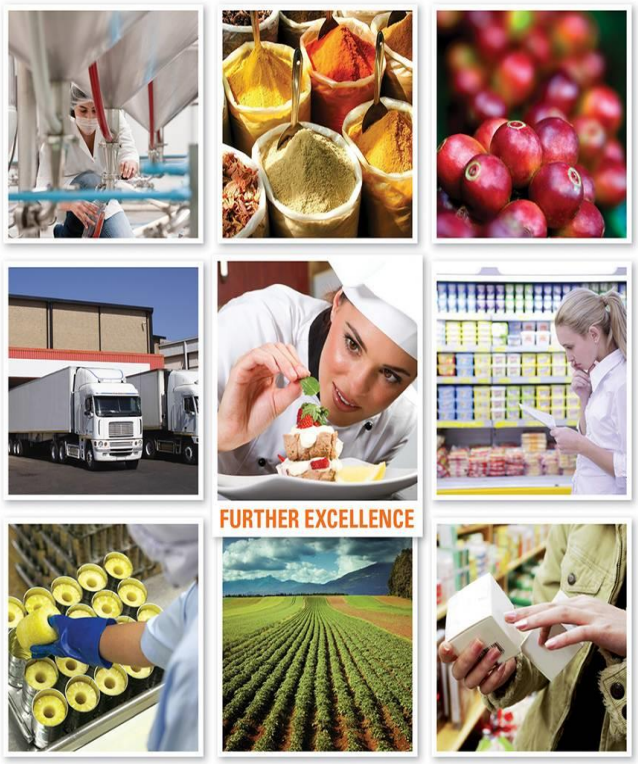
cGMP 审核报告

Current Good Manufacturing Practice Audit Report

现行良好操作规范审核报告



Report Date 报告日期: 01/08/2020

Organisation 组织名称	**Guilin Layn Natural Ingredients Corp.** **桂林莱茵生物科技股份有限公司**		
Site Registration Number 场所注册号	**Uniform social credit code 统一社会信用代码：** **91450300723095584K(1-1)**		
Address 地址	**No.19 South Renmin Road, Lingui District, Guilin City, Guangxi Zhuang Autonomous，Region, P. R. China** **中国广西壮族自治区桂林市临桂区人民南路 19 号**		
City 城市	**Guilin City 桂林市**	**Postcode 邮编**	**541199**
Country 国家	**P. R. China 中国**		
Client Representative 客户代表	**Ms. Ou Daoying** 欧道英 女士	**E-mail** 邮箱	**ou.daoying@layn.com.cn**
Auditor details 审核员	**Name 姓名: Jason WANG 王坚** **Signature 签名:**		

cGMP 审核报告

Scheme Reference: **审核标准**	☒ **Subpart B cGMP of 21 CFR part 117PREVENTIVE CONTROLS FOR HUMAN FOOD** ☒ **21 CFR Part 111: Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling, or Holding Operations for Dietary Supplements**		
Site(s) audited 审核地点：	Same as address 同公司地址		
Start and end date of audit: **审核开始和结束日期**	July 13-17,2020 2020 年 07 月 13-17 日	**Last Date Previous Audit** **上次审核日期**	Initial audit , N/A 初次审核，不适用
		Certificate Expiry Date: **证书过期日期**	Initial audit , N/A 初次审核，不适用
Total Man Days **总审核人天**	**5 MD**	**Preventive Controls Qualify Individual PCQI 人员**	Ou Daoying, Lu Jianmei, Zhen Chuanqi 欧道英、陆建梅、郑传奇
No. of FTE Employees **员工人数:**	FTE:430 Other:	**No. of Shifts:** **班次**	3
Lead auditor 审核组长:	Mr. Jason WANG 王坚 先生		
Team members 审核组成员:	N/A		
Additional attendees and roles: 其他参加者和角色	N/A		
Scope of certification **认证范围**	Production of Monk Fruit Extract, Stevia Leaf Extract, Citrus Extract, Grape seed Extract, Pomegranate Extract, Green tea Extract, Green Coffee Bean Extract, Rosemary Extract, Sweet Blackberry Leaf (Rubus leaf) Extract , Neohesperidin Dihydrochalcone(NHDC) , Gingko Extract, Rhodiola Extract, Epimedium Extract, Kelp Extract and Mango Leaf Extract, bulk packed in PE plastic bag or aluminum-plastic compound bag 罗汉果提取物、甜叶菊提取物、柑橘提取物、葡萄籽提取物、石榴提取物、绿茶提取物、绿咖啡豆提取物、迷迭香提取物、甜茶提取物、新甲基橙皮苷二氢查耳酮（NHDC）、银杏提取物、红景天提取物、淫羊藿提取物、海带提取物、芒果叶提取物的生产，使用聚乙烯塑料袋或铝箔复合袋包装		
Exclusions from Scope **范围中的删减**	None		
Description of Organisation **组织简介**	Guilin Layn Natural Ingredients Corp. is established on 2013 and is engaged in the production of plant extracts. This company is the first listed company in the domestic plant extraction industry. The products are widely used in food and beverage, health care products industry. This company moved into its current production location from 2017. This site covers an area of 300 mu and production facility has a construction area of 15,000 square meters .Annual raw material processing capacity is more than 60,000 tons. The number of employees is 430 and they are operated in three shifts. 70% of products are sold in the United States, Europe and other countries and regions. Monk fruit extract and stevia extract produced by the company have passed the US FDA GRAS certification. The company has also passed FSSC22000/Chin HACCP /ISO9001 certification		

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	桂林莱茵生物科技成立于 2000 年，专业生产植物提取物，是国内植提行业第一家上市公司。公司产品广泛应用于食品饮料、保健品行业。 公司在 2017 年搬入目前的生产地址。占地面积 300 亩，生产设施建筑面积 1.5 万平方米，年处理原材料能力可达 6 万吨以上。员工人数 430 人，分 3 班运作。70%产品销售美国，欧洲等国家和地区。 公司生产的罗汉果提取物和甜叶菊提取物分别通过了美国 FDA GRAS 认证。公司目前也已通过 FSSC22000/Chin HACCP/ISO9001 认证。

Is the facility registered with US FDA? **该工厂是否已在 US FDA 注册**	☒ Yes ☐No
Within the past 2 years, has the facility issued a food safety recall? If yes, explain in section 8 of the report. **过去 2 年中，是否发生过由食品安全引起的产品召回?如果是，请在本报告的第 8 部分解释。**	☐ Yes ☒No
Are there any pending/recent US FDA compliance actions? **是否存在任何悬而未决的/最近的 US FDA 符合性行动?**	☐ Yes ☒No
Does the facility hold a valid existing GFSI or ISO 22000 Certification(s)? 该公司是否已通过 GFSI 或 ISO22000 标准认证	☒ Yes (Specify certificate(s) and scope(s): PASS FSSC22000 certification certified by DNV. Certification scope: production of plant extracts. ☐No

AUDIT OBJECTIVES 审核目的

The objectives of this audit were 本次审核的目的是:

- To confirm that the management system conforms with all the requirements of the audit standard.
  确认管理体系符合审核标准的所有要求;
- To confirm that the organization adheres to its own policies, objectives and procedures;
  确认组织有效地策划并实施管理体系;
- ability to identify as applicable areas for potential improvement
  能够识别潜在改进的适用领域的能力。

1. CURRENT AUDIT FINDINGS AND CONCLUSIONS 本次审核发现和结论

NUMBER OF NON-CONFORMITIES 不符合项数量	
Critical 危重	0
Major 严重	0
Minor 一般	9

This audit focused on significant aspects and , risks required by the standard(s). A sampling process was used, based on the information available at the time of the audit. Methods of assessment included interviews, observation and review of documentation.

该审核侧重于标准要求的重要方面和风险。 基于审核时可获得的信息采用了抽样过程程序。所采用的审核方法包括面谈，观察活动及评审文件和记录
The audit team concludes that the organization ☒ has ☐ has not established and maintained its management system in line with the requirements of the standard and demonstrated the ability of the system to systematically achieve agreed requirements for products or services within the scope and the organization's policy and objectives. 审核组结论为该组织☒已 ☐未 根据标准的要求建立和维护其管理系统，并证明其系统有能力在范围内和组织的方针和目标内系统地达成对产品或服务的商定要求。
Based on the result of this audit the audit team recommends that certification be **根据本次审核结果，审核组建议管理体系认证结果为** **☒ Granted 推荐发证/ ☐ Continued 证书继续有效/ ☐ Withheld 终止/ ☐ Suspended until satisfactory corrective action is completed 暂停直至采取了有效的纠正措施.**

2. SCOPE OF CERTIFICATION 认证范围

Has this scope been amended as a result of this audit? 本次审核确认范围是否更改	YES
This is a multi-site audit and an Appendix listing all relevant sites and/or remote locations has been established (attached) and agreed with the client 这是一个多现场审核，已建立一份附加的清单以列出所有相关现场和/或远程场所，并经客户确认。	NO
For integrated audits, confirm the current level of the client's IMS integration 对于整合审核，确认客户整合体系的现有水平	NO

3. NON-CONFORMITIES 不符合项

Number 编号	Grade 级别	Clause 条款	Details of Non-Conformance 不符合项的详细描述	Cause 原因分析	Planned Actions / Corrective Action 所策划的措施/纠正措施	Date to Complete Action 措施完成日期
1	Minor	111.15a 117.20a	Onsite audit found that floor of cool warehouse in the workshop was damaged seriously and standing water was also found in this floor. 现场审核发现，生产车间冷库内，地面严重破损，且有积水。	1、车间物料进出冷库时，叉车与地面碰撞接触导致地面破损。When the materials were moved in and out of the cold storage, the forklift truck collided with the ground, causing damage to the ground. 2、地面积水是冷凝水。The accumulated	1.1 安排施工队对冷库地面修补；Arrange the construction team to repair the cold storage ground; 1.2 规范转运车辆的使用，将冷库地面纳入维护保养；Standardize the use of transfer vehicles and include the ground of cold storage into maintenance plan; 2.每天清扫积水。Clean up the water every day.	2020.07.30

				water on the ground is condensed water.		
2	Minor	111.15c 117.35b	Onsite audit found that one drum chemical which was stored in chemical warehouse in packaging area had no any identification. Onsite audit found scale inhibitor used in RO water treating process had no identification. 现场审核发现，干燥车间内化学库内存在的一桶化学品无标识。 现场审核发现，用于 RO 水处理的阻垢剂无标识。	1、车间配制的消毒剂溶液，配制后没有及时贴标签。The disinfectant solution prepared in the workshop was not labelled in time after preparation. 2、厂家发货时未贴标签，提供了该批次出厂报告，初检验收时核对了厂家提供的报告等发货信息。The manufacturer did not label when delivery, but provided the delivery report of the batch, and we checked the delivery information such as the report provided by the manufacturer during the initial inspection.	1.1 补充标识完善；Add label to perfect； 1.2 针对标签标识管理，做全员培训。All staff shall be trained for label & identification management. 2.1 联系厂家提供该批次阻垢剂标签，并贴在包装桶外； Contact the manufacturer to provide the label of this batch of scale inhibitor and paste it outside the packaging barrel; 2.2 对采购员、仓管员、质管验收员进行培训物料验收标准。Train the purchaser, warehouse keeper and quality control inspector on the material acceptance standard.	2020.07.22
3	Minor	111.27 117.40	Onsite audit in the packaging workshop found that stainless steel handles of the two knives are not sealed at the top and it is inconvenient to clean. 包装车间内，2 个刀具的不锈钢手柄顶部未封闭，不便清洁。	购买该刀具时，没有考虑刀柄口未密封可能带来的清洁困难问题。When purchasing the tool, the cleaning difficulty caused by unsealed hilt edge was not considered.	1.1 刀柄未封口的刀具已移出洁净区，不再使用；The tool with unsealed hilt has moved out of the clean area and is no longer used; 1.2 检查洁净区使用的其他工器具，不得出现器具端口未封闭的现象。Check other tools and instruments used in the clean area, and do not have the phenomenon that the tool edge is not closed.	2020.7.21
4	Minor	117.15d 117.35c	Several small broken holes were found screen of one external window in the discharge area of the stevia centrifuge equipment	忽略了纱窗的细小破损可能带来的飞虫进入风险。The risk of flying insects entering into the screen	1.1 关闭窗户，纱窗更换前不得开启；Close the window and do not open it before replacing the screen window;	2020.7.24

