CSB Nutrition Corporation

Food Safety Plan

CSB NUTRITION CORPORATION

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CSB NUTRITION CORPORATION

2600 North Main ST
Spanish Fork, Utah 84660
Phone: (801) 804-7552
FDA #: 15472697994

1.0 Facility Information

CSB Nutrition Corporation manufactures dietary supplements and foods. Products are manufactured under Good Manufacturing Practice for food/dietary supplements.

CSB Nutrition Corporation manufactures dietary supplement and foods in powder, capsules, and stick pack form. Batching, blending, Weighing, Encapsulation, and Packaging of the products are carried out by the company.

Type of Dietary Supplements: Non-Sterile, Solid Dosage
Forms: Capsule, Powders, Stick Packs

Facility Description:

Location: The site is located in a light industrial area of Spanish Fork, Utah. The building is a single location built in 1993. The building is fabricated from sheet metal in a metal framed building. The building has a floor area of approximately 100,848 square feet. The warehouse is separate from the production areas. Office space, break room and rest rooms are separate from the warehouse and production areas. The building has sealed concrete floor with windows that do not open. Production room walls are painted with epoxy for easy cleaning. The building is designed to prevent the cross-contamination and mix-up of dietary supplement/foods by way of:

- Appropriate space to carry out the operations of the facility
- Separate production and non-production areas; and
- Sealed building surfaces (e.g. windows, floors, ceilings and production surfaces) made of materials that facilitate maintenance and sanitation.

Employee Description:

CSB Nutrition Corporation has a total of 130 employees, and two shifts. The first shift (Morning) works 5 days a week. The 2nd shift (Swing) work 4 days a week. The number of employees are broken down as follow:

- QA/QC: 15
- Engineering: 6
- R&D: 4
- Manufacturing: 50
- Packaging: 40
- Administration: 15

The Food Safety Team:

Director of Quality: Michael Pugh (Primary Contact)
Director of Maintenance: Norberto Perez
Director of Manufacturing: Lael Call
Director of Operations: Rick Whetten

2.0 Flow Diagram Process

Supplier/Vendor Qualification

Supplier/vendors are qualified by either one of the following: Supplier/vendor survey questionnaire, Site survey, and/or the supplier/vendor regulatory inspection report (Foreign Country Inspection, FDA Inspection Report, or a third-party inspection). Quality Assurance reviews and accesses the supplier/vendor history, and rates them. Quality Assurance may work with a supplier/vendor to help them achieve compliancy. Once Quality Assurance approves and qualifies the supplier/vendor, they are added to the approved list.

- A full analysis is conducted at appropriate intervals and compared to the Certificate of Analysis
- If we have a failed item, it will be moved back to being tested every time we receive the raw material until it has passed 3 times.
- Approved supplier/vendor list is updated when needed

Handling of Starting Materials

Raw materials are assigned a unique identifying number. Raw materials are sampled and submitted to the lab for the appropriate lab testing according to the specification and placed in the raw material quarantine area location. ID testing is performed on raw materials, skip lot heavy metals, vitamin/mineral testing, and any problem ingredients are tested for the problem every time.

- Every trailer is checked for any signs of potential contamination and for any damage to the materials prior to unloading.
- The material is counted once it is received.
- Receiving will verify that all appropriate documents came with each shipment (BoL, Packing Slip, and Certificate of Analysis).
- The raw materials are stored in a climate control warehouse. The temperature and humidity is monitored daily.

General Production Process (Powders)

- Batch records are issued by a Production Manager or trained delegate and is approved by Quality Assurance.
- Raw Materials are staged for production orders.
- Materials are weighed. Weighing and ingredient identity checked by person performing the task and documents with signature. A second person checks the task as it is being done and documents with signature.
- Mixing room checked for cleaning and line clearance.
- Powders charged into mixer and mixed.
- Mixed batch discharged.
- Filling room is checked for cleanliness and line clearance.
- Powder is taken into filling room and filling hopper charged.
- Product is filled into containers and container closures are applied.
- Weighing checks are performed regularly throughout the filling process.
- Samples for quality control retrieved at intervals throughout the filling process.
- Filled and sealed containers are labelled and packed into outer cartons and placed on pallets.
- Labelled product is put on hold pending release by QA personnel.

