GMP Registration Annual Audit

Company/Contact Information		Audit Information	
Facility# - Name	4K881 - Shaanxi Jiahe Pharmaceutical Co., Ltd.	**Audit# - Visit#**	1193740 - 908529
Address	No. 45 Hongguang RoadHeping Gongye Yuan, WeiyangquXi'an 710077,,,China,	**Audit Type**	GMPA
		Template Version	1.7
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Facility Contact	Ms. Zhao Jiaying	**Audit Year**	2015
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Email		**Auditor**	Mekal Bian
Audit Contact	Mrs. Yanhong Fan	**Audit Start Time**	10-AUG-2015 08:30:00 AM
Corporate # - Name	4K880 **-** Mr. Yuhu Hui	**Audit End Time**	12-AUG-2015 05:00:00 PM
Corporate Contact	86 298 433 3954		

Visit Summary

The GMP Registration Annual Audit was conducted by Mekal Bian. In attendance at the audit opening meeting were Mr. Hui Yuhu, QA Director; Ms. Zhao Jiaying, QA Manager; Mr. Cui Peng, QC Manager; Mr. Cheng Jun, Production Manager; Ms. Liu Na, Logistics Manager; Mr. Yang Shishuai, QA Member. During the audit assistance was provided by Mr. Hui Yuhu, QA Director; Ms. Zhao Jiaying, QA Manager; Mr. Yang Shishuai, QA Member. Mr. Hui Yuhu, QA Director; Ms. Zhao Jiaying, QA Manager; Mr. Cui Peng, QC Manager; Mr. Cheng Jun, Production Manager; Ms. Liu Na, Logistics Manager; Mr. Yang Shishuai, QA Member attended the audit closing meeting at which time the draft findings of the audit were presented by Mekal Bian. Thanks to the staff that attended the meetings and assisted with the audit. The goal of the audit is to help the facility ensure that they are operating in a way that will produce safe product and meet GMP requirements.

Specific findings from the audit are detailed in this report. Corrective action for any non conformance noted should be entered through NSF On-Line and is due within 30 days of receipt of the report. If you have any questions regarding the report, please feel free to contact your Certification Project Manager Rongqin (Allen) Chen at .

Non-Conformance Summary

SECTION	**Major**	Minor
21 CFR 111: Subpart B: Personnel	2	0
21 CFR 111: Subpart C: Physical Plant and Grounds	1	2
21 CFR 111: Subpart D: Equipment and Utensils	2	1
21 CFR 111: Subpart E: Production and Process Control System	0	0
21 CFR 111: Subpart F: Production and Process Control System: Requirements for Quality Control	0	0
21 CFR 111: Subpart G: Production and Process Control System: Requirements for Components, Packaging, and Labels	0	0
21 CFR 111: Subpart H: Production and Process Control System: Requirements for the Master Manufacturing Record	0	0
21 CFR 111: Subpart I: Production and Process Control System: Requirements for the Batch Production Record	1	0
21 CFR 111: Subpart J: Production and Process Control System: Requirements for Laboratory Operations	1	0
21 CFR 111: Subpart K: Production and Process Control System: Requirements for Manufacturing Operations	0	0
21 CFR 111: Subpart L: Production and Process Control System: Requirements for Packaging and Labeling Operations	0	0
21 CFR 111: Subpart M: Holding and Distributing	0	0
21 CFR 111: Subpart N: Return of Dietary Supplements	0	0
21 CFR 111: Subpart O: Product Complaints	0	0
21 CFR 111: Subpart P: Records and Record Keeping	0	0
21 CFR 11: Electronic Records; Electronic Signatures	0	0
NSF Policies – GMP - Facility Registration Audits	0	0
NSF Policies - Product Certification Audits	0	0
TOTAL	**7**	**3**

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21 CFR 111: Subpart B: Personnel				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
1	**111.10a**	**Major**	Procedures have been established that define work requirements for personnel to prevent microbial contamination from illness. **Operator hygiene procedure #SMP-OF-2008 is available. Medical examination and supervisory observation for all operators are performed to prevent microbial contamination from illness. Also operators report health conditions to their supervisors.**	**Acceptable**
2	**111.10b1,2,3**	**Major**	Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled or contaminated. **During audit, operators followed the written hygiene practice and dressing code properly. Operators wore the clean outer garments and caps in product exposed area.**	**Acceptable**
3	**111.10b4**	**Major**	Procedures for removal of jewelry and other items or appropriate coverings. **Previous CAR IMPLEMENTED. Operators has not worn earring and been trained hygiene knowledge. Auditor reviewed training and inspection records.**	**Acceptable**
4	**111.10b5,6,8,9**	**Major**	Procedures for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources. **NON-COMPLIANCE: One box of medicine for Huoxiang Zhengqi was observed in the working table around column chromatography area, that was against its SOP.** **柱层析区域的工作柜内有藿香正气水的药品**	**Not Acceptable***
5	**111.10b7**	Minor	Appropriate change rooms are available if needed and there is adequate storage of personal effects.	**Acceptable**
6	**111.12c**	**Major**	Personnel must be qualified and have adequate training, experience and/or education necessary to perform job functions.	**Acceptable**
7	**111.12b**	**Major**	Quality responsibilities are distinct and separate from operations. **Updated organization chart is available. The QA Manager reports directly to the General Manager.**	**Acceptable**
8	**111.13a**	**Major**	Procedures have been established to define the requirements for personnel who will supervise activities.	**Acceptable**
9	**111.13b**	Minor	Personnel who are designated as supervisors are qualified and have written requirements.	**Acceptable**
10	**111.14a,b**	**Major**	Procedures have been established and records are maintained documenting compliance to these procedures. **NON-COMPLIANCE: Some of operators were trained GMP knowledge on April 16, 2015, but the printed or typed names of these attendees were not included in this documentation.** **2015年4月16日GMP培训记录中缺少应到员工的名字**	**Not Acceptable***
11	**111.12a**	**Major**	Job descriptions are available for all personnel and personnel have received GMP and appropriate training for their assigned functions. **Job descriptions #SMP-ME-1001/OF-1011 etc for all personnel are available.**	**Acceptable**
Section Note:				