			甜叶菊离心设备卸料区域有一扇对外的窗户的纱网已多处发现有小的破损。	window due to small damage is ignored.	1.2 已完成更换纱窗；The window screen has been replaced; 1.3 本月 7 月 24 日，安排员工进行虫害防控知识的培训。On July 24 of this month, staff will be arranged for training on pest control knowledge.	
5	Minor	111.70e	Identity was not defined in the specification of Monk fruit 50% extract . Although this organization provided the species identification report of the raw materials of Monk fruit and identification testing result of the type test report RT101172FAT00612 was passed. 罗汉果提取物 50%质量标准中，并未明确鉴别方法。尽管公司提供了罗汉果原料的种属鉴别报告，罗汉果的提取物的型式检测报告 RT101172FAT00612 也证实鉴别合格。	制定质量标准时，没有考虑鉴别方法。The identification method was not taken into account in the development of quality standards.	在所有认证产品标准里加入鉴别方法的内容。The content of identification method should be included in all certified product standards.	2020.7.30
6	Minor	111.205	Current version of RO system operation manual PF05-(GC-CS)001 was B2. But onsite audit found that RO system operation manual PF05-(GC-CS)001 used in first level RO water treatment system was version B1. 纯水操作手册 PF05-(GC-CS)001 的当前版本号为 B2。但现场审核发现，一级 RO 水处理区域的纯水操作手册的版本为 B1。	文件改版后，发放给该岗位主管，主管没有及时更换版本回收旧的版本文件。质管部文控也未及时检查文件版本的一致性。After the revision, the document was distributed to the supervisor of the post. The supervisor did not change the version in time and recycle the old version of the document. And the document	1.1 重新下发最新版本纯水操作手册，并回收旧版本文件；Re issue the latest version of water purification post operation manual, and recycle the old version of documents; 1.2 同时检查各岗位的操作手册，如有文件版本不一致，重新下发，确保文件一致性；At the same time, check the operation manual of each post. If there is any inconsistency in the document version, issue it again to ensure the	2020.7.20

				control specialist of the QA department did not check the consistency of the document version in time.	consistency of the document; 1.3 对各部门文件管理人员进行培训。Conduct training for document management personnel of all departments.	
7	Minor	111.210	It is defined that expected minimum yield in finished product filling step shall be more or equal to 98.5% in finished product monitoring procedure PF 13-01, but the maximum yield is not defined. 成品监控管理规程 PF13-01 规定，每批产品包装时预期收率不得少于 98.5%,但并未规定最大收率。	管理规程已考虑了收率下限，默认上限是 100%，未在文件中写明。The lower limit of yield has been considered in the management procedure, and the default upper limit is 100%, which is not stated in the document.	修改成品监控管理规程 PF13-01，增加收率上限要求。Modify the *finished product monitoring management procedure* PF13-01 and add the upper limit requirement of yield.	2020.7.24
8	Minor	111.365 117.80c	Only two testing pieces , Fe1.5mm and SUS 2.5mm, which was uses to test metal detector was found in packaging area when onsite audit. As per requirement , 3 type testing pieces shall be used for testing of metal detector, Fe1.5mm, SUS 2.5mm and Non-Fe 2.5mm. Although the packaging process was not started at that time. 现场审核发现，包装车间用于测试金属探测器金属测试片只有 Fe1.5mm 和 SUS 2.5mm 两种。依据控制要求，需使用 3 种测试片测试金属探测器，包括 Fe1.5mm ,SUS 2.5mm 和 Non-Fe	手动金属探测器有模块有两套，一套备用，使用前未仔细检查模块精度，现场模块管理不当。There are two sets of manual metal detector modules, one for backup. The module accuracy was not carefully checked before use, and the module management was improper.	备用模块不得存放在生产现场，交由质管部保管，现场只保留一套模块。The backup modules shall not be stored on the production site, and shall be kept by the QA department. Only one set of modules shall be reserved on site.	2020.7.20

			2.5mm。尽管生产尚未开始。			
9	Minor	111.420	This organization did not establish the requirement apply to repackaging and relabelling Although no repackaging and relabelling incidents happened in recent years. 公司未建立重新包装和重新贴标的要求。尽管近几年未发生重新贴标或重新包装的事件。	由于未发生过重新包装和贴标的情况，因此未充分识别重新包装和重新贴标的工作流程。Since no repackaging and relabeling has occurred, the workflow for repackaging and relabelling is not fully identified.	建立重新包装和重新贴标的管理规定，完善工作流程并进行培训。Establish management regulations for repackaging and relabeling, improve work flow and conduct training.	2020.7.28

Reviewed and Accepted by: **评审和接收人**	Jason WANG	**Date:** **日期**	2020.08.01

4. PREVIOUS AUDIT RESULTS 上次审核的结果

The results of the last audit of this system have been reviewed, in particular to assure appropriate correction and corrective action has been implemented to address any nonconformity identified. This review has concluded that:
已对上一次审核结果进行了评审，特别是确保对所提出的不符合项已采取适当的纠正和纠正措施。如果某个不符合没有充分解决则在本次审核中提出:

☐ The management system has not adequately addressed nonconformity identified during previous audit activities and the specific issue has been re-defined in the nonconformity section of this report. 管理体系对于上一次审核提出的不符合项没有充分地解决，这一问题在本次审核报告的不符合项部分已被再次提出。

☐ N/A, There is no finding raised in CAR(s) from previous visit
N/A，上次审核没有不符合项。

☐ For Renewal and Surveillance Visit: Results and evidences for previous visit non-conformance closure are addressed in the table below. 复审和监督审核： 上次不符合项关闭的结果和证据已在下表中阐述。

N° _ of __ 编号	**Grading 级别**	**Details of Non- Conformance 不符合项的详细描述**	**Evidence of Conformity 符合的证据**	**Closed 关闭**
Initial audit. N/A.				

5. GENERAL OBSERVATIONS & OPPORTUNITIES FOR IMPROVEMENT 总体观察项及改善点

Clause 条款	**Commentary 述评**

NIL	

6. AUDIT ATTENDANCE RECORD – (OPENING, SITE AUDIT, CLOSING) 首末次会议参会者记录

Name 姓名	Position 职位	Opening 首次会议	Site Audit 现场审核	Closing 末次会议
Mr. Frank XIE	Vice president	Y	Y	
Ms. Daoying OU	QA manager	Y	Y	Y
Mr. Mingzhu WANG	Vice production manager	Y	Y	Y
Ms.Yanping Tang	Warehouse manager	Y	Y	Y
Ms. Jianmei LU	QA supervisor	Y	Y	Y
Ms. Jie WEN	QA	Y	Y	Y

7. AUDIT FINDINGS 审核发现

The audit team conducted a audit focusing on significant aspects and risks. The audit methods used were interviews, observation of activities and review of documentation and records.
审核组完成了审核，关注审核标准所要求的重要因素和风险。所采用的审核方法包括面谈，观察活动及评审文件和记录。

The management system documentation demonstrated conformity with the requirements of the audit standard and provided sufficient structure to support implementation and maintenance of the food safety management system. ☒Yes ☐ No
食品安全管理体系文件展现出和审核标准是相符合的，并且提供了充分的架构以支持食品安全管理体系的实施和维护

The organization has demonstrated effective implementation and maintenance / improvement of its food safety management system. ☒Yes ☐ No
组织的食品安全管理体系在有效地实施、维护及改善中。

The cGMP review process demonstrated capability to ensure the continuing suitability, adequacy and effectiveness of the food safety management system. ☒Yes ☐ No
cGMP 评审过程能够确保组织食品安全管理体系持续的适宜性、充分性和有效性。

The organization is in good faith. ☒Yes ☐ No
组织是诚信的。

Throughout the audit process, the food safety management system demonstrated overall conformance with the requirements of the audit standard. ☒Yes ☐ No
整个审核过程显示，组织的食品安全管理体系与审核标准的要求总体上是符合的。

8. AUDIT SUMMARY 审核总结

Describe any changes in the management systems since the last audit:
描述自从上次审核以来管理系统的变化

Please include any changes in the management team, management structure, product type etc.
请包括管理团队，管理结构，产品类型等方面的任何变化

This is initial audit .

Summarise any recalls or withdrawals since the last audit:
总结从上次审核以来发生的召回或撤回

If there are none please write none. Summarize the recalls/withdrawals, actual notification to the CB and the effect on the operational FSMS.

如果没有，请写明 None。总结召回/撤回，发给认证机构的实际通知和对 FSMS 运行的影响。

No product recall in recent 2 years.

AUDIT RESULT&CONCLUSIONS
审核结果和结论

☒ 21 CFR Part 111: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

- **Provide a response for each requirement below . Where not applicable, this shall be indicated with justification. 每个栏目都需给出结论。当不适用时，应说明理由。**
- **For non-conformity, include identification of specific requirement which is not fulfilled 对不符合项，包括未被满足的特定要求的识别**
- **For conformity, include description of objective evidence(s) 对符合项，包括客观证据的描述**

Subpart B	**Personnel 人员**	
111.8	Establish and follow written procedures under subpart B B 子部分下的书面程序的制定和遵守	Conformance **Yes**
	Written procedure was in place. Please refer to 111.10-111.13.	
111.10	Requirements that apply for preventing microbial contamination from sick or infected personnel and for hygienic practices 对于防止微生物污染与接触病弱或感染人员的要求	Conformance **Yes**
	Written procedure PF01(07) was in place , covering the management requirement of personnel health and Personnel hygiene facilities. New employee must get the health certificate before working in production area and Health screen was conducted once a year for general staff. Health certificate of Ms.Li Huaxiu, Mr. Guo Rongyou , Mr. QiN Guojun; Ms.Jiang Xueming; Ms.Mo Xiaozhen; Ms.Qin Guizhen in production and packaging workshops were checked during audit. . The health certificates proved that they all passed health screen. Written procedure PF01(04) was established for hygiene practices, including requirement on working wears, personal cleanliness, handing washing and so on.	

	Onsite audit observed that hygiene practices were well followed: operators wore cleaning protective clothing in production and packaging area. No watch, jewellery, rings are worn by the employees and managements. Personnel hygiene is is checked and monitored by the appointed employee before into the workshop.	
111.12	Personnel qualification requirements 人员资质要求	Conformance **Yes**
	Organization chart is clearly documented in the quality manual LAYN-MM. Quality department is responsible for quality control during processing. As an independent department, the quality control department is independent from the production department and reports directly to the director of the plant extraction division (the company's executive vice president). The quality manual LAYN-MM clearly defined the responsibilities of the department: the quality control department is responsible for the formulation of quality labels, and the quality supervision of the production process. The inspection center is responsible for the sampling and inspection of materials, semi-finished products and finished products. Written job descriptions was established for each job related with quality control , which includes job requirements ,reporting structure. Job descriptions and education &training &experience requirement.	
111.13	Supervisor requirements 主管人员要求	Conformance **Yes**
	Written job description was established for supervisors, which include job requirements ,reporting structure. Job descriptions and education &training & experience requirement. Samples: PF03(GW-ZG)002, job description of quality manager PF(03)-(GW-ZG)003 job description of quality supervisor	
111.14	Records requirements under subpart B B 子部分 需要保持的记录	Conformance **Yes**
	Written procedure was made and kept under subpart B, please refer to 111.10-111.13 for details. Training plan was established. Training records sampled as following: Clean and disinfection training ： 20200204 Management of food contact surface, food safety and food defence: 20200601 Allergen training :20200211-0222 Chemical safety training: 20200429 HACCP training:20200429 GMP training: 20191220 New employee training :20200302, including HR policy, production , quality , food safety , halal training.	
Subpart C	**Plant and Ground 厂房和地面**	
111.15	Sanitation requirements that apply to physical plant and grounds 厂房和地面的卫生要求 a)Ground 地面	Conformance **No**
	On site verification, the fabrication of grounds is suitable for the intended purpose. Grounds of workshop and warehouse are materials which can be easily cleaned and drained and are regularly maintained. ***But one minor CAR was raised in this audit :*** ***Onsite audit found that floor of cool warehouse in the workshop was damaged seriously and standing water was also found in this floor.***	
	b) Physical plant facilities	Conformance