General Production Process (Capsules)

- Batch records are issued by a Production Manager or trained delegate. It is approved by Quality Assurance.
- Raw materials are pulled from warehouse locations and staged in batching area.
- Material for batch weighed, weights are double checked along with ingredient identity. Person performing the task documents with signature. A second person checks the task as it is being done and documents with signature.
- Mixing room checked for cleaning and line clearance.
- Powders charged into mixer and mixed. The person performing the task documents with signature, a second person checks the task as it is being done and documents with signature.

- The Mixed batch is discharged.
- Powder charged into hopper of capsule machine.
- Capsules filled.
- Capsules visually inspected on trays and inspection documented.
- Capsules are placed in sealed containers and labelled with batch identification.
- Labelling/filling areas are checked for line clearance.
- Bottles filled
- Labels applied
- Labelled product packed into outer cartons pending release by Quality Control Personnel.

3.0 GMP & Other Prerequisite Programs

Personnel

- Training needs are identified by Upper Management, Quality and Production Managers/ Supervisors and by processing the results of internal and external audits/inspections of observations.
- Employees for the applicable departments are trained on all relevant SOP's and work instructions to their role by a designated trainer. The training is based on understanding and knowledge of Standard Operating Procedures, Work Instructions, Processes and Tasks and on the job training.
- Training involves the use of: reviews of SOP's, lectures from in house staff and consultants, discussions and other applicable training tools.
- When applicable: Registered consultant Training is introduced for operations staff to further increase staff skills/process understanding.
- Efficacy of training is assessed by: Verbal discussion and reviewing of the training; and or by assessment of performance.
- Retraining needs are identified by monitoring of staff performance and by review of annual training requirements.
- Records of training are on file with a training register.

Health Requirements for Personnel Engaged in Production

- Management and Employees have the responsibility for reporting health problems.
- Management has the responsibility to monitor employees for health conditions.
- If an employee is unfit for duty because of health condition in the Operations area, it is the responsibility of the employee to report their condition to the Operation Manager/Supervisor or Quality Management before commencing their task, so alternate duties can be assigned.
- All Employees working in the Operation area; are subject to the same monitoring.
- Restrooms are provided along with two change rooms with washbasins.
- A lunchroom is provided for employees. The lunchroom is provided with a refrigerator, microwave ovens and a sink.
- Production staff entering the Operation areas: are required to have uniforms and hair covers before entering.
- The uniforms are provided and laundered.
- Training is conducted on Personnel Hygiene and GMP Policy.

Plant and Grounds

- The facility must have sufficient space for the proper and safe handling of equipment, materials, and products.
- Warehouse, production, packaging, and common areas are isolated from the outdoors and separated from each other by sealed barriers like walls, doors, and windows.
- Walls, doors, and windows shall be kept in good condition, to prevent contamination or cross-contamination of products and materials.
- Production area's different processes shall be separated from each other by sealed barriers to prevent cross-contamination of products and materials.
- Any packaging process that could possibly cause cross-contamination with other processes should be separated by a sealed barrier.
- Warehouse shall be organized into rows and columns with labelled locations, to prevent mix up of products and materials.

- Walls and ceilings in the production and packaging areas should be sealed, smooth, and without cracks, and holes.
- Floors should be smooth, without cracks and holes.
- The facility's premises are to be kept clean and orderly.
- The facility shall be properly sealed off from the outdoors to prevent the entry of insects and animals.
- Grass and hedges must be maintained in a well-kept manner to reduce the possibility of harbouring pests.
- Grass and hedges are maintained by subcontractors.

