Audit Report Global Standard Food Safety Issue 9

1. Audit Summary			
Company name	Qingdao Bright Moon Seaweed Group Co., Ltd.	Site code	2601001
Site name	Qingdao Bright Moon Seaweed Group Co., Ltd.		
Scope of audit	Washing, digesting, calcification, decalcification, dehydration, neutralization, drying, grinding, packing of Sodium (Calcium, Potassium) alginate with polyethylene film and coat compound bag. Dissolving, isomerization, hydrogenation, concentration, crystallization, drying, packing mannitol powder into polyethylene film and coat compound bag.		
Exclusions from scope	Production of sorbitol, compound additives.		
Justification for exclusion	The compound additive is produced in another workshop and is completely separated. As a by-product of mannitol production process, sorbitol is transported to another workshop in liquid form for subsequent processing after the crystallization process.		
Audit start date	2024-07-08	Audit finish date	2024-07-10
Re-audit due date	2025-08-03	Head office	No

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose a module	Choose an item		
Choose a module	Choose an item		

2. Audit Results					
Audit result	Certificated	Audit grade	B+	Audit programme	Unannounced – mandatory 1 in 3 years
Previous audit grade	B		Previous audit date	2023-07-06	
Certificate issue date	2024-08-15		Certificate expiry date	2025-09-14	

2. Audit Results

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	11

3. Company Details

Site address	No.777, Mingyue Road, Huangdao, Shandong Province.		
Country	P. R. China	Site telephone number	008653288196957
Commercial representative name	Pang Jinlong	Email	Pjl@bmsg.com
Technical representative name	Li Zhenguang	Email	zj@bmsg.com

4. Company Profile

Plant size (metres square)	10-25K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Shift pattern	3 shift 8 hours per shift in the pre-production area; 8 hours a shift in the packaging area; 7 days per week	
Seasonal site	No	
Seasonal opening times (Start/end date)	Click or tap to enter a date.	Click or tap to enter a date.
Other certificates held	ISO9001, ISO14001, ISO22000, HACCP, KOSHER and Halal	
Outsourced processes	No	

4. Company Profile	
Outsourced process description	N/A
Regions exported to	North America South America Europe Asia Choose a region Choose a region
Company registration number	12237028401527
Major changes since last BRCGS audit	No major changes since last BRCGS audit.

Company Description

The company was established in 2006, located in Huangdao, Qingdao City, Shandong Province. There are several workshops in the plant area. Currently, there are only two workshops within the scope of certification, namely, alginate workshop and mannitol workshop. The plant area was about 170000 square meters, including about 5000 square meters of alginate workshop and about 10000 square meters of mannitol workshop.

At present, the company has 600 employees. The production department has three shifts every day, with about 80 effective employees per shift. The rest of the departments have only day shifts.

The workshops within the scope of certification use seaweed as raw material to produce sodium (Calcium, Potassium) alginate and glucose as raw material to produce mannitol. The products are used as raw materials or ingredients for other food factories and are not directly edible.

Main equipment including liquid tank, ion exchange column, simulated moving bed, crystallization tank, fluidized bed, dryer, launder, granulator, pulverizer and metal detector etc.

The output in 2023 is 10000 mt of sodium (Calcium, Potassium) alginate and 7000 mt of mannitol. 60% of the products were sold in domestic and and 40% were export to foreign markets, mainly exported to North America, South America and Europe.

The company is a Sino-foreign joint venture. Beside BRCGS, the company also got the ISO 9001, ISO 22000, ISO14001, HACCP, Kosher and Halal certificated.

5. Product Characteristics	
Product categories	15 - Dried food and ingredients Category Category Category Category

5. Product Characteristics

	Category Category Category
Finished product safety rationale	Ambient, the shelf-life was 24/36 months, Water content: sodium (Calcium, Potassium) alginate is less than 15%, mannitol is 0.5%.

High care	No	High risk	No	Ambient high care	No

Justification for area	All final products were used as food additivities for other food factories and were not ready to eat food, ambient stable products, so based on BRCGS decision tree, only low risk areas and enclosed areas were in place.
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	None
Product recalls in last 12 months	No
Products in production at the time of the audit	sodium alginate and mannitol

6. Audit Duration Details

Total audit duration	24 man hours	Duration of production facility inspection	12 man hours
Reasons for deviation from typical or expected audit duration	None		

6. Audit Duration Details	
Combined audits	None
Next audit type selected	Unannounced – mandatory 1 in 3 years

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)

Name	Job title	Opening meeting	Site inspection	Procedure review	Closing meeting
Li Zhenguang	Vice President	X	X		X
Guo Yanli	HR supervisor	X		X	X
Liu Feiyu	Supplier chain supervisor	X		X	X
Zhang Lin	QA manager	X	X	X	X
Bu Changping	QA	X	X	X	X
Wang Lian zhong	Mannitol factory director	X	X		X
Shi Jian sheng	Director of alginate factory	X	X		X
Xu Qiang	Manager of Warehousing and Logistics Department	X	X		X
Yin Yue hong	Group Inspection Center Manager	X		X	X
Chen Xin bing	Director of alginate factory	X	X		X

GFSI Post Farm Gate Audit History

Date	Scheme/Standard	Announced/Unannounced	Pass/Fail

2023-11-15	HACCP	Announced	Pass
2023-07-06	BRCGS for food safety Issue 9	Announced	Pass

Document control			
CB Report number	051A1207005I		
Template name	F908 Food Safety Audit Report Template		
Standard issue	9	*Template issue date*	2022-12-16
Directory allocation	Food	*Version*	1.1

Non-Conformity Summary Sheet

Critical or Major Non-Conformities Against Fundamental Requirements			
Clause	Detail	Critical or Major	Re-audit date

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1.1.1	Onsite audit found the employee in charge of the metal detector calibration in the inner packaging process failed to explain the factory's food quality and safety policies.	1. The company conducted re-training on the quality policy and food safety policy for workshop employees. 2. The company posted quality and food safety policies at the entrance of the workshop for promotion, making it easy for employees to view and memorize them at any time.	1. Communicate with employees in other workshops of the group and evaluate their understanding of the quality policy and food safety policy. 2. After the unified training, each department will periodically ask employees questions to ensure that they have a good grasp of the company's quality policy and food safety policy.	1. After the company's regular training, the promotion was not posted prominently in the workshop, resulting in employees being unable to remember it proficiently over time. 2. After the company regularly organizes training and assessments, each department does not conduct further interviews or inquiries with employees regarding their understanding of the situation.	2024-08-05	Felix Wang
2.5.1	Onsite audit found NaClO was added to in the washing and soaking process, but it	1. The company immediately supplemented and improved the process flow chart based on the existing technology,	1. The company has organized training for the members of the food safety review team and	1. The food safety team was not meticulous enough in confirming the production process of	2024-08-05	Felix Wang

Minor						
	was not described in the flow diagram, although related control measures were established and followed, no food safety risk was found.	and marked the addition points of sodium hypochlorite in the process chart by the food safety team. 2. The food safety team re-evaluates and confirms the production process of sodium alginate, investigates and confirms the integrity of its process flow.	proposed specific requirements for product process review. 2. Factory management personnel confirm the product process every six months, and report any missing items to the food safety team for review and revision.	sodium alginate, and overlooked the use of sodium hypochlorite in the process. 2. The factory failed to re-confirm the details of the product production process and did not provide any suggestions for modifying the process flowchart during the production process.		
4.2.4	Onsite audit found the inlet of the HCl intake pipe for one HCl external storage tank was not locked, although CCTV could cover this area to ensure food security.	1. The company immediately implemented lock management on the unlocked hydrochloric acid tanks. 2. The company immediately conducted a risk assessment on the products of the day.	1. The company has organized an investigation and confirmation of other doors, tanks, etc. that require locking management to ensure that they are all locked according to requirements. 2. The company provides training to relevant personnel and requires them to manage according to the requirements of designated personnel for	1. After feeding hydrochloric acid, the operator neglected to effectively lock the hydrochloric acid tank. 2. The patrol personnel failed to detect abnormalities in a timely manner.	2024-08-05	Felix Wang

Minor						
			locking management, in order to enhance their awareness of food safety protection.			
4.4.7	There is a large gap in a window of the sodium alginate front workshop.	1. The company immediately closed the windows tightly. 2. The company conducted a risk assessment of the products on that day.	1.The company has provided training on pest control measures to relevant employees. 2. The company organized an inspection of all insect prevention measures for doors and windows. 3.In the next internal audit and future GMP inspections, the company will focus on inspecting the anti-insect net facilities.	1. The company employee neglected to close the window while cleaning the anti-insect net. 2. The company's workshop management personnel did not discover the problem in a timely manner during the inspection.	2024-08-05	Felix Wang
4.6.2	Onsite audit found the stainless-steel protection shelfs next to the conveyor belt in the sodium alginate inner packaging workshop after unloading were hollow and both ends were not sealed, with	1. The company immediately stopped using the conveyor belt. 2. The company shall immediately thoroughly clean the residual products inside	1. The company organizes a comprehensive inspection of other equipment and facilities in the workshop. 2. The company has provided foreign object control training to	1. The company did not seal the openings at both ends when installing the conveyor belt. 2. The company failed to detect the issue in a timely manner during routine inspections.	2024-08-05	Felix Wang

Minor						
	little product residue inside.	the conveyor belt guardrail pipeline. 3. The company seals the openings at both ends of the conveyor belt guardrail.	employees and requires timely reporting of equipment and facilities with foreign object risks found in the workshop.			
4.7.1	Onsite audit found the metal cover of an electric air fan in Neutralization Zone of workshop was slightly rusted.	1. The company immediately stopped using the fan. 2. The company organized personnel to carry out rust removal and maintenance on the fan. 3. The company conducted a risk assessment of the products on that day.	1. The company organized inspections and maintenance of all auxiliary cooling equipment. 2. The company has organized special training on foreign object control, requiring timely shutdown and adoption of protective measures for equipment that may introduce foreign object risks.	1. After discovering the problem, the company employees did not realize the risk of introducing foreign objects and did not report the issue in a timely manner. 2. The management personnel failed to detect it in a timely manner during daily inspections.	2024-08-05	Felix Wang
4.8.7	Onsite audit found there was steamed bun in the office desk of the calcium aging processing area of sodium alginate workshop.	1. The company immediately confiscated the Steamed Bread. 2. The company immediately conducted a risk assessment for all products on that day.	1. The company organized relevant personnel to conduct a comprehensive inspection of each process. 2. The company provides training on foreign object control for workshop employees, requiring	1. The company employee personally carries the unfinished Steamed Bread into the workshop as violation of the relevant regulations. 2. The company management failed to	2024-08-05	Felix Wang