	厂房设施	**Yes**
	Physical plant facilities management procedure PF05 was in place , which includes facilities checking and maintenance requirements. Onsite audit verified that production facilities was maintained in a clean and sanitary condition and in a proper state of repair.	
	c)Cleaning compounds, sanitizing agents, pesticides, and other toxic materials. 清洁剂、消毒剂、杀虫剂、和其他有毒物品	Conformance **No**
	Chemical management procedures PF01(06) was in place , which included the requirements for the procurement, labeling, storage and use of chemicals. Chemical cleaning agents, disinfectants and lubricants used on site by the company. The company uses food-grade cleaning agents, disinfectants, and food-grade lubricants. Samples: Alcohol for disinfection: supplier -Guangxi Haiying, providing food-grade alcohol production license, type test report S2020-0239, testing passed according to GB31640-2016 edible alcohol standard Sodium hydroxide, Supplier -Xinjiang Zhongtai, providing food additive production license, type test report 2020X-J-NHG03042, according to GB1886.20-2016 food additive sodium hydroxide test qualified. ***But one minor CAR was raised in this audit:*** ***Onsite audit found that one drum chemical which was stored in chemical warehouse in packaging area had no any identification.*** ***Onsite audit found scale inhibitor used in RO water treating process had no identification***.	
	d) Pest control. 害虫控制	Conformance **No**
	Pest control procedure PF01(06) was in place. The pest control was outsourced to Xinjiali , a professional pest control company. Pest control plan was established for target pest rat, fly. Pest control facility used on this site included rat station, fly-killing lamp, rat trap, rat glue. Pesticides is only used outside the workshop ,not permitted inside the workshop. Pesticide were carried by pest companies and not permitted to store in the factory. Onsite audit checked the trend analysis records for the second quarter of 2020, and the analysis result proved that the pest activities were under control . ***But one minor CAR was raised in this audit:*** ***Several small broken holes were found screen of one external window in the discharge area of the stevia centrifuge equipment***	
	e) Water supply 水供应	Conformance **Yes**
	The company establishes water safety management procedures PF(01)(01). The company uses municipal water supply as raw water, which meets the requirements of Drinking water standard GB5749, and is used for production after reverse osmosis. The first-level RO water is used in extraction, resin chromatography, cleaning and disinfection, and the second-level RO water is used for the cleaning and disinfection of the D-level area. A water quality monitoring plan was established. Internal laboratory samples will be taken to test the conductivity and microorganisms at the primary and secondary water outlets monthly. Each workshop will be tested for microorganisms on a monthly basis and third-party laboratory testing will be conducted annually. Samples as following:	

	Third-party inspection report: 4508009200014, tested according to National Drinking Water Standard GB5749, Testing agency: Nanning Customs Technology Center, a ISO17025 certified lab, CNASL0254. Test report of internal laboratory (Rid Testing), a ISO17025 certified lab. Second-level RO water test report HJY20202987/May 2020, HJY2020057/April 2020, passed the test First -level RO water test report HJY20204891/June 2020, HJY20202983/May 2020, passed the test.	
111.15	f) Plumbing 管道	Conformance **Yes**
	The water distribution plan is established in place. Stainless pipes are used for distribution of purified water. No cross-contamination risk for potable water and disable water	
	g) Sewage disposal 污水处理	Conformance **Yes**
	Waste water treatment station run in this site. All the waste water is collected in this treatment station and must be treated according to local environment protection regulation before discharging.	
	h) Bathrooms 盥洗室	Conformance **Yes**
	Onsite audit observed that men and woman bathrooms are adequately segregated and do not open directly into production and storage. All the bathroom kept clean, no odour. . Enough hand washing facilities with soft soap, hand dryer and disinfection provided.	
	i) Hand-washing facilities 洗手设施	Conformance **Yes**
	Hand washing facilities is provided in each entrance of clean area, - hand free taps - liquid soap - Disinfection is realized via 75% ethyl alcohol or quaternary ammonium disinfectant - Hand washing policy is defined and posted.	
	j) Trash disposal 垃圾处理	Conformance **Select**
	Waste control procedure defined in environment control procedure is implemented. No food waste is supplied for animal feed. Waste is collected and removed by local official department. External waste collection containers are managed well to minimise risk. Unsafe products or substandard trademarked materials are handled should be destroyed by own staffs at first with control record and then confirm with contractor.	
	k) Sanitation supervisors 卫生主管人员	Conformance **Yes**
	GMP patrol inspection by Quality supervisor. Qualification requirements were documented in job description , including requirement education , training or experience For example: PF03(GW-ZG)002, job description of quality manager PF(03)-(GW-ZG)003 job description of quality supervisor	
111.16	Requirements under this subpart C for written procedures C 子部分要求的书面程序	Conformance **Yes**

	Written procedure for cleaning and pest control was established, including: Plant cleaning procedure PF28-01 for cleaning of plant facilities. Equipment cleaning SOP was documented in operation manuals of each working area, e.g. cleaning requirement , method and frequency for packing equipment was documented in PF05-(BZ-BZ)001 packing equipment operation manual . Pest control procedure PF01(06) was in place.	
111.20	design and construction requirements apply to physical plant 厂房的设计和建筑要求	Conformance **Yes**
	On site verification, the construction of the buildings and facilities such as the wall and floor are suitable for the intended purpose. Walls, floors, drainages, doors, ceiling and overheads are regularly maintained. . In the workshop verification, floors are designed to meet the requirement of the process. And drainage is designed and maintained to minimise risk of product contamination. No stagnant water is observed. Existing glass windows fitted with shatter checking regularly. The lights for lighting in the workshop and warehouse have been well protected and the light is adequate in most processing area. Exhaust fans are in place and routinely checked. Map of drains shows the direction of flow and location of any equipment fitted to prevent the back-up of waste water. The flow of drains not raised a risk of contamination. Drying and packaging workshop was designed as D clean grade workshop to reduce cross-contamination.	
111.23	Records requirements under subpart C C 子部分要求建立和保持的记录	Conformance **Yes**
	Related records were kept according to subpart c, including cleaning record, pest control record , water testing records.	
Subpart D	**Equipment and Utensils 设备和工器具**	
111.25	Requirements under this subpart D for written procedures D 子部分要求建立的书面程序	Conformance **Select**
	Written procedure was in place, e.g. Monitoring and measuring equipment management procedure PF07 and Physical plant facilities management procedure PF05/ Detailed refer to 111.27 and 111.30.	
111.27	Requirements that apply to the equipment and utensils used 使用的设备和工器具的要求	Conformance **No**
	Main equipment: crusher, extraction equipment, pressure column, centrifugal equipment, concentration, sterilization tank, spray drying equipment, filling equipment, etc. Equipment contact surfaces are made of stainless steel. Engineers aware of the requirement. Equipment have been specified before purchase and tested and commissioned prior to use. Equipment is positioned normally to facilitate cleaning and service. Equipment is positioned to facilitate cleaning and service. After cleaning for equipment and utensils use out, these equipment and utensils are stored in a locked room, restricted access. The point of use of food-grade lubrication has been identified, For example, the spray drying equipment uses Total 68#, and the centrifuge uses Total 2# lubricant; The 2020 annual maintenance plan is divided into monthly, quarterly, and annual maintenance. Monitoring and measuring equipment management procedure PF07 is in place. Calibration records samples as following: Thermometer No. QGG0001, QGG0002, QGG0003, QGG0004 used on pasteurization tank , calibrated on Aug. 06,2019.	

	Thermometer No.TT1 and TT2 of No.1 spray drying tower, TT1 and TT2 of No.2 spray drying tower, TT1 and TT2 of No.3 spray drying tower and TT1 and TT2 of No.4spray drying tower, calibrated on Dec.03,2020. PT 100 precision platinum resistance, calibrated on Mar.13,2020 PH meter 2913249, calibrated on Mar.03,2020 Electronic scale 01407049009, calibrated on May 07,2020 Electronic scale 001919064008, calibrated on May 07,2020. ***One minor CAR was raised :*** ***Onsite audit in the packaging workshop found that stainless steel handles of the two knives are not sealed at the top and it is inconvenient to clean***.	
111.30	Requirements that apply to automated, mechanical and electronic equipment 自动、机械或电子设备的要求	Conformance **Yes**
	Automated, mechanical, or electronic equipment must be functioning properly and be adequately designed. No adverse findings in this audit.	
111．35	Records requirements under subpart D D 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart D was kept, including maintenance ,cleaning, sanitizing ,calibration records and so on.	
Subpart E	**Requirement to Establish a Production and Process Control System** **制定生产与过程控制系统要求**	
111.55	Requirements to implement a production and process control system 对运行生产和过程控制系统的要求	Conformance **Yes**
	A system of production and process control was established and implemented by this organization ,covering the all processing of plant extracts.	
111.60	Design requirements for the production and process control system 生产、过程控制系统的设计要求	Conformance **Yes**
	Production and process control requirement was established by master production instructions covering production , packaging , labelling and storage. Main production processes include crushing , extraction, resin chromatography, crystallization (only for Stevia Leaf Extract)centrifugation , concentration, sterilization, spray drying, filling, packaging and storage. Onsite audit confirmed that all the production instruction was all approved by quality manager, e.g. production instruction T20200601-01 for centrifugation process of stevia Leaf Extract and production work instruction T20200604-01 drying process of Monk Fruit Extract.	
111.65	Requirements for quality control operations 质量控制的操作要求	Conformance **Yes**
	Quality control requirements was documented and implemented , including 1)approving master production instructions 2) approving specifications of finished product ,raw materials, processing aids, labels 3) approving testing procedure and testing result of QC lab 4) Oversight of sampling and retain programs. 5) Determining if specifications are met 6) Supplier approving and audit 7) Internal GMP audit 8) ensuring procedures are followed according to production instructions 9)document control	

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111.70	Specifications to be established 必须建立的标准 a) specification for any point, step, or stage in the manufacturing process 一些需要监控的控制点、步骤或阶段制的标准	Conformance **Yes**
	Specification for any point, step, or stage in the manufacturing process was documented in master production instructions of each process, e.g. PH and moisture requirement . All these production instructions must be approved by quality manager.	
	b) component specifications 组分的标准	Conformance **No**
	Main raw materials are plants. 15 raw material specifications were established including identification ,the content of main components, heavy metals, pesticide residues, etc. For examples: Monk Fruit quality standard PF06-(QS/YL)016, stevia quality standard PF06(QS/YL)049, mango leaf quality standard PF06-(QS/YL)-017 These raw material specifications were established according to China standard, EU and USA standard. E.g. US FDA Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed was considered for established raw material specification . Specification PF06(QS-FL)001 to PF06(QS-FL)0025 for supplementary materials was established, e.g. specification for alcohol, Sodium hydroxide and oxidized starch. All the supplementary materials must be food grade. Following external testing report for raw materials were checked during audit : 1）Monk Fruit Monk Fruit test report ZBJC2020050911, aflatoxin, heavy metal lead, cadmium, mercury, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Monk Fruit test report GZF20-000208-01, 411 pesticide residues were not detected, inspection agency: SGS Guangzhou Branch 2）Stevia Leaf Stevia leaf testing report: ZBJC2020050911, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Stevia leaf testing report GZF20-002028-03, 411 pesticide residues were not detected, inspection agency: SGS Guangzhou Branch Citrus raw material test report 3. Citrus Citrus raw material inspection report: ZBJC2020050900, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Citrus raw material inspection report: RT101279DAT00372, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 4. Grape seed Grape seed material inspection report: ZBJC2020050906, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Grape seed material inspection report: RT101279DAT00376, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 5. Pomegranate Pomegranate material inspection report: ZBJC2020050907, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Pomegranate material inspection report: RT101279DAT00371, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 6. Green tea	

	Green tea material inspection report: ZBJC2020050908, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Green tea material inspection report: RT101279DAT00382, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 7. Green Coffee Bean Green Coffee Bean material inspection report: ZBJC2020050910, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Green Coffee Bean material inspection report: RT101279DAT00369 DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 8. Rosemary Rosemary material inspection report: ZBJC2020050904, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Rosemary material inspection report: RT101279DAT0037, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 9. Rubus leaf Rubus leaf material inspection report: ZBJC2020050902, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Rubus leaf material inspection report: RT101279DAT00378, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 10. NHDC NHDC material inspection report: ZBJC2020050912, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo NHDC material inspection report: RT101279DAT00381, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 11. Gingko Gingko material inspection report: ZBJC2020050905, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Gingko material inspection report: RT101279DAT00379, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 12. Rhodiola Rhodiola material inspection report: ：ZBJC2020050903, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Gingko material inspection report: RT101279DAT00380, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 13. Epimedium Epimedium material inspection report: ：ZBJC2020050913, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Epimedium material inspection report: RT101279DAT00374, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 14. Kelp Kelp material inspection report: ：ZBJC2020050914, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Kelp material inspection report: ZBJC20200509144, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT 15. Mango Leaf Mango Leaf material inspection report: ：ZBJC2020050909, aflatoxin, heavy metal lead, cadmium, pesticide residue chlordane, lindane, etc. were not detected. Testing agency: Guangzhou Zhebo Kelp material inspection report: RT101279DAT00373, DDT, aldrin, heptachlor, dieldrin, heptachlor epoxy, etc. were not detected. Testing agency: Guilin RIT