Sanitary Operations

- Plumbing shall be maintained up to code, to ensure proper operation and clean water supply.
- Utilities such as air, ventilation, and water supplies shall be designed and maintained as to prevent contamination.
- Air and ventilation systems shall be filtered so that only clean air enters the facility and prevents the entry of foreign materials, insects, and animals.
- Employees are provided with adequate, readily accessible toilet facilities.
- Toilet facilities must be kept clean to prevent potential source of contamination of food.
- All employees working directly with dietary supplement products, equipment, and contact surfaces must wash and sanitize their hands and wear gloves.
- Employees working in production areas must wash their hands thoroughly after each break, lunch break, and after restroom use.
- Employees must wash hands after handling soiled articles, and any other activity that will cause contamination.

Equipment and Utensils

- Cleaning procedures will be broken up into 2 categories; Partial Cleaning and Full Cleaning/Sanitizing.
- The line supervisor and quality will decide which type of cleaning is required.
- QC shall clear the room for use by inspecting the room for cleanliness and swab testing critical areas for micro
- If the room passes QC shall put a sign up notifying the room is ready to use.
- If the room does not pass, it shall be cleaned again and re-inspected until it passes.
- If a room or piece of equipment are not used within 72 hours of being cleaned and passed inspection, the room or piece of equipment shall have a partial cleaning and inspection (micro and cleaning) before use.
- Each inspection shall be logged into the appropriate quality log.
- Every year each employee shall be trained on cleaning.
- Cleaning and toxic substances are stored properly to avoid cross contamination.

Partial Cleaning

- This is done when the same product is running but lot number has changed or the shift has ended before finishing.
- No tear down of machine or room is required but the use of air, cleaning cloths, and sanitizers.
- Cleaning is done when no particulate, stains or soiled areas are present.
- Sanitizing is done by spraying a light mist of IPA on all contact surfaces, letting it sit for 5 seconds and wiping it off with a cleaning cloth or letting it air dry.
- All surfaces should be dry before use.

Full Cleaning

- This is done when a different product is going to be used.
- Total tear down of equipment and room is required and cleaning of all surfaces are required to pass micro swabbing and cleaning inspection.
- Cleaning is done when no particulate, stains or soiled areas are present and swab testing has passed.
- Sanitizing is done by spraying a light mist of IPA on all contact surfaces, letting it sit for 5 seconds and wiping it off with a cleaning cloth or letting it air dry.
- All surfaces should be dry before use.

4.0 Hazard Analysis & Preventive Measures

HAZARD ANALYSIS/PREVENTIVE MEASURES PROCESS CATEGORY: CSB Nutrition PRODUCT EXAMPLE: All Powders			
Process Step	HAZARDS Biological (B) Including Microbiological Chemical (C) Physical (P)	Preventive Measures	Examples of How Hazard Is Introduced
Receiving	P (Physical) Heavy metals contaminate raw ingredients	Test all raw material for HM first 3 times and skip lot after **(Heavy Metal log)**	Polluted soils and waters where the raw material is grown
	C (Chemical) Chemical adulterants are added to enhance the effectiveness of the herb	All ingredients are ID by NIR and validated by TLC or HPLC **(Form #020)**	Ingredients are sometimes adulterated to mimic or enhance activity
	B (Biological) harvest and storage conditions result in unacceptable microbial growth	All ingredients are accepted on vendor micro tests unless we find one that fails and then it is listed to be tested every time for micros.	Raw ingredients are harvest all over the world under less than clean conditions
Warehouse	P (Physical) Temperature/Humidity can affect raw material and finished product	Every day we monitor temp/humidity **(Form #039)**	If we lost power or our air conditioner fail we could lose control of the environmental stability of our warehouse
	C (Chemical) Allergens are found in many of our ingredients	All allergens are identified and stored to avoid cross contamination **(Gen.QA.015, Allergen Sticker)**	Allergens are found naturally in ingredients and cause health concerns in small amounts