Minor						
			them not to bring any production related items into the workshop according to regulations.	detect the issue in a timely manner.		
4.9.3.2	Onsite audit found the alarm on the equipment in the calcified aging area was made of hard plastic but it was not included in the list of fragile items.	1. The company immediately checks and confirms the integrity of the alarm on the equipment in the calcified aging area. 2. The company immediately reviewed and revised the list of fragile items, and added a warning plastic cover to the list of fragile items for the calcification process.	1. The company has organized inspections and confirmations of fragile items in various workshops and processes. 2. The company has provided training to workshop employees, requiring them to count and confirm according to the updated list of fragile items.	1. Alarm devices on equipment not included in the list of fragile items for calcified aging areas. 2. The company did not promptly identify missing items on the fragile goods list.	2024-08-05	Felix Wang
4.9.5.1	Onsite audit found there was a wooden handle brush inside an office desk in the sodium alginate workshop's calcification aging process.	1. The company immediately confiscated the wooden handle brush. 2. The company conducted a risk assessment of the products on that day.	1. The company organized relevant personnel to conduct a comprehensive inspection of each process. 2. The company provides training on foreign object control for workshop employees, requiring them not to bring any production related items	1. The company staff personally carry the wooden handle brush into the workshop without official authorization according to regulations. 2. The company management failed to detect the issue in a timely manner.	2024-08-05	Felix Wang

Minor						
			into the workshop according to regulations.			
4.10.4.1	During the on-site audit, it was found that there was a little metal powder left on a magnetic bar in the sodium alginate inner packaging workshop that had not been completely cleaned (the inner packaging process had not yet begun during onsite audit time).	1. The company immediately stopped using permanent magnet tubes. 2. The company thoroughly cleans the permanent magnet cylinder again according to the cleaning procedures.	1. The company has organized a comprehensive inspection of other equipment and facilities in the workshop. 2. The company provides re-training on cleaning procedures for employees, requiring them to follow the cleaning procedures for cleaning. When the permanent magnet cylinder is handed over, the handover personnel will confirm again.	1. The workshop staff did not clean the permanent magnet cylinder according to the cleaning regulations. 2. The workshop staff failed to confirm the cleanliness of the permanent magnet cylinder in a timely manner due to shift handover.	2024-08-05	Felix Wang
4.14.1	Onsite audit found there was a spider on the wall at the entrance of the sodium alginate workshop.	1. The company immediately implements product protection around pest activities to prevent pest contamination of the products. 2. The company immediately carries out physical killing of the discovered pests.	1. The company immediately conducted a comprehensive inspection of pest control in each workshop. 2. The company provides pest control training to workshop employees, clarifying the frequency of pest control facility	1. Due to the recent heavy rain in Qingdao for several consecutive days, the risk of pests entering the workshop with personnel has increased. 2. production operator did not thoroughly inspect the wall per day.	2024-08-05	Felix Wang

Minor						
		3. The company has organized a risk assessment of the products on that day.	inspections and usage methods. 3. The company would enhance inspection by inspector per day.			

Comments on non-conformities
None

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical		
Clause	Detail	Re-audit date

Major						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor						
Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Audit team

Lead auditor		
Auditor number	**First name**	**Second name**
21939	Felix	Wang

Audit team				Attendance (YYYY/MM/DD, 24hr: MM)			Presence	
First name	Second name	Auditor number	Role	Audit Date	Start time	End time	Remote or physical	Professional recognition number
Felix	Wang	21939	Leader Auditor	2024-07-08	8:30	18:00	physical	
Felix	Wang	21939	Leader Auditor	2024-07-09	8:00	17:30	physical	
Felix	Wang	21939	Leader Auditor	2024-07-10	8:00	14:30	physical	

1. Senior management commitment

The senior managements (President Mr. Zhang) put their commitments. Corporate policy was established by senior management and covered the requirements of legislation, quality, food safety etc. And clearly defined and written quality policy in place in the Food Safety and Quality Manual (BM000069). The factory food safety policy (MC01-003-QM-06) was defined as bellow: “Implement laws and regulations, strengthen hygiene awareness, strictly control processes, and provide safe products.” The explanation of the policy states the commitment of senior managers to continuously improve food safety culture. The policy and objectives were communicated to all related staff via meeting, training, notice, etc. factory posted relevant policies at the office and the entrance of the workshop to publicize employees.

The site’s senior management has defined and maintained a clear plan for the development and continuing improvement of a food safety and quality culture. Activities related to food safety culture are defined in the procedure. The food safety cultural activities in 2024 year were defined. Such as: food safety internal audit, food safety training and test from July of 2023 to Jun. of 2024 once per month, food safety promotional video study about 3.15, Collect rationalization suggestions from July 2023 and so on. The factory carried out food safety cultural activities according to the schedule and evaluated the effects of the activities. Evaluation means include Management evaluation, employee interview, questionnaire survey, etc. The last evaluation was from April to May of 2024 which met the requirements.

The company’s senior management had defined food safety and quality objective in the Food Safety and Quality Manual (BM00539).) Quality objectives were established as follows:
1. The qualification rate of the raw materials, additives, and packaging materials used is 100%,
2. The one-time inspection qualification rate of semi-finished and finished products is greater than 99% (for impurities), and 100% for hygiene,
3. Conduct process improvement once a year at least,
4. Food safety complaints are less than 1 case per year, complaints treatment rate 100%, no major food safety issues.
And the general objective was break down to 8 items by each department, the monitoring and evaluation frequency was monthly or quarterly, sampled the objective monitoring record of 2024 and 2024 year was available, and all objects were achieved.

There was Management review control procedure (BM002804) was available. Management review was carried out at least once a year. Internal audit, second part, third part, customer performance indicators, completion of quality objective, incidents, resource requirements, HACCP, food safety and quality culture and authenticity review etc. are reviewed, and associated records were kept. The latest management review was conducted on 2024-07-02 and hosted by Mr. Liu ZHZH (President). During the meeting, the decisions and measures of the previous year were reviewed, two decisions were raised in the management review including In-depth implementation of marketing breakthrough year, Breakthrough year of scientific and technological innovation and Basic management promotion year. Management review outputs were communicated to relevant departments. A plan of action for improvement with timescales has been devised.

Quality management meeting was hold by President, V. President and Quality Manager every month, report any non-conformance and food safety issue in the meeting, and the management discuss and solve it in the quality meeting, checked related meeting summary, the records show the managements hold meeting every month, and the meeting summary kept, such as 2024-06-02 & 2024-05-02, etc. and all issued raised were followed by actions with timescales.

A confidential reporting procedure (BM011762) was established and all staffs know that they could report concerns relating to product safety, integrity, quality and legality by fixed suggestion box at the entrance of first floor of quality building. All employs were trained about the confidential reporting method and sampled

2 staff in workshop and both of them known the method, the quality dept. responsible staff would collect the suggestion once per month and report to quality Vice GM and quality Vice GM response the confidential report, and would take relevant action, the factory said no report has been provided from staffs since last audit.

During the audit, it was found that the senior management provided sufficient human and material resources for food safety.

The company was kept informed of scientific and technical development, industry codes of practice and relevant legislation applicable in the country, also the new risks to authenticity of raw materials which was listed in the legislations and laws list including GB1886.243-2016, GB1886.308-2020, GB29988-2013, GB1886.177-2016, BP2024, USP-NF2024, FCC9. There was Law and regulation identification control procedure (BM000065), QA Dept. was responsible for collect relevant scientific and technical developments industry codes of practice and relevant legislation. Control of this information was according to Document control procedure. Special department for regular or codex collection was in place.

The site has a genuine, original electronic version of the current Standard available and was aware of any changes to the Standard or protocol that are published on the BRCGS website.

The due date of BRCGS for this site was 2024-08-03, and this unannounced BRCGS audit was carry out on 2024-07-08~10.

The management representative attended the opening and closing meeting of the audit for BRCGS Certification and discussed on food safety culture during auditing.

All NCRs raised on latest BRCGS audit were verified by the auditor during on-site audit and all nonconformities were closed.

The facility knew how to use the BRC Global Standards logo and references to certification status and would not use it on the products.

The production of food additives by the company has obtained permission from regulatory authorities, license number: SC12237028401527.

The company organization chart was defined in procedure BM002757. All Departments' responsibility and detail FSMS responsibility were defined in these programs. Levels of responsibility and accountability (BM000432) for key staff were defined in responsibility description sheet, President, Quality (HACCP team leader), production and R&D Assistant, V. President, quality, system, purchasing manager; production manager, sales manager etc. responsibilities were defined. Documented arrangements to cover for the absence of key staff were established, such as President, deputy R&D VP, etc.

Relevant responsibilities were defined in the Quality Manual. Job descriptions of all employees including managers and supervisors as well as workers were available for review during audit. During on-site audit, the production staffs especially CCP monitors operated expertly and were familiar with the responsibilities of the position.

The site has established reporting mechanism to help staff identify and report any risks or any evidence of unsafe or out-of-specification product, equipment, packaging or raw materials. For any corrective actions, straight line report was available, and the operators could report issues and suggestions for quality and food safety promotion via confidential report system.

No external expert used at present.