	Raw material identification was conducted and plant identification records were checked during audit , e.g. Monk Fruit o identification certificate - Layn 20170140-01, October 14, 2017 Mango Leaf Identification Certificate MGY-190803-01, May 18, 2020 Stevia identification certificate TYJ-190804-01, May 27, 2020. Identification agency: Guangxi Institute of Botany ***But one minor CAR was rasied:*** ***Identity was not defined in the specification of Monk fruit 50% extract . Although this organization provided the species identification report of the raw materials of Monk fruit and identification testing result of the type test report RT101172FAT00612 was passed.***	
	c) in-process production 中间过程产品	Conformance **Yes**
	In-process production specification was documented in production instruction of related production process. E.g. according to production instruction L20200518-01 of resin chromatography process of Monk fruit extract, PH extract liquid after passing H01 resin chromatography shall be controlled ≤5.5. onsite audit checked that this PH was tested by operators and reviewed by QA.	
	d) specifications for dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements 膳食补充剂标签的标准(标签标准)，和接触膳食补充剂的包装标准(包装标准)	Conformance **Yes**
	Label approving procedure was established. Main intended use of plant extract is used as food additives or raw material of dietary supplement. Labels were designed by clients mainly. QA is responsible for approve the label and checking it in the processing. Main primary packaging material is food grade PE bag of aluminum-plastic compound bag. Related specifications were established: PF06(QS/NB)001 for PE bag PF06(QS/WB)002 for aluminum-plastic compound bag This organization provided the food grade testing report WZJ2019-Q-0342 for PE bag and W01907100658 for aluminium-plastic compound bag to prove that the two packaging material met the limit of food grade and is safe for finished product, including odour, migration ,heavy metal and so on.	
	e) product specifications for each dietary supplement 每种膳食补充剂的产品标准	Conformance **No**
	Product specifications was established for each finished product, according to national standards M-T2-2004 Green industry standard of medicinal plants and preparations for foreign trade, and the requirements of importing countries such as the United States and the European Union Solvent residue limit is established according to Chinese Pharmacopoeia, USP and , customer requirements. For example: The quality standard of 50% Monk fruit extract is PF06-(QS/CP)017-42, established according to GB2762, GB1886.7, WM-T2-02004 and the requirements of importing countries such as the United States and the European Union, including physical, chemical and microbiological indicators. Stevia extract（RA97%） specification PF06-(QS/CP)017-42, in accordance with GB2762, GB2870, WM-T2-02004 and the requirements of importing countries such as the United States and the European Union, including physical, chemical and microbiological indicators. Other products as following : Citrus extract specification PF06-(QS/CP)131-01,	

	Rhodiola extract specification PF06-(QS/CP)011-35 NHDC extract PF06-(QS/CP)113-02 Green coffee bean extract specification PF06-(QS/CP)120-06 Epimedium extract specification PF06-(QS/CP)137-02 Rosemary extract specification PF06-(QS/CP)154-01 Quality standard of specification PF06-(QS/CP)124-01 sweet tea extract specification PF06-(QS/CP)044-10 Mango Leaf Extract specification PF06-(QS/CP)138-01 specification of kelp extract PF06-(QS/CP)139-01 specification of green tea extract PF06-(QS/CP)125-07 specification of grape seed extract PF06-(QS/CP)021-30 Following full compliance testing records according to product specification was reviewed during audit which was tested by internal lab -RIT testing lab, a ISO17025 certified lab. Samples as following : Monk fruit extract specification PF06(QS/CP)028-41, full testing report RT100322DAT00063-1 and RT100322DAT00063-2 for content, moisture, heavy metals, solvent residues, microorganisms and and so on Stevia extract（RA97%） specification PF06-(QS/CP)017-42, full testing report RT101172FAT00612 for content, moisture, heavy metals, solvent residues, microorganisms and so on, 30 pesticides not detected sweet tea extract specification PF06-(QS/CP)044-10, full testing report RT100348DAT00098, for content, moisture, heavy metals, solvent residues, microorganisms and so on, 30 pesticides not detected in report YL20200643 Mango leaf extract specification PF06-(QS/CP)138-01, 59 residual solvent (USP467) and 71 pesticides reside(USP561) testing report AR-20-SU-034971-01-E(tested by eurofins)； type testing report RT100318DAT00044 for content, moisture, heavy metals, solvent residues, microorganisms and so on Grape seed extract specification PF06-(QS/CP)021-30, type testing report RT10185DAT00458 for content, moisture, heavy metals, solvent residues, microorganisms and so on Citrus specification PF06-(QS/CP)131-01, type testing report RT103908DAT00919 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200419 , 30 pesticides not detected Green test extract PF06-(QS/CP)125-07, type testing report RT10160DAT000420 for content, moisture, heavy metals, microorganisms and so on; pesticides residue testing report YL20200191 , 30 pesticides not detected Green coffee bean extract specification PF06-(QS/CP)120-06, type testing report RT101509DAT00406-1 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200191 , 30 pesticides not detected Ginkgo Biloba extract PF06-(QS/CP)180-02(USP), type testing report RS102500DAT00516 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200110 , 30 pesticides not detected Pomegranate extract specification PF06-(QS/CP)124-01, type testing report RT10094Ddat00021 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200401 , 30 pesticides not detected Epimedium extract specification PF06-(QS/CP)137-02, , type testing report RT1002227DAT00470-1 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200469 , 30 pesticides not detected Seaweed extract specification PF06-(QS/CP)139-01, type testing report RS10089DAT00220 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200457 , 30 pesticides not detected , NHDC specification PF06-(QS/CP)113-02, type testing report RS102500DAT00516 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200310 , 30 pesticides not detected ,

	Rhodiola Rosea specification PF06-(QS/CP)011-35, type testing report RS100521DAT00124 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200196, 30 pesticides not detected Rosemary extract specification PF06-(QS/CP)154-01, type testing report RS100532DAT00137 for content, moisture, heavy metals, solvent residues, microorganisms and so on; pesticides residue testing report YL20200125, 30 pesticides not detected According to the test plan, each batch of products must be tested for moisture, appearance, content, microorganisms. Identification, solvent residues, heavy metals shall be tested every 10 batches, and pathogenic bacteria shall be tested at least once a year. Product shelf life is 3 years. Product stability test report was reviewed during audit : Mogroside 50% stability test report LAYN(WD)040-B0, including accelerated test (40±2℃, 75±5% humidity), and product stability test (25±2℃, 60±10% humidity) , The final conclusion is stable within 3 years Steviol glycoside RA95% (SRE09) report LAYN(WD)050-B0, including accelerated test (40±2℃, 75±5% humidity), and product stability test (25±2℃, 60±10% humidity) , The final conclusion is stable within 3 years ***But one minor CAR were raised:*** ***Identity was not defined in the specification of Monk fruit 50% extract . Although this organization provided the species identification report of the raw materials of Monk fruit and identification testing result of the type test report RT101172FAT00612 was passed.***	
	f) Specification for a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) 仅进行包装和贴签来自供应商的膳食补充剂 (并进行分销而不是退回给供应企业) 的标准	Conformance **Not Applicable**
	No such operation up to now. All the products were produced by this organization .	
	g) specifications for the packaging and labeling of the finished packaged and labeled dietary supplements 膳食补充剂成品的包装与贴签作业标准	Conformance **Yes**
	Packaging and labelling operation standard PF04-002 was established, which covered the packaging and labelling operation specifications. Finished product monitoring and management procedure PF13-001was in place , which also covered the packaging control requirements.	
111.73	Facility's responsibility for determining whether established specifications under 117.70 are met 确定制定的标准是否已经满足的系统	Conformance **Yes**
	Control procedure PF34 was in place, including keeping samples of raw materials and finished products, sampling methods, test items and test frequencies, including test items and test frequencies for raw materials, packaging materials, semi-finished products and finished products.	
111.75	Requirements for determining whether specifications are met 判定标准是否得到满足的操作	Conformance **Yes**
	The organization has established holding and release procedures PF16, which clearly stipulates the release requirements for raw materials, packaging materials, finished products and semi-finished products. The quality department is responsible for the holding and release of materials and products. Establish material purchasing and supplier management procedures PF20. The raw materials are divided into A and B grades. Monk fruit and stevia are grade A raw materials, other materials are classified into grades B and C, and food contact materials are grade A materials. All raw material suppliers must be approved before purchasing.	

cGMP 审核报告

	Provide the 2020 qualified supplier list, updated on December 27, 2019. Including raw materials, auxiliary materials and chemicals. Sampling of supplier qualifications, type inspection reports, supplier evaluation records in 2019 (quality, warehouse, procurement and production evaluation), A grade l raw materials need to be audited on site. Monk fruit supplier: Longsheng Surabaya, on-site audit date August 27, 2019. Stevia supplier: Linze Minsheng, Gansu, on-site audit date October 10, 2019 Edible alcohol suppliers: Guangxi Mashan, Guangxi Baichen PE inner bag, supplier: Suzhou Qingyi Plastic PE barrel (for semi-finished product packaging), supplier: Foshan Nanhai	
111.77	Requirements if established specifications are not met 不符合标准时的需采取的措施	Conformance **Yes**
	Non-conforming product management program PF08 was established and the handling of nonconforming products must be reviewed by the quality department and finally approved by the general manager. The company has established product hold and release procedure PF16. Raw materials, semi-finished products and finished products can not be released if not meet related control requirements.	
111.80	Requirements for representative samples that must be collected 代表性样品的取样要求	Conformance **Yes**
	Sampling procedure for raw material and finished products PF34 was established, covering sampling of raw material, packaging material and finished products. Raw material shall be sampled according to quantity. Finished product shall be sampled according to different production periods ,including production start , middle and production end.	
111.83	Requirements for reserve samples 产品留样要求	Conformance **Yes**
	Each batch of finished products was sampled. Establish the control program PF34 for keeping samples of raw materials and finished products. The number of samples for each batch of finished products is twice the total inspection volume, and each batch number is sampled for 2 bags of 50g/bag. The packaging method is the same as that of the finished product. The retention period is one year after the shelf life. The finished product samples were placed in the finished product warehouse. Onsite audit observed that the retained samples were kept in PE bags and aluminum foil bags, with the batch number and product name indicated, and they were in good condition.	
111.87	Identifying who conducts a material review and makes a disposition decision 谁来对物料进行审核并作出处理决定	Conformance **Yes**
	The company has established product hold and release procedure PF16. Raw materials, semi-finished products and finished products can not be released if not meet related control requirements. All the action of holding or releasing must be approved by quality department.	
111.90	Requirements that apply to treatments, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification is not met 在处理、中间过程调整，以及返工中出现的偏差或未预期事件，或不符合所制定的标准时的处理要求	Conformance **Select**
	Non-conforming product management program PF08 was established and the handling of nonconforming products must be reviewed by the quality department and finally approved by the general manager. The company has established product hold and release procedure PF16. Raw materials, semi-finished products and finished products can not be released if not meet related control requirements. Non-conforming handling record sampled as following:	

	2002005001, the colour of the cable tie is deviated, and the batch were rejected by quality 201908001, the moisture of raw mango leaves exceeds the standard, and the raw materials are rejected by quality 201907001, the raw bitter orange was wet during transportation, and the moisture and other indicators were tested after the final drying, and used in production after evaluation. The above handling were all approved by the quality manager.	
111.95	Records requirements under subpart E E 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart E was established. Detailed please refer to 111.60-111.90.	
Subpart F	**Production and Process Control System: Requirements for Quality Control** **生产和过程控制系统: 质量控制要求**	
111.103	Requirements under this subpart F for written procedures F 子部分的书面程序要求	Conformance **Yes**
	Organization chart is clearly documented in the quality manual LAYN-MM. Quality department is responsible for quality control during processing. As an independent department, the quality control department is independent from the production department and reports directly to the director of the plant extraction division (the company's executive vice president).	
111.105	Responsibilities of quality control personnel 质量控制人员的职责	Conformance **Yes**
	Responsibilities of Quality Control Department PF03-(GW-ZG)001 1. Responsible for the formulation of control standards, inspection procedures, sample retention and sampling system 2. Process approval 3. Process monitoring 4. Holding or releasing of raw materials, intermediate products, and final product release 5. Quality accident investigation 6. Changing approval (Change management procedure PF17 is in place)	
111.110	Quality control operations required for laboratory operations associated with the production and process control system 与生产与过程控制系统的相关实验室操作的质量控制	Conformance **Yes**
	Quality department has established processes and procedures for laboratory operations including sample handling, results reporting, release/rejection procedures and deviation investigations. Related procedures include Quality procedure RID-GLCX01-RID-GLCX45, Lab Work instruction GLCX-(SMP)001 and Non-conformance control procedure RID-GLCX09 Quality department is responsible to review and approve test methods and results from internal laboratories Quality department releases or rejects product according to compliance to established specification .	
111.113	Quality control operations required for a material review and disposition decision 物料处置决定需要什么样的质量控制	Conformance **Yes**
	Non-conforming product management program PF08 was established and the handling of nonconforming products must be reviewed by the quality department and finally approved by the general manager. The company has established product hold and release procedure PF16. Raw materials, semi-finished products and finished products can not be released if not meet related control requirements.	