Batching/Mixing	P (Physical) Foreign Material found in raw ingredients	All raw materials are screened and some are run by a magnet in blending **(Form # 009)**	Foreign material can be incorporated during harvest and manufacturing of raw material
	C (Chemical) Allergens are found in many of our ingredients	All batching/mixing records contain a warning of Allergen, allergens are measure separately, room is cleaned and swab tested for Allergens **(Batch Record Allergen Sample)**	Allergens are found naturally in ingredients and cause health concerns in small amounts
	B (Biological) micro contamination can be introduced during batching and mixing	All blends are tested for full micro before they move on to the next step of packaging	Micro counts can be introduced by ingredients that have hot spots, employees and unclean equipment
	C (ID) blends are ID to prevent mistakes of wrong ingredients or blends being used	All Blends are ID and verified as the correct blend	On rare occasions human error can mix paper work or labels and thus the wrong product is in the wrong packaging
Powder Fill	P (metal detection) metal from manufacturing can make it into the powder	All powder is ran through a metal detection unit **(Form #101-A)**	In blending or screening metal parts or pieces of screen can make it into the blend
	B (micro) is run on every 10th lot of material ran through powder fill (skip lot)	This is a validating process to insure our cleaning, swab testing and lab testing are meeting our needs	We want to be ever vigilante on micro and show our processes are working
Encapsulation	B (micro) is run on every 10th lot of encap. run (skip lot)	This is a validating process to insure our cleaning, swab testing and lab testing are meeting our needs	We want to be ever vigilante on micro and show our processes are working

Encap Packaging	P (metal detection) metal from manufacturing can make it into the capsule	All capsules are run through a metal detection unit **(Form #101-B)**	In blending, screening or encapsulating machine parts or broken screens can find their way into the powder or capsules
Stick Pack	B (Biological) is run on every 10th lot of stick pack (skip lot)	This is to validate our processes that insure our swab testing, cleaning and lab work are meeting our needs	We want to be ever vigilante on micro and show our processes are working
	P (Physical) Foreign Material found in raw material	There is a magnet inline that catches all metal shavings found in the powder **(Appendix 9: Form #147)**	In blending, screening or encapsulating machine parts or broken screens can find their way into the powder or capsules

5.0 CCP Determination

CCP DETERMINATION (A CRITICAL CONTROL POINT IS DEFINED AS A POINT, STEP OR PROCEDURE AT WHICH CONTROL CAN BE APPLIED AND A FOOD SAFETY HAZARD CAN BE PREVENTED, ELIMINATED, OR REDUCED TO ACCETABLE LEVELS)						
Process Step	**HAZARD(S)** **Biological – B** **Chemical – C** **Physical – P** **Hazard Description**	**Q1. Do Preventive Measures Exist for The Identified Hazard(s)?** ***If no= not a CCP- identify how and where this hazard will be controlled** ***If yes= move to next question**	**Q2. Does This Step Eliminate or Reduce the Likely Occurrence of a Hazard(s) To an Acceptable Level?** *If no=move to the next question *If yes= CCP	**Q3. Could Contamination with Identified Hazard(s) Occur in Excess of Acceptable Levels or Could These Increases to Unacceptable Levels?** ***If no=not a CCP** ***If yes=move to the next question**	**Q4. Will A Subsequent Step Eliminate Hazard(s) Or Reduce the Likely Occurrence to An Acceptable Level?** ***If no=CCP** ***If yes= not a CCP**	**#CCP**
Receiving	P- Heavy Metals	Yes	Yes			A1
	C- Chemical (ID)	Yes	Yes			A2
	B- micro	Yes	Yes			A3
Warehouse	P-Temp/humidity	Yes	Yes			B1
	C- Allergens	Yes	Yes			B2
Batching/Mixing	P-Foreign Material	Yes	Yes			C1
	C- Allergens	Yes	Yes			C2
	B- Biological	Yes	Yes			C3
	C- ID	Yes	Yes			C4
Powder Fill	P-Foreign Material	Yes	Yes			D1
	B - Micro	Yes	Yes			D2
Encapsulation	B- Micro	Yes	Yes			E1
Encap Packaging	P-Foreign Material	Yes	Yes			F1

