------|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Initiate Additional Product Inspection
<input type="checkbox"/> Initiate Re-work of product. Reference re-work protocol or describe in supporting information
<input type="checkbox"/> Reject product. Reference or provide details in supporting information
<input type="checkbox"/> Other – as described in supporting information |
|-------------------------------|---|

Name	Title	Signature	Date
Completed By: (Author)			

**AQL –Inspection Form**

Form: B-905-F5

CCR No. CC-23-0009

Revision: 0

AQL Inspection Subject

Lot #		Product Name	
Unit Type		# of Units	
Location		Date / Time	

Critical Level Inspection Parameters

AQL		Sample Size		Ac Limit		Re Limit	
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Based on the number of “units” contained in the batch or portion of the batch under inspection, determine and record the inspection parameters for this AQL. NOTE: “Ac Limit” = Accept Limit and Re Limit = “Reject Limit.”

Defect	Defect Count	Pass – Inspected and no defects found	Pass – Inspected and defects found that meet the accept limits	Fail – Inspected and defects found the exceed or equal the reject limits	N/A – Not applicable or not inspected.
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> N/A or <input type="checkbox"/> Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Inspection Supporting Information (notes, comments, references) N/A See Below**Inspection Actions** (none or all actions that apply)

- | | |
|-------------------------------|---|
| <input type="checkbox"/> None | <input type="checkbox"/> Initiate Additional Product Inspection
<input type="checkbox"/> Initiate Re-work of product. Reference re-work protocol or describe in supporting information
<input type="checkbox"/> Reject product. Reference or provide details in supporting information
<input type="checkbox"/> Other – as described in supporting information |
|-------------------------------|---|

Name	Title	Signature	Date
Completed By:			