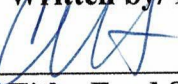
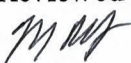
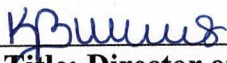
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		Effective Date 09/01/23	Page Page 1 of 18
Written by/ Date  08/18/23	Reviewed by/ Date  08-21-23	Approved by/ Date  08/21/23	
Title: Food Safety & Regulatory Supervisor	Title: Director of Operations	Title: Director of Quality Assurance	

1.0 Purpose

The purpose of this procedure is to define the process for the cleaning and sanitizing of the manufacturing/production areas and equipment.

2.0 Scope

This procedure applies to all manufacturing/production areas and equipment in use at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of all production personnel to strictly follow this procedure.
- 3.2 It is the responsibility of department supervisors and managers to implement this procedure in their respective departments and to ensure that the procedure is followed.
- 3.3 It is the responsibility of the QC inspectors to inspect and verify the cleaning of all manufacturing/production areas and equipment that have been utilized.

4.0 Definitions

- 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 **BPR** – Batch Production Record

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- 4.4 **SKU** – Stock Keeping Unit; a unique identifier for each product and each component used to manufacture a product
- 4.5 **CDT** – Cleaning Decision Tool; a tool used to help determine the level of cleaning needed
- 4.6 **CIP** – Clean in Place; refer to equipment that cannot be easily removed for cleaning and must be cleaned at its permanent location
- 4.7 **PPE** – Personal Protective Equipment; equipment worn to reduce the risks of injury from chemical use during production or cleaning
- 4.8 **Approved Chemical and Lube List** – a list that has been approved by Quality Management, containing current approved cleaning and sanitizing chemicals established for cleaning the facility
- 4.9 **IPA** – 70% Isopropyl Alcohol; used as a sanitizing agent
- 4.10 **Non-PCS** – Non-Product Contact Surfaces; equipment surfaces or parts that do not contact product
- 4.11 **PCS** – Product Contact Surfaces; equipment surfaces or parts that contact product; this includes equipment that contacts items that contact product (i.e. cappers, bottle unscramblers, sorters)
- 4.12 **PDT** – Product Detail Tag; a document available as part of each batch production record, which provides information about the product and includes all of the information necessary to answer questions in the CDT
- 4.13 **Degreaser** – chemicals found in the Approved Chemical List that are used for loosening and removing soil and buildup from surfaces
- 4.14 **Primary Packaging Room** – a room in which product is filled into primary packaging containers as this is written; this does not include liquid bottling

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- 4.15 **Secondary Packaging Room** – a room in which already packaged product undergoes further packaging (i.e. labeling, sleeving, cartoning, shrink wrapping)
- 4.16 **NOP OS** – National Organic Program’s Organic Standards
- 4.17 **QC** – Quality Control

5.0 References

- 5.1 C-111, SOP, Redzone General Use
- 5.2 C-109, SOP, Redzone Operator Activities
- 5.3 C-110, SOP, Redzone QC Inspector Activities
- 5.4 C-107, SOP, Redzone Reviewer Activities
- 5.5 B-111-F1, Form, Area Group 1 Cleaning Decision Tool
- 5.6 B-111-F2, Form, Area Group 2 Cleaning Decision Tool
- 5.7 B-111-F3, Form, Area Group 1 Cleaning Form
- 5.8 B-111-F4, Form, Area Group 2 Cleaning Form
- 5.9 B-111-F5, Form, Area Group 4 Cleaning Form
- 5.10 B-111-F6, Form, Sanitization and Cleaning Approval Form
- 5.11 B-103, SOP, Small Parts Cleaning and General Sanitation
- 5.12 B-104, SOP, Floor Drain Cleaning and Sanitizing Procedure
- 5.13 B-105, SOP, Preparation of Cleaning and Sanitizing Chemicals for Production and Warehouse
- 5.14 RPT-20-0033, Report, Production Cleaning Risk Assessment

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- 5.15 D-111, SOP, Allergen Testing of Production Equipment
- 5.16 D-116, SOP, ATP Testing for Production Equipment
- 5.17 QS-106, SOP, Allergen Control
- 5.18 CV-LAB-19-186, Protocol, Cleaning Validation for Organic Products
- 5.19 PRTCL-20-0010, Protocol, Dry Clean Report for P1/P2 Powder Filling Rooms

6.0 Procedure

6.1 Process Overview

6.1.1 This procedure defines different levels of cleaning (i.e. major, reduced major, minor) for various operations areas (area groups). This procedure provides a cleaning decision tool (CDT) specific to each area group, to determine the level of cleaning required based on information about the product used on the equipment before cleaning (previous SKU) and the product scheduled for the equipment after cleaning (next SKU). The CDT for each area is based on cleaning requirements associated with product characteristics of the previous and next SKU (i.e. allergen category, whether the product is classified as a drug or not, product certifications).

