# Health Sciences Certification

# GMP Audit Report

**Facility Name:** Vidya Herbs Pvt. Ltd.

**Address:** Plot No. 101, Jigani Ind. Area Phase IIAnekal Taluk, Bangalore 562106, India

**Facility #** C0075973

**Audit Type :** Dietary Ingredients GMP Registration Audit

**Audit# – Visit#:** 2942515 - 2404064

**Audit Date:** 08-JUN-2022 to 10-JUN-2022

| Summary of GMP Audit Results | | | |
|---|---|---|---|
| **Critical NCs*** | **Major NCs*** | **Minor NCs*** | **Grade** |
| **0** | **0** | **2** | **A** |

* NCs represents Nonconformances

# Dietary Ingredients GMP Registration Audit

| Company/Contact Information | | Audit Information | |
|---|---|---|---|
| **Facility# - Name** | C0075973 - Vidya Herbs Pvt. Ltd. | **Audit# - Visit#** | 2942515 - 2404064 |
| **Address** | Plot No. 101, Jigani Ind. Area Phase IIAnekal Taluk, Bangalore 562106, India | **Audit Type** | 173GMPDI |
| | | **Template Version** | 1.8 |
| | | **Audit Category** | REASSESSMENT |
| **Facility Contact** | B Shetty | **Audit Year** | 2022 |
| **Phone** | 91-8475508978 | **Period** | |
| **Fax** | | | |
| **Email** | shyamprasad@vidyaherbs.com;bshetty@vidyaherbs.com | **Auditor** | Jitendra Nautiyal |
| **Audit Contact** | Mr. B Shetty | **Audit Start Time** | 08-JUN-2022 09:00:00 AM |
| **Corporate # - Name** | C0075972 **-** Vidya Herbs Pvt. Ltd. | **Audit End Time** | 10-JUN-2022 04:55:00 PM |
| **Corporate Contact** | Mr. K Shyamprasad | | |

This report summarizes the Dietary Ingredients GMP Registration Audit audit of C0075973 - Vidya Herbs Pvt. Ltd..

The purpose of this audit is to evaluate the facility's compliance with the Dietary Ingredients GMP Registration Audit program requirements. The audit focuses on the following areas: administration and regulatory, quality management, CAPA, complaints, supplier qualification, product safety, facilities, production and process controls, laboratory controls, warehouse and distribution. The audit represents a finite sample of processes and records and may not have captured every instance of potential nonconformance.

Draft findings from the audit were presented during the closing meeting. Any nonconformances cited are detailed in this report. Corrective action for these must be submitted through NSF Connect and approved within of receipt of the corrective action notification. If you have any questions regarding the report, please feel free to contact your Account Manager Seema Mallya at 1-734-214-6130.

**Audit Result**

| Audit Report | Critical NCs | Major NCs | Minor NCs |
|---|---|---|---|
| 15-JUN-2022<br>REASSESSMENT | **0** | **0** | **2** |



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| Audit Nonconformance Summary | | | |
|---|---|---|---|
| **SECTION** | **Critical** | **Major** | **Minor** |
| Administration & Regulatory | 0 | 0 | 0 |
| Quality Management | 0 | 0 | 0 |
| Corrective and Preventive Action (CAPA) | 0 | 0 | 0 |
| Supplier Qualification | 0 | 0 | 0 |
| Food Safety | 0 | 0 | 0 |
| Facilities | 0 | 0 | 2 |
| Production and Process Controls | 0 | 0 | 0 |
| Laboratory Controls | 0 | 0 | 0 |
| Warehouse and Distribution | 0 | 0 | 0 |
| **TOTAL** | **0** | **0** | **2** |

| GMP Policies Audit Summary | | |
|---|---|---|
| | **Acceptable** | **Not Acceptable** |
| GMP Policies | 3 | 0 |