Process Step	HAZARD(S) Biological – B Chemical – C Physical – P Hazard Description	Q1. Do Preventive Measures Exist for The Identified Hazard(s)? *If no= not a CCP- identify how and where this hazard will be controlled *If yes= move to next question	Q2. Does This Step Eliminate or Reduce the Likely Occurrence of a Hazard(s) To an Acceptable Level? *If no=move to the next question *If yes= CCP	Q3. Could Contamination with Identified Hazard(s) Occur in Excess of Acceptable Levels or Could These Increases to Unacceptable Levels? *If no=not a CCP *If yes=move to the next question	Q4. Will A Subsequent Step Eliminate Hazard(s) Or Reduce the Likely Occurrence to An Acceptable Level? *If no=CCP *If yes= not a CCP	#CCP
Stick Pack	B-Micro	Yes	Yes			G1
	P- Foreign Material	Yes	Yes			G2

6.0 HACCP PLAN

HACCP PLAN PRODUCT: Powder Manufacturing (powders, capsules, stick pack)							
Process Step	**Biological – B Chemical – C Physical – P Hazard Description**	**CCP**	**Critical limits**	**Monitoring Procedures/Frequency/ Person Responsible**	**Corrective/ Preventive Action/Person Responsible**	**HACCP Records**	**Verification Procedures/ Person Responsible**
Receiving	P – Heavy Metal	A1	Arsenic <3ppm Cadmium <3ppm Lead <5ppm Mercury <3ppm Is standard OR refer to the raw material specs for special limits	New ingredient lots are tested 3 times and then it is skip lot tested after every 10th batch after receiving Quality Personal **(Heavy Metal Log)**	If ingredient fails HM it is rejected and returned. Next 3 lots need to pass before going back on skip lot testing /Quality Receiving Personal	Logged in the receiving office along with skip lot computer spreadsheet **(Heavy Metal Log)**	Each product is verified when received by the Quality personal and documented. A Certificate of Analysis is produced for each lot received
	C – Chemical	A2	Each ingredient is modeled using TLC, HPLC and NIR. A finger print is established. The ingredient is compared each time received. We also test color.	This is done every time we receive in an ingredient. Quality personnel sample each lot received and send it to the lab. It is not released until they have received positive results on a Certificate of Analysis. **(QLT.QC.003, WI.QLT.QC.003-2)**	If the ingredient fails it is rejected and sent back to the vendor. This is done by Quality Control Manager **(WI.QLT.QC.003-8)**	All CofA's are logged onto the LIM's system. QC logs all testing, and all receiving documents are kept and can be accessed. We also keep a log of all rejected items.	QC reviews all results and releases product by computer system and applying a green sticker to each package, box or bag