6.1.2 During normal operation, follow the steps below to complete cleaning:

6.1.2.1 Production collects information about the previous SKU and the next SKU. This information is available in the PDT for each product.

6.1.2.2 Production completes the CDT applicable to the area group associated with the area subject to cleaning. Redzone initiates a CDT data sheet automatically when a “cleaning run” starts for the subject location.

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6.1.2.3 Production will complete the level of cleaning determined by the CDT. Redzone automatically initiates the appropriate cleaning data sheet when CDT data sheets are completed.

6.1.2.4 Quality completes the visual inspection, ATP testing, and allergen testing as applicable and based on the result of the CDT. Redzone automatically initiates the appropriate inspection forms when the production cleaning data sheet is completed.

6.2 Documentation

6.2.1 Redzone data sheets are available to control the entire process. Production must initiate a “cleaning run” to start the process in the subject location. After the run starts, the CDT data sheets automatically initiate. As production completes the CDT data sheets, Redzone initiates additional data sheets as necessary, including the data sheets to document cleaning and inspection. After all data sheets are complete and the cleaning run ends, Quality will provide a final sign-off of the cleaning run. Redzone provides tools to review all completed runs. This tool allows for the review of both the previous SKU and the next SKU around the cleaning run and serves as a log for production and cleaning for that location.

6.2.2 The forms provided with this procedure give detailed content of the CDT for each defined area group and provide detailed content for cleaning of various areas. The forms provided also serve as a backup documentation option if the Redzone data sheets are not available for use. Use Redzone data sheets if available. When Redzone data sheets are not available, use the associated forms and store copies of the forms with both the previous SKU and next SKU batch records.

6.3 Cleaning Decision Tool

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6.3.1 This procedure provides a CDT as a form, specific for each area group. Use the applicable tool to determine the level of cleaning required.

6.4 Cleaning Levels

6.4.1 Major

6.4.1.1 Forms B-111-F3, B-111-F4, and B-111-F5 define steps required for a major clean for each specific area.

6.4.1.2 Major cleans are required when the CDT for the area determines that a major clean is required.

6.4.1.3 A major clean is required after maintenance activities that introduce dust, debris, or other materials that may affect the safety or purity of a product or production material.

6.4.1.4 A major clean is required after unplanned incidents that could contaminate drains. Examples include backflow of drains, plumbing leaks, roof leaks.

6.4.1.5 A major clean is required on equipment brought to the cleaning area prior to the return of that equipment to a production room.

6.4.2 Reduced Major

6.4.2.1 Form B-111-F4 defines the steps requires for a reduced major clean

6.4.2.2 Reduced major cleans are required when the CDT for the area determines that a reduced major clean is required.

6.4.3 Minor

6.4.3.1 Forms B-111-F3, B-111-F4, and B-111-F5 define the steps required for a minor clean.

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6.4.3.2 Minor cleans are required when the CDT for the area determines that a minor clean is required.

6.4.3.3 A minor clean is required after minor maintenance activities that are not likely to introduce dust, debris, or other materials that may affect the safety or purity of a product or production material.

6.4.4 Sanitization

6.4.4.1 Form B-111-F6 defines the steps required for sanitization.

6.4.4.2 After a cleaning operation is complete (major, reduced major, minor), a sanitization step is the last step of the process.

6.4.4.3 Sanitization is required prior to startup of manufacturing if the room/equipment remains idle for more than 36 hours.

6.4.4.4 Sanitization is required after minor maintenance activities.

6.5 Cleaning Requirements based on Product Characteristics

6.5.1 The level of cleaning required depends on the properties of the previous SKU manufactured before the cleaning and the properties of the next SKU scheduled for manufacturing after the cleaning. The sections that follow define how the product characteristics of these SKUs determine the cleaning level required. Other parameters determine cleaning levels defined here.