21 CFR 111: Subpart C: Physical Plant and Grounds				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
12	**111.15a1,2,3**	Minor	Grounds have been properly maintained through removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc.	**Acceptable**
13	**111.15a4**	Minor	Waste treatment and disposal is adequate and does not provide a source of potential contamination.	**Acceptable**
14	**111.15b1,2**	**Major**	Production Facility is maintained in a clean and sanitary condition and in a proper state of repair.	**Acceptable**
15	**111.15a5**	Minor	Entrances to the facilities are properly controlled and maintained to prevent contamination. **Previous CAR IMPLEMENTED. Facility has maintained this door and inspected it every day. Auditor reviewed maintenance and inspection records.**	**Acceptable**
16	**111.15c1**	**Major**	Cleaning and sanitizing compounds have been established for cleaning the facility. These agents are safe and adequate under the conditions of use; and are free from microorganisms of public health significance.	**Acceptable**

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17	**111.15c3**	**Major**	Cleaning and sanitizing agents, pesticide chemicals, and fungicides have been identified, used, and held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials.	**Acceptable**
18	**111.15d1,2**	**Major**	Procedures have been established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc. **NON-COMPLIANCE: One screen on the window was broken in raw material dosing area, but it was not maintained in time.** **原料投料区1扇纱窗破损，但它没有及时被维修**	**Not Acceptable***
19	**111.15d3**	**Major**	Pest control procedures have been established for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc.	**Acceptable**
20	**111.15e**	**Major**	The water supply is safe and sanitary and under suitable temperature and pressure. Water that may contact a product contact surface or is in fact a component must meet U.S. Federal, State and Local requirements for drinking water. **Municipal drinking water was tested on July 18, 2015 by Shanxi WQTC to meet its potability requirement. Conductivity and pH for RO water was tested every day by internal operator. Total plate count for RO water was tested every week.**	**Acceptable**
21	**111.15e,f3**	**Major**	Water sources do not act as a potential source of contamination of the dietary supplement, either due to water purity or due to the configuration and construction of the water delivery system.	**Acceptable**
22	**111.15f**	Minor	Plumbing is of adequate size and design for intended usage. **NON-COMPLIANCE: The steam pipe leaked in #1 extracting tank, but it was not maintained in time.** **#1提取罐的蒸汽管道泄漏，但它没有及时被维修**	**Not Acceptable***
23	**111.15g**	Minor	Sewage and waste disposal is properly plumbed from the facility and does not provide a potential source of contamination to contact surfaces, products, components, water supplies, etc.	**Acceptable**
24	**111.15f4**	Minor	Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.).	**Acceptable**
25	**111.15f5**	Minor	Backflow and cross-connection prevention is in place.	**Acceptable**
26	**111.15h**	Minor	Bathrooms are provided and are of adequate number and location. **The bathroom is located in the outside of production facility. It is maintained in proper condition.**	**Acceptable**
27	**111.15h**	Minor	Bathrooms and hand washing facilities are kept clean and are not a potential source of contamination to components, products, contact surfaces, etc.	**Acceptable**
28	**111.15i**	Minor	Hand washing facilities are constructed and located in appropriate areas to ensure proper hand washing by personnel. **Hand washing facilities were equipped at entrance to production area. The faucets were hand free type, hand dryers were equipped and hand cleaning chemicals were supplied.**	**Acceptable**
29	**111.15j**	Minor	Solid waste and trash are disposed of appropriately and not allowed to accumulate.	**Acceptable**
30	**111.15j2,3**	Minor	Solid waste and trash does not provide a potential source of contamination to components, products, contact surfaces, etc.	**Acceptable**
31	**111.15j4**	Minor	Hazardous waste is properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc.	**Acceptable**
32	**111.15k**	**Major**	Sanitation supervisors have been assigned and are qualified.	**Acceptable**
33	**111.16**	**Major**	Procedures have been established for cleaning of the plant. **Plant cleaning procedure #SMP-CLE-2002 is available. Also internal audit of sanitary practices was conducted and documented every week.**	**Acceptable**
34	**111.20a**	**Major**	All facilities are of adequate size, construction, and design for their intended use.	**Acceptable**
35	**111.20b**	Minor	There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding.	**Acceptable**
36	**111.20c**	**Major**	There are adequate precautions against contamination by microorganisms, chemicals, filth, or other extraneous materials. **Previous CAR IMPLEMENTED. Facility has covered Maca in raw material warehouse and trained operator. Auditor reviewed operator training and inspection records.**	**Acceptable**
37	**111.20c1**	Minor	Areas have been clearly defined or separated for receiving, inspecting and identifying, holding and withholding from use components, dietary supplements, packaging, and labels that will be used.	**Acceptable**
38	**111.20c2**	Minor	Areas have been provided for quarantine and release of materials to be used in the manufacture, packaging, or labeling of dietary supplements.	**Acceptable**