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111.117	Quality control operations required for equipment, instruments, and controls 对设备、仪器和控制需要什么质量控制操作	Conformance **Yes**
	According to Quality procedure RID-GLCX01-RID-GLCX45, quality department is responsible for s reviewing and approving all processes and/or procedures for calibrating equipment, instruments, and controls; including the periodical review of calibration records, etc.	
111.120	Quality control operations required for components, packaging, and labels before use in the manufacture of a dietary supplement 用于生产膳食补充剂的组分、包装与贴签在使用前的质量控制	Conformance **Yes**
	The company has established product hold and release procedure PF16. Raw materials, semi-finished products and finished products can not be released if not meet related control requirements.	
111.123	Quality control operations required for the master manufacturing record, the batch production record, and manufacturing operations 对于主生产记录、批生产记录与生产操作的质量控制操作	Conformance **Yes**
	Quality department is responsible for reviewing and approving all master manufacturing records , batch production record and any changes. Quality department is responsible for l reviewing and approving all completed batch records prior to product use . Onsite audit checked production process control work order (master manufacturing records)： L20200518-01 resin chromatography process of Monk fruit extract,T20200604-01 drying process of Monk fruit extract, T20200601-01 Centrifugal equipment process of Stevia Leaf Extract. All these production process control work orders were approved by QA manager. Batch production record checked as following: 50% Monk Fruit ,batch MOV04-19080501, batch record were reviewed by checked by QA manager Stevia Leaf Extract,：RA80,steviol glycosides95%， batch 190910-01, batch record were reviewed by checked by QA manager.	
111.127	Quality control operations required for packaging and labeling operations 包装与贴签操作的质量控制操作	Conformance **Yes**
	Finished product monitoring procedure PF-13-001 was established, including quality control operations required for packaging and labeling operations.	
111.130	Quality control operations required for returned dietary supplements 退回的膳食补充剂的质量控制操作	Conformance **Yes**
	Returned product handling procedure PF08-22 is in place. All returned product must be hold in the designated locations. Quality department is responsible for approving final disposition decisions relating to returns (salvage, redistribution, reprocessing and so on.). No returned product in recent years.	
111.135	Quality control operations required for product complaints 产品投诉的质量控制操作	Conformance **Yes**
	Written procedure -complaint handling procedure PF18 is in place. Sales is responsible for receiving the complaints and quality department is responsible for handling it , including root cause analysis and approving related correction and corrective acitons Sample: Complaint handling record: Stevia product ,complaint date 20190321 Complaints report including name and description of the dietary supplement batch No. complaint date, nature of the complaint, root cause analysis and corrective actions ,reply for this complaint.	
111．140	Records requirements under subpart E F 子部分要求建立和保持的记录	Conformance **Yes**

	Records requirements under subpart E were established, including responsibilities of Quality Control Department, quality control procedures, nonconformance and deviation handling procedures ,etc. Details refer to 111.103-111.135.	
Subpart G	**Production and Process Control System: Requirements for Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling as a Dietary Supplement 生产与过程控制系统: 对组分、包装与标签以及你所接收的产品以待包装与贴签成膳食补充剂的要求**	
111.153	Requirements under this subpart G for written procedures G 子部分的书面程序要求	Conformance **Yes**
	Witten procedure required in subpart G was established.	
111.155	Requirements that apply to components of dietary supplements 对膳食补充剂组分的要求	Conformance **Yes**
	The company has established product hold and release procedure PF16. Raw materials, semi-finished products and finished products can not be released if not meet related control requirements. Following material checking record was reviewed during audit. They were all inspected and approved by quality department before releasing to production: According to the raw material testing plan, content and moisture are mandatory items. Heavy metals shall be tested every 5 batches, and pesticide residues shall be tested every year. Stevia batch number TYJ-181211-04, supplier: Linze Minsheng, inspection items include content, moisture, and qualified. The delivery vehicle was checked for sanitation. Monk Fruit number AC20190102-01/30, supplier: Yongfu, inspection items include content, heavy metals, pesticide residues, and pass the test. The delivery vehicle was checked for sanitation. The batch number of sweet tea raw materials: TIC-191003-01, supplier: Yongfu Yongan, the inspection items include sweet tea glycosides, heavy metals, pesticide residues, and passed the test. The delivery vehicle was checked for sanitation. Calcium oxide batch number Y190524-01, supplier: Guilin Red Star, supplier batch number: 20190520, inspection items include content, heavy metals, etc., vehicle hygiene inspection is qualified, supplier COA is provided Ferrous sulfate Y190217-01, supplier: Jiangsu Kelunduo, supplier batch number: 18120601, vehicle sanitation inspection is qualified, and supplier COA is provided. 95% alcohol, batch number Y190415-01, (3529) Supplier: Mashan, Guangxi, the incoming inspection items include heavy metals, methanol and ethanol content, the vehicle hygiene inspection is qualified, and the supplier COA is provided. Onsite audit observed all the raw materials stored in the warehouse were identified with product name, lot number and delivery date to keep traceability.	
111.160	Requirements applying to packaging and labels received 包装与标签的要求	Conformance **Yes**
	The company has established product hold and release procedure PF16. Raw materials, semi-finished products and finished products can not be released if not meet related control requirements. Following packaging material checking record was reviewed during audit. They were all inspected and approved by quality department before releasing to production: PE primary packaging bag batch number: 20190528, supplier: Suzhou Qingyi, supplier batch number: 190503-31, inspection items include appearance and microorganisms, including supplier COA	

	PE primary packaging batch number: 200102-06, supplier: Suzhou Qingyi, supplier batch number: 200102-6, inspection items include appearance and microorganisms, including supplier COA Onsite audit observed all the primary packaging materials stored in the warehouse were identified with product name, lot number and delivery date to keep traceability.	
111.165	Requirements applying to a product received for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) 对于接收后待包装或标签的膳食补充剂(用于分销而不是退回给供应企业)	Conformance **Not Applicable**
	All the products are manufactured by this organization itself. No such operation were conducted up to now in this site.	
111.170	Requirements applying to rejected components, packaging, and labels, and to rejected products that are received for packaging or labeling as a dietary supplement 对于拒绝的组分、包装与标签，和拒绝收到的产品待用于包装或贴签的要求	Conformance **Yes**
	The company has established product hold and release procedure PF16. Raw materials and packaging materials can not be released if not meet related control requirements. Non-conforming handling record sampled as following: 2002005001, the color of the cable tie is deviated, and the batch were rejected by quality 201908001, the moisture of raw mango leaves exceeds the standard, and the raw materials are rejected by quality 201907001, the raw bitter orange was wet during transportation, and the moisture and other indicators were tested after the final drying, and used in production after evaluation. The above handling were all approved by the quality manager.	
117.180	Records requirements under subpart G G 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart G was established. Details refer to 11.155-117.170.	
Subpart H	**Production and Process Control System: Requirements for the Master Manufacturing Record 生产和过程控制系统: 主制造记录要求**	
111.205	Requirement to establish a master manufacturing record 建立主生产记录的要求	Conformance **No**
	Word order (production process control work order) are established for processes of each products. ***One minor CAR was raised:*** ***Current version of RO system operation manual PF05-(GC-CS)001 was B2. But onsite audit found that RO system operation manual PF05-(GC-CS)001 used in first level RO water treatment system was version B1.***	
111.210	Requirements for master manufacturing record 主生产记录的内容要求	Conformance **No**
	Word orders(production process control work order) are established for processes of each products. Onsite audit checked production process control work order (master manufacturing records)： L20200518-01 resin chromatography process of Monk fruit extract,T20200604-01 drying process of Monk fruit extract, T20200601-01 Centrifugal equipment process of Stevia Leaf Extract. These work orders included following requirements: • Semi-finish product or product name • Process control parameters for the process steps in the manufacturing process ,e.g. speed, temperature , time, etc • Sampling procedures	

	• Specific actions to perform and verify control steps, e.g. PH, moisture testing after the process • Signature of operator, reviewer and approver ***But one minor CAR was raised:*** ***It is defined that expected minimum yield in finished product filling step shall be more or equal to 98.5% in finished product monitoring procedure PF 13-01, but the maximum yield is not defined.***	
Subpart I	**Production and Process Control System: Requirements for the Batch Production Record** **生产和过程控制系统: 对批生产记录要求**	
111.255	Requirement to establish a batch production record 建立批生产记录的要求	Conformance **Yes**
	Batch Production Records are available per Subpart P for each batch products which are manufactured in this site. QA is responsible for reviewing and approving the batch production record before product releasing.	
111.260	Requirements for batch record 批记录的内容要求	Conformance **Yes**
	Batch Production Records are available per Subpart P for each batch products which are manufactured in this site. • Batch production Records include: • Batch number or lot number, production date • Product equipment and processing line • Record of cleaning and sanitizing • Lot number of raw material and packaging material • Weighing record • Testing or examination result during processing • Time of performance records • Yield calculation • Filling ,packaging and labelling records • Finished product inspection record • Signature (operator name) • QA is responsible for reviewing and approving the batch production record before product releasing. Following batch records were checked during audit : Monk Fruit extract 50%, batch number MOV04-19080501, 420Kg. • Extraction: 20190216, using Luo Han Guo batch number AC20190102-01/30 • H21 resin chromatography: 20190217-18, • H01 resin chromatography, 201900219-2- • H18 resin chromatography: February 20-21, 2019, flow rate 2000L/h (standard 20-3T/h), • Sterilization: temperature 95℃, time 5:08-7:08, (standard sterilization temperature ≥80℃, time ≥30 minutes) • Drying: inlet air temperature is 190℃, outlet wind is 78° C (control standard inlet wind 170-200° C, outlet wind 70-95° C), moisture content ≤5%. • Semi-finished product batch number L190216-T2, February 22, 2019 • Semi-finished product test report: BCP20190030, the content of Mogroside V is 50.39. • Packing: 20190805, use semi-finished product batch number L190216-T2, stir for 30 minutes, pass through 80 mesh screen, check the screen before and after production OK. • CCP metal detection, using Fe 1.5mm, SUS 2.5mm, Non-Fe2.5mm test piece, start and end the test pass. • The batch number of the PE inner bag is 20190528, and the material balance rate is 99.87%.	

- Provide pre-production inspection and post-production cleaning records, including equipment, tools, wall and floor cleaning
- Finished product testing includes appearance, identification, moisture content ≤5%, ash content ≤2%, ethanol content ≤53000ppm, methanol content ≤200ppm, heavy metal arsenic ≤1ppm, lead ≤1pp, mercury ≤0.1ppm, cadmium ≤0.3ppm, pathogenic bacteria Salmonella , Staphylococcus aureus and Escherichia coli not detected and other tests all passed ,including identity pass, the moisture content is 3.3%, and the methanol and ethanol residue testing result is OK.
- QA supervisor was responsible for the release of finished product by OA system, according to batch records, inspection results, deviation handling, non-conforming and out-of-conformance investigation (OOS investigation),

Stevia Extract : RA80, 95% total glycosides, batch number 190910-01, 1034.20Kg

- The finished product standard is based on the requirements of client Cargill, including total glycosides ≥95%, moisture ≤6%, PH4.5-7.0, ethanol content ≤5000ppm, methanol content ≤200ppm, heavy metals arsenic, lead, mercury ≤1ppm, pathogenic bacteria Salmonella, large intestine The detection of bacilli varies. The QA supervisor is responsible for the release of finished product by OA system, according to batch records, inspection results, deviation handling, non-conforming and out-of-conformance investigation (OOS investigation), inspection of the production environment and production water consumption.
- Packaging: September 10, 2019
- Use semi-finished product batch numbers XA1908340, XA1908350, mix for 30 minutes, the final yield is 99.99%. Pass the 50-mesh screen, check the screen before and after production OK.
- CCP metal detection, using Fe 1.5mm, SUS 2.0mm, Non-Fe2.0mm test piece, start and end the test pass.
- Provide pre-production inspection and post-production cleaning records, including equipment, tools, wall and floor cleaning
- Primary bag batch number 20190809s
- Semi-finished product batch number XA1908340, provide semi-finished product inspection report: RA (Rebaudioside A 81.60%, total glycosides 97.79% (steviol glycosides)
- Extraction: 20190602, using stevia lot number TYJ-181211-04
- Flocculation: 20190602, batch number TA190602, using calcium oxide batch number Y190524-01, ferrous sulfate 18120601
- H18 resin chromatography: TA190602-01, 20190604, flow rate 5/h (standard 5-6T/h),
- Batch number of concentrated extract: TA190602-01, date 20190604-05
- Decolorization and drying: batch number TA190602-X01, date 20190604,
- Crystallization: use crystal batch number CA190801-Y18, crystal 20190807, use 95% alcohol, batch number Y190415-01
- Sterilization: temperature 80.6-80.7℃, time 12:55-13:25, (standard sterilization temperature ≥80℃, time ≥30 minutes)
- Drying: The inlet air temperature is 152° C, the outlet air temperature is 76.3° C (control standard inlet air 150-170° C, outlet air 70-95° C), moisture content ≤5%.