6.5.2 General Requirements

6.5.2.1 A major clean with allergen testing is required if the previous SKU is not known.

6.5.2.2 A major clean is required if the next scheduled SKU is not known.

6.5.2.3 A major clean is required at least every 10 days during a campaign of product that qualifies for minor or reduced major cleaning. Specific

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products may require more frequent major cleans, or may be capable of supporting a longer timeframe between major cleans. The product batch record may override this timeframe. If the batch record does not specify a frequency for major cleans during a campaign, then the timeframe associated with this procedure applies.

6.5.3 Same SKU

6.5.3.1 A minor clean is required when the previous SKU and the next SKU are the same. As a special case, treat two different SKUs as the same SKU if all ingredients in the previous SKU are also present in the next SKU.

6.5.4 Drug Product

6.5.4.1 The same SKU rule applies to drug products.

6.5.4.2 Perform a major clean before and after the manufacturing of each drug product batch.

Note: For drug product manufacturing, a cleaning validation is required to assess that the removal of that product is complete and that subsequent products will have levels of actives below the maximum acceptable carryover limits (MACO). Prior to the completion of the cleaning validation, perform appropriate analytical testing before releasing the equipment for other manufacturing use.

6.5.5 Allergen

6.5.5.1 The same SKU rule applies to allergen products.

6.5.5.2 Perform a major clean, followed by allergen testing verification, after each batch of product containing an allergen.

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6.5.5.3 If the previous SKU and the next SKU are both allergens, a reduced major clean is acceptable as long as the previous SKU does not contain any allergen classes (i.e. dairy, soy, etc.) that is not also in the next SKU.

6.5.5.4 If a major clean is required, allergen testing is also required.

6.5.6 Probiotic

6.5.6.1 The same SKU rule applies to probiotic products.

6.5.6.2 Perform a major clean after each batch of product containing a probiotic.

6.5.7 Product Certifications

6.5.7.1 The same SKU rule applies to Non-GMO Project Verified, Certified Organic, Kosher, Halal and Gluten-Free products.

6.5.7.2 Always perform a major clean before manufacturing a product with one of these certifications.

6.5.8 Product Type

6.5.8.1 Ion Labs assigns each product a product type during the onboarding process for the product. The product type is based on the definitions below:

6.5.8.1.1 Type 1 – includes dietary supplement products, cosmetic products, or pet products that are not allergens and contain no probiotics. Type 1 products do not contain components with strong odors, colors, or flavors.

6.5.8.1.2 Type 2 – includes dietary supplement products cosmetic products, or pet products, products that are certified

organic, kosher, halal, gluten-free, contain allergens, and/or contain probiotics. Type 2 products include products that do not contain these characteristics, but do contain components with strong odors, colors or flavors, making them difficult to clean.

6.5.8.1.3 Type 3 – drug products.

6.5.8.2 The table below defines cleaning from a previous SKU to the next SKU based on the assigned product type.

Product Type		If the Previous SKU is a		
		Type 1	Type 2	Type 3
If the Next SKU is a	Type 1	Reduced Major	Major	Major
	Type 2	Reduced Major	Major / Follow CDT form for exceptions	Major
	Type 3	Major	Major	Major / Follow CDT form for exceptions

6.6 Area Groups

6.6.1 Some areas and equipment accommodate all three cleaning types, while other areas do not. Area groups as defined below have similar functions and/or cleaning processes.

Area Group	Description
1	<p>This group defines different cleaning processes for major and minor cleans. This group does not define reduced major cleans. The CDT for this group is simple, requiring a major clean if the SKU processed prior to cleaning is not the same SKU processed after the cleaning. This group applies to manufacturing areas not defined in another are group. This is the default area group and includes areas like:</p> <ul style="list-style-type: none"> • Powder Blending • Liquid Blending • Encapsulation • Tableting • Coating • Liquid Packaging

2	<p>This group defines different cleaning processes for major cleans, reduced major cleans, and minor cleans. The CDT for this group includes additional decision steps when compared to area group 1, to accommodate the three cleaning options. The area group includes the following areas:</p>
	<ul style="list-style-type: none"> • Powder Packaging • Solid Dose Packaging • Blister Packaging • Pouch Packaging
3	<p>This group defines a single cleaning process. There are no direct product contact points in this area group. There is no CDT for this area group. The same cleaning process applies when changing batches processed in this area. This area group includes the following areas:</p>
	<ul style="list-style-type: none"> • Flexible Packaging
4	<p>This group defines different cleaning processes for major and minor cleans. The CDT for this area is identical to area group 1, but a different cleaning process applies to this area. This group does not define reduced major cleans. This area group includes the following areas:</p>
	<ul style="list-style-type: none"> • Gummy Manufacturing

