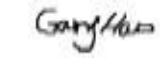
NON-FOOD FACTORY ASSESSMENT

Comprehensive QMS GMP Factory Assessment

SUPPLIER INFORMATION			
Supplier Name:	Tangshan Burak Hotel Supplies Co.,Ltd	Address of Facility:	Xiaodaodi Village East Chahe Town Fengnan District Tangshan Hebei China
City:	Tangshan	State,Zip code:	064002
Country:	China	Phone:	0315-2346093
Key Contact:	Han Kun	Title:	15830506182
e-mail address:	hankun@tangshanburak.com	Fax:	
Emergency contact:	Diana	Emergency contact phone:	18617512373
Products produced in facility:	Chafing Fuel,Oil Cartridge,Oil Table Lamp		
FDA Registration number(US only	NA	Does the facility hold any certificate such as SQF,BRC?	No
Signature of Auditor:	GARY	Signature of Factory Representativ	Ms. Han kun
Signature of Technical Reviewer:		Date reviewed:	
AUDIT INFORMATION			
Auditor:	Gary hao	Date of audit:	Jul2-3,2018
Date/Time started:	9:00	Date/time ended:	17:30
Date of last audit:	NA	Auditing Company:	SGS
SGS Work Order Number			

SCORING SUMMARY

Overall Score %:	90%	Number Of Critical Violations	0
Overall Grade:		Number Of Major Violations	3
		Number Of Minor Violations	6



1.0 Administration & Regulatory Compliance									
No.	Question	Audit Charcter	Score		N/A	non-conformance			Comments
						minor	major	critical	
1.1	Does the facility have a written Quality & Safety Policy that is communicated to all levels of the organization?	This should include the facility's commitment to quality and safety and an outline of working practice and methods.	20	√					It has been described in quality manual as "Take science and technology as the guide, strive for survival by quality, seek development with sincerity, and seek benefits through management".
1.2	Has the owner or Senior Management demonstrated the commitment to make resources available to implement and maintain quality and safety?		20	√					Ms. Han, as the head of the factory, made the commitment.
1.3	Does the quality and safety policy include documented procedures, methods and practices to achieve recognized quality standards?		20	√					The company has established a document architecture and has passed ISO9001 certification.
1.4	Does the facility have a documented training program on safety and quality for all associates including upper management?		20	√					The factory has set up a training plan of 2018 annual training plan, including the guidelines and strategies in ISO9001.
1.5	Does the facility operate in accordance with the Quality and Safety policy?		20	√					OK.

1.6	Is the Quality & Safety Policy readily available to relevant personnel?		20	√					OK.
1.7	Is the Quality & Safety Policy reviewed on at least an annual basis to determine the effectiveness of the procedures and methods?		20	√					For the management review conducted in June 1, 2018, the quality and safety guidelines were included in the input information.
1.8	Does the facility have a current organizational chart which shows all individuals responsible for safety and quality?	The chart must indicate the reporting structure of all individuals responsible for safety and quality to upper management and their relationship to each other	20	√					The quality manual defines the organizational chart, including the management department, the production technology department and the sales department.
1.9	Does the facility have a designated Quality Assurance or Safety Manager?		20	√					Mr. Li, as QA manager.
1.10	Are all required licenses present and current?	This refers to licenses issued by local, state or federal governments	20	√					It could provide the business license.
1.11	Does the facility have a system in place to correct all violations noted on regulatory & third party inspections?		20	√					On site verify the immplentment, it was OK.

1.12	Does the facility have a written records management policy?	The policy must include all aspects of records management including identification, collecting, filling, retention time & disposition	20	√					It has established the records control procedure as BLK/QMS/CX-02-2018.
1.13	Does the facility have a written and documented customer complaint program?	The program must be documented and must include protocols for handling complaints including the identification of parties responsible for the investigation,time frames for resolution, follow-up-notification to the customer and procedures for closing out the complaint. In addition, corrective actions must be documented and trend analyses conducted.	20	√					The process of customer complaint handling has been established.