Sweet tea extract, batch number STL06-20052801, 1001.54Kg

- Finished product standards, including identification, Rubusoside ≥70%, moisture ≤5%, ash content ≤5%, ethanol content ≤53000ppm, methanol content ≤200ppm, heavy metal arsenic ≤1ppm, lead ≤1pp, mercury ≤0.3ppm, pathogenic bacteria Salmonella, Staphylococcus aureus and Escherichia coli NOT detected
- QA supervisor was responsible for the release of finished product by OA system, according to batch records, inspection results, deviation handling, non-conforming and out-of-conformance investigation (OOS investigation),
- Packaging: May 28, 2019

	• Use semi-finished product batch numbers TICP2005002, TICP2005003, mix for 60 minutes, and the final yield is 99.94%. • Go through an 80 mesh screen. After sieving, it is packaged after passing through a magnet sieve, and there is no foreign matter on the magnet. Weigh each bag and check the screen before and after production. • Use PE inner bag lot number 200102-06 • CCP metal detection, using Fe 1.5mm, SUS 2.0mm, Non-Fe2.0mm test piece, start and end the test pass. • Provide pre-production inspection and post-production clearance records, including equipment, tools, wall and floor cleaning • Semi-finished product batch number TICP2005002, • Sterilization: 20200522, temperature 80.6-80.7° C, time 11:37-11:57, (standard sterilization temperature ≥80° C, time ≥30 minutes) • Drying: 20200522, inlet air temperature 185° C, outlet air 95° C (control standard inlet air 175-200° C, outlet air 90-100° C), moisture content ≤5%. • Extraction: TIC-Q2005002,20200514, • Crushing: 20200514, raw material batch number TIC-191003-01 Following finished product inspection were all checked during audit : • 60% Mango leaf powder/Batch MF01-190101301, 20191013; • Pomegranate extract 40%/Batch PHE02-20031501,20200315 • Rosemary extract 10% Rosmarinic acid/Batch RME12-20011801, 20200118 • Grape seed extract proanthocyanidins 95%/Batch GSE01-2002701, 20200227 • Cistus extract /batch CBE54-2003501, 20200305 • Green tea extract/batch GTE04-19111201, 20191112(extracted by water, no residual solvent) • Green coffee bean extract total chlorogenic acids 50%/batch COF06-19111501, 20191115 • Ginkgo Biloba extract USP40/batch GBE17-20031001,20200310 • Epimedium extract 60% icarlin/batch EGE11-20022201, 20200222 • Seaweed extract 80% fucoidan/batch KEL14-20031601,20200316 • Neohesperidin dihydrochacone NHDC96/batch NHDC-20021401,20200414 • Rhodiola Rosea extract RHO12/batch RHO12-20011902, 20200119	
	Production and Process Control System: Requirements for Laboratory Operations **生产和过程控制系统: 实验室操作要求**	
111.303	Requirements under this subpart J for written procedures J 部分的书面程序要求	Conformance **Yes**
	Written procedure was established for management of laboratory operation, including : Quality manual RID-GLSC Quality procedure RID-GLCX01-RID-GLCX45 Work instruction GLCX-(SMP)001 Non-conformance control procedure RID-GLCX09 PF16 holding and release procedure (Quality department review and approve the testing result according)	
111.310	Requirements for the laboratory facilities use 使用的实验室设施要求	Conformance **Yes**
	Written procedure for management of laboratory operation was established ,please refer to 111.303. Internal lab- RID lab is a ISO17025 qualified lab. ISO17025 certificate No: CNAS L7609, effective to Apr.8,2024. Internal lab is used in raw material testing, processing control testing and finished products testing. Testing items include moisture, identity , content , heavy metal, solvent residue , pesticide residue and so on.	

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	External lab is also be used to verify compliance of raw material and finished products. All the external lab must be managed in accordance with ISO17025 and must be approved by quality department before using .	
111.315	Requirements for laboratory control processes 实验室控制过程要求	Conformance **Yes**
	Quality procedure RID-GLCX01-RID-GLCX45 was in place. Laboratory inspectors were trained and evaluated before working on the position. Sample: 20200311 training report for new inspector engineer Mr. Rong on Inorganic testing, 20200311 training report for new inspector engineer Mr. Rong on using of balance and Pipette All the training result must be evaluated by quality controller of lab. After training and evaluation ,Mr.Rong got the working qualification certificate which was approved by technical director.	
111.320	Requirements that apply to laboratory methods for testing and examination 实验室测试或检查方法要求	Conformance **Yes**
	Internal lab- RID lab is a ISO17025 qualified lab. ISO17025 certificate No: CNAS L7609, effective to Apr.8,2024. Lab testing methods was documented in CLCX(SOP/JYE) .Testing method is established according Chinese Pharmacopoeia, USP Pharmacopoeia, China national testing method , QA is responsible for determine the testing method Testing equipment was calibrated as planned. Calibration samples: GC RLDGL-YJY008 for pesticide testing, calibration report 205701002, effective to Jan. of 2022 HPLC RIDGL-YJE003 for purity testing , calibration report 1962010059, effective to Aug. of 2021 ICP-MS RIDGL-YJY002 for heavy metal testing , calibration report IGA19011444-0019A, effective to Aug. of 2020 Air oven 170384 for moisture testing, calibration report CZX-9240MBE, effective to Oct. of 2021 Microbial incubator RIDGL -WSW006 for salmonella testing , calibration report IGA19011444-0015, effective to Aug of 2020	
111.325	Records requirements under subpart J J 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart J was in place.	
Subpart K	**Production and Process Control System: Requirements for Manufacturing Operations** **生产和过程控制系统: 制造操作要求**	
111.353	Requirements under this subpart K for written procedures K 部分的书面程序要求	Conformance **Yes**
	Written procedures were established, please refer to detailed in below clauses.	
111.355	Design requirements for manufacturing operations 生产操作的设计要求	Conformance **Yes**
	Production requirement was documented in production work order which was prepare by technical department and approved by quality department .	
111.360	Requirements for sanitation 卫生要求	Conformance **Yes**
	Process cleaning requirements are documented in related operation manual, including clean inspection before production and cleaning after each production, covering equipment, tools, wall and floor cleaning Onsite audit observed that most manufacturing areas kept clean .	
111.365	Precautions to take to prevent contamination	Conformance

	防止污染的预防措施	**No**
	Cross contamination control procedure PF01(03) was established and well followed. Zoning: Drying area and filling area is D grade cleaning area. And the other areas are normal cleaning area. Process cleaning requirements are documented in related operation manual. .CIP and COP shall be conducted when product changing or at least once month for continuous production according to related cleaning plan in working instruction: CIP: RO water flush, 2.0% alkali liquor cleaning , RO water flushing and drying by hot air COP: RO water cleaning , 2.0% alkali liquor cleaning , RO water cleaning and disinfection by using 75% alcohol. Samples: CIP record on 20200505 and 20200505 for three-effect concentration in No.1 workshop according to PF05-(ZD1-SX)007 Three-effect concentration operation manual. PH testing result of final rinse water was 7. Cleaning record on 20200506, 20200508 by RO water and 2.0% alkali liquor for V301-3 centrifugal equipment in No.1 workshop according to PF05-(ZD1-TCM)004 centrifugal equipment Operation manual. PH testing result of final rinse water was 7. Production supervisor was responsible for monitoring the cleaning effectiveness. Production environment and cleanness was monitored according to monitoring procedure PF01(02)-011 each month. Samples as following: Suspended particles testing record HY20171704 Settling bacteria and planktonic bacteria testing record: HJY20204874,HJY20204879 EB swabbing testing record: HJY20204889 Pasteurizing was used in processing to control microbiological hazard: temperature ≥80℃ and time ≥30℃. Samples refer to batch record in this report. For control of foreign body, sieve , magnet bars(≥10000GS) and metal detector were used in packaging process. Magnet checking record on 20200430 Samples refer to batch record in this report. Allergen control procedure PF14 is place.12 allergens were controlled in this site, covering eight main allergens, e.g. egg, milk, peanut, soy, nut, seafood, gluten and crustaceans. Most recent allergen evaluation was conducted on 20200202. After evaluation , no allergen materials were used in this site currently. ***One minor CAR was raised:*** ***Only two testing pieces , Fe1.5mm and SUS 2.5mm, which was used to test metal detector was found in packaging area when onsite audit. As per requirement , 3 type testing pieces shall be used for testing of metal detector, Fe1.5mm, SUS 2.5mm and Non-Fe 2.5mm. Although the packaging process was not started at that time.***	
111.370	Requirements that apply to rejected dietary supplements 被拒膳食补充剂的控制要求	Conformance **Yes**
	Non-conforming product management program PF08 was established . All the rejected products must be isolated in the designated location with clear identification . Only quality department can determine how to handle the rejected products.	
111.375	Records requirements under subpart K K 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart K was established and implemented.	

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Subpart L	Production and Process Control System: Requirements for Packaging and Labeling Operations 生产和过程控制系统: 对包装与粘贴标签操作要求	
111.403	Requirements under this subpart L for written procedures L 部分的书面程序要求	Conformance **Yes**
	Written procedures were established: Labelling management PF04-002 was in place. Packaging operation SOP PF13-001 was in place.	
111.410	Requirements that apply to packaging and labels 对包装与贴签的要求	Conformance **Yes**
	Packaging processing work order will be issued for each packaging operation and requirement of packaging will be printed the work order, including packaging material, packaging method. QA is responsible for checking label before releasing , including product name, batch, SKU ,production date and so on.	
111.415	Requirements applying to filling, assembling, packaging, labeling, and related operations 对灌装、组装、包装、贴签和相关操作要求	Conformance **Yes**
	Packaging operation manual PF05-(BZ-BZ)001 is in place, including machine operation instruction and sanitary handling requirements. CIP and COP shall be conducted when product changing or at least once month for continuous production: CIP: RO water flush, 2.0% alkali liquor cleaning , RO water flushing and drying by hot air COP: RO water cleaning , 2.0% alkali liquor cleaning , RO water cleaning and disinfection by using 75% alcohol. Sample: Cleaning record of No.1 packaging line on 20200408 Cleaning record of No.3 packaging line on 20200412 Each packaged product was assigned a unique batch number and representative samples were taken according the sample procedure. Each batch finished products must be tested according to related product specification before releasing .	
111.420	Requirements that apply to repackaging and relabeling 对重新包装和重新贴标签的要求	Conformance **No**
	Minor CAR:This organization did not establish the requirement apply to repackaging and relabelling Although no repackaging and relabelling incidents happened in recent years.	
111.425	Requirements applying to a packaged and labeled dietary supplement that is rejected for distribution 对拒收的已包装的和贴签的膳食补充剂的要求	Conformance **Yes**
	Non-Conformance control procedure PF08 is in place。 All rejected dietary supplement shall be stored in designated location with red label. No rejected dietary supplements were found in this audit .	
111.430	Records requirements under subpart L L 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart L was established and implemented.	
Subpart M	**Holding and Distributing** **存储与分销**	
111.453	Requirements under this subpart L for written procedures K 部分的书面程序要求	Conformance **Yes**
	Warehouse management procedure PF 38 is in place.	

	Raw material warehouse, packaging material warehouse, chemical warehouse, semi-finished product& finished products warehouse are used in this site.	
111.455	Requirements that apply to holding components, dietary supplements, packaging, and labels 对于组分、膳食补充剂的储存、包装和贴签的要求	Conformance **Yes**
	Warehouse management procedure PF 38 is in place。 Raw material warehouse : humidity ≤75% Semi-finished product and finished product warehouse : temperature ≤30℃ and humidity ≤75%. Cooling warehouse for Semi-finished products : temperature -4℃- 10℃.. Onsite audit verified that raw material and finished product were stored in accordance with storage requirement and with clear label for identification .	
111.460	Requirements applying to holding in-process material 对过程物料的储存要求	Conformance **Yes**
	Warehouse management procedure PF 38 is in place。 Semi-finished product was stored in the finished product warehouse , controlled : temperature ≤ 30℃ and humidity ≤75%.	
111.465	Requirements applying to holding reserve samples of dietary supplements 对膳食补充剂留样的储存要求	Conformance **Yes**
	Establish the control program PF34 for keeping samples of raw materials and finished products. The packaging method of samples is the same as that of the finished product. The retention period is one year after the shelf life. The finished product samples were placed in the finished product warehouse. Onsite audit observed that the retained samples were kept in PE bags and aluminum foil bags, with the batch number and product name indicated, and they were in good condition.	
111.470	Requirements applying to distributing dietary supplement 膳食补充剂的分销要求	Conformance **Yes**
	In accordance with warehouse management procedure PF 38 , the final packaged and labelled product can not be distributed until the dietary supplement has been released by quality. Vehicle hygiene must be inspected before loading: Samples: 50% Monk Fruit, batch number MOV04-19080501, 420Kg. Distribution date: From September 12, 2019 to November 20, 2019, QA is responsible for monitoring at the time of shipment, including label, batch number inspection and vehicle sanitation inspection records. Provide QA shipment monitoring records. Stevia extract : RA80, 95% total glycosides, batch number 190910-01, 1034.20Kg Distribution date September 24, 2019, 1000Kg shipped, 1Kg sample, 33Kg inventory. QA is responsible for monitoring, including label, batch number, weight, inspection and vehicle sanitation inspection records. Provide QA shipment monitoring records.	
111.475	Records requirements under subpart M M 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart M was established, including warehouse management procedure , product storage and distribution records.	
Subpart N	**Returned Dietary Supplements** **退回的膳食补充剂**	
111.503	Requirements under this subpart N for written procedures N 部分的书面程序要求	Conformance **Yes**
	Non-Conformance control procedure PF08 is in place. Returned product handling procedure PF08-22 is in place.	