6.7 Re-Cleaning

6.7.1 Re-cleaning is required under the following conditions:

6.7.1.1 Cleaning activity does not pass a visual inspection

6.7.1.2 Cleaning activity does not pass an ATP swab test

6.7.1.3 Cleaning activity does not pass an allergen test

6.7.2 Document a re-cleaning by issuing the appropriate Redzone data sheet or on applicable paper forms.

6.7.3 Repeat the inspection that failed (i.e. visual inspection, ATP testing, or allergen testing) after re-cleaning.

6.8 Post-Maintenance Cleaning

6.8.1 Quality and Operations will determine the level of cleaning required after maintenance activities conducted during a production run.

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6.8.1.1 Select major clean with sanitization after maintenance activities that introduce dust, debris, or other materials that may affect the safety or purity of a product or production materials.

6.8.1.2 Select a minor clean with sanitization after maintenance activities that are not likely to impact product contact surfaces.

6.8.1.3 Sanitization.

6.8.2 Document cleaning in Redzone on the applicable data sheet or on the appropriate paper forms if Redzone is not available.

6.9 QC Cleaning Inspection

6.9.1 Form B-111-F6 Sanitization and Cleaning Approval defines steps required for a QC inspection.

6.9.2 Complete a QC inspection after every sanitization is completed.

6.9.3 Complete ATP swab testing during visual inspection per SOP D-116 ATP Testing for Production Equipment.

6.9.4 Complete allergen swab testing if the CDT indicates that allergen testing is required. Conduct allergen testing per SOP D-111 Allergen Testing for Production Equipment.

6.9.5 Swabbing is not required after a re-sanitization if previous swabbing results pass.

6.10 Hoses

6.10.1 All production hoses will be cleaned, sanitized, and stored so that they will not become contaminated.

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6.10.2 Production hoses should be stored in or as close as possible to the production room they are used in and hung in such a manner as to allow all water to freely drain. Water or liquids are not to pool inside the stored production hose.

6.10.3 While the production hose is stored, a breathable, durable, and sanitary hose cover will be placed over each open end of the hose.

6.10.4 The hose cover should have an elastic opening which will allow for a snug fit over the hose end. Selection of the size hose cover will depend on the size of the hose and should fit snugly over the end of the production hose and/or hose adapter.

6.10.5 Each hose cover will be disposed of after use.

6.11 Mobile Equipment

6.11.1 Any product contact equipment that is not returned to a production room must be covered and stored in a designated equipment storage area, wrapped and labeled indicating that it will need a minor clean if it is returned to production. Equipment that is not used for product contact (i.e. vacuums, dust filters) can be stored in the equipment storage area without being covered, but is not recommended.

6.11.2 Equipment that is covered should be loosely covered after it is completely dry so as not to harbor water on equipment surfaces and have an equipment status sign indicating the current state of clean.

6.12 Redzone Specific Details

6.12.1 Production must initiate a run in the location being cleaned as follows:

6.12.1.1 Start a “cleaning” product to document initial cleaning. When a cleaning product run starts, all necessary data sheets will start automatically.

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6.12.1.2 Start a “cleaning continuation” product if the cleaning spans across sifts or into the next day. This product does not start any data sheets. Finish data sheets started under the cleaning product run (above) to continue documentation of the cleaning.

6.12.1.3 Start a “cleaning after idle” product to document re-sanitization after a cleaning has already completed, but the room has sat idle for too long before use. When the cleaning after idle product run starts, the re-sanitization data sheet will start without the CDT data sheets. The CDT data sheets are not necessary after a completed cleaning.

6.12.1.4 When starting a cleaning, cleaning continuation, or cleaning after idle product run in Redzone, always use the previous batch number as the Redzone Run ID. If the previous batch number is not known, use NA-MM/DD/YY, where MM/DD/YY is the current date for starting the cleaning run. Enter the estimated time in minutes as the required quantity field.

Note: the date format is not critical when providing a run ID for an unknown previous SKU. Dashes (-) or slashes (/) may be used to represent the date.