Minor NC 1 was raised against 1.1.1, for details, please refer to NC summary list.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
None	N/A

2. The Food Safety Plan – HACCP

HACCP team was established with 18 members from multiple depts. Most of the team members participated in the training on BRGGS for food safety issue 9 on May 7-8, 2023 by INTERTEK and obtained certificates. The members of HACCP team included Assistant President, Quality Manager, Food safety system Manager, Production Manager, Admin, Equipment Supervisor, warehouse supervisor and Marketing staff. And A.P. Mr. Li, was appointed as HACCP team leader who was trained properly and 20 years of manufacturing management experience of food industry and better understanding of HACCP principles and their application.

All audited products (Mannitol powder, sodium (Calcium, Potassium) alginate) and processing in audit scope was defined by HACCP team in HACCP plan.

The company had established the PRP defined in the HACCP documents (Part2) special procedure for all items required and list in the column. It included personal hygiene management, cross contamination prevention, cleaning and disinfection management, pest controlling management, foreign body prevention etc. The PRP is verified once a year. The latest verification was conducted on 2024-06-07, and the results showed satisfactory.

The product descriptions for the audit products are filed. The characteristics, origin, key process, intended using, packaging, shelf life, storage and distribution, related standards and label information are included. Such as sodium alginate shall comply with GB1886.243, Pb ≤ 5.0 mg / kg, water content less than 15%, pH 6.0-8.0, stored at normal temperature, and the shelf life is 24 months etc. Mannitol: drying loss less than 0.3%, PH 4.0-7.5, shelf life 36 months. The production water used in processing of Mannitol is described as tap water, but the actual production water is also used purified water or deionized water.

The intended use of each product was clearly defined in HACCP documents, the products are used as raw materials or ingredients food factories and are not directly edible.

The main flow charts were synoptically described as bellow:
For sodium (Calcium, Potassium) alginate:
soaking - washing vegetables - digestion - dilution - filtration - floating - fine filtration - calcification - decalcification - dehydration - neutralization - centrifugation - granulation - drying - milling – sieving(ccp1)- metal detection(ccp2)- packaging – Storage
For mannitol powder:
dissolution - chemical isomerization - decolorization filtration - ion exchange - hydrogenation - decolorization filtration - ion exchange(ccp1)- concentration - primary crystallization - secondary crystallization - decolorization filtration - tertiary crystallization - tertiary centrifugation - drying - milling - sieving - metal detection(ccp2)- packaging.
The diagram verification was latest conducted on 2024-05-06, HACCP team verification signature in place, no major change.

Hazard analysis has been completed from raw material, processing to final products, including of biological, chemical, physical hazards, allergen, radiological and fraud. Likely occurrence of hazard and severability of the effects considered fully during the hazard analysis. Suitable control measures for each kind of hidden hazard were documented. Hazard analysis was conducted covering all potential hazards such as metal piece, heavy metal, pesticide residual, etc. The official standards, customers' requirements and current scientific literature are used for hazard analysis.

Suitable control measures (such as PRP, SOP, OPRP and CCP) for each kind of potential hazard were documented. OPRPs were identified, details as bellow:
For alginate:
OPRP1: seaweed acceptance, OPRP2: inner packaging material acceptance, OPRP3 final filtration, OPRP4 drying, OPRP5 packaging.
For Mannose:
OPRP1: glucose acceptance, OPRP2: inner packaging material acceptance, OPRP3 decolorization and filtration, OPRP4 fluidized bed drying, (130-164 ℃) OPRP5: screening, OPRP6: packaging.
In the hazard control plan, OPRP's action criterion specify limits, frequency, monitoring personnel, etc.
The factory has used OPRP to control the hazards of raw material acceptance, filtration, drying, and other processes, but has not provided the validation evidence.

The decision tree was used to assess the hazard controls at each process step and the results were documented.
Each CCP was identified in HACCP plan as the following.
The HACCP plan (BM001296-000007) for mannitol:
CCP1: ion exchanging for heavy metal control.
The limit is conductance<=30μs/cm.
The monitoring frequency is per hour.
CCP2: metal detection for physical hazard control.
The limits are Fe=0.8mm, non-Fe=0.8mm and SUS=1.2mm and detection times<=3 times/shift. The monitoring frequency is start, middle and end of every shift.
The HACCP plan (BM001350-000005) for sodium (Calcium, Potassium) alginate:
CCP1: screening for physical hazard control.
The limit is 20 meshes.
The monitoring frequency is per shift.
CCP2: metal detection for physical hazard control.
The limits are Fe=1.0mm, non-Fe=1.5mm and SUS=2.0mm and detection times<=3 times/shift. The monitoring frequency is start, middle and end of every shift.

All critical limits are based on subjective data. HACCP validation records are retained on file and last was conducted on 2024-05-16. Procedures of validation and verification to confirm that the HACCP system working effectively is in place. Validation and verification were conducted annually.

The interviews with persons in charge of CCP monitoring indicated that the procedure is implemented. Review of records and interviews with processing staff showed that they were aware of the CCPs and the actions to be carried out. The CCPs can always keep the product under control. Records of CCP monitoring including dates, time, responsible staff and results are in place. Such as record in vertical audit: The mannitol with lot No.112404025, product on 2024-04-13~17, CCP1 ion exchanging, conductance between 11.3-12.7 μs/cm, CCP2 metal detection for physical hazard control, test by block Fe=0.8mm, non-Fe=0.8mm and SUS=1.2mm, all qualified. The sodium alginate with lot No. 052404111, product on 2024-04-16, CCP1, the screening for physical hazard control is 20 meshes, already checked,CCP2 metal detection for physical hazard control, test by block Fe=1.0mm, non-Fe=1.5mm and SUS=2.0mm, all qualified.

The company has defined corrective actions in the case that critical limits are exceeded. The actions to be taken about the process and the product have been defined. Such as: 1) holding the products within 1 hour; 2) inform QA for further evaluation.

The verification for HACCP plan included the review of CCP monitoring records, internal audit results, complaints, and deviation. Last verification was conducted on 2024-06-11, the results show the HACCP plan is appropriate.

The company operates a formal sign off process for all new products and significant changes and new equipment which includes sign off by the HACCP Team leader to confirm the impact of any changes have been assessed. The company reviews its HACCP system and PRPs yearly, or when any changed. Last review was conducted on 2024-06-13.

The retaining time for records is shelf life plus 12 months.

Minor NC 2 was raised against 2.5.1, for details, please refer to NC summary list.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
None	N/A

3. Food safety and quality management system

3.1 Food safety and quality manual, 3.2 Document control, 3.3 Record completion and maintenance

Food safety and quality manual (BM000069) was in place. The Food safety and quality manual was available for key staff in every department. Total at least 100 procedures, programs, instructions have been established including document control procedure, records control procedure and etc. All procedure and work instructions were clearly legible, unambiguous and suitable in appropriate languages and sufficiently detailed to enable their correct application by appropriate staff.

The company has established the document and record control procedure BM0000065. The company has the controlled documented lists indicating the document codes and current version No. The records sampled, such as MD records, raw material receiving inspection records, neutralization monitoring records, polymerization records are legible and maintained well. A master list of documents maintained. Maintained with retention time, description, revision status and revision date. Quality manager prepares and review the procedures and is approved by President. Document change request format was used for seeking revision/changes to documents. A copy of draft changes with change request submitted to VP for approval. After approval distribution was done by QC. The details of the replaced documents are recorded in amendment format.

The record control procedure (BM000068) is available. The electronic records are backed up monthly. The record retaining time is shelf life plus 1 year. The product shelf life is 24 or 36 months. Sampled test reports for microbiology test, quality control records were found maintained to demonstrate the effective control of product safety, legality and quality.

3.4 Internal audits

Documented internal audit procedure with No. BM000066 was established and it was conducted throughout the year and at least 4 times per year, and for every internal audit scope was based on risk assessment and the whole year covered all relevant requirements of standard and all relevant department, the whole year scheme dated 2023-12-06 was in place for review. The last internal audit was carried out on 2024-1-18/19, 2024-04-08/09, 2024-6-12/14 covering all element of BRCGS food safety issue 9, others were planned in Sep. of 2024 year and the internal audit results were maintained on files.

The internal auditors included Quality president Mr Li and other 4 inner auditors, who were competent and received BRCGS internal auditor training course. The internal audit was conducted audit plan and relevant standards BRCGS were used and all internal auditors were independent of the areas they audited.

Internal audit records included audit scheme of the whole year, audit plan, attendance record of open/close meeting, conformity and non-conformities record, summary report, corrective action report and internal audit checklist were in place including positive and negative evidence.

7 minor NCs were raised in the internal audit of 2024 year about tap map control, warehouse cleaning, water treatment workshop equipment control, equipment rusty, electronic balance calibration record control, measurement label was not pasted in workshop, window curtain control issues. Audit findings were confirmed with the auditee, root cause was analysed by method of “5 why” and the corrective and preventive actions and timescales were also confirmed. Internal audit team leader was responsible for verify the corrective and preventive action taken by the auditee.

Daily hygiene and GMP checking (self-checking) for processing area and storage area was carried out and the records were kept on file. And sampled Jun. of 2024 year and found the fabric, hygiene and equipment were checked and raised non-conformities were followed, root cause was analysed by method of “5 why” and relevant corrective and preventive actions were verified.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

The company had undertaken the documented risk assessment for all each raw materials, ingredient, packaging materials in HACCP plan (BM001395). Risk assessment about raw materials was conducted every year, including allergen, chemical, foreign body, microbiological contamination, substitution or fraud, variety or species cross-contamination. Assessment is based on risk assessment on 2024-06-20, the suppliers categorized in risk levels A & B.

Purchase control procedure with no. BM007870 was established. All suppliers of products and services must be approved at first and then entered onto the system before they can be used. All suppliers must be collected relevant license, certificates and valid test reports. The suppliers in levels A without GFSI-benchmarked standard certification must conducted the on-site audit with a scope to include product safety, traceability, HACCP, TACCP, VACCP and GMP etc. yearly, levels B supplier must provide questionnaire report before being approved and at least once per 3 years after approval and in case of any changes. The VP is responsible to ensure suppliers effectively manage safety and quality risks of raw materials.