39	**111.20c3**	Minor	Areas have been provided to separate the manufacturing, packaging, labeling, and holding of different product types (e.g. foods, cosmetics, pharmaceuticals) from dietary supplements.	**Acceptable**
40	**111.20c4,5,6,7**	Minor	Separate or defined areas exist for laboratory analysis and holding of laboratory supplies and samples, cleaning of contact surfaces, packaging and labeling, and holding of components or dietary supplements.	**Acceptable**
41	**111.20d1i**	Minor	Walls, floors, ceilings can be adequately cleaned and kept in good repair. **Previous CAR IMPLEMENTED. Facility has cleaned this wall and trained operator. Auditor reviewed operator training and cleaning records.**	**Acceptable**
42	**111.20d1ii**	Minor	Fixtures, ducts, piping, etc. are kept clean, do not drip or leak or provide a source of condensation that could contaminate components, products, or contact surfaces. **NON-COMPLIANCE: Cobweb on the steel stair was observed around extracting area.** **提取区域的楼梯上有蜘蛛网**	**Not Acceptable***
43	**111.20d1iii**	**Major**	Adequate ventilation and airflow is provided in all areas of the facility.	**Acceptable**
44	**111.20d1iv**	**Major**	Temperature and humidity control equipment is of adequate design for its intended function and is functioning properly.	**Acceptable**
45	**111.20d1v,d2**	Minor	Working areas have adequate access and space, aisles are clear, etc. to allow for persons to perform their duties and protect against contamination or mix-ups. Use of fans and other air blowing equipment must be located and operated in a manner that minimizes the potential for contamination with particulates and microorganisms.	**Acceptable**
46	**111.20e**	Minor	Adequate lighting is provided in all production and examination areas where equipment is cleaned and examined, etc. **Previous CAR IMPLEMENTED. Facility has maintained this light and trained operator. Auditor reviewed operator training and maintenance records.**	**Acceptable**
47	**111.20f**	Minor	Lighting that is suspended or located above areas where materials or equipment are exposed must be safety-type or the facility must be constructed in a manner that will protect against contamination with glass, etc.	**Acceptable**
48	**111.20g**	**Major**	In areas where open vessels are used, there is adequate protection against contamination, (e.g. use of protective coverings, physical location, use of skimming equipment).	**Acceptable**
49	**111.20h**	**Major**	Production areas do not provide a haven for pests, pest infestation, filth, etc. (adequate screening and other measures are used).	**Acceptable**
50	**111.23a,b**	**Major**	Records have been maintained for plant cleaning and pest control, and in accordance with Subpart P.	**Acceptable**
51	**111.23c**	**Major**	Records have been maintained to show that the quality of water, when used as a component of the dietary supplement, meets the requirements of 111.15(e)(2).	**Acceptable**
Section Note:				

21 CFR 111: Subpart D: Equipment and Utensils				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
52	**111.25a,b**	**Major**	Procedures have been established for calibration of all instruments, controls, automated, mechanical, and electronic equipment, etc. **Equipment calibration procedure #SMP-QC-2044 is available. Also the thermometer and balance in production facility were calibrated on July 13, 2015 by Xian MTC.**	**Acceptable**
53	**111.25c**	**Major**	Procedures have been established for the cleaning and sanitization of all utensils and equipment. **Equipment cleaning procedure #SOP-PRD02-3019 etc is available. 75% alcohol solution is used as the disinfectant in clean area.**	**Acceptable**
54	**111.25c**	**Major**	Procedures and programs have been established for maintaining equipment. **NON-COMPLIANCE: Equipment preventative maintenance program was updated on Jan.1, 2015, but the used boiler was not included in this procedure.** **公司使用的锅炉没有放在2015年设备预防性维修保养计划内**	**Not Acceptable***
55	**111.27a1**	Minor	All equipment and utensils are corrosion resistant, made of nontoxic materials, and of suitable design, construction, and workmanship for their intended use.	**Acceptable**
56	**111.27a2**	Minor	Equipment and utensils are of appropriate design and construction so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants. **Previous CAR IMPLEMENTED. Facility has maintained this S/S hammer and trained operator. Auditor reviewed operator training and maintenance records.**	**Acceptable**