6.12.2 To Accommodate Schedule Changes

6.12.2.1 If a cleaning is in process and answers about the next SKU changes for any reason, the type of clean required may also need to change. For example, if the previous schedule identified a SKU that would require a minor clean, a schedule change may identify a SKU that may require a major clean. If this occurs, there are options to document this in Redzone.

6.12.2.2 One option is to start the cleaning process completely over again. The CDT process will start over and allows documentation of the updated

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scheduled next run SKU. This is the preferred method. If the identified cleaning is identical to the cleaning already completed, cancel any redundant data sheets.

6.12.2.3 A second option is to retest data sheets that inquire about the next SKU and correct the information. Before completing this action, cancel incomplete data sheets, as retesting a data sheet will initiate the appropriate actions. Cancel any redundant or unnecessary data sheets generated in this process.

6.12.2.4 Add comments to explain the schedule change and any cancelled data sheets.

6.12.3 Redzone Run Signoff

6.12.3.1 Quality is responsible for signing off all cleaning runs.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/27/10	New	-	-
1	07/10/13	Updated SOP, added major and minor cleaning	13-371	M. Wienke
2	02/17/14	Expanded and detailed cleaning agents, added cleaning agents to form	14-0127	M. Wienke
3	07/11/14	Added step 6.1.5. and note to major cleaning	14-0567	S. Millar
4	09/12/14	Added post-maintenance cleaning steps. Added note to label all chemicals. Defined contact and non-contact.	14-0733	D. Popp
5	12/11/14	Added note to run the water outlet thirty seconds prior to use.	14-1002	S. Kovalik
6	12/01/15	Revised for clarification.	15-0968	D. Popp
7	03/10/16	Added reference to list of chemicals, solutions, and lubricants. Added reference to lab chemicals and solutions.	16-0221	S. Millar
8	06/21/16	Added coating and liquid departments. Added new process for tagging equipment to be cleaned.	16-0610	V. Zelaya
9	11/15/17	Complete procedure rewrite.	17-1246	K. Tyrrell
10	11/20/18	Removed sections mentioning specific hold times for equipment. Specific names of cleaning chemicals were removed and substituted with the more general term "degreaser". Clarified the Minor Clean process and when it is performed on idle equipment or during a Lot# change in a production room.	18-0193	K. Tyrrell
11	12/09/20	Added Organic Clean references, added references to cleaning risk assessment as well as cleaning validation for the powder filling rooms.	CC-20-0691	J. Maignan
12	08/05/21	Added Gummy Room cleaning procedure. Added form B-111-F3. Added Certified Organic, Kosher, Halal, non-GMP Project Verified to appropriate areas.	CC-21-0314	P. Wilson
13	03/08/22	Complete rewrite to accommodate Redzone use.	CC-22-0096	K. Burris
14	08/15/23	Adding Gluten-Free to sections 6.5.7 and 6.5.8.1.2.	CC-23-0413	C. Horelle

8.0 Attachments

8.1 Attachment 1 – PDT Example

8.2 Attachment 2 – Room Placard Example for Completed Cleaning Level

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Attachment 1 – PDT Example



PRODUCT DETAIL TAG

GARCINA CAMBOGIA TABLET

PRODUCT SKU



SCT00001FGP01X0090

BATCH NUMBER

PROBIOTIC: NO

ORGANIC: YES

DRUG: NO

ALLERGEN: YES

ALLERGEN GROUP: DAIRY

PRODUCT TYPE: 2

Attachment 2 – Room Placard Examples for Completed Cleaning Level

Minor Cleaning

**CLEAN
AFTER MINOR
Date:**

Major Cleaning

**CLEAN
AFTER MAJOR
Date:**

Reduced Major Cleaning

**CLEAN
AFTER REDUCED
MAJOR
Date:**

Allergen Cleaning

**CLEAN
AFTER ALLERGEN
Date:**

Secondary Packaging Cleaning

**CLEAN
Date:**



Cleaning Decision Tool – Area Group 1 and Area Group 4

Form: B-111-F1

CCR No. CC-23-0413

Revision: 1

**Cleaning Decision Tool – Area Group 1 and Area Group 4
Blending, Encapsulation, Tableting, Coating, Liquid Packaging, Gummies
Default Tool if Area is not defined in another group**

Cleaning Location	Assessment Date
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Section 1 – Product Information