The criteria for ongoing assessment of suppliers were in place including onsite audit report at least once per 3 years or collecting GFSI recognized certificate per year or questionnaire report at least once per 3 years and performance evaluation report (including quality 50%, delivery in time rate 20%, price 15% and service 15% etc.), score more than 60 then qualified and less than 60 not qualified, such as performance evaluation report dated Jan. of 2024 for all suppliers were in place for review, and the results met the requirements.

Supplier's approval and performance evaluation evidence random checked as bellow:
Glucose supplier DX, HACCP certificate from CQM in valid period, annually performance evaluation record dated 2024-01-06 with score 93, test report dated 2024-04-01 by CTI covering 420 items was in place.

Food grade NaOH and HCl supplier QD HW HX, was audited by the quality department and supply chain department on 2023-04-26, and is considered a qualified supplier. The audits with a scope to include product safety, traceability, HACCP, TACCP, VACCP and GMP etc. The audit report was kept and show above mentioned supplier were qualified, then be approved, test report of NaOH based on GB1886.20-2016 dated 2024-05-22 and HCl test report dated 2024-05-22 based on GB1886.9-2016 was in place and annually performance evaluation record dated 2024-01-06 with score 95 was in place for review.

Glacial acetic acid trade supplier named Qingdao HLJ and manufacture supplier Shandong HD, was audited by the quality department and supply chain department on 2024-03-07, and is considered a qualified supplier. The audits with a scope to include product safety, traceability, HACCP, TACCP, VACCP and GMP etc. The audit report was kept and show above mentioned supplier were qualified, then be approved, test report of glacial acetic acid based on GB1886.10-2015 dated 2024-03-06 and annually performance evaluation record dated 2024-01-06 with score 93 was in place for review.

CaCl2 supplier Shandong HH, was audited by the quality department and supply chain department on 2024-03-11, and is considered a qualified supplier. The audits with a scope to include product safety, traceability, HACCP, TACCP, VACCP and GMP etc. The audit report was kept and show above mentioned supplier were qualified, then be approved, test report of CaCl2 based on GB1886.45-2016 dated 2024-05-10 and annually performance evaluation record dated 2024-01-06 with score 93 was in place for review.

Inner plastic bag supplier Zibo SY, was audited by the quality department and supply chain department on 2022-08-08, and is considered a qualified supplier. The audits with a scope to include product safety,

traceability, HACCP, TACCP, VACCP and GMP etc. The audit report was kept and show above mentioned supplier were qualified, then be approved, test report of inner plastic bag based on GB/T 24984-2010 and GB4806.7-2016 dated 2024-04-25 and annually performance evaluation record dated 2024-01-06 with score 97 was in place for review.

The approved supplier list version 24 was in place and updated on 2024-03-25 including raw material suppliers, ingredients and chemicals and packaging material suppliers.

The traceability system of suppliers was evaluated during on-site audit or by collecting their GFSI recognized certificates or by collecting their traceability test report.

Some materials were purchased from agent and broker and its manufactures were also be investigated. The factory collects the relevant COA, commodity inspection and test report, and the final manufacturer information is collected and archived. Some raw materials were purchased from the bother factory such as giant algae. Upon receiving the goods, QC have checked the import commodity quarantine certificate of the product and are able to identify the specific foreign processors/traders.

There is no requirement for emergency procurement and all suppliers must be admitted in accordance with the approval procedures.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

The original supplier labels and product received were verified through the warehouse storage area for onsite evidence check and records of receiving and dispatch were also verified.

The acceptance standards for raw material, ingredients and chemicals with no. BM000906/Q/01MYZ050 and packaging materials with no. Q/01MY010 were in place and all standards were reviewed annually, and the parameters for acceptance and frequency of testing were clearly defined in it. Different checking measures were defined including internal inspection, checking COA and test report etc such as for raw material glucose, inner lab test texture, odour, taste, colour, moisture, chloride, PH and specific rotation etc. and supplier provided COA per batch based on GB/T 20880-2018.

Sampled raw material glucose with batch number 2024032613 inspection record dated 2024-03-28 was in place and items covered texture, odour, taste, colour, moisture, chloride, PH and specific rotation etc. and COA from supplier dated 2024-03-28 based on GB/T 20880-2018 was in place for review, food grade HCl with batch number 20240409 inspection record dated 2024-04-10 including total acid and appearance and COA from supplier dated 2024-04-09 was in place, giant kelp with batch number 10050-2312005 inspection record dated 2024-01-01 including appearance, moisture, gel content was in place for review and result was ok.

The procedure was in place to ensure that approved changes to raw materials (including primary packaging) were communicated to goods receipt personnel and that only the correct version of the raw material is accepted. Related training and assessment records were retained.

Quality department issued the approved changes to raw materials and communicated to goods receipt personnel. Information on raw materials and inner packings requirements and type of checks is provided to the relevant staff or known by the relevant staff.

Labelling check was also done for packaging once arrival to ensure only correct version of packaging and product labels were accepted and released into production.

3.5.3 Management of suppliers of services

Supplier approval and assessment management procedure defined the approval and monitoring of suppliers of services such as: transport and distribution, waste management. All service providers have

signed formal contracts, which clearly specify the service expectations and ensure that the potential food safety risks related to the service are solved.

The company has signed service contracts with various service providers. For instance, transportation service was outsourced by QD FYL (2021.11.05-long-time), waste management was provided by SD DS HB (2023-08-25-2024-08-24) were in place.

According to the procedure requirements, the performance of service suppliers is evaluated annually, the records were kept and the result shows the suppliers were qualified, such as transportation service supplier QD LLT evaluated on 2024-3-12, and got 92 points.

3.5.4 Management of Outsourced processing

N/A, No outsourced processing.

3.6 Specifications

Documented specification of raw materials, final products, packaging etc. according to national or international standards and customer's requirements were established by the factory. For example: Kelp specification (BM003404) and other materials (BM000903-000019) were issued in 2022-07-01.

The final products shall comply with the requirements of customers or national standards, such as: mannitol according to GB1886.177, sodium alginate according to GB1886.243, calcium alginate according to GB1886.308, potassium alginate according to GB 29988, export products are in accordance with BP2024, USP-NF2024, FCC9 standards.

The specification review frequency defined in document control procedure was once per three years, recently in 2024-03-20 to 2024-05-10, and the review on the spec is done by the plant QA dept., with final confirmation by Quality department, Group Company.

3.7 Corrective and preventive actions

Corrective and Preventive Action Control Procedure (BM000053&BM000054) was established and implemented, analyse the root cause and CAs were taken. "5 Why" method was determined for the completion of root cause analysis and implementation of preventive action.

The investigation of the root cause of non-conformity would be performed and corrective actions would be taken once non-conformity was raised per authority supervision, internal/external audit, complaints, recall, or raised during lab monitoring test and online monitoring test against related specifications.

Corrective actions were agreed by QA manager with signature and date. The effectiveness of corrective actions was verified. The company could show the corrective actions records following to internal audit, quality meeting, management review and third-party audit.

3.8 Control of non-conforming product

Non-conformity products control procedure (BM000052) and rework process of non-conformity products (BM005875) had been implemented to control of non-conforming material, semi-finished products and final products, including rejection, acceptance by concession, or regarding for an alternative use. Decisions were approved by QA manager. In workshop, NC product area set to separate NC product during production; in warehouse, NC products were placed unqualified product area and marked clearly. At present, from previous audit to now, no major non-conforming products occurred.

3.9 Traceability

The company had established traceability system including materials coding program, production coding program (BM000031), traceability SOP (BM004921, incoming date, plus batch No. for traceability), finished products were coded with administrative region number, products code, production date plus batch No could be traced through all food chain.

During auditing, it was found that the raw materials, semi-finished products, finished products and packaging materials are marked with traceability code, and the product traceability code is recorded in the production record.

The traceability system was tested per year from FP to RM and vice versa by the company, such as: the most recent traceability test was implemented from final product to raw material on 2024-06-19, final product sodium alga acid H052405131-04/05, 5 tons, delivery date 2024-06-12, all raw materials and ingredients and packaging used quantity and batch number could be trace such as giant kelp with batch number 20240303, 18786 kg was used etc. all relevant records were maintained on file, within 2 hours.

From raw material to final product was conducted on 2024-06-15, raw material food grade NaOH with batch number 20240517, 8085 kg, all were used from 2024-05-20 to 2024-05-23, for finished product named sodium alga acid, 5 batches from H052405131-01 to 05, 12.5 tons, and the relevant records could be provided for reviewing including quantity check and mass balance. The duration was about 3 hours.

The traceability initiated by auditor on site was final product the sodium alginate with batch number 052404111, delivered on 2024-06-26/27 and 2024-07-04 and produced on 2024-04-16; Semi-finished batch A20240410-3/A20240411-2;
Packaging on 2024-04-16, using 121 inner bags from batch 240229006.
2024-04-10 Centrifuge foaming, calcification, neutralization, etc., using a total of 6900 kg of alcohol from batches 20240407, calcium chloride from batches 20240410, and 8 kg of chitin from batches 20240318,
Feed on 2024-4-07, using batch 20231230 of raw material giant algae, total 12485 kg.
The traceability test was finished within 4 hours, Quantity check / mass balance was evaluated, and the check result was OK.

Another products mannitol with batch number 112404025 was also selected onsite and traced and result was ok.

The re-work operation traceability required in the Product identification and traceability control procedure. Only the same category products rework allowed in the production, no mixed up with other category of raw material that facility had the ability to trace raw material into finished products and to first level of distribution.

3.10 Complaint-handling

The customer complaint handling procedure with no. BM000115 was established and implemented. Sales dept. was responsible for complaints collecting and then discussed with production manager and QA director. After discussing and analysis, QA department and/or production department will find the cause and make a decision how to take the corrective action. QA manager would verify the corrective actions and preventive actions taken and sales department would reply customer.

The complaints were recorded and investigated, and the results of the investigation were recorded. 4 complaints occurred since last BRCGS audit about outer packaging issue, foreign matter between inner and outer packaging, outer packaging broken issues. The cause analysis and corrective and preventive actions were taken, and the trend was also analysed to avoid recurrence. No major food safety complaint in recent years.