57	**111.27a3iv**	Minor	Equipment and utensils are designed and constructed to withstand the environment in which they are used and do not degrade upon exposure to components, process materials, cleaning agents, etc.	**Acceptable**
58	**111.27a3v**	Minor	Equipment and utensils protect components and dietary supplements from contamination from any source. **NON-COMPLIANCE: One S/S mesh was stored on the floor directly after it was used and cleaned in clean area.** 洁净区1个不锈钢的筛网在清洁后被直接放在地上	**Not Acceptable***
59	**111.27a4**	Minor	Equipment and utensils are constructed as seamless, or if seams exist, are easily cleanable and do not provide a place for accumulation of potential contaminants.	**Acceptable**
60	**111.27a3i,ii,iii**	Minor	Equipment is installed and maintained to facilitate cleaning. Equipment and utensil surfaces are corrosion-resistant , made of non-toxic materials and are inspected at routine intervals for signs of wear, damage, etc.	**Acceptable**
61	**111.27a5**	**Major**	Equipment such as freezers, refrigerators, etc. that are used to hold components or dietary supplements must be functioning properly and adequately designed. **The facility declared that freezers and refrigerators were not used.**	**Not Applicable**
62	**111.27a6,b,c**	Minor	Instruments and controls that are used in all areas must be accurate and precise (calibrated as required), maintained, and adequate in number. Instruments and controls must be calibrated before first use (and then after at the frequency specified by the manufacturer or at routine intervals) and must be repaired when they are not able to be adjusted to agree with a reference standard.	**Acceptable**
63	**111.27a7**	Minor	Process gases that are used and contact dietary supplements, components, and contact surfaces must be controlled so as not to cause contamination (e.g. filters).	**Acceptable**
64	**111.27d**	**Major**	All equipment, instruments, utensils, contact surfaces etc. must be maintained, cleaned and sanitized as necessary. **NON-COMPLIANCE: Brown material on the smashing machine was still observed after it was used and cleaned in clean area.** 洁净区粉碎机清洁后仍然有残留的褐色物质	**Not Acceptable***
65	**111.27d1**	Minor	Equipment, utensils, etc. must be disassembled as necessary to assure maintenance, cleaning, and sanitization.	**Acceptable**
66	**111.27d2**	**Major**	Low moisture processing: Equipment, utensils, and contact surfaces are dry and sanitized. If wet-cleaned, drying and sanitization is performed.	**Acceptable**
67	**111.27d3**	**Major**	Wet Processing: Contact surfaces are cleaned and sanitized before use and after any interruptions.	**Acceptable**
68	**111.27d4**	Minor	Surfaces that do not come into direct contact with components or dietary supplements are cleaned.	**Acceptable**
69	**111.27d5**	Minor	Disposable items (single-service) are stored in appropriate containers; handled, used, dispensed, and disposed of in a manner that protects against contamination.	**Acceptable**
70	**111.27d6**	Minor	Cleaning and sanitizing agents are adequate and safe for their intended use.	**Acceptable**
71	**111.27d7**	Minor	Portable equipment and utensils are properly stored after cleaning and sanitization.	**Acceptable**
72	**111.30a,b,c**	**Major**	Automated, mechanical, or electronic equipment must be functioning properly and be adequately designed.	**Acceptable**
73	**111.30d,e**	**Major**	Procedures are in place showing equipment is suitable for use and controls are functioning properly to maintain use.	**Acceptable**
74	**111.35a,b1iii**	**Major**	Procedures for maintenance, cleaning, sanitization of all equipment, utensils, and contact surfaces are established and records of sanitation are maintained.	**Acceptable**
75	**111.35b2**	**Major**	Equipment logbooks have been maintained for each equipment and includes the date of use, and any documentation of cleaning, sanitization, maintenance, etc. (unless the documentation is in the batch record).	**Acceptable**
76	**111.35b3,b4**	**Major**	Records are available of calibrations, inspections, and checks of any automated, mechanical, or electronic equipment.	**Acceptable**
77	**111.35b5i,ii**	Minor	Backup electronic files have been maintained of the following; current software programs, outdated software programs that may be necessary to retrieve past records, and data that was entered. Backup files are an exact and complete record and are secure from alterations, erasures, or loss and damage. **Backup electronic files are not used.**	**Not Applicable**
78	**111.35b6**	Minor	Documentation of controls used that ensure that equipment functions in accordance with its intended use.	**Acceptable**
Section Note:				