2.0 Process/Product Controls									
No.	Question	Audit Charcter	Score		N/A	non-conformance			Comments
						minor	major	critical	
2.1	Does the facility have and operate in accordance with written process control procedures which include instructions and reference documents which are critical to product safety & quality?	Procedures must include the identification of all critical parameters essential to the quality and safety of the product. In addition, the procedures must describe the entire manufacturing process and should describe activities used to monitor production processes and compliance to product specifications i.e. Temp., flow rate, viscosity, weights, and other specification parameters	20	√					It has established the products testing SOP as BLK/QMS/GF-01-2006.
2.2	Are the process control procedures available to all necessary personnel?		20	√					OK.

2.3	Does the facility have written procedures for the determination and implementation of corrective action in the event of non-conformity relating to product safety & quality? Are the records securely stored and readily available accessible?		20	√					It has established the corrective action procedure BLK/QMS/CX04-2018.
2.4	Are the written processing procedures verified on a routine basis & documented?	Procedures should be verified and reviewed at least annually.	20	√					The performance has been reviewed per year.
2.5	Are the processing procedures reviewed by management on an annual basis or when there are process changes?		20	√					Processing procedures reviewed by management on an annual.
2.6	Are the processing records maintained for at least one year or as required by legislation?		20	√					The requirement for record retention period in BLK/QMS/CX-03-2018 was definded as two years.

2.7	Does the facility maintain product specifications for all raw materials, ingredients & packaging which is available to all relevant personnel?	Specifications may include physical, microbiological, chemical and shelf life parameters etc. Supplier test results must include lab used, sampling plans,tests performed, methodologies,etc. Specifications must be readily available & accessible to personnel when needed.	20	√					Product quality inspection instruction BLK/QMS/GF-01-2006 was included the Diethylene glycol, lids,and metal pots etc.
2.8	Are incoming raw materials purchased and received according to written specifications?	Raw material specifications must be maintained and available for review by necessary personnel including receiving staff.	20	√					According to the requirements of inspection, the raw materials and accessories are checked. It was OK.

2.9	Is there a written & documented program in place to verify raw materials for compliance to specifications?	Verification may include physical checks, mirobiological & analytical testing, chemical residue analysis,etc. Raw material verification must be documented.	20	√					There is a written & documented program in place to verify raw materials.
2.10	Does the facility have a written vendor approval process for all packaging materials, ingredients, services and other items which may impact quality & safety?		20	√					The supplier management was defined in Quality manual.
2.11	Does the facility require and maintain letters of guarantee or Certificates of Analysis (COA) for incoming raw materials, ingredients & packaging?		20	√			√		Wick, plastic bottle, lid,and label does not contain supplier's COA.
2.12	Does the facility maintain finished product specifications which include microbiological, chemical & quality parameters and are they readily available to relevant staff?		20	√					The facility maintain finished product specifications, including the heating time, sealing, weight etc.

2.13	Does the facility conduct final product testing to insure all products meet specifications?		20	√					The facility conduct final product testing to insure all products meet specifications, it was OK.
2.14	Is all product properly labeled in accordance to pertinent regulations?		20	√					The labels were OK.
2.15	Does the facility maintain product retention samples for an appropriate length of time?	Retention sample time is usually determined by the shelf life of the product or as determined by the customer.	20	√					The SOP has been established and as the customer requirement, it should be kept for 4 months.
2.16	Are retention samples stored in a proper manner separate from regular finished product?		20	√					Retain the sample area, leave the samples for identification.
2.17	Does the facility have a written and documented product development procedure?	The procedure should include development records, performance testing, packaging testing, compliance to regulations, production capabilities etc.	20	√			√		It could provide the written and documented product development procedure, but it could provide related records for process according to R&D SOP, such as review, validation, verification process.