3.11 Management of incidents, product withdrawal and product recall

The crisis management procedure (BM000449) was established to collate and assess incidents. The procedure included control procedure, staff requirement, operate instruction etc., which covered the company would act in case of incident such as water flood or water supply not enough, the fire, interruption of transportation, malicious contamination or sabotage. etc. The mock test was planned to conduct per year. The latest emergency drill was conduct on 2024-04-10 in the alginate workshop. Relevant records have been kept and the conclusion is that the drilling effect is good.

The product trace and recall procedure (BM000399) were in place to control non-conforming products which was placed on market or customer complaint. The procedure included identification of key personnel constituting the recall, the responsibility, updated list of recall and withdrawal team, a communication plan, and so on, no external specialist attended this team.

The recall team leader is Vice President the members are production, logistic manager, quality manager, admin manager, R&D manager and so on. The key contact information such as Email, office telephone, mobile phone and so on is included in this up-date-list.

At present, no actual recall or withdrawal occurred this year, mock recall test annually, latest on 2024-06-10, sodium alginate with batch No.052404177 (Unqualified simulated viscosity), delivery date was 2024-05-01, quantity was 200 kg, and Assistant President was responsible for it and defined the responsibility. The mock recall showed the timings of key activities, which could be regarded to be capable of being operated at any time.

It was defined in the procedure that in the event of a product recall, INTERTEK shall be informed within three working days of the decision to issue a recall. It was defined in the procedure that in the event of a product recall or food safety issues, INTERTEK shall be informed within three working days of the decision to issue a recall, related analysis report should be also informed within 21 calendar days. No such recall nor food safety issued in last year.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.4	No outsourced process.

4. Site standards

4.1 External standards

The factory was in the industrial area which established by the group company. There are other chemical products or industrial Alginic acid production in the factory park, but they are all in different workshops/pipelines, and have their own warehouses, so cross contamination will not occur.

The site is of suitable size, location, and construction to allow the production of safe and legal products. The buildings are in good repair and maintained. An outside layout map and the assessment were in place and there are no local activities that could affect production by introducing contaminants to products.

The perimeter of the site is in good order. Planted areas are kept to a minimum and are well maintained. External travel routes in the premises are surfaced hard bottom and in a state of repair that does not present a risk, grassed areas are also suitably kept. The building fabric was noted to be in a good condition and the factory was well proofed to reduce the risk of contamination, ingress of water and pests. GMP audits and planned maintenance inspections monitor the building.

Guards (two shifts) are set for factory gate, visitors are required to fill the register form, related staff was trained on food defence, and related staff know related security procedure via remote interview. All relevant personnel filling in the questionnaire before entering restricted area. Interviewed staffs from production area and factory guard showed they got training about site security procedures and food defence. The staff in the site all were trained with food defence, the latest training was done on 2023-10-12.

4.2 Site security and food defence

The company had established the security arrangement programme (BM001922) and the security arrangement plan (BM005005) to define the control of security to prevent access of unauthorized persons to production and storage areas. The terrorism treatment was defined in crisis treatment procedure, and responsible by Admin dept security team. Process and storage areas were identified restricted areas. The relevant inspection records were available. Food defence plan was reviewed once a year, the latest was done on 2024-06-17. None of raw materials or products are identified as being at particular risk.

The company had arranged special guard person to ask the visitor to show the authorised certification of entry the site. Process and storage areas were restricted areas and regulated by workshop supervisor, visitors can enter when they were accompanying with staff who was authorized. All the key access (staff entrance, pack and storage areas) were with monitor camera system and special monitor staff, contractors and visitors were asked to register by security guard at factory entrance and were required to answer health questionnaire before entering. Locked doors of all storage areas; CCTV are in sensible points.

External storage tanks for liquid chemicals such as HCl, NaOH, alcohol, CaCl, NaClO and intake pipes with external opening were in place and the external openings were locked and protected except one.

The staff in the site all were trained with food defence, the latest training was done on 2023-10-12.

Minor NC 3 was raised against 4.2.4, for details, please refer to NC summary list.

4.3 Layout, product flow and segregation

The process areas were identified low-risk areas or enclosed product area according to standard. Most materials are produced in pipelines, liquid tanks, reactors, etc. There are two workshops within the scope of certification, among which the mannitol workshop has two floors and an external hydrogenation reaction

tanks area. Two floors of alginate workshop. The two workshops have different personnel entrance, material entrance and changing room according to different processes.

The site plan has been made. There are dedicated areas for key activities, such as material input area, drying and polymerization area and packing areas.

Contractors and visitors are all required to review a GMP & medical screening questionnaire as well as reading and signing to comply with the site's GMP and personal hygiene rules prior to entering production areas. Contractors involved in maintenance are supervised by production manager or designee while on site.

During the site audit the process flow could minimise the risk of food contamination.

The plant provided sufficient space for placement of equipment and storage of materials for the maintenance of sanitary operations and the production of safe food.

No temporary structures found on site audit.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The factory building was completed and put into use in 2006. The main processing is chemical reaction. The facilities are old, but the factory continues to invest in improvements. Basically, meet the requirements of production.

The walls were made from concrete and coated. Floors are constructed of cement floor in the pre-production area and are constructed of epoxy resin in packaging room, it was noted to be facilitate cleaning. Suitable drainage was noted in all factory areas and no evidence was seen of water pooling.

Ceilings are constructed from concrete and coated with painting in pre-processing area and are maintained in good condition and did not present any contamination risk. Suspended ceilings were present in the inner packaging room of the 2 workshops; the adequate access to the void is provided to facilitate inspection for pest activity, pest inspection was carried out monthly.

Elevated platforms over open product were maintained properly.

Windows are suitably designed and screened to prevent pest ingress. All windows screen were in satisfactory condition during auditing except one.

Doors (internal and external) were maintained in good order; external doors were suitably proofed to prevent pest ingress. Any that needed to be open during production were fitted with floor and wall. The standard of lighting was adequate in all areas that included storage, process, GMP areas to allow inspection of product and monitor results of cleaning.

Adequate ventilation and extraction were also provided in key areas. During the site inspection it was noted that the factory storage and process areas were satisfactorily ventilated and there were no signs of condensation or excessive dust.

Air of packing workshops was treated by three levels filter. The filter element shall be replaced regularly by the maintenance department.

The soft curtains in the warehouse and workshop are in good condition. No obvious condensation was found.

Minor NC 4 was raised against 4.4.7, for details, please refer to NC summary list.

4.5 Utilities – water, ice, air and other gases

Water is supplied via the city network water. Municipal water supplied should be tested by authoritative laboratory once a year. The latest test comply with GB5749 was conduct on 2024-04-22 by CTI (43 test items covered microbiological and chemical quality). Having water treatment equipment to produce pure water. Purified water is used for cleaning and processing of mannitol workshop and alginate workshop.

An up-to-date water distribution system plan was in place. The company had established the water self-control specification and water distribution plan; conductivity, heavy metals, TPC and Coliform. Cover the entire outlet in a year. Such as on 2024-06-24, YCO1 faucet was tested for conductivity, heavy metals, etc., and all were qualified.

The compress air only used in alginate foaming process, though filter, Air was tested every quarter, and the test records show that they meet the requirements. The steam would not connect with the products directly. Self-made hydrogen is used in the production of Mannitol, and the content of H2 is measured by gas chromatography every day. The records in 2024 are more than 99.99%.

4.6 Equipment

Equipment management control procedure was in place (BM004841), This includes equipment selection and procurement management regulations, equipment installation and debugging management regulations, equipment updates and renovation management regulations, equipment acceptance management regulations, etc.

Main equipment including liquid tank, ion exchange column, simulated moving bed, crystallization tank, fluidized bed, dryer, launder, granulator, pulverizer and metal detector etc. Equipment and the facility were well designed and kept in good condition. The equipment's were suitable for the scope. The food contact equipment was made of stainless steel. In the Alginic acid granulation process, the ordinary broom jacket strainer mesh screen was used as the collection tool, and the surface of the strainer mesh screen was damaged through on-site inspection.

Risk based adjustment procedure was established, all new installed equipment would be adjusted by supplier and site engineer, then assessed by HACCP team according to change management procedure, such as: verification of the function and clean status would be double checked and kept in the change approval record, refresh training of operators for the changing items etc. After the last audit, the Mannitol workshop updated and added some equipment. Before the new equipment was put into use, full trial production and product safety verification were carried out. Equipment is positioned well to facilitate cleaning and service.

The production equipment was static, and they were all stay at the designed location, no removing in last year. Once removal activity happened, it would be complied with change management procedure.

When the equipment is not used, it will be completely turned off and marked. If it is stored in the production area, it will also be listed in the daily cleaning plan for cleaning. Before re-use, all equipment shall be thoroughly cleaned according to the procedure requirements and the cleaning result would be checked by QC. Only qualified equipment can be used.

Forklift was used in the warehouse for the product transportation from packing area to the warehouse, the forklift condition was kept good, no contamination was found.

No battery charging facility in open production area.

Minor NC 5 was raised against 4.6.2, for details, please refer to NC summary list.

4.7 Maintenance

35 in-house engineers report to equipment director Mr. Gao. Regular equipment preventative maintenance plan of 2024 was developed and covered all equipment for production. And the maintenance plan would be developed if new equipment started to use. Preventive maintenance plan was implemented with records and was defined on annually basis, and broken down to first grade maintenance (once per 2 months) and second grade maintenance (once per year) and big maintenance (once per year), daily equipment onsite inspection was also done. Sampled pulverizer, air blender machine and vibrating screen preventative maintenance record of 2024 was in place, items including fastening parts, adding lubrication oil, inspection motor, pipes and wires, function test etc. and result was ok.

Regular equipment inspection was carried out daily to detect the foreign body contamination from damaged of equipment and random sampled record of Jun. of 2024 was in place for review.

If temporary repairs were necessary, safety of product would be protected. Tools and parts into workshop were counted and collected at beginning and finishing, the equipment was cleaned and sanitized and the task was documented before being returned for use in processing, repair record of pump for HCl with No. MYJS11-01 III119 was sampled and reviewed dated 2024-06-25 was in place for review, sealing part was leakage and was changed, result was ok.