21 CFR 111: Subpart E: Production and Process Control System				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
79	**111.55**	Minor	Production and process control systems have been implemented for each production process and/or product. **Process control procedure #SMP-PR-2004 is available.**	**Acceptable**
80	**111.60**	Minor	Production and processes have been designed to ensure the quality of the product and the Quality Control Unit has approved the control systems.	**Acceptable**
81	**111.65**	Minor	Quality Control operations have been identified and implemented.	**Acceptable**
82	**111.70, 111.70c2**	**Major**	Specifications have been established for components, in-process materials, labels, packaging components, and finished product. The basis is adequately documented for how meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the dietary supplement specifications will be met. **Specifications #STP-QCP-029 etc for components and packaging components etc are available. Specifications #STP-QCP-031 etc for finished product are available.**	**Acceptable**
83	**111.73**	**Major**	A system has been established to determine if all specifications that are established have been met. **Nonconformity control procedure #SMP-QA-2014 is available. Also the facility declared that there was no nonconformity in 2015.**	**Acceptable**
84	**111.75a1**	**Major**	Dietary ingredients are sampled, tested, and confirmed (released) prior to use in production. Conduct at least one appropriate test or examination to verify the identity of dietary ingredient (unless company has submitted a petition for an ID test exemption that has been approved by the FDA). **Raw material release procedure #SOP-QA-3005 is available. The identity for Salix babylonica, Maca and Echinacea purpurea etc were conducted every batch.**	**Acceptable**
85	**111.75a2i**	**Major**	Other raw materials or components (i.e., those that are not dietary ingredients) are sampled, tested (or confirmed), and released prior to use in production. Conduct appropriate tests or examinations (or rely on the COA from the qualified supplier). **Raw material release procedure #SOP-QA-3005 is available. Other components for alcohol and active carbon etc were tested every batch.**	**Acceptable**
86	**111.75a2iia, b,c,d,e**	**Major**	Supplier Qualification Procedures are established and include initial qualification, periodic examination (re qualification), and procedures for disqualification. **Supplier control procedure #SMP-QA-2006 is available. All suppliers were evaluated and approved on Jan. 13, 2015.**	**Acceptable**
87	**111.75b.c,c3 ,d**	**Major**	Proper testing procedures or programs have been established to determine if in process and finished product specifications for purity, composition, strength of the dietary supplement have been met. The basis for performing reduced testing is adequately documented and it justifies how the testing procedures or program selected will help ensure that the full -specifications for the dietary supplement will be met. **Finished product release procedure #SOP-QA-3007 is available. The identity and concentration for Salix babylonica, Maca and Echinacea purpurea extracts etc were tested every batch.**	**Acceptable**
88	**111.75e**	Minor	For products that are received for packaging and labeling, visual examinations are performed and documentation is available to determine whether the product meets established specifications.	**Acceptable**
89	**111.75f**	Minor	Packaging and labeling materials are visually examined, at a minimum, and are reviewed against the supplier's invoice to determine conformance with specifications.	**Acceptable**
90	**111.75g**	Minor	Packaging and labeling of the finished packaged and labeled dietary supplement are visually examined, at a minimum, to determine that the correct packaging and labeling has been used.	**Acceptable**
91	**111.75h**	Minor	Scientifically valid methods are used and include at least one of the following, a gross organoleptic analysis, macroscopic analysis, microscopic analysis, chemical analysis, or another scientifically valid method.	**Acceptable**
92	**111.77**	**Major**	Procedures and controls have been established for investigation and handling of materials that do not meet specification requirements.	**Acceptable**
93	**111.80**	**Major**	Procedures have been established for the collection of representative samples.	**Acceptable**
94	**111.83**	**Major**	Procedures have been established for the collection of reserve samples for each lot of finished material. **Sample reserve procedure #SMP-QC-2017 is available.**	**Acceptable**
95	**111.87**	**Major**	The Quality Control Unit conducts all material reviews and makes disposition decisions.	**Acceptable**
96	**111.90**	**Major**	Procedures have been established for the handling of unexpected events.	**Acceptable**

97	**111.90a,b**	Minor	Reprocessing controls have been established and meet all requirements and have been approved by the Quality Control Unit. **Reprocessing control procedure #SMP-PR-2024 is available. Also the facility declared that there was no reprocessing in 2015.**	**Acceptable**
98	**111.95**	**Major**	Records are maintained specifications, supplier qualification and testing to ensure product meets purity, strength and composition.	**Acceptable**
Section Note:				

21 CFR 111: Subpart F: Production and Process Control System: Requirements for Quality Control				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
99	**111.103**	**Major**	Procedures have been established for the responsibilities of the Quality Control operations. **Quality duty procedure #SMP-QA-1001 is available.**	**Acceptable**
100	**111.105**	**Major**	Quality Control Personnel have established roles and responsibilities. **Internal audit procedure #JHZH-16 was available. Last internal GMP audit was conducted on March 2, 2015. Two nonconformities for record filling and chemical control were described. Also they were all corrected on March 4, 2015.**	**Acceptable**
101	**111.110**	**Major**	Quality Control Laboratory Operations have been established.	**Acceptable**
102	**111.113a**	**Major**	Quality Control Operations responsibilities include the authority to reject any component or product if any specification is not met.	**Acceptable**
103	**111.113b**	**Major**	Quality Control Personnel may authorize a treatment, in-process treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.	**Acceptable**
104	**111.113c**	**Major**	The Quality Control person responsible for making the material review and disposition decision has documented the review and disposition decision at the time of performance.	**Acceptable**
105	**111.117**	**Major**	Quality Control Operations review and approves all processes and/or procedures for calibrating equipment, instruments, and controls; including the periodical review of calibration records, etc.	**Acceptable**
106	**111.120**	**Major**	Quality Control Operations must review and approve components, labels and packaging materials for intended use.	**Acceptable**
107	**111.123a1-a3**	**Major**	Quality Control Operations and authority have been established for master manufacturing record and the batch production record.	**Acceptable**
108	**111.123a4-a8**	**Major**	Quality Control Operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.	**Acceptable**
109	**111.123b**	**Major**	Quality Control has not approved and released product in any form that does not meet the specifications unless Quality Control approved deviations have been documented.	**Acceptable**
110	**111.127**	**Major**	Quality Control Operations have been established for packaging and labeling.	**Acceptable**
111	**111.130**	**Major**	Quality Control Operations have been established to handle returned dietary supplements.	**Acceptable**
112	**111.135**	**Major**	Quality Control Operations ensures that product complaints, deviations, and unplanned occurrences are handled properly.	**Acceptable**
113	**111.140, GMP-PP-7**	**Major**	Quality Control Operations prepares and maintains all records required by subpart F.	**Acceptable**
Section Note:				