2.18	Does the facility have an internal audit system in place to audit systems and procedures which are critical to safety & quality?		20	√					Internal audit control program BLK/QMS/CX05-2018.
2.19	Are packaging materials appropriate for the intended use and purchased according to written specifications?		20	√					It was OK,packaging materials were appropriate for the intended use.
2.20	Does the facility have a written process for changes in specifications?	The procedure must identify the process in which vendors are notified of spec changes and have approved the changes.	20	√					It has established the written process for changes in specifications.
2.21	Does the facility have a written inventory control procedure to insure all materials and product are used in the correct order and within the shelf life parameters?		20	√					The factory has established the inventory management procedure, and the factory has set up an outgoing account.
2.22	Are the inventory control procedures being followed?	All raw materials used in production must be with-in shelf life parameters and in proper rotation.	20	√					OK.

4.0 Sanitation									
No.	Question	Audit Charcter	Score		N/A	non-conformance			Comments
						minor	major	critical	
4.1	Does the facility have a Master Sanitation Schedule (MSS)?	The MSS must show cleaning frequencies, list of all equipment and areas to be cleaned and to whom those responsibilities are assigned.	20	√					The factory has established plant cleaning procedures, factory equipment maintenance cleaning tables, including equipment.
4.2	Does the facility have written Standard Sanitation Operating Procedures (SSOP's)?	SSOP's must include standard cleaning methods (chemicals to be used, chemical concentrations, contact time, temperatures, frequency, rinsing procedures & re-cleaning procedures)	20	√					The factory has established plant cleaning procedures.

4.3	Do records and inspections indicate that the MSS is being properly executed?	Auditor should inspect equipment (food & non-food) and areas for cleanliness and examine records for proper sign-off & execution.	20	√		√			Sample cleaning records, 20180115，20180131, etc., part of the cleaning frequency does not meet the requirements of the cleaning system, such as weekly and daily frequency.
4.4	Does the facility have measures in place such as a pre-operative inspection program, to verify that cleaning methods are effective and that equipment is in good repair?	Facility should have a pre-operative inspection program to verify the effectiveness of cleaning methods. It should describe procedures used, methods of verification (rapid test kits, audits,etc.) and corrective actions. Pre-op program must also include visual checks of equipment for loose, missing & damaned parts, wear,excessive crease or scale.	20	√					Maintenance record 20180509.20180610 and other maintenance records.

4.5	Does the factility conduct regular, documented sanitation training?	Training should be conducted with sanitation workers at initial hire and at least annually thereafter.	20	√					Sampled training plan of 2018.
4.6	Is there a procedure in place to insure that Clean-in-Place (CIP) product lines are flushed prior to start-up?	Procedure should be documented and verified to insure that no chemical residues remain in the lines prior to start of production.	20	√	NA				Factory does not involve CIP process.
4.7	Are test kits available to monitor the concentrations of sanitizers used on equipment and are the concentrations monitored and documented?	Documentation must include the type of sanitizer used, concentration, target range and any corrective actions	20	√	NA				Factory does not involve CIP process.
4.8	Is there a system in place for the prevention of cross contamination with cleaning equipment & tools, such as labeling or color coding?	A program must be in place to insure that cleaning equipment & tools are used only for their intended purposed & on the equipment for which it was intended.	20	√					Using labels to provide clean areas, such as logo management.