Based on risk assessment, food grade lubricant oil was used for some parts of equipment, the NSF registration H1 grade number 122675 could be seen and no allergen was contained based on the information of specification and the assurance letter from supplier was available.

No major breakdowns in last 12 months. No temporary repair cases were observed during site checking.

Documented hygiene inspection on start-up completed by production supervisors. The maintenance work was followed by documented hygiene clearance procedure with records to show the necessary cleaning conducted after maintenance job. The equipment was checked before return back to production line.

The engineering workshop was separated from the processing workshop and was maintained in tidy and no obvious contamination was found to products.

Minor NC 6 was raised against 4.7.1, for details, please refer to NC summary list.

4.8 Staff facilities

Staff facilities are suitably designed and operated to ensure the minimum of risk of product contamination. Changing facilities for factory personnel included male and female workers, management level employees.

Visitors and contractors are provided the designated changing facilities in changing room. The changing facilities allow direct access to the production, packing or storage areas without recourse to any external area. Storage rooms were of a suitable size to accommodate all personal items.

There was no crossover of outdoor clothing and factory work wear noted during the visit. Each employee has a suitable locker for personal items storage, special container for dirty production clothing storage, the cleaning production clothing was hanged on the separate shelf in isolated room.

There are hand-washing facilities at the entrance of all production areas and as required within production areas. Appropriate “wash hands” signs were available in appropriate locations. Hand washing facilities are hands free taps and supplied with warm water, liquid soap, and disposable towels / air dryers.

Adequate toilets are provided that do not open directly into production, packing or storage areas and at provided with hand wash facilities supplied with hot water, liquid soap and disposable towels / adequate air dryers. According to the risk analysis results, the rough processing of mannitol and alginate workshops is equipped with simple changing rooms, but complete hand washing facilities are installed.

The company had assigned special smoking areas far away the process and storage areas, adequate arrangements for dealing with smokers’ waste was provided at smoking facilities. Electronic cigarettes shall not be permitted to be used or brought into production or storage.

Foods are not allowed to bring into manufacturing premises by the company. Eating area is located far away from process and storage areas. Catering facilities are provided on the premise but located far away from process and storage area and was suitably controlled to prevent contamination of products. No issues were noted when inspecting these areas.

No auto-vendor equipment.

Minor NC 7 was raised against 4.8.7, for details, please refer to NC summary list.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Chemical control measures were defined in procedure with no. BM002803 including leakage management and abandon chemical and empty container management, MSDS (75% food grade alcohol for disinfection, liquid soap, processing agent such as HCl, NaClO, NaOH etc., lubrication oil was used in processing area etc., chemicals in lab.) and disinfectant preparation records were available. Chemicals were registered, stored in dedicated locked storage or tanks with label, all chemicals were suitable for food industry use such as NaClO test report dated 2024-05-11 according to GB/T19106-2013 and food grade alcohol test report dated 2024-01-23 according to GB31640-2016 and GB10343-2008 was in place. Designated staffs were in charge of dispensing of these chemicals. No strong scented chemical in use.

4.9.2 Metal control

The foreign body control procedure with no. was established and implemented, and no staples were used in production area and no snap-off blade knives were used in workshop and warehouse. The metal tools used such as needles were checked twice every day by processing monitor and hygiene staff and the checking records were in place and in case of breakage, the broken needle must be found.

4.9.3 Glass, brittle plastic, ceramics and similar materials

The Procedures for handling glass and other brittle materials are defined in the Glass & Plastic Control Procedure (BM004832) and foreign materials control procedure (BM001737). They include the easy broken control list of all glass, brittle and similar materials detailing location, number and type and cleaning and replacing methods. The Glass & Plastic Register was updated. The register includes: - item/type location, number and condition - checks of condition based on risk – weekly - records of cleaning and replacing when damaged Checks of glass, brittle, and similar materials are conducted daily, the Glass and plastic substance daily inspection record from Jan to May 2024 available for review. In the drying process of Alginic acid workshop, found the employees used Mercury glass thermos bottles.

Foreign materials control procedure (BM001737) requires how to treatment glass breakage issue in process areas that production stops, product and area is isolated, cleaned and inspected. Authorization is required before production can recommence, work wear is changed, footwear inspected, and records completed.

All glass windows were in the processing and storage areas where there was open product were protected with breakage-proof film.

Where they pose a risk to product, bulbs and strip lights were installed with breakage-proof cover; The electric fly-killer devices were adequately protected and register in easy broken control list, checking in regular.

Minor NC 8 was raised against 4.9.3.2, for details, please refer to NC summary list.

4.9.4 Products packed into glass or other brittle containers

N/A. No brittle container is used.

4.9.5 Wood

Wood policy was in place, wood was not allowed to be used in workshops and storages, except wooden pallets used in enclosed product area. The intactness of wooden pallets was inspected by warehouse supervisor regularly.

Minor NC 9 was raised against 4.9.5.1, for details, please refer to NC summary list.

4.9.6 Other physical contaminants

The physical contamination control procedure (BM001737) was in place, prior to packaged raw materials being taken into open product or processing areas, the outer packaging was required to remove and the internal package was visually checked for any potential sources of contamination and cleaned if necessary.

Other physical contaminants included raw material outer-packaging and control of pens. In the dry process of the alginate workshop, the pen used by the personnel on duty is a regular pen (with small parts).

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

The company established foreign body control requirement, filter, sieves and metal detector was being used in process, and be detail defined in requirement.

The type, location, and sensitivity of the foreign body detection and/or removal method were clearly defined in HACCP plan and relevant specification.

The frequency of the testing of the foreign body detection and/or removal equipment is defined in HACCP plan and relevant specification.

The corrective actions include a combination of isolation and re-detection of all products produced since the last accepted test of the metal detector.

4.10.2 Filters and sieves

In mannitol workshop, sieves with 40 mesh and above shall be used before packaging. 20 mesh and above sieves were used during sodium alginate processing. The intactness and the mesh sizes of them

are checked and recorded per shift. The records in Dec. 2023, April and June 2024 were reviewed. The screen was inspected on site and found to be complete without damage.

4.10.3 Metal detectors and X-ray equipment

Metal detection is used for the audited product. Risk assessment had been used to determine the need for metal detection equipment located in the end of line. The metal detection was one CCP for all certificated products, the HACCP plan and work instruction was clearly defined the testing responsibilities, operating effectiveness and sensitivity, method and frequency of testing, and recording of checks.

Metal detector testing procedures includes tests carried out using separate test pieces containing ferrous metal(Fe Φ= 1.0 mm), stainless steel(SUS Φ= 2.0 mm) ,and typically non-ferrous metal(Non-Fe Φ= 1.5 mm)(mannitol-Fe 0.8mm Non-Fe 0.8 mm, SUS 1.2 mm), a test to prove that both the detection and rejection mechanisms are working effectively; tests of the metal detector by passing successive test packs through the unit at typical line operating speed, test piece inserted within a clearly identified sample pack of the food being produced at the time of the test; test piece shall be placed in the product flow; verification test by test pieces was conducted at the beginning of production, hourly during production, and final check following completion of the production shift. The metal detectors were observed working in properly during this audit.

No X-ray equipment used in audit site.

4.10.4 Magnets

Magnet was installed after vibrating screen, strength of magnets was 8000 Gauss. The procedure defines the inspection, cleaning, strength testing and integrity checks frequency. Sample the inspection record was full conforms to the procedure. Clean the foreign matters on the magnetic rod once every shift, and compare the magnetic strength once every quarter. According to the inspection records of January, 2024, April, 2024, July, 2024, the magnetic force is all above 9000 Gauss.

Minor NC 10 was raised against 4.10.4.1, for details, please refer to NC summary list.

4.10.5 Optical sorting equipment

N/A. No optical sorting equipment is used in the facility.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

N/A. Glass jars, cans and other rigid containers are not used.

4.10.7 Other foreign-body detection and removal equipment

Fluidized bed was used and was well controlled.

4.11 Housekeeping and hygiene

The satisfactory standards of hygiene were seen on all premises and equipment throughout the site inspection except it was found in the Alginate packaging room that there was product powder in the storage tank that was not cleaned in time.

Cleaning requirements have been defined and processing equipment cleaning SOPs. Processing equipment is daily cleaned for outer surfaces, and thorough cleaning is required to be conducted at least every half year, and at the time of production stop for a long period, and the time of product change and

after maintenance/repair on product contact surfaces. The filtered steam and water are used for processing equipment thorough cleaning.

General processing equipment sanitation is checked every shift. Besides, safety staff checked the workshop sanitation at least twice a week. The equipment directly contacts food and raw materials could be implemented completes cleaning, and the complete cleaning schedule was in accordance with special equipment maintenance plan.

The cleaning equipment was fit for food process areas and with suitably identified. Cleaners and sanitizers were fit for food processing. Cleaning tools are stored in designated areas. They were kept clean. And no high-care and high-risk areas in audit site. Cleaning chemicals are fit for its purpose. The testing reports are in place to demonstrate food grade requirements are met.

Housekeeping and cleaning systems were in place through workshops cleaning instructions in SSOP for the building, workshops and all equipment and tools and 5S which ensured that appropriate standards of hygiene are maintained and that risk of contamination to the product is minimised.

4.11.7 Cleaning in place (CIP)

N/A. No CIP.

4.11.8 Environmental monitoring

The company has formulated an environmental monitoring plan in the Lab manual for the product open area, which clearly defines the location, method, frequency and judgment limit of the detection. At present, the food contact surface, employees' work clothes, workshop air and processing water are monitored. The main monitoring objects include TPC, E-coli, mold and yeast etc. For example, food contact surfaces should be tested once a month with a limit of TPC<500 cfu/cm2, mold and yeast less than 100 cfu/cm2, and coliform bacteria should not be detected.

Laboratory personnel carried out the tests as planned and kept records, e.g. on 2024-5-26, fluidized bed in mannitol workshop, TPC=7 cfu/cm2, mold and yeast is zero, and coliform bacteria was not detected, on 2024-5-26, swab the employee's hand and the result is normal.