21 CFR 111: Subpart G: Production and Process Control System: Requirements for Components, Packaging, and Labels				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
114	**111.153**	Minor	Receiving, sampling, testing, release procedures have been established to fulfill this Subpart. **Raw material and auxiliary material control procedure #SMP-ME-2001 is available.**	**Acceptable**
115	**111.155**	**Major**	Quality Control requirements have been established for components. **Previous CAR IMPLEMENTED. Facility has added the lot number for stored garner seed and trained operator. Auditor reviewed operator training and inspection records.**	**Acceptable**
116	**111.160**	**Major**	Quality Control requirements have been established for packaging materials and labels.	**Acceptable**
117	**111.165**	**Major**	Quality Control requirements have been established for products that are received for packaging and labeling as a dietary supplement and bulk finished product.	**Acceptable**
118	**111.170**	**Major**	Rejected components, packaging, labeling, and products are appropriately quarantined and dispositioned.	**Acceptable**

119	**111.180**	**Major**	Records have been established and are being maintained to meet the requirements of Subpart G.	**Acceptable**
Section Note:				

21 CFR 111: Subpart H: Production and Process Control System: Requirements for the Master Manufacturing Record				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
120	**111.205a**	**Major**	Master Manufacturing Records have been prepared for each unique formulation and batch size of the dietary supplement. **Document control procedure #SMP-DO-2002 is available for creation, change, approval and control of MMRs.**	**Acceptable**
121	**111.205b1,2**	**Major**	The Master Record identifies specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement.	**Acceptable**
122	**111.210**	**Major**	Master Manufacturing Records contain all of the required elements. **Master records #STP-TSP-124 for astragalus mongholicus extract, #STP-TSP-088 for senna leaf extract and #STP-TSP-108 for liquorice extract etc are available. Last updating was approved on Dec. 16, 2014.**	**Acceptable**
Section Note:				

21 CFR 111: Subpart I: Production and Process Control System: Requirements for the Batch Production Record				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
123	**111.255a,d**	**Major**	Batch Production Records are available per Subpart P for each batch of dietary supplement that has been manufactured. **Record control procedure #SMP-QA-2005 is available for creation, change, approval and control of BPRs.**	**Acceptable**
124	**111.255b,c**	**Major**	The Batch Production Record contains complete information relating to the production and control of each batch.	**Acceptable**
125	**111.260**	**Major**	The Batch Record follows the master record and each step is performed appropriately. **Previous CAR IMPLEMENTED. Facility has documented the initial of operator in verifying step and trained operator. Auditor reviewed operator training and batch records.** **NEW FINDING: Some of #BFXY150716-3 senna leaf extract was blended on July 6, 2015, but its identification of this used blender was not documented in the batch record.** **在2015年7月6日混合#BFXY150716-3批次的番泻叶提取物，但其使用混合机的编号没有记录**	**Not Acceptable***
Section Note:				

21 CFR 111: Subpart J: Production and Process Control System: Requirements for Laboratory Operations				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
126	**111.303**	**Major**	Procedures have been established for laboratory operations. **NON-COMPLIANCE: The #JH/ZY-C-11procedure to test solvent residue was required to be updated on July 1, 2015, but no evidence to show this updating was conducted in time in lab.** **实验室#JH/ZY-C-11测试溶剂残留的程序要求在2015年7月1日进行更新，但该更新没有及时完成**	**Not Acceptable***
127	**111.310**	**Major**	Laboratory facilities used are adequate for testing of components, in-process materials, and dietary supplements. **Equipment calibration procedure #SMP-QC-2044 is available. Also the incubator and HPLC in lab were calibrated on Apr. 14, 2015 by Shanxi MTC.**	**Acceptable**
128	**111.315a**	**Major**	Laboratory controls have been established and have been approved by Quality Control, including criteria for establishing specifications.	**Acceptable**
129	**111.315b,c,d,e**	**Major**	Parameters have been set for laboratory controls for sampling plans, criteria for examination and testing methods, and standard reference materials. **Sampling control procedure #SOP-QA-3002 for raw material is available. Also sampling control procedure #SOP-QA-3004 for finished product is available.**	**Acceptable**
130	**111.320**	**Major**	Quality Control responsibilities for laboratory test methods and examinations used to test each specification requirement have been defined, are appropriate for their intended use, and are being followed. Test methods and examinations are used according to established criteria.	**Acceptable**
131	**111.325, GMP-PP-7**	**Major**	Quality Control Operations have maintained appropriate records as required.	**Acceptable**