Information Question	Previous SKU	Next SKU
What is the Product SKU?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below
What is the Batch Number?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below
Is the product a Probiotic?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is the product Organic, Kosher, or Halal	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is the product a Drug?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is the product an Allergen?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
What Allergen Group is the product?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below
What is the assigned product type?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below

Section 2 – Decision Questions

Question	Answer
1A – Do you know the previous SKU? (If not, mark N/A in Previous SKU Product Information section above)	<input type="checkbox"/> Yes – Go to 1B <input type="checkbox"/> No – Major Clean with Allergen Testing
1B – Do you know the next SKU? (If not, mark N/A in Next SKU Product Information section above)	<input type="checkbox"/> Yes – Go to 1C <input type="checkbox"/> No – Go to 1D <input type="checkbox"/> N/A – Question not executed
1C – Are the previous and next SKUs the same? * Special case minor cleans require management approval prior to execution	<input type="checkbox"/> Yes – Minor Clean <input type="checkbox"/> No – Go to 1D <input type="checkbox"/> N/A – Question not executed <input type="checkbox"/> Special Case – Minor Clean* * Management Approval:
1D – Is the previous SKU an allergen?	<input type="checkbox"/> Yes – Major Clean with Allergen Testing <input type="checkbox"/> No – Major Clean <input type="checkbox"/> N/A – Question not executed

Performed By/Date:	Approved By/Date:
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Cleaning Decision Tool – Area Group 2

Form: B-111-F2

CCR No. CC-23-0413

Revision: 1

**Cleaning Decision Tool – Area Group 2
Powder Packaging, Solid Dose Packaging, Blister Packaging, Pouching**

Cleaning Location		Assessment Date	
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Section 1 – Product Information

Information Question	Previous SKU	Next SKU
What is the Product SKU?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below
What is the Batch Number?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below
Is the product a Probiotic?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is the product Organic, Kosher, or Halal?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is the product a Drug?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is the product and Allergen?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
What Allergen Group is the product?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below
What is the assigned product type?	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below	<input type="checkbox"/> N/A <input type="checkbox"/> Record Below

Section 2 – Decision Questions

Question	Answer
1A – Do you know the previous SKU? (If not, mark N/A in Previous SKU Product Information section above)	<input type="checkbox"/> Yes – Go to 1B <input type="checkbox"/> No – Major Clean with Allergen Testing
1B – Do you know the next SKU? (If not, mark N/A in Next SKU Product Information section above)	<input type="checkbox"/> Yes – Go to 1C <input type="checkbox"/> No – Go to 1F <input type="checkbox"/> N/A – Question not executed
1C – Are the previous and next SKUs the same? * Special case minor cleans require management approval prior to execution	<input type="checkbox"/> Yes – Minor Clean <input type="checkbox"/> No – Go to 1D <input type="checkbox"/> N/A – Question not executed <input type="checkbox"/> Special Case – Minor Clean * Management Approval:
1D – Is the previous SKU a Probiotic??	<input type="checkbox"/> Yes – Minor Clean <input type="checkbox"/> No – Go to 1D <input type="checkbox"/> N/A – Question not executed
1E – Is the next SKU Organic, Kosher, or Halal?	<input type="checkbox"/> Yes – Go to 1F <input type="checkbox"/> No – Go to 2A <input type="checkbox"/> N/A – Question not executed



Cleaning Decision Tool – Area Group 2

Form: B-111-F2

CCR No.

CC-23-0413

Revision: 1

Section 2 – Decision Question (continued)