111.510	Requirements that apply when a returned dietary supplement is received 对退回的膳食补充剂的要求	Conformance **Yes**
	Returned product handling procedure PF08-22 is in place. According to the procedure, all returned product must be isolated with yellow label before final treatment.	
111.515	Requirements applying to returned dietary supplement to be destroyed, or otherwise suitably disposed of 必须销毁或者适当处理退回的膳食补充剂的要求	Conformance **Yes**
	Returned product handling procedure PF08-22 is in place. QA is responsible for determining the final handling method after evaluation and checking .All non-conformance dietary supplement must be hold with red label and handle according to Non-Conformance control procedure No dietary supplement returned in recent years.	
111.520	When may a returned dietary supplement be salvaged 什么时候可以回收操作退回的膳食补充剂?	Conformance **Yes**
	Returned product handling procedure PF08-22 is in place. According to the procedure, all returned product shall be isolated with yellow label and evaluated by QA. QA is responsible for determining the final handling method after evaluation and checking, including outer packaging checking , moisture, content, identification, microorganism and so on. All salvaged dietary supplement must be approved by QA. No dietary supplement returned in recent years.	
111.525	Requirements applying to a returned dietary supplement that quality control personnel approve for reprocessing 质量控制人员批准返工的退回的膳食补充剂的要求	Conformance **Yes**
	Returned product handling procedure PF08-22 is in place. According to the procedure, QA is responsible for approving or rejecting any reprocessed returned products. No dietary supplement returned in recent years.	
111.530	Requirements applying to when must an investigation be conducted of facility's manufacturing processes and other batches 什么时候必须进行调查生产工艺和其他批次的要求	Conformance **Yes**
	Returned product handling procedure PF08-22 is in place. If the reason for a return implicates other batches, an investigation must be performed to determine if those batches comply with specifications according to this procedure. No dietary supplement returned in recent years.	
111.535	Records requirements under subpart N N 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart N was established.	
Subpart O	**Product complaints 产品投诉**	
111.553	Requirements under this subpart O for written procedures O 部分的书面程序要求	Conformance **Yes**
	Written procedure -complaint handling procedure PF18 is in place.	
111.560	Requirements that apply to the review and investigation of a product complaint 产品投诉的审核和调查要求	Conformance **Yes**
	Written procedure -complaint handling procedure PF18 is in place. Sales is responsible for receiving the complaints and quality department is responsible for handling it . Sample:	

	Complaint handling record: Stevia product ,complaint date 20190321 Complaints report including name and description of the dietary supplement batch No. complaint date, nature of the complaint, root cause analysis and corrective actions ,reply for this complaint.	
111.570	Records requirements under subpart O O 子部分要求建立和保持的记录	Conformance **Yes**
	Records requirements under subpart O was established.	
Subpart P	**Records and Recordkeeping** **记录和记录保持**	
111.605	Requirements that apply to records 记录的建立和保持要求	Conformance **Yes**
	Document and record control procedure PF 02 is in place. Record shall be retained 5 year. Shelf life of products are 3 years.	
	All electronic records must comply with 21CFR part 11 of this chapter. 电子记录应符合 21 CFR Part 11 的要求	Conformance **Not Applicable**
	No electronic records were used in this site.	
111.605	Records must be made available to FDA FDA 要求必须获得的记录	Conformance **Yes**
	All the records were kept by related departments. Product shelf life is 3 years . All the related records in 5 years were available if required by regulatory authorities.	

☒ **Subpart B cGMP of 21 CFR part 117PREVENTIVE CONTROLS FOR HUMAN FOOD**

- **Provide a response for each requirement below . Where not applicable, this shall be indicated with justification. 每个栏目都需给出结论。当不适用时，应说明理由。**
- **For non-conformity, include identification of specific requirement which is not fulfilled 对不符合项，包括未被满足的特定要求的识别**
- **For conformity, include description of objective evidence(s) 对符合项，包括客观证据的描述**

117.10	**Personnel 人员**	
(a)	Disease control includes employees and visitors.疾病控制,包括员工和访问者	Conformance **Yes**
	Written procedure PF01(07) was in place , covering the management requirement of personnel health and Personnel hygiene facilities. New employee must get the health certificate before working in production area and Health screen was conducted once a year for general staff. Health certificate of Ms.Li Huaxiu, Mr. Guo Rongyou , Mr. QiN Guojun; Ms.Jiang Xueming; Ms.Mo Xiaozhen; Ms.Qin Guizhen in production and packaging workshops were checked during audit. . The health certificates proved that they all passed health screen.	
（b）	Methods of maintaining personal cleanliness 清洁卫生的维护	Conformance **Yes**
	Sufficient hand-washing facilities are provided at the entrance of workshops - Hand washing station provided at each processing workshops entrances; - liquid soap	

	- Disinfection is realized via 75% ethyl alcohol or quaternary ammonium disinfectant - Hand washing policy is defined and posted. Operator must change work cloth , cap and footwear before entering workshop. Food is only provided in canteen and outside production area and storage area. Designated smoking room located outside the production area and storage area, GMP training and refresh training was conducted at least once a year .The most recent GMP training was conducted on 20191220 Onsite audit observed that hygiene practices were well followed: operators wore cleaning protective clothing in production and packaging area. No watch, jewellery, rings are worn by the employees and managements. Personnel hygiene is is checked and monitored by the appointed employee before into the workshop.	
117.20	**Plant and Ground 厂房和地面**	
（a）	Grounds 地面	Conformance **No**
	On site verification, the fabrication of grounds is suitable for the intended purpose. Grounds of workshop and warehouse are materials which can be easily cleaned and drained and are regularly maintained. ***But one minor CAR was raised in this audit :*** ***Onsite audit found that floor of cool warehouse in the workshop was damaged seriously and standing water was also found in this floor.***	
（b）	Plant construction and design 厂房结构和设计	Conformance **Yes**
	On site verification, the construction of the buildings and facilities such as the wall and floor are suitable for the intended purpose. Walls, floors, drainages, doors, ceiling and overheads are regularly maintained. . In the workshop verification, floors are designed to meet the requirement of the process. And drainage is designed and maintained to minimise risk of product contamination. No stagnant water is observed. Existing glass windows fitted with shatter checking regularly. The lights for lighting in the workshop and warehouse have been well protected and the light is adequate in most processing area. Exhaust fans are in place and routinely checked. Map of drains shows the direction of flow and location of any equipment fitted to prevent the back-up of waste water. The flow of drains not raised a risk of contamination. Drying and packaging workshop was designed as D clean grade workshop to reduce cross-contamination.	
117.35	**Sanitary Operations 卫生操作**	
（a）	General maintenance: 整体维护 Buildings, fixtures, and other physical facilities of the plant maintained in a clean and sanitary condition and kept in adequate repair; cleaning and sanitizing of utensils and equipment is conducted properly 必须对建筑物，固定装置以及其他实体设施进行维护，保持清洁和卫生，并进行充分的修缮。工器具和设备的清洁和消毒应充分和恰当	Conformance **Yes**
	Physical plant facilities management procedure PF05 was in place , which includes facilities checking and maintenance requirements. Onsite audit verified that production facilities was maintained in a clean and sanitary condition and in a proper state of repair.	

（b）	Substances used in cleaning and sanitizing; storage of toxic materials 用于清洗和消毒的物质；有毒有害化合物的存放	Conformance **No**
	Chemical management procedures PF01(06) was in place , which included the requirements for the procurement, labeling, storage and use of chemicals. Chemical cleaning agents, disinfectants and lubricants used on site by the company. The company uses food-grade cleaning agents, disinfectants, and food-grade lubricants. Samples: Alcohol for disinfection: supplier -Guangxi Haiying, providing food-grade alcohol production license, type test report S2020-0239, testing passed according to GB31640-2016 edible alcohol standard Sodium hydroxide, Supplier -Xinjiang Zhongtai, providing food additive production license, type test report 2020X-J-NHG03042, according to GB1886.20-2016 food additive sodium hydroxide test qualified. ***But one minor CAR was raised in this audit:*** ***Onsite audit found that one drum chemical which was stored in chemical warehouse in packaging area had no any identification.*** ***Onsite audit found scale inhibitor used in RO water treating process had no identification***.	
（c）	Pest Control 虫害控制	Conformance **No**
	Pest control procedure PF01(06) was in place. The pest control was outsourced to Xinjiali , a professional pest control company. Pest control plan was established for target pest rat, fly. Pest control facility used on this site included rat station, fly-killing lamp, rat trap, rat glue. Pesticides is only used outside the workshop ,not permitted inside the workshop. Pesticide were carried by pest companies and not permitted to store in the factory. Onsite audit checked the trend analysis records for the second quarter of 2020, and the analysis result proved that the pest activities were under control . ***But one minor CAR was raised in this audit:*** ***Several small broken holes were found screen of one external window in the discharge area of the stevia centrifuge equipment***	
（d）	Sanitation of food-contact surfaces 食品接触面卫生	Conformance **Yes**
	Process cleaning requirements are documented in related operation manual, including clean inspection before production and cleaning after each production, covering food contact surface cleaning , including equipment and tools, Onsite audit observed that most manufacturing areas kept clean .	
（e）	Sanitation of non-food-contact surfaces 非食品接触面卫生	Conformance **Yes**
	Process cleaning requirements are documented in related operation manual , including clean inspection before production and cleaning after each production, covering non- food contact surface cleaning , including wall , floor, ceiling and so on. Onsite audit observed that most manufacturing areas kept clean .	
（f）	Storage and handling of cleaned portable equipment and utensils 已清洁的可移动设备和工器具的保存和处理	Conformance **Yes**
	Cleaned portable equipment with food contact and utensils was stored in designated cabinet with clean identification , including cleaning date and effective date.	
117.37	**Sanitary facilities and controls 卫生设施和控制**	
（a）	Water supply 供水	Conformance

		Yes
	The company establishes water safety management procedures PF(01)(01). The company uses municipal water supply as raw water, which meets the requirements of Drinking water standard GB5749, and is used for production after reverse osmosis. The first-level RO water is used in extraction, resin chromatography, cleaning and disinfection, and the second-level RO water is used for the cleaning and disinfection of the D-level area. A water quality monitoring plan was established. Internal laboratory samples will be taken to test the conductivity and microorganisms at the primary and secondary water outlets monthly. Each workshop will be tested for microorganisms on a monthly basis and third-party laboratory testing will be conducted annually. Samples as following: Third-party inspection report: 4508009200014, tested according to National Drinking Water Standard GB5749, Testing agency: Nanning Customs Technology Center, a ISO17025 certified lab, CNASL0254. Test report of internal laboratory (Rid Testing), a ISO17025 certified lab. Second-level RO water test report HJY20202987/May 2020, HJY2020057/April 2020, passed the test First -level RO water test report HJY20204891/June 2020, HJY20202983/May 2020, passed the test.	
（b）	Plumbing 输水设施	Conformance **Yes**
	The water distribution plan is established in place. Stainless pipes are used for distribution of purified water. No cross-contamination risk for potable water and disable water	
（c）	Sewerage disposal 污水处理	Conformance **Yes**
	Waste water treatment station run in this site. All the waste water is collected in this treatment station and must be treated according to local environment protection regulation before discharging.	
（d）	Toilet facilities 卫生间设施	Conformance **Yes**
	Onsite audit observed that men and woman bathrooms are adequately segregated and do not open directly into production and storage. All the bathroom kept clean, no odour. . Enough hand washing facilities with soft soap, hand dryer and disinfection provided.	
（e）	Hand-washing facilities 洗手设施	Conformance **Yes**
	Hand washing facilities is provided in each entrance of clean area, - hand free taps - liquid soap - Disinfection is realized via 75% ethyl alcohol or quaternary ammonium disinfectant - Hand washing policy is defined and posted.	
（f）	Rubbish and offal disposal 垃圾及废料处理	Conformance **Yes**
	Waste control procedure defined in environment control procedure is implemented. No food waste is supplied for animal feed. Waste is collected and removed by local official department. External waste collection containers are managed well to minimise risk. Unsafe products or substandard trademarked materials are handled should be destroyed by own staffs at first with control record and then confirm with contractor.	
117.40	**Equipment and utensils 设备和工器具**	
（a）	Equipment and utensils 设备和工器具	Conformance