132	**Preamble 21CFR 111 Final Rule**	**Major**	For all products that bear expiration date or a statement of product shelf life, the shelf life must be supported. **Shelf life test procedure #SOP-QC-3002 is available. The declared shelf life for astragalus mongholicus extract was 2 years. Also its last test was conducted on July 9, 2015. Its concentration and total plate count were conformity.**	**Acceptable**
Section Note:				

21 CFR 111: Subpart K: Production and Process Control System: Requirements for Manufacturing Operations				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
133	**111.353**	**Major**	Procedures, including sanitation, operation and control have been established for manufacturing operations.	**Acceptable**
134	**111.355**	Minor	Manufacturing processes have been designed to produce a product that consistently meets specifications.	**Acceptable**
135	**111.360**	Minor	Manufacturing Operations are conducted using adequate sanitation principles.	**Acceptable**
136	**111.365a-g**	**Major**	Precautions have been taken to prevent contamination, such as microbial, filth, chemical, foreign material, etc., throughout the manufacturing process. **Glass control procedure #SMP-FA-2007 is available. Also allergen control procedure #SMP-QA-2029 is available.**	**Acceptable**
137	**111.365h,i**	**Major**	Manufacturing operations have included controls in manufacturing steps to prevent contamination, including metal detection. **S/S sieve with 80 mesh and magnet are used to prevent contamination.**	**Acceptable**
138	**111.365j,k**	Minor	Manufacturing operations have included the identification of all process lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number, and when necessary, the phase of manufacturing.	**Acceptable**
139	**111.370**	Minor	Rejected Dietary Supplements are removed from Manufacturing Operations and placed in quarantine until disposition is determined.	**Acceptable**
140	**111.375**	**Major**	Records have been established and are being maintained to meet the requirements of Subpart K.	**Acceptable**
Section Note:				

21 CFR 111: Subpart L: Production and Process Control System: Requirements for Packaging and Labeling Operations				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
141	**111.403**	**Major**	Procedures have been established for all packaging and labeling operations. **Label control procedure #SMP-QA-2010 is available. Packaging control procedure #SMP-PRD03-2008 is available.**	**Acceptable**
142	**111.410a**	**Major**	The condition of packaging meets the specifications required to ensure the quality of the dietary supplements being packaged.	**Acceptable**
143	**111.410b**	**Major**	Packaging and labels are controlled for issuance and are reconciled after use. Note: Reconciliation is not necessary for cut or rolled labels when 100% examination is performed by appropriate electronic or electromechanical equipment during or after completion of operations.	**Acceptable**
144	**111.410c**	**Major**	Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record.	**Acceptable**
145	**111.410d**	**Major**	Records are maintained to allow a complete history and control of the packaged and labeled dietary supplement through distribution.	**Acceptable**
146	**111.415**	**Major**	A Master Manufacturing Record has instructions for filling, assembling, packaging, labeling, and other related operations.	**Acceptable**
147	**111.415a**	**Major**	Procedures have been established for cleaning and sanitizing all filling and packaging equipment and utensils.	**Acceptable**
148	**111.415d**	**Major**	Physical separation is implemented to prevent mix-ups with other components and dietary supplements.	**Acceptable**
149	**111.415b,c**	**Major**	Filling and packaging operations are appropriately protected from contamination sources (i.e., airborne) by using sanitary handling procedures.	**Acceptable**
150	**111.415e**	**Major**	Procedures have been established to identify unlabeled materials that will be held for future labeling operations to prevent mix-ups.	**Acceptable**
151	**111.415f**	**Major**	Procedures have been established for assigning a lot or batch number for each lot of packaged and labeled dietary supplement. **Lot number control procedure #SMP-PR-2006 is available.**	**Acceptable**

152	**111.415g**	**Major**	Procedures have been established to sample a representative number of units to assure compliance with specifications.	**Acceptable**
153	**111.415h**	**Major**	Disposal procedures have been established for disposing of labels or packaging materials that are obsolete or incorrect to ensure that they are not used.	**Acceptable**
154	**111.420a**	Minor	All repackaging or relabeling operations have first been approved by the Quality Control Unit.	**Acceptable**
155	**111.420b**	Minor	Representative samples of each batch of repackaged or relabeled dietary supplement have been examined to determine if they conform to specifications.	**Acceptable**
156	**111.420c**	Minor	Quality Control Unit has dispositioned each batch of repackaged or relabeled dietary supplement prior to release for distribution.	**Acceptable**
157	**111.425**	Minor	An appropriate quarantine system has been established for holding any rejected packaged and labeled dietary supplement. Procedures have been established and records are kept for the quarantine system.	**Acceptable**
158	**111.425**	Minor	Areas for storing rejected packaged and labeled dietary supplements have been demonstrated to meet the necessary requirements.	**Acceptable**
159	**111.430**	**Major**	Records have been established and are being maintained to meet the requirements of Subpart L.	**Acceptable**
Section Note:				

21 CFR 111: Subpart M: Holding and Distributing				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
160	**111.455**	**Major**	Dietary supplements, components, labeling, and packaging are held under the appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration. **Warehouse management procedure #SMP-ME-2009 is available.**	**Acceptable**
161	**111.460**	Minor	In-process materials are held under appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration.	**Acceptable**
162	**111.465**	**Major**	Reserve samples are held under appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration.	**Acceptable**
163	**111.470**	Minor	Distribution of product must occur under conditions that will protect against contamination and deterioration. **Product distribution procedure #SMP-ME-2023 is available.**	**Acceptable**
164	**111.475b1**	**Major**	Procedures have been established for the holding and distribution operations.	**Acceptable**
165	**111.475b2**	**Major**	Product distribution records have been retained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.	**Acceptable**
Section Note:				