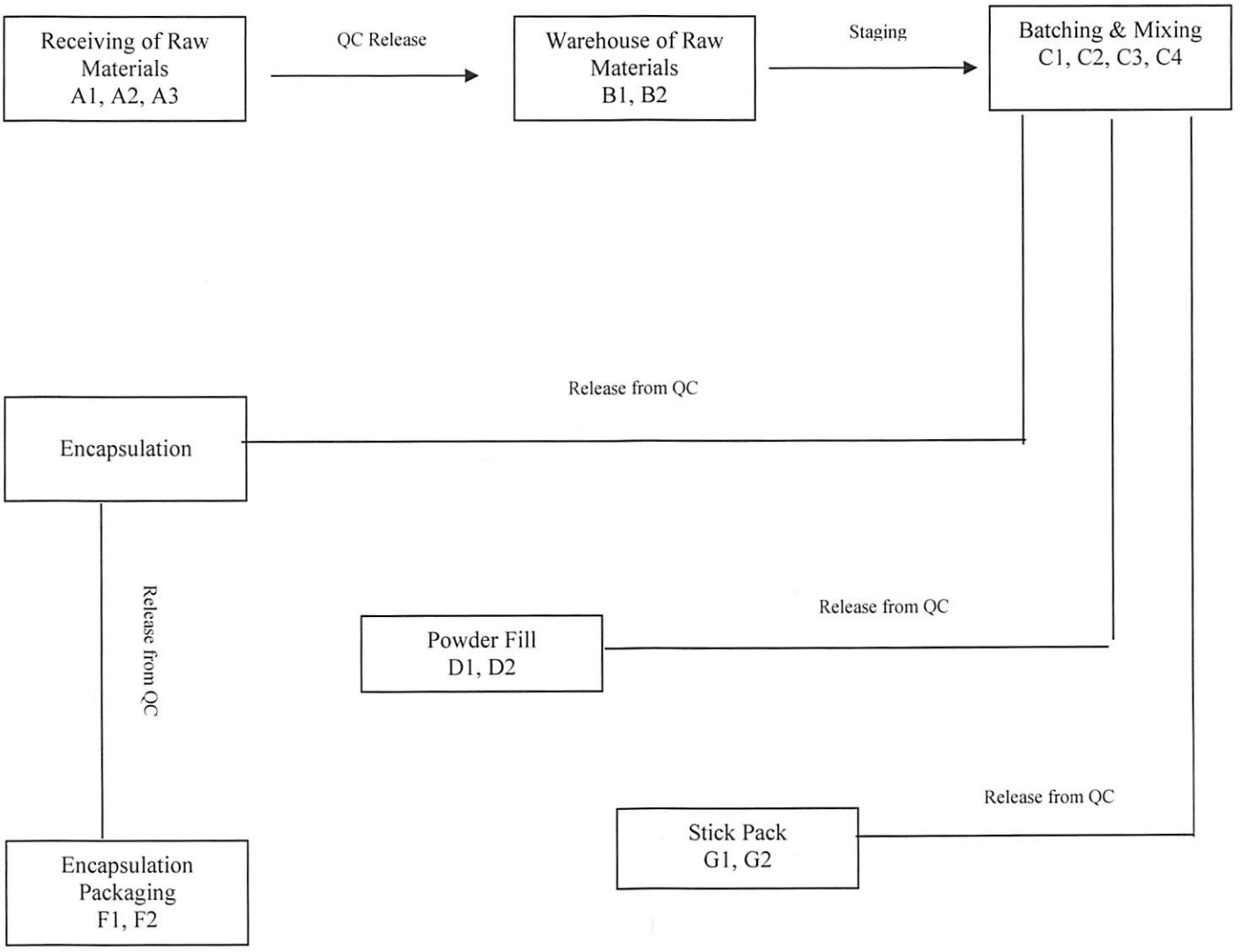
Process Step	Biological – B Chemical – C Physical – P Hazard Description	CCP	Critical limits	Monitoring Procedures/Frequency/ Person Responsible	Corrective/ Preventive Action/Person Responsible	HACCP Records	Verification Procedures/ Person Responsible
Receiving	B- Micro	A3	These parameters are all set in the raw material specs	Most ingredients are received on micro from vendor CofA unless we have customer requirements wanting lower counts or we have had material issues and we do not have confidence in the vendor supplied CofA. QC maintains those specs and makes sure ingredients follow the proper process	If an ingredient fails it is rejected and sent back to the vendor. QC will reject, document and start the process of sending back **(QLT.QC.003, WI.QLT.QC.003-8)**	All CofA's are logged onto the LIM's system. QC logs all testing, and also all receiving documents are kept and can be accessed. We also keep a log of all rejected items.	QC receiving reviews all releases and makes sure that all testing is done and passes before releasing in the system or applying green stickers for release.
Warehouse	P- Temperature/ Humidity	B1	Temp: 53°F to 80° F Humidity: ≤ 55%	QC has a log book where temperature and humidity are logged in every day. We also monitor temp/humidity electronically and they are logged continually. QC monitors our temp/humidity controls in 5 different areas of the facility (Form #039)	If temp/ humidity goes out of spec then they are closely monitored for the next 48 hours and maintenance is notified. If they are still out of spec past 48 hours then a material review board is convened and all sensitive ingredients and products are examined (GEN.QC.010)	We have a temp/humidity log book and we use our corrective action plan in case of failure (GEN.QA.018)	QC manager verifies daily and logs the info.