The site evaluates the environmental monitoring plan once a year and keeps relevant records. The result is that the current plan is suitable for the site.

4.12 Waste and waste disposal

Waste control procedure was established. Waste from processing, maintenance, lab and living waste was identified and handling measures were defined, they were stored in containers and disposed by outsourced party.

The garbage cans inside the workshop shall be placed at the designated location and cleaned regularly by the designated staffs. The external waste collection containers were provided and kept tidy. Those containers were clearly labelled and maintained clean.

4.13 Management of surplus food and products for animal feed

The surplus customer-branded products are disposed in accordance with customer-specific requirements. Customer brand names would be removed from packed surplus products under the control of the factory before the product enters the supply chain.

No products were used as animal feed.

4.14 Pest management

Pest control procedure was established and implemented and was covered in PRP. The regular inspection to deter pest infestation was contracted by inner PCO Mrs. Zhang L and their training certificate was in place for review. The target organisms including: rodent, flies, crawler, birds and others pest. The MSDS and pesticide register certificates of pesticides were in place such as alpha-cypermethrin 5% pesticide register number WP121-90 was in place. The pesticide preparation and using records were maintained and followed its label's requirements.

Fly killers and glue boards were used for in house treatment; mouse cages were used in external environment. Inspection frequency for fly killers, mouse cages and glue boards were per day, fly killers' light bulbs were changed every 1600 hours. Pest control location map dated 2022-03-13 was in place for review. The trend analysis for pest control result was conducted quarterly based on the checking result.

The current depth pest control survey was conducted once per year at least and last on 2024-05-15 by inner pest expert. The frequency was defined as at least annually in documented file based on risk. In the survey report, the follows contents were reviewed: the pest control proofing, and fabric of the building, equipment and machinery etc. The PCO reviewed the survey report and necessary measures were taken.

The site carried out bird infestation risk assessment and take some measures to prevent bird entry building including bird scarer.

No evidence of infestation had recently been reported and no pest infestation was found during visit tour. No issues highlighted through trending reports.

The general pest control awareness training for all staffs were conducted annually and last training was held on 2024-04-02.

Minor NC 11 was raised against 4.14.1, for details, please refer to NC summary list.

4.15 Storage facilities

The documented storage control procedure was established and the facilities used for the storage of product were suitable for the purpose. Different warehouses such as raw material store, packaging store, liquid chemicals tanks, processing aid store and finished product store were available, maintained in normal repair and in the cleaning condition.

Inspection was conducted at least twice per day and relevant inspection was in place for review.

The products were stored on the pallets and kept 30cm away from the wall and 15cm off the floor. The finished products were stored at normal temperature.

The batch numbers with receiving dates were marked on the onsite labels when materials and products storing and were also recorded in the computer system. Onsite verification found the stock rotation system was established and FIFO principle was followed.

No controlled atmosphere storage in site

4.16 Dispatch and transport

The company has Sale and Transportation vehicle control procedure (BM000746) in place to maintain product safety and quality during loading and transportation, to ensure that the management of dispatch and of the vehicles and containers used for transporting products from the site do not present a risk to the safety, security or quality of the products.

All vehicle or containers are inspected for cleanliness and suitability, to ensure they are free from strong odours, prevent damage to products during transit.

A shipping employee was interviewed regarding carrier inspection and answered per the documented procedure.

Transport is managed by approved third party contractors. One of the third-party contractors used, and requirements are included in contract included the requirements of this section of the standard.

Sampled the vehicles clean inspection records dated on 2024-04-27, these records were available.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
4.3.5	At present, no temporary structure.
4.9.4	No brittle container is used. The products are packed into soft PE bag
4.10.5	No optical sorting equipment is used in the facility
4.10.6	Glass jars, cans and other rigid containers are not used
4.11.7	No CIP
4.15.3	Temperature is not controlled
4.15.4	At present, no required atmosphere storage.
4.15.5	There is no storage outside
4.16.3	At present, ambient product and raw materials.

5. Product control

5.1 Product design/development

The Product Design and Development Control Procedure (BM005172) details how new products or processes and any changes to product, packaging or manufacturing processes are managed to ensure that safe and legal products are produced. A design department is in the company, the leader is Vice President, at least 10 engineers and staff reported to Vice President. All new products and changes to product formulation, packaging or methods of processing shall be formally approved by the HACCP team leader; there were no new products introduced since previous audit. If trials are required to validate that product formulation and manufacturing processes produce a safe product of the required quality, these are also documented according to the procedure.

A science-based justification for the assigned shelf life is documented in HACCP plans. The Shelf-life Verification Control 11SM01002-4 was done, as well as organoleptic assessments and chemical tests are carried out to validate shelf life. Records of shelf-life trials were reviewed for calcium alginate and mannitol. Shelf-life testing includes all the testing item in the COA, such as: Mannitol, from Oct 17, 2022, lot No.112210003, according GB1886.177-2016, all COA test items were qualified.

5.2 Product labelling

A label control procedure (PC04-001-QM-06) is in place. The label content must meet with the nation standard (GB7718 & GB 29924), client requirement, and the label review records were available and signed by HACCP team leader.

Some labels information was provided by customer, and the content of labels included name, new weight, production date, shelf life, origin or product and country of origin were reviewed by the facility before contract signed. QA and sales staff responsible for checking information.

No cooking instructions were provided.

5.3 Management of allergens

The company consider the allergen contamination in raw materials risk assessment. And the company implemented the allergen questionnaire survey for each raw materials supplier, all relevant investigate records were available for review.

Allergen control procedure was established and implemented. Allergens list was identified refer to the standard, no allergen contained in the raw materials and finished products. At present, only chitin may contain allergens, and the Allergy test report has been collected on 2023-7-18, shrimp allergen: ND.

The allergen training was provided for all staffs. Last training course was held on 2024-04-01 and the records were maintained.

All possible allergens within the company are identified on the allergen list, including canteen food. Staffs were not allowed to take foods into production area and materials storage area.

No issues reported in most recent management review.

No claim was made regarding the suitability of a food for allergy or food sensitivity sufferers.

5.4 Product authenticity, claims and chain of custody

The facility established the processes with no. BM001434 to access information on threats to supply chain and implemented documented vulnerability assessment through taking into account of historical evidence, economic factors, complexity of access and testing, and nature of raw materials. HACCP team leader and purchase dept. were in charge of the assessment, they were both familiar with the raw materials and fraud risks in supply chain.

The documented vulnerability assessment was conducted and updated on 2024-05-20 and would be reviewed every year and any change happened to raw materials/suppliers, new risks collected, food safety issues (e.g. recall).

All materials were defined as 3 risk level, high, middle and low, all materials were identified as low risk, and all materials were monitored and checked every batch and COA of each kind of materials were required from supplier, third party test report was also required at least once per year and the relevant reports and records were maintained.

Appropriate controls were established to ensure the integrity of the product claims. The company was 'Kosher certified' and 'Halal certified', control procedure was in place to maintain the necessary certification status.

The process flow to produce products was documented. And potential areas for contamination or loss of identity were identified. Appropriate controls were established to ensure the integrity of the product claims. No claims have been made for finished products that depend on the specific formulas and production processes.

5.5 Product packaging

Internal packaging supplier in approved suppliers list. The relevant certificates and reports were available. All packaging items complied with relevant legislative requirements such as Chinese National Standard. The company required the packaging materials supplies must understand the corresponding packaging materials specification and detailed technical requirements, each supplier must receive the special specification, confirm the detailed technical requirements, signed with official seals and fax back to company's Purchase Dept.

At present, only plastic bags are used as inner packaging materials. Qualified third-party laboratory reports have been collected, and COA has been collected during receiving inspection. Sealing strength and sensory inspection have been carried out, and the records meet the requirements.

All packaging materials are well protected with covers. They are also well identified.

The company stipulates that expired packaging materials will be discarded, when discarded, all information on the label will be destroyed. No expired packaging materials are found on site.

5.6 Product inspection, on-site product testing and laboratory analysis

The company has established product inspection and test management procedure. Every batch of finished product is tested by the internal lab accord with final product test SOP as well as customer's requirements.

Random check the COA issued by internal lab as bellow:
Sodium alginate, 2024-4-16, batch number 052404111, according to GB1886.243-2016 and customer requirement, test sensory, heavy metals, odour, viscosity, PH, moisture, ash, TPC, mould and yeast and Coliform etc.
Mannitol, 2024-04-17, batch number 112404025, according to GB 1886.177-2016 and customer requirement, test content, characters, assay, PH, reducing sugar, loss on drying, residue on ignition, heavy metals, TPC and Moulds and Yeast and salmonella and S.A. (microbiological items according to customer requirement) and result was ok.

Besides, the company send the product sample to the external lab for quality verification twice a year. Microbe tests are not applicable because the product audited is not the microbiologically sensitive product.

The company had established the special test results analysis rule and implemented annually.

On-going shelf-life assessment is being implemented with records kept according with CN GB standard. The frequency of on-going testing was every half year, and on-going for at least 3 years. The parameters defined in the national standard were tested during the shelf life tests, and the trail results indicated that these parameters are stable during the product shelf life.

In-house lab was in place, which was capable for sensory, microorganism, physical and chemical testing. The laboratory is located at another building, separated from the production areas. Laboratory ventilation system is independent. Access to the laboratory is restricted. The GLP program has been established. More than 30 internal lab technicians were in its lab.
Raw materials, semi-finished products and finished products inspection plan (BM001362, BM000300, BM003407 and so on) were in place. Testing and inspection schedules and methods are established for raw materials, packaging materials and finished product.

All testing methods were established according to national standards (GB/FCC/BP/USP/JP). Four lab technicians sampled, who are graduated from the special of food science and engineering and biological engineering, operate test as per the regulation. Test comparison is carried on yearly. On 2023-12-14, compared with PONY for the COA items of sodium alginate with batch number H052310041 01, the results are satisfactory.

When there is any product out of specification (OOS), OOS Lab Investigation Record is used to record the investigation with appropriate actions. The product is then investigated in accordance with the nonconforming product procedure.