4.9	Are all hoses stored off of the floor in a sanitary manner?		20	√	NA				There was no using for hoses.
4.10	Are all floors, walls, ceilings, fans, blowers, racks, carts, etc, clean?		20	√					Meet the requirements of processing chafing fuel products,and it did not contact foods.
4.11	Are all floor drains clean and covered with grates?		20	√					Meet the requirements of processing chafing fuel products,and it did not contact foods.
4.12	Is all garbage, trash and other waste materials disposed of in identified, covered containers?		20	√					Meet the requirements of processing chafing fuel products,and it did not contact foods.
4.13	Are all pallets spaced an adequate distance from walls to facilitate cleaning and monitoring for pests?		20	√					Meet the requirements of processing chafing fuel products,and it did not contact foods.
4.14	Are wooden pallets prohibited from wet areas?		20	√	NA				There was no wet processing and area.
4.15	Are waste containers clearly identified as to their intended purpose?		20	√					The factory has established a waste storage area and locked.
4.16	Is waste removed from processing areas on a regular basis?		20	√					The factory has signed a hazardous waste agreement, which is processed by third parties.

5.0 Worker Health & Hygiene									
No.	Question	Audit Charcter	Score		N/A	non-conformance			Comments
						minor	major	critical	
5.1	Does the facility have a written personal hygiene policy that is adopted by all personnel, including visitors?	The policy must be reviewed & documented by all associates upon initial hire and by visitors upon entering the facility. The policy must addresses protective clothing, hair restraints, hand washing, jewelry, gloves, etc.	20	√					The factory has set up the staff health management system, which stipulates the requirements for work clothes, hair, washing hands and so on.
5.2	Are plant employees wearing company issued, clean uniforms, smocks or other protective clothing?	Clothing, including shoes, must be appropriate for the work conditions.	20	√					The company provide the work clothes.

5.3	Are employees following the personal hygiene policy regarding hand washing?	Auditor should observe hand washing practices before starting work, during production, after breaks, sneezing, after using the restroom or other unsanitary practices. If sanitizing hand dips are used, the concentration must be checked and documented on a routine basis	20	√					The workshop is equipped with a hand wash area.
5.4	Are hand washing signs posted above all handsinks in the facility?	Handwashing signs must instruct employees to wash hands after breaks, using the restroom, etc.	20	√					The company has a logo in the hand wash.
5.5	Are employees observed wearing jewelry, nail polish, long or fake fingernails?	Jewelry, except for plain wedding bands, should not be worn. Watches, long fingernails and fake fingernails are also not permitted.	20	√					It was OK with verfication on site.

5.6	Are eating, drinking, chewing gum or tobacco and smoking prohibited from production and warehouse areas?		20	√					Factory prohibition of eating in warehouse and production area.
5.7	Do employees have a designated break area with refrigeration for storage of personal food items away from food production and storage areas?	Associates may not store food items in locker rooms, restrooms, warehouse or coolers.	20	√	NA				There was no refrigeration for persional food.
5.8	Are restrooms & break areas adequate, properly stocked and all fixtures functioning properly?	Restrooms and break areas must have adequate handwashing facilities with hot and cold or tempered running water. Handwashing stations must be adequately stocked with soap & disposable towels. Restroom doors must be self- closing and cannot open into production areas.	20	√					The washing room was located outside of workshop.

6.0 Physical Plant &Equipment									
No.	Question	Audit Charcter	Score		N/A	non-conformance			Comments
						minor	major	critical	
6.1	Is the exterior of the facility including the grounds,parking lot & dumpster areas maintainer in a clean and sanitary manner?	The grounds and parking lots must be graded to prevent standing water. Vegetation next to the building should be minimal and must be properly maintained to prevent harborage of pests	20	√					It was OK for chafing fuel processing.
6.2	Are all waste products being disposed of on a regular basis and in the proper manner?	Waste materials must be removed in a timely manner to prevent unwanted accumulation.In addition,the disposal of such materials must be in a legal manner.	20	√					Waste is handled by a specialized and qualified institution.

6.3	Is the facility designed,constructed and maintained to control the risk of product contamination?	Flow of product and materials through the facility must be designed to minimize the risk of cross contamination.Storage and work areas must be adequate.	20	√					The factory has set up the raw material storehouse, workshop workshop and so on.
6.4	Are all hand sinks in processing area supplies with hot & cold(or tempered)water under pressure?		20	√					The factory is equipped with cold and hot water in the hand wash area.
6.5	Are walls properly designed, constructed,finished and maintained?	Walls must be constructed of durable,cleanable materials and in such a manner to prevent the accumulation of dirt & mold and to facilitate cleaning.	20	√					Factory walls meet design requirements to meet product processing needs.