Process Step	Biological – B Chemical – C Physical – P Hazard Description	CCP	Critical limits	Monitoring Procedures/Frequency/ Person Responsible	Corrective/ Preventive Action/Person Responsible	HACCP Records	Verification Procedures/ Person Responsible
Warehouse	C-Allergens	B2	All raws that are allergens are tagged and controlled from receiving.	QC receiving monitors all raws coming in and makes sure they are tagged as allergens. If they do not know, they contact their supervisor. (GEN.QA.015, Allergen Sticker)	Raws are not received unless they are tagged correctly. QC monitors the warehouse and does a Corrective Actions if raw materials and blended materials are not stored correctly (GEN.QA.018)	All raws that are allergens are tagged. This is recorded in the data base in Infinity. (Batch Record Allergen Sample)	QC personal check each receiving record and makes sure the material is properly marked.
Batching/ Mixing	P – Physical	C1	There is a zero tolerance for metal or any foreign substance in our powders	There is an in-line magnet that attracts any metal and a screen that traps foreign material. This is done on every blend. After each blend, the magnet and screened are examined for foreign particles (Form #009)	If foreign material is found the mix is Quarantined. An investigation is started by QC. Material review board is called to decide proper action (GEN.QA.009)	A log book is kept in each mixing room. After each blend the screen and magnet are inspected for foreign material, logged and approved by QC.	QC will make sure every blend is logged in the room with what was found on the magnet and screen. They will sign each log entry.

Process Step	Biological – B Chemical – C Physical – P Hazard Description	CCP	Critical limits	Monitoring Procedures/Frequency/ Person Responsible	Corrective/ Preventive Action/Person Responsible	HACCP Records	Verification Procedures/ Person Responsible
Batching/ Mixing	C-Allergens	C2	Non-detection on all swab testing and well documented paper work	All batching and packaging rooms will have proper signage indicating an allergen is being run. After a batching room, mixing room, or packaging room has contained an allergen, they shall be fully cleaned and swab tested for allergens. QC will do the swab testing. (PRD.OT.003)	If swab testing does not pass, the room shall be cleaned again and swab tested until it passes (WI.PRD.OT.003)	Log book in the room for cleaning and log book in the QC managers office for swab testing (Log Book Sample)	This shall be verified by the QC personal doing the swab testing and clearing the room
	B-Micro	C3	Micro is preset to 30 RLU for contact surfaces and 90 for non- contact food surfaces. All ingredients mixed have finished product spec listing the limits for micros.	After the blend is done a sample is pulled for micro. The product will not leave the facility until we have clean micro results. Also, the room is swab tested using a hand-held device. (PRD.OT.003)	If micros do not pass the product is rejected and MRB is convened. If the room does not pass it is cleaned again and tested. (GEN.QA.009)	Our batch records will have a CofA and also the LIMs will have the micro information. The cleaning of the room is logged in the log book in the room and the swab testing is logged in the QC manager's office. (Log Book Sample)	This will be verified by our QC worker on the floor. They will log the information and make sure the room passes. The product will go through a review process and the review form will be found in the finished batch record.
	C-Chemical	C4	Pass NIR ID testing	This will be done for every mix. It will be sampled by QC personnel and submitted to the lab for ID and color.	If mix fails the product is put on QC hold and a MRB is convened to investigate the reason. (GEN.QA.009)	This will appear on the mix CofA and will be stored with the batch record.	This will be reviewed before it moves on to the next stage by Quality and it will be released by Quality both electronically and physically by sticker.

Process Step	Biological – B Chemical – C Physical – P Hazard Description	CCP	Critical limits	Monitoring Procedures/Frequency/ Person Responsible	Corrective/ Preventive Action/Person Responsible	HACCP Records	Verification Procedures/ Person Responsible
Powder Fill	B-Micro	D-2	These limits will be set by the FPS on the product being produced.	Micros will be run on every 10th item run in powder fill. This will be kept by QA personnel and written on the batch record. The CofA which will be stored in the batch record. Quality will release all product	If product fails the product will be held and not released. MRB will convene and an investigation will ensue. Product will be destroyed if not usable. Quality will lead the investigation. (GEN.QA.009) (Vitamin & Minerals Spreadsheet)	All finished CofA will be stored in the batch record. All MRBs will be required to follow the MRB SOP. (GEN.QA.018)	Quality Manager will be responsible to make sure the processes are followed and proper paperwork is done.
Stick Pack	B-Micro	G1	These limits will be set by the FPS on the product being produced	Micros will be run on every 10th item run in stick pack. The product will not be cleared to ship until it has received a clean CofA which will be stored in the batch record. Quality will release all product.	If product fails the product will be held and not released. MRB will convene and an investigation will ensue. Product will be destroyed if not useable. Quality will lead the investigation (GEN.QA.009)	All finished CofAs will be stored in the batch record. All MRBs will be required to follow the MRB SOP. (GEN.QA.009)	Quality Manager will be responsible to make sure the processes are followed and proper paperwork is done.