		No
	Main equipment: crusher, extraction equipment, pressure column, centrifugal equipment, concentration, sterilization tank, spray drying equipment, filling equipment, etc. Equipment contact surfaces are made of stainless steel. Engineers aware of the requirement. Equipment have been specified before purchase, and tested and commissioned prior to use. Equipment is positioned normally to facilitate cleaning and service. Equipment is positioned to facilitate cleaning and service. After cleaning for equipment and utensils use out, these equipment and utensils are stored in a locked room, restricted access. ***One minor CAR was raised :*** ***Onsite audit in the packaging workshop found that stainless steel handles of the two knives are not sealed at the top and it is inconvenient to clean***.	
（b）	Seams on food-contact surfaces smoothly bonded or maintained 食品接触面的接缝应平滑地结合，并得到良好维护	Conformance **Yes**
	Seams on food-contact surfaces are smoothly bonded or maintained. No adverse findings were found in this audit .	
（c）	Equipment that is in areas where food is manufactured, processed, packed, or held and does not come into contact with food constructed that it can be kept in a clean and sanitary condition 在食品生产，加工和储存区域内，不与食品接触的设备的构造必须使其能够保持清洁卫生。	Conformance **Yes**
	Cleaning schedule is established, and cleaning record is kept on files, all equipment is kept in clean condition. No adverse findings were observed in this audit.	
（e）	Freezer and cold storage compartment fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device 冷冻库和冷藏库，必须配备指示用的温度计，温度测量设施或温度记录器。	Conformance **Yes**
	A Cold storage warehouse is used for Semi-finished products : temperature -4℃- 10℃. Indicating thermometer was installed in this warehouse and the storage temperature was monitored each shift. Onsite audit confirmed that temperature in this cold storage was under control and temperature was monitored as per requirement.	
（f）	Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity etc. are accurate, precise, adequately maintained, adequate in number 用于测量，调节或记录温度，PH,酸度，水分活度等的仪器和控制装置必须是精确，精准，并得到充分维护	Conformance **Yes**
	Monitoring and measuring equipment management procedure PF07 is in place. Calibration records samples as following: Thermometer No. QGG0001, QGG0002, QGG0003, QGG0004 used on pasteurization tank , calibrated on Aug. 06,2019. Thermometer No.TT1 and TT2 of No.1 spray drying tower, TT1 and TT2 of No.2 spray drying tower, TT1 and TT2 of No.3 spray drying tower and TT1 and TT2 of No.4spray drying tower, calibrated on Dec.03,2020. PT 100 precision platinum resistance, calibrated on Mar.13,2020 PH meter 2913249, calibrated on Mar.03,2020	

（g）	Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment treated in such a way that food is not contaminated with unlawful indirect food additives 以机械方式注入食品，或用于清洁食品接触面或设备的压缩空气和其他气体必须经过适当的处理，避免食品收到非法间接食品添加剂的污染	Conformance **Not Applicable**
	Onsite audit confirmed that no compressed air or other gases would contact food or food contact surface in the processing.	
117.80	**Processes and controls 过程和控制**	
（a）	General 总则	Conformance **Yes**
	Word orders(production process control work order) are established for processes of each products. Onsite audit checked production process control work order (master manufacturing records)： L20200518-01 resin chromatography process of Monk fruit extract,T20200604-01 drying process of Monk fruit extract, T20200601-01 Centrifugal equipment process of Stevia Leaf Extract. These work orders included following requirements: • Semi-finish product or product name • Process control parameters for the process steps in the manufacturing process ,e.g. speed, temperature , time, etc • Sampling procedures • Specific actions to perform and verify control steps, e.g. PH, moisture testing after the process • Signature of operator, reviewer and approver Quality department is responsible for reviewing and approving all master manufacturing records , batch production record and any changes. Quality department is responsible for l reviewing and approving all completed batch records prior to product use .	
（b）	Raw materials and other ingredients 原料和其他成分	Conformance **Yes**
	Main raw materials are plants. 15 raw material specifications were established including identification ,the content of main components, heavy metals, pesticide residues, etc. For examples: Monk Fruit quality standard PF06-(QS/YL)016, stevia quality standard PF06(QS/YL)049, mango leaf quality standard PF06-(QS/YL)-017 These raw material specifications was established according to China standard, EU and USA standard. E.g. US FDA Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed was considered for established raw material specification , including Aflatoxin ≤20ppb. Specification PF06(QS-FL)001 to PF06(QS-FL)0025 for supplementary materials was established, e.g. specification for alcohol, Sodium hydroxide and oxidized starch. All the supplementary materials must be food grade Following material checking record was reviewed during audit. They were all inspected and approved by quality department before releasing to production: According to the raw material testing plan, content and moisture are mandatory items. Heavy metals shall be tested every 5 batches, and pesticide residues shall be tested every year. Stevia batch number TYJ-181211-04, supplier: Linze Minsheng, inspection items include content, moisture, and qualified. The delivery vehicle was checked for sanitation. Monk Fruit number AC20190102-01/30, supplier: Yongfu, inspection items include content, heavy metals, pesticide residues, and pass the test. The delivery vehicle was checked for sanitation. The batch number of sweet tea raw materials: TIC-191003-01, supplier: Yongfu Yongan, the inspection items include sweet tea glycosides, heavy metals, pesticide residues, and passed the test. The delivery vehicle was checked for sanitation.	

	Calcium oxide batch number Y190524-01, supplier: Guilin Red Star, supplier batch number: 20190520, inspection items include content, heavy metals, etc., vehicle hygiene inspection is qualified, supplier COA is provided Ferrous sulfate Y190217-01, supplier: Jiangsu Kelunduo, supplier batch number: 18120601, vehicle sanitation inspection is qualified, and supplier COA is provided. 95% alcohol, batch number Y190415-01, (3529) Supplier: Mashan, Guangxi, the incoming inspection items include heavy metals, methanol and ethanol content, the vehicle hygiene inspection is qualified, and the supplier COA is provided.	
（c）	Manufacturing operations 生产操作	Conformance **No**
	Cross contamination control procedure PF01(03) was established and well followed. Zoning: Drying area and filling area is D grade cleaning area. And the other areas are normal cleaning area. Process cleaning requirements are documented in related operation manual. .CIP and COP shall be conducted when product changing or at least once month for continuous production according to related cleaning plan in working instruction: CIP: RO water flush, 2.0% alkali liquor cleaning , RO water flushing and drying by hot air COP: RO water cleaning , 2.0% alkali liquor cleaning , RO water cleaning and disinfection by using 75% alcohol. Samples: CIP record on 20200505 and 20200505 for three-effect concentration in No.1 workshop according to PF05-(ZD1-SX)007 Three-effect concentration operation manual. PH testing result of final rinse water was 7. Cleaning record on 20200506, 20200508 by RO water and 2.0% alkali liquor for V301-3 centrifugal equipment in No.1 workshop according to PF05-(ZD1-TCM)004 centrifugal equipment Operation manual. PH testing result of final rinse water was 7. Production supervisor was responsible for monitoring the cleaning effectiveness. Production environment and cleanness was monitored according to monitoring procedure PF01(02)-011 each month. Samples as following: Suspended particles testing record HY20171704 Settling bacteria and planktonic bacteria testing record: HJY20204874,HJY20204879 EB swabbing testing record: HJY20204889 Pasteurizing was used in processing to control microbiological hazard: temperature ≥80℃ and time ≥30℃. Samples refer to batch record in this report. For control of foreign body, sieve , magnet bars(≥10000GS) and metal detector were used in packaging process. Magnet checking record on 20200430 Samples refer to batch record in this report. Allergen control procedure PF14 is place.12 allergens were controlled in this site, covering eight main allergen, e.g. egg, milk, peanut, soy, nut, seafood, gluten and crustaceans. Most recent allergen evaluation was conducted on 20200202. After evaluation , no allergen materials were used in this site currently. Sterilization process was conducted in processing to control microbiological risk and drying process was conducted to control the moisture in the finished products. Samples: Monk Fruit extract 50%, batch number MOV04-19080501, 420Kg.	

	• Sterilization: temperature 95℃, time 5:08-7:08, (standard sterilization temperature ≥80℃, time ≥30 minutes) • Drying: inlet air temperature is 190℃, outlet wind is 78° C (control standard inlet wind 170-200° C, outlet wind 70-95° C), moisture content ≤5%. • Finished product testing result , moisture 3.3%(standard ≤5%)， pathogenic bacteria Salmonella , Staphylococcus aureus and Escherichia coli not detected . Stevia Extract : RA80, 95% total glycosides, batch number 190910-01, 1034.20Kg • Sterilization: temperature 80.6-80.7℃, time 12:55-13:25, (standard sterilization temperature ≥ 80℃, time ≥30 minutes) • Drying: The inlet air temperature is 152° C, the outlet air temperature is 76.3° C (control standard inlet air 150-170° C, outlet air 70-95° C), moisture content ≤5%. • Finished product testing result , moisture ≤5%， pathogenic bacteria Salmonella , Staphylococcus aureus and Escherichia coli not detected . ***One minor CAR was raised:*** ***Only two testing pieces , Fe1.5mm and SUS 2.5mm, which was used to test metal detector was found in packaging area when onsite audit. As per requirement , 3 type testing pieces shall be used for testing of metal detector, Fe1.5mm, SUS 2.5mm and Non-Fe 2.5mm. Although the packaging process was not started at that time.***	
117.93	**Warehousing and distribution 仓储和配送**	
	Storage and transportation 储存和运输	Conformance **Yes**
	Warehouse management procedure PF 38 is in place. Raw material warehouse, packaging material warehouse, chemical warehouse, semi-finished product& finished products warehouse are used in this site. In accordance with warehouse management procedure PF 38 , the final packaged and labelled product can not be distributed until the dietary supplement has been released by quality. Vehicle hygiene must be inspected before loading: Samples: 50% Monk Fruit, batch number MOV04-19080501, 420Kg. Distribution date: From September 12, 2019 to November 20, 2019, QA is responsible for monitoring at the time of shipment, including label, batch number inspection and vehicle sanitation inspection records. Provide QA shipment monitoring records. Stevia extract : RA80, 95% total glycosides, batch number 190910-01, 1034.20Kg Distribution date September 24, 2019, 1000Kg shipped, 1Kg sample, 33Kg inventory. QA is responsible for monitoring, including label, batch number, weight, inspection and vehicle sanitation inspection records. Provide QA shipment monitoring records.	
117.95	**Holding and distribution of human food by-products for use as animal food. 用于动物食品的人类食品副产品的保持和配送**	
（a）	Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor,, must be held under conditions that will protect against contamination 无需人类食品加工厂的额外生产或加工的人类食品副产品作为动物食品配送，必须在防止污染的条件下进行	Conformance **Not Applicable**
	Human food by-products were all scrapped, not used as animal food.	
（b）	Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed. 用通用或常用用名称标识副产品的标签必须贴在或附在人类食品副产品上，以便在分发时用作动物食品	Conformance **Not Applicable**
	Human food by-products were all scrapped, not used as as animal food.	
（c）	Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to	Conformance

	use. 运输容器（例如， 手提箱，桶和桶）和用于分发人类食品副产品用作动物食品的散装车辆必须在使用前进行检查，	**Not Applicable**
	Human food by-products were all scrapped, not used as as animal food.	
117.110	**Defect action levels 缺陷限量**	
（a）	The manufacturer, process or,packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible. 食品生产、加工、包装和存储企业必须始终通过质量控制操作，将食品中 自然存在或不可避免的缺陷降至目前可行的最低水平。	Conformance **Yes**
	Word orders(production process control work order) are established for processes of each products Internal lab- RID lab is a ISO17025 qualified lab. ISO17025 certificate No: CNAS L7609, effective to Apr.8,2024. Internal lab is used in raw material testing, processing control testing and finished products testing. Testing items include moisture, identity , content , heavy metal, solvent residue , pesticide residue and so on. External lab is also be used to verify compliance of raw material and finished products. All the external lab must be managed in accordance with ISO17025 and must be approved by quality department before using Quality department is responsible for reviewing and approving all completed batch records prior to product use Process records, process inspection and finished products samples as following: Onsite audit checked production process control work order (master manufacturing records)： L20200518-01 resin chromatography process of Monk fruit extract,T20200604-01 drying process of Monk fruit extract, T20200601-01 Centrifugal equipment process of Stevia Leaf Extract. All these production process control work orders were approved by QA manager. Batch production record checked as following: 50% Monk Fruit ,batch MOV04-19080501, batch record were reviewed by checked by QA manager Stevia Leaf Extract,：RA80,steviol glycosides95%， batch 190910-01, batch record were reviewed by checked by QA manager.	
(b)	Mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. 不得将因缺陷水平过高导致发生掺杂的食品与其他批次食品进行混合，无论合后最终产品的缺陷水平是否符合限量要求。	Conformance **Yes**
	Non-conformance control procedure PF08 is in place. Mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted in this site. All the products containing defects must be reworked or discarded according to evaluation result after approved by quality .	