6.6	Are the floors properly designed, constructed,finished and maintained?	Floors must be constructed of durable,impervious materials and designed to meet the needs of the process & properly drained.Floor wall junctures should be properly covered to facilitate cleaning.	20	√					Ground design meets requirements.
6.7	Are all floor drains properly constructed,easily cleaned,covered with a removable grate and functional?	Floor drains must be of sanitary construction,provided with traps and vented to the outside.	20	√					Drainage design meets the needs of product processing.
6.8	Are ceilings provided in all processing areas and properly designed, constructed, finished and maintained?	Ceilings must be constructed of proper materials to prevent the accumulation of dirt,mold,condensation and to facilitate cleaning.	20	√					Ceiling design meets the needs of processing.
6.9	Are all external doors tightly self closing and adequately proofed against flies and vermin?	Dock levelers must also be tight with no openings to the outside.	20	√		√			The doors and windows of the workshop are not kept closed, and they are kept open at the site audit, which is not conducive to pest control.

6.10	Are all windows that are designed to be opened, adequately screened to prevent the entry of pests?		20	√					It was OK.
6.11	Is there adequate lighting throughout all areas of the facility to facilitate cleaning & sanitation?		20	√					Lighting meets the requirements.
6.12	Are all lights in throughout the plant shielded or shatter proof?	Lights must be shielded or shatterproof in all production and storage areas including receiving,docks and storage areas.	20	√					The lights were protected by shielded including the production and storage area.
6.13	Is the facility properly ventilated and is the system properly maintained?	Adequate ventilation must be provided throughout the facility including processing areas to properly exhaust all steam,heat,fumes,etc . to the outside.Ventilation systems must be properly designed and easily maintained.	20	√					Ventilation facilities meet the needs of processing.

6.14	Is the water supply to the facility and water used for processing potable?	Water must be tested for potability on a regular basis and results must be available for review by the auditor.The volume of water must be sufficient to allow for times of maximum production capacity.	20	√					Water can be used for cleaning the outer surface to satisfy the processing needs.
6.15	Are all water systems protected from back flow and cross connections? Are all back flow devices checked on a routine basis to verify functionality?	Back flow prevention devices must be installed on all hose bibbs:water line & equipment must be protected from cross connections, submerged inlets,etc. Facility must maintain inspection and test records of all back flow devices.	20	√	NA				The production process book is used to clean the outer surface of the tank and to use municipal water.
6.16	Are there any treatment systems on water lines such as filters, chlorination systems, softeners, etc. and if so, are they maintained on a routine basis?	Auditor should examine the maintenance records of any water treatment systems.	20	√	NA				The production process book is used to clean the outer surface of the tank and to use municipal water.

6.17	Is all manufacturing equipment clean and in good repair with no temporary repairs that may affect safety and quality?		20	√					
6.18	Is broken and malfunctioning equipment identified and tagged or removed from the floor?		20	√					All manufacturing equipment clean and in good repair with no temporary repairs.
6.19	Are reusable containers clearly marked or color coded for their designated purpose?	Re-usable containers would include rework,bulk storage bins,etc.	20	√					Reusable containers clearly marked.
6.20	Is all equipment installed in a manner to facilitate maintenance and cleanability?		20	√					It was OK.
6.21	Are all ladders,bridges and walkway that span exposed product areas, shielded to prevent product contamination?		20	√	NA				No using it in processing.