Process Step	Biological – B Chemical – C Physical – P Hazard Description	CCP	Critical limits	Monitoring Procedures/Frequency/ Person Responsible	Corrective/ Preventive Action/Person Responsible	HACCP Records	Verification Procedures/ Person Responsible
Stick Pack	P- Foreign Material	G2	There is zero tolerance to metal found in the powder.	There is an in-line magnet feeding the stick pack machines. This magnet is checked after every run and logged into the log book for that machine. (Form #147)	If metal is detected on the magnet, the product is put on QC hold and a MRB is started. From the investigation a decision will be made on what will correct or destroy the product. (GEN.QA.009)	Each product magnet inspection will be logged onto the room log book.	Quality personnel will inspect the magnet and log it into the log book.
Encapsulation Packaging	B-Micro	F1	These limits will be set by the FPS of the product.	These will be tested on every 10th capsule run. This will be written on the batch record and kept track of by QA documentation in a spread sheet format	If we have increased failures we will do a CCR action in cleaning and handling (GENQA.018)	Spread sheet in QA and LIMs system for CofA	QA personnel will track and monitor our encapsulation skip lot program.
Encapsulation Packaging	P- Foreign Material	F2	There is zero tolerance to metal found in the capsules.	Each bottle is passed under the metal detector. The metal detector is calibrated before each run and is monitored by QC on the floor (Form #101-B)	If the metal detector rejects a bottle the line is stopped and an investigation is started. If metal is found, the product is pulled and we go the MRB and due a full investigation (GEN.QA.009)	The calibration is logged in the log book on the packaging line. (Form# 009)	Quality verifies that the metal detector is calibrated and also closes the line if problems arise.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D1, D2
Release from QC
Release from QC
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F1, F2
Stick Pack
G1, G2

7.0 Allergens

- All raw materials introduced into the warehouse will be reviewed by QC receiving.
- QC personnel shall identify if raw material is an allergen.
- All allergen ingredients shall be stored in the allergen control area.
- When the batch records are printed, "ALLERGEN" will appear in a box on the top of the first page.
- Each room (weighing, mixing, encapsulation, stick pack, powder fill, and packaging) shall identify that the room or line has an allergen being processed.
- After a run of an allergen, QC will perform a swab test on the line/equipment to ensure proper cleaning was performed.
- The room or line shall keep the sign until the room is cleaned and cleared by QC.
- Each room after running an allergen shall run a full cleaning and sanitizing.
- QC will take down the sign and the room will be ready for use once the room is cleared by QC.
- Employees will be trained on Allergen once a year.
- All allergens are weighed and batched last to avoid cross contamination.

8.0 Recall

- CSB Nutrition Corporation is a contract manufacturer and supports clients when applicable on product recalls.
- The Recall Coordinator (Director of Quality) and committee will assemble together, and gather all pertinent data, and evaluate the risk associated with the product.
- The name of the suspected product, along with the identification codes (lot numbers, expiration date, etc.) manufacture date, and any other methods for identifying the product.
- Mock recalls are done semi-annually.

9.0 Reanalysis of Food Safety Plan

CSB Nutrition Corporation will review The Food Safety Plan every 3 years or when a change has occurred in one of the processes.

10.0 Authorized Signatures

APPROVED BY:	Bob Gillispie	**DATE:** 100819
PREPARED BY:	Paulina Munoz	**DATE:** 10.08.19