21 CFR 111: Subpart N: Return of Dietary Supplements				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
166	**111.503**	**Major**	Procedures have been established for the handling of returned dietary supplements. **Product return procedure #SOP-QA-3012 is available. Also the facility declared that there was no returned product in 2015.**	**Acceptable**
167	**111.510**	Minor	Returned supplements have been appropriately quarantined until dispositioned by the Quality Control Unit.	**Not Observed**
168	**111.515**	Minor	Any returned dietary supplement must be either destroyed or disposed of unless the Quality Control Unit has determined that the material can be salvaged or reprocessed.	**Not Observed**
169	**111.520**	Minor	Any salvaged material has been so designated by the Quality Control Unit.	**Not Observed**
170	**111.525**	Minor	Any reprocessed material has met its original specification and the Quality Control Unit has appropriately dispositioned the material (release or reject).	**Not Observed**
171	**111.530**	Minor	If the reason for a return implicates other batches, an investigation has been performed to determine if those batches comply with specifications.	**Not Observed**
172	**111.535a**	**Major**	Procedures have been established for salvage and reprocessing operations according to Subpart P.	**Acceptable**
173	**111.535b1,2,3**	**Major**	Documentation has been maintained for material reviews and dispositions, all testing results, any reevaluations by the Quality Control Unit for reprocessed materials.	**Not Observed**
174	**111.535b4**	**Major**	All Quality Control Unit evaluations and decisions have been documented.	**Not Observed**

175	**111.535**	**Major**	Records for returned dietary supplements have been maintained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.	**Not Observed**
Section Note:				

21 CFR 111: Subpart O: Product Complaints				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
176	**111.553**	**Major**	Procedures have been established describing how product complaints will be received, investigated, and documented. **Customer complaint procedure #SMP-QA-2013 is available. The facility declared that there was only one complaint for foreign material in 2015. Also they were all reviewed and corrected.**	**Acceptable**
177	**111.560a**	**Major**	All product complaints have been reviewed by a qualified person to determine if the complaint was the result of a failure of the dietary supplement to meet any of its specifications or quality.	**Acceptable**
178	**111.560b**	**Major**	The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit.	**Acceptable**
179	**111.560c**	**Major**	The investigation for a product complaint was appropriately extended to other batches, products, processes, etc.	**Acceptable**
180	**111.570a**	**Major**	Records for each product complaint and investigation have been maintained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.	**Acceptable**
181	**111.570bii**	Minor	Product complaint information has included adequate information.	**Acceptable**
Section Note:				

21 CFR 111: Subpart P: Records and Record Keeping				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
182	**111.605**	**Major**	Procedures have been established that describe the requirements for record retention under Subpart P. **Record control procedure #SMP-QA-2005 is available. Records were maintained for 1 year after the shelf life date.**	**Acceptable**
183	**111.605a**	**Major**	Records will be maintained for 1 year after the shelf life date or 2 years beyond the date of distribution of the last batch associated with those records.	**Acceptable**
184	**111.605b**	**Major**	All records are maintained as original record, as true copies or as electronic records.	**Acceptable**
Section Note:				

21 CFR 11: Electronic Records; Electronic Signatures				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
185	**21 CFR 11**		Are electronic GMP records being created?	**No**
186	**21 CFR 11**		Are electronic signatures being used on GMP records?	**No**
Section Note:				

NSF Policies – GMP - Facility Registration Audits				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
187	**GMP-GP-3**	Minor	Prompt and thorough access is granted to the auditor during the NSF audit.	**Acceptable**
188	**GMP-GP-4**	Minor	Documents requested during the NSF audit are provided in timely a manner.	**Acceptable**
189	**GMP-PP-9**	**Major**	The NSF GMP Registered Facility Mark is not used on materials, ingredients, components, or finished products.	**Acceptable**
190	**NSF GMP 8.1**	**Major**	Procedures have been established to define the recall of a product. **Recall control procedure #SOP-QA-3013 is available. Also last mock recall for bilberry extract with batch number #CMYJ20141031 was conducted on Feb. 10, 2015.**	**Acceptable**

191	**NSF GMP 8.2**	**Major**	Manufacturers of dietary supplements shall submit application to US FDA for registration, receive a registration number, and provide the registration number upon request. **Updated USFDA registration number was 12789796600.**	**Acceptable**
192	**NSF GMP 8.3**	**Major**	Procedures shall be established and followed for reporting serious adverse events to the US FDA in accordance with the dietary supplement and non-prescription drug consumer protection act. **The facility declared that its distributor was responsible for reporting serious adverse events to the USFDA.**	**Not Applicable**
Section Note:				

NSF Policies - Product Certification Audits				
No	**Policy Reference**	**Type**	**Question/Notes**	**Answer**
	N/A			
Section Note:				

* Represents Non Compliances.