8.0 Pest Control									
No.	Question	Audit Charcter	Score		N/A	non-conformance			Comments
						minor	major	critical	
8.1	Does the facility maintain a documented pest control program that is either performed by in-house personnel or contracted by an outside provider?	Program must include service reports, identification of target pests, list of pesticides used, map of facility showing the location of all pest control devices, MSDS sheets and specimen labels. All pest control records must be available and maintained.	20	√		√			The company controls pest control by itself, and the company has established a pest control program, but it does not include pest facilities layout, MSDS and so on.

8.2	If the facility is serviced by an outside provider, is a copy of the technician's license on file? If performed by in-house personnel, are they properly licensed and trained?	If in-house services are used, the responsible parties must be identified and licensed/ certified. It is also acceptable for those parties to be under the direct supervision of someone who is licensed or certified.	20	√		√			The personal did not train for pest control.
8.3	Do pest control records indicate noted activity, deficiencies in the plant or structure that may lead to a pest problem and corrective actions?		20	√		√			No record of pest control were kept.
8.4	Are there an adequate number of rodent control devices in the facility?	Interior rodent control devices should be spaced along exterior walls and on either side of exit doors.	20	√					Plant use mouse plate to control rodent damage.

8.5	Are there an adequate number of exterior bait stations?	Bait stations must be secured and placed around the exterior of the facility. The stations must be clean, baited, locked and in good repair. Bait stations are not permitted in the interior of the facility.	20	√		√			No outside bait station in the factory.
8.6	Are flying insect traps properly located near exterior doors?	Only non-electrocuting devices are permitted in food processing and storage areas.	20	√			√		There were no control measures for flying insects in the factory.
8.7	If pesticides are stored on site for an in-house program are they properly stored & labeled in a designated, restricted and locked area?		20	√					There were no flying insect traps properly located near exterior doors.
8.8	Is the pest control program effective?	Evidence of rodents (droppings, nests, etc.) is an indication that the program is not effective.	20	√					OK.
8.9	Are domestic animals prohibited from the premises?		20	√					Defined in SOP.

9.0 Operational Practices									
No.	Question	Audit Charcter	Score		N/A	non-conformance			Comments
						minor	major	critical	
9.1	Does the facility have a written inbound receiving program for all raw materials and materials?	The program must include documentation & acceptable parameters of trailer conditions, condition of product, temperatures (if applicable) & code dates. The written program must be available for all receiving personnel.	20	√					The SOP for testing was provided as BLK/QMS/GF-01-2006 which was defined the raw material receiving.
9.2	Does the facility have a written procedure for handling rejected inbound products?	Procedures must describe how rejected products will be protected from contamination or segregated to prevent contamination.	20	√					The plant has set up a waste disposal control program.

9.3	Does the facility have a pallet management program including specifications for pallets?	Pallets should be inspected for cleanliness and physical condition upon receipt and prior to reuse. Wooden pallets should be examined for cleanliness, splintered wood and loose nails	20	√					The plant has set up a pallet management control program.
9.4	Are receipt dates clearly marked on all incoming materials?		20	√					OK.
9.5	Are all outbound trailers in good repair, clean & inspected prior to loading?		20	√					Container transportation, pre service inspection.
9.6	Are records of trailer conditions (cleanliness, temperature, etc.) accessible and available for review?		20	√					Container checklist was provided. Transportation at room temperature without special requirements.

9.7	Are all packaging materials, raw materials and finished product stored properly in a manner to protect from contamination and to preserve quality?	All packaging materials, raw ingredients and finished product must be stored off of the floor and away from walls and ceilings.	20	√					Are all packaging materials, raw materials and finished product stored properly in a manner to protect from contamination.
9.8	Does the facility have a written procedure & documentation for routine calibration of all measuring devices including thermometers and other instruments used in production?	Instruments must be checked for accuracy on a frequent basis. Calibrations must be recorded and the records kept on file.	20	√					Providing weights and calipers and other measuring instruments on site.
9.9	Are all processing chemicals property labeled and stored?	Processing chemicals must be stored separately from production and food storage areas.	20	√					All processing chemicals property labeled.