Question	Answer
1F – Is the previous SKU an Allergen?	<input type="checkbox"/> Yes – Major Clean with Allergen Testing <input type="checkbox"/> No – Major Clean <input type="checkbox"/> N/A – Question not executed
2A – Is the previous SKU a Drug?	<input type="checkbox"/> Yes – Go to 1F <input type="checkbox"/> No – Go to 2B <input type="checkbox"/> N/A – Question not executed
2B – Is the next SKU a Drug?	<input type="checkbox"/> Yes – Go to 1F <input type="checkbox"/> No – Go to 3A <input type="checkbox"/> N/A – Question not executed
3A – Is the previous SKU an Allergen or Probiotic?	<input type="checkbox"/> Yes – Go to 3B <input type="checkbox"/> No – Go to 4A <input type="checkbox"/> N/A – Question not executed
3B – Is the next SKU an Allergen?	<input type="checkbox"/> Yes – Go to 3C <input type="checkbox"/> No – Major Clean with Allergen Testing <input type="checkbox"/> N/A – Question not executed
3C – Are the previous and next SKUs in the in the same Allergen Class?	<input type="checkbox"/> Yes – Reduced Major Clean <input type="checkbox"/> No – Go to 3D <input type="checkbox"/> N/A – Question not executed
3D – Are there any Allergens in the previous SKU that are not in the next SKU?	<input type="checkbox"/> Yes – Major Clean with Allergen Testing <input type="checkbox"/> No – Reduced Major Clean <input type="checkbox"/> N/A – Question not executed
4A – Is the previous SKU classified as a Type 1 Product?	<input type="checkbox"/> Yes – Reduced Major Clean <input type="checkbox"/> No – Major Clean <input type="checkbox"/> N/A – Question not executed

Performed By/Date:		Approved By/Date:	
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Area Group 1 Cleaning Form

Form: B-111-F3

CCR No. CC-23-0413

Revision: 1

Room Name/Number: _____

Asset Number: _____

Action	Minor	Major	By/Date/time
General Requirements / Preclean			
<ul style="list-style-type: none"> All detergents and degreasers are at concentrations required as outlined in SOP B-105 All appropriate PPE is worn while chemicals are in use and only clean, potable water used 	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
<ul style="list-style-type: none"> Proper signage (major, minor, allergen) is posted to identify the room All power sources or water sensitive equipment is de-energized and/or covered Lockout/tagout procedures are performed as applicable All raw materials, product, utensils, and related documents are removed from the room When cleaning surfaces of the room and equipment, always start from the top and work downwards and from the back of the room and work towards the doors 	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
Clean			
<ul style="list-style-type: none"> All excessive powder on equipment is removed using a clean and approved brush or cleaning rag. If needed, equipment is vacuumed internally and externally Dust off safety glass as applicable Sweep floor to clear area of any powder, debris or trash as needed 	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
<ul style="list-style-type: none"> All PCS on CIP equipment should be washed and rinsed using approved PCS degreasers and potable water. All removable PCS and utensils are removed, placed on a cart labeled as dirty and cleaned at the equipment cleaning area via SOP B-103 All visible powder on non-PCS is removed using cleaning rag, vacuum or other approved method 	N/A	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
<ul style="list-style-type: none"> Wash and rinse control panels, equipment motors, table tops, walls and scales using approved degreaser for PCS or non-PCS (depending on the location of use) and rinse with potable water. Ensure PCS surfaces are covered if using non-PCS degreasers. All removable non-PCS are removed, placed on a cart labeled as dirty and cleaned at the equipment cleaning area via SOP B-103 	N/A	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:

Comments



Area Group 2 Cleaning Form

Form: B-111-F4

CCR No. CC-23-0413

Revision: 1

Room Name/Number: _____

Asset Number: _____

Action	Minor	Reduced Major	Major	By/Date/time
General Requirements / Preclean				
<ul style="list-style-type: none"> All detergents and degreasers are at concentrations required as outlined in SOP B-105 All appropriate PPE is worn while chemicals are in use and only clean, potable water used 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
				By/End Time/Date:
<ul style="list-style-type: none"> Proper signage (major, minor, allergen) is posted to identify the room All power sources or water sensitive equipment is de-energized and/or covered Lockout/tagout procedures are performed as applicable All raw materials, product, utensils, and related documents are removed from the room When cleaning surfaces of the room and equipment, always start from the top and work downwards and from the back of the room and work towards the doors 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
				By/End Time/Date:
Clean				
<ul style="list-style-type: none"> All excessive powder on equipment is removed using a clean and approved brush or cleaning rag. If needed, equipment is vacuumed internally and externally Dust off safety glass as applicable Sweep floor to clear area of any powder, debris or trash as needed 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
				By/End Time/Date:
<ul style="list-style-type: none"> All PCS on CIP equipment should be washed and rinsed using approved PCS degreasers and potable water. All removable PCS and utensils are removed, placed on a cart labeled as dirty and cleaned at the equipment cleaning area via SOP B-103 All visible powder on non-PCS is removed using cleaning rag, vacuum or other approved method 	N/A	N/A	<input type="checkbox"/>	By/Start Time/Date:
				By/End Time/Date:
<ul style="list-style-type: none"> Wash and rinse control panels, equipment motors, table tops, walls and scales using approved degreaser for PCS or non-PCS (depending on the location of use) and rinse with potable water. Ensure PCS surfaces are covered if using non-PCS degreasers. All removable non-PCS are removed, placed on a cart labeled as dirty and cleaned at the equipment cleaning area via SOP B-103 	N/A	N/A	<input type="checkbox"/>	By/Start Time/Date:
				By/End Time/Date:

Comments



Area Group 4 Cleaning Form

Form: B-111-F5

CCR No. CC-23-0413

Revision: 1

Room Name/Number: _____

Asset Number: _____

Action	Minor	Major	By/Date/time
General Requirements / Preclean			
<ul style="list-style-type: none"> All detergents and degreasers are at concentrations required as outlined in SOP B-105 All appropriate PPE is worn while chemicals are in use and only clean, potable water used 	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
<ul style="list-style-type: none"> Proper signage (major, minor, allergen) is posted to identify the room All power sources or water sensitive equipment is de-energized and/or covered Lockout/tagout procedures are performed as applicable All raw materials, product, utensils, and related documents are removed from the room When cleaning surfaces of the room and equipment, always start from the top and work downwards and from the back of the room and work towards the doors 	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
Clean			
<ul style="list-style-type: none"> Steam clean and flush kettles / lines / pumps / hopper with hot water Clean the inside of tanks using a bristle brush Flush all components of the gummy line listed above with de-ionized water and drain Run IPA through dosing pumps to flush lines and prevent microbial growth Inspect condensate pan, bristle spinners, and blue belt to ensure cleanliness Spray IPA on brushes, under blue belt, and on condensate pan Remove housing from high-shear mixer and clean 	<input type="checkbox"/>	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
<ul style="list-style-type: none"> Disassemble and clean the inside of the pumps and high-shear mixer Disassemble and clean hopper and CFA mixer. Move ancillary equipment to the center of the room near the cooling tunnel Spray walls (including empty drying room) with Simple Green pump sprayer Scrub walls with bristle brush and let stand for 10 minutes Rinse Walls with hot water and wipe down with a clean pad Mop or wet vacuum water from edge of the walls and place equipment back against the walls. Remove condenser tray and wipe down entirety of tray with IPA rag Lightly spray IPA into condenser coils to sanitize heat transfer area Remove both product bristle brushes, remove any residual product with sprayer and liberally spray with IPA followed by water Spray Simple Green under the machine and on any product stains on the floor. Let sit for 10 minutes. Mop with hard water leaving the floor wet Squeegee water to drains or wet vacuum Mop over floor to soak up any excess water and allow to dry Clean drying room walls as described above and send drying racks for cleaning 	N/A	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:
<ul style="list-style-type: none"> Wash and rinse control panels, equipment motors, table tops, walls and scales using approved degreaser for PCS or non-PCS (depending on the location of use) and rinse with potable water. Ensure PCS surfaces are covered if using non-PCS degreasers. All removable non-PCS are removed, placed on a cart labeled as dirty and cleaned at the equipment cleaning area via SOP B-103 	N/A	<input type="checkbox"/>	By/Start Time/Date:
			By/End Time/Date:



Sanitization and Cleaning Approval Form

Form: B-111-F6

CCR No. CC-23-0413

Revision: 1

Sanitization – All Areas and Equipment

This form is to be used after all other aspects of cleaning have been performed (major, minor, reduced major) or when a room has been idle for more than 36 hours

Room Name/Number: _____

Asset Number: _____

Section 1 (To be completed by the Operator)

Table with 4 columns: Action, Completed By, Date, Time. Section 1: Sanitize. Rows include: Spray IPA 70% on touch points, scales, and utensils as needed; Spray IPA 70% on all product contact surfaces and allow to air dry; Spray IPA 70% on all surfaces and allow to air dry; Use germicidal bleach to mop floors.

Cleaning Approval - QC

Section 2 (To be completed by the QC Inspector)

Table with 4 columns: Action, Completed By, Date, Time. Section 2: Inspect. Rows include: Are all aspects of clean performed adequately; There is no visible powder or odors in the room that may contaminate subsequent batches; ATP testing has been performed and has passed; If applicable, allergen testing has been performed and has passed; Circle the appropriate choice: Pass Fail.

Comments:

Large empty box for handwritten comments.