5.7 Product release

The factory established release procedure to ensure that finished product is not released unless all agreed procedures have been followed. Products could be released after all test or inspection results were reviewed and confirmed to be satisfactory by Quality Manager.
The products held before release are identified with a manual system.

5.8 Pet food and animal feed

N/A. No pet food and animal feed produced in this factory

5.9 Animal primary conversion

N/A. No animal primary conversion on site.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.4	No cooking instruction printed on the package or labels.
5.3.6	At present, no claim is made for allergen warning of unavoidable allergens.
5.3.7	No allergen claims made.
5.4.5	At present, no products with raw material claims or processing method claims were processed.
5.8	No pet food and animal feed were produced in the factory.
5.9	No animal primary conversion on site.

6. Process control

6.1 Control of operations

All audited process SOP (BM004173--198) covers all processes including packing.

The HACCP plan had been transferred into day-to-day production control. Each CCP was properly under control during the inspection. In addition, the system also sets OPRP:
Mannitol: including glucose acceptance, packaging material acceptance, decolorization filtration, drying, screening and packaging.
Sodium alginate: including raw material acceptance, packaging material acceptance, fine filtration, drying and packaging.

Main parameters also include:
Mannitol production process - isomerization temperature and time, decolorization temperature and time, hydrogenation pressure and temperature, drying temperature and time, crystallization concentration and temperature, etc.
Sodium alginate production process - concentration of soda ash added in digestion, temperature and time, calcium water flow during calcification, neutralization pH value, drying temperature and time, etc.
The production records of batch 112404025, mannitol and batch 052404111, sodium alginate were checked, the results shows that the key processes were properly under control. For decolorization and

filtration after the third crystallization of OPRP2 produced by Mannitol, 1- required to check whether there is active carbon leakage at any time, 2-the clarity is less than 1, 3-the filter plate is checked for the integrity of the filter screen every day, and the corresponding monitoring records cannot be provided for 1 and 3.

The company had established the operation processing instructions according to each equipment and step; all instructions verified that the processes and equipment employed could produce consistently safe and legal product with the desired quality characteristics.

Thermometers, pressure gages and scales for processing monitoring were calibrated per year and maintained well.

The procedure states that when equipment was abnormal, at-risk products will be traced and isolated. After evaluation or testing, they will be processed.

6.2 Labelling and pack control

Label and packaging control rules was in place, QC is responsible for inspecting the packaging and label by the signed standard packaging when arriving, storekeeper is responsible for delivery the label and packaging according to the materials requisition, production check and used the packaging and label.

QC monitored the labelling checking during the start & end of the packing run, also once an hour during the production. During the audit, the packaging and label inspection records in the traceability test was checked (sodium alginate, batch 052404111), inspected as required, and found no problems.

At present, not used on-line vision equipment for label checking.

The company had established the commencing production management rule defined it, the packaging operation instruction was in place and QC online would check the packing process when manufacturing, and relevant checking records were available.

6.3 Quantity, weight, volume and number control

In the packaging workshop, the net weight of the finished product was controlled by the operators each bag and sampled randomly by workshop leader or quality staff. Packed to minimum weight which met customers and legal requirement. Sampled checking for a finished product stored in the warehouse showed that the results were acceptable.

Balances used were periodically verified to ensure correct measuring results.

Electronic scales were used in packing workshop and calibrated by official, and the certificate was in place.

No auto weigher with rejection mechanism for packaging.

6.4 Calibration and control of measuring and monitoring devices

The company has identified the measuring equipment used to monitor CCPs and product safety and legality. And the records of results of calibration and verification were maintained. Measuring and monitoring devices register list was in place. All identified measuring devices, including new equipment, have been checked and where necessary adjusted.

All reference measuring equipment calibrated by local official calibration agency, relevant calibration certificates were in place, such as:
Pressure sensor, No.: 054f226, calibrated on 2024-2-20,
Scale, TCS-15, B718063173, calibrated on 2024-06-27,
Digital thermometer, SW001, calibrated on 2024-2-20, above mentioned equipment all calibrated by JIANGSU SHITONG MEASURE INSTRUMENTS SERVICE CO.,LTD.
Once the prescribed measuring and monitoring devices are found not to be operating within specified limits. The actions included products identification, segregation and treatment, measuring and monitoring devices re-adjusted to ensure accuracy unauthorized adjustment of measuring and monitoring devices was prohibited.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.2.4	No on-line vision equipment used to check product labels & printing
6.3.3	No on-line automatic weighting equipment is used.

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

The training procedure was established to guide the staffs how to get and arrange the training, and the training plan of 2024 including HACCP knowledge, CCP control, food safety, pest control, WI, allergen, cleaning and disinfection, chemical control, label and information etc. was in place. All staffs including temporary staffs were included in the training plan.

Sampled some training records such as packing and label control training on 2023-08-04, and CCPs control training on 2023-09-14, GMP awareness training on 2023-09-07, chemical control training on 2024-01-08/10 and all relevant information including the name of trainer/trainee/date/training contents/duration, training effectiveness and signature were included in it.

The company reviews the competencies of its staffs routinely, usually every year or when work changes. The refresh training was holding every year and the records were maintained.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

The personal hygiene requirement was detailed described in the Hygiene Control Procedure BM000645. On the site the staff could meet the personal hygiene requirement.

The requirements of personal hygiene are defined in writing. Personal hygiene is inspected every shift.

Hands washing and disinfecting requirement was defined in personnel hygiene rule, staff washed their hands before commencing work, after visiting toilet, becoming soiled. There was hand washing sinks at entrances to processing areas, or appropriate areas convenient to staff for washing hands when they

became soiled. Operators were aware of washing their hands prior to entering the processing areas during the audit.

Personnel hygiene rule required the relevant content, and on site they did well.

Blue metal detectable strip is available and had been verified by the metal detector. Onsite verification showed that the strip can be detected by the metal detector.

Personal use medicines (defined in personnel hygiene rule) were control well, in the event of disease, the staff should report to her supervisors according to requirement.

7.3 Medical screening

The personal hygiene program BM000645 is defined that how to report infection, disease, or condition when returning to work or which they have in contact is on site.

The site has made employees aware of the symptoms of infection, disease or condition, which would prevent them working with open food through the new employee training and refresh good hygiene practices course.

Hygiene management program of employee and visitor was reviewed. Visitors and contractors review a health questionnaire, which is checked by an appropriate manager, or confirm that they are not suffering from any symptoms, which may put product safety at risk before entering the raw material preparation, processing, packing, and storage areas.

Employees were checked for body annually, and contractors or visitors were investigated before entry into factory, Health certificates kept and valid, Issued by Qingdao West Coast New Area People's Hospital/Qingdao West Coast New Area Second Traditional Chinese Medicine Hospital.

7.4 Protective clothing: employees or visitors to production areas

Suitable site-issued protective clothing was worn by employees, contractors or visitors working in or entering production areas. In the packing workshop, protective clothing must be changed in changing room before to toilet and use of canteen and smoking. In the packing room of the Mannitol workshop, there are no changing clothes instructions set up to inform employees or visitors.

The personal hygiene policy in SSOP had stated such requirements. Changing rooms were provided.

Only in the packing workshop, the The protective clothing was of suitable design. Two pairs of colour coded uniforms are provided to all the staff. The uniforms are suitable without buttons. The uniform includes head gear which is fully covering the hair.

The working uniform is washed by inner employee within the laundry room; the laundry procedure is in place. No cross contamination during site tour. The record for protecting clothes washing and disinfecting was in place and effectiveness was checked visually and by EMP monitor. Working uniforms were required to be changed every day and per contamination occurred.

Gloves are used in production and they are suitable for food use and of a distinguishable colour(blue).

Shoes were washed by staffs themselves and regularly checked by production supervisor and QC.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
None	N/A

8. Production risk zones – high risk, high care and ambient high care production risk zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
Not applicable
8.2 Building fabric in high-risk and high-care zones
Not applicable
8.3 Equipment and maintenance in high-risk and high-care zones
Not applicable
8.4 Staff facilities for high-risk and high-care zones
Not applicable
8.5 Housekeeping and hygiene in the high-risk high-care zones
Not applicable
8.6 Waste/Waste disposal in high risk, high care zones
Not applicable
8.7 Protective clothing in the high-risk high-care zones
Not applicable

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification

9. Requirements for traded products
9.1 The food safety plan - HACCP
Not applicable
9.2 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.3 Specifications
Not applicable
9.4 Product inspection and laboratory testing
Not applicable
9.5 Product legality
Not applicable
9.6 Traceability
Not applicable

Module 11: Meat Supply Chain Assurance	
Scope	Click or tap here to enter text.
11.1 Traceability	
Click or tap here to enter text.	
11.2 Approval of meat supply chain	
Click or tap here to enter text.	

11.3 Raw material receipt and inspection
Click or tap here to enter text.
11.4 Management of cross-contamination between species
Click or tap here to enter text.
11.5 Product testing
Click or tap here to enter text.
11.6 Training
Click or tap here to enter text.

Module 13: Meeting FSMA Requirements for Food – July 2022
Preventive Controls for Human Food: 21 CFR Part 117 (Clauses 13.1.1 – 13.1.33)
Click or tap here to enter text.
Preventive Controls for Animal Food: 21 CFR Part 507 (Clause 13.2.1)
Click or tap here to enter text.
Food Defence: 21 Part 121 (Clauses 13.3.1 – 13.3.11)
Click or tap here to enter text.
Sanitary Transportation: 21 CFR Part 1 Subpart 0 (Clauses 13.4.1 – 13.4.9)
Click or tap here to enter text.
Produce Safety: 21 Part 112 (Clauses 13.5.1 – 13.5.18)
Click or tap here to enter text.

14.1 Additional Specifier Requirements
14.1 Traceability
Click or tap here to enter text.
14.2 Environmental Monitoring
Click or tap here to enter text.
14.3 Product inspection and laboratory testing
Click or tap here to enter text.
14.4 Protective clothing: Employees or visitors to production areas
Click or tap here to enter text.