| Visit Summary | | |
|---|---|---|
| **No** | **Policy Reference** | **Question/Notes** |
| 1 | 1 | Opening Meeting attendees: Name and Title<br>**B. Shetty -Sr. Manager Admin, Audit and Marketing, Arun kumar. G, Manager - Production, Shreekantha. HP - Manager- QA, Kumar. U - EHS and Sanitation officer, Dr. Karibasappa - Manager – Microbiology.** |
| 2 | 2 | Employees who provided assistance during the audit:<br>**B. Shetty -Sr. Manager Admin, Audit and Marketing, Arun kumar. G, Manager - Production, Shreekantha. HP - Manager- QA,** |
| 3 | 3 | Closing Meeting attendees: Name and Title<br>**B. Shetty -Sr. Manager Admin, Audit and Marketing, Arun kumar. G, Manager - Production, Shreekantha. HP - Manager- QA, Kumar. U - EHS and Sanitation officer, Dr. Karibasappa - Manager – Microbiology.** |

| Client Logistics | | |
|---|---|---|
| **No** | **Policy Reference** | **Question/Notes** |
| 1 | 1.1 | Overview of the manufacturing site.<br>**Facility size: 90,000 square feet**<br>**Number of unit : 1 No of buildings/block : 9**<br>**Building # 1 to # 4: Manufacturing block for herbal extract**<br>**Building # 5: Raw material storage warehouse**<br>**Building # 6: Quality control laboratory**<br>**Building # 7: Manufacturing block for herbal extract (Spray drying)**<br>**Building # 8: Packaging unit.**<br>**Building # 9: Administration office**<br>**Other buildings : Boiler, Generator and water plant.** |
| 2 | 1.2 | Locations audited during visit and description of operations.<br>**Shift pattern: 3 shifts (6 am to 2 pm, 2 pm to 9 pm and 9 pm to 6 am) operating 7 days a week with general shift from 9 am to 5.30 pm.**<br>**Number of employees: 178.**<br>**Campus Location #1: Plot No. 101, Jigani Ind. Area Phase II Anekal Taluk, Bangalore 562106 India.** |
| 3 | 1.3 | Company/Brand/Affiliates names are included on the FRS.<br>**Included in FRS** |
| 4 | 1.4 | Length of time facility has been in operation.<br>**18 years** |
| 5 | 1.5 | Type of Audit<br>**On-Site Audit** |

| Administration & Regulatory | | | |
|---|---|---|---|
| **No** | **Requirement Number** | **Question/Notes** | **Answer** |
| 1 | A.1.1 | Facility shall be registered with the US Food & Drug Administration (USFDA) or relevant regulatory authorities based on product manufacturing and distribution.<br>**FDA registration information was downloaded from FDA website www.access.fda.gov. Registration status was "VALID". The registration valid till 2022-12-31. Document consisted of 11 Sections. All sections were reviewed and found correct (like facility address, scope etc.). There was an email on file from FDA containing the Registration number which was xxxxxxx2982 on file.** | **Acceptable** |
| 2 | A.2.1 | Procedures for regulatory visits, inspections shall be established and implemented.<br>**The facility has approved SOP VH/QAD/SOP/082 rev 02 dated 2/11/2020 for "Regulatory Inspection" in place. The facility has VH/TL/F30 regulatory inspection records available with them but no visit has taken place from last audit.** | **Acceptable** |

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| 3 | A.3.1 | Procedures for personal hygienic practices shall be established and implemented.<br>**Previous CAR # 2834928-1: Implemented.**<br>**The following SOPs were reviewed;**<br>**a) Personal hygiene policy SOP VH/QAD/SOP/006 rev 07 dated 1/6/2021.**<br>**b) Dress code and cleanliness policy VH/QAD/SOP/005 rev 02 dated 2/11/2020**<br>**c) Disease control policy VH/QAD/SOP/008 rev 06 dated 2/11/2020**<br>**d) Covid Guidelines policy VHPL/CMP-01 rev 08 dated 10/8/2021**<br>**Hair nets and snoods have to be worn in drum filling areas. Wearing of jewelery and piercings was not permitted. Glasses needed to be threaded. Hand washing rules were indicated. Rules on taking medicines and behavior in case of medical conditions were included. Rules for wearing gloves were indicated. The medical test are done annually which was dated 19/4/2022 from M/s Institute of Occupational health and environment was verified on file. The personal hygiene checklist are filled on daily basis reference VH/HR/07 with records for May 2022 sighted on the file.** | **Acceptable** |
| 4 | A 3.2 | Protective garments shall be worn in exposed product areas.<br>**# Reviewed policy on Dress code and cleanliness policy VH/QAD/SOP/005 rev 02 dated 2/11/2020. Also, during site tour same was followed to be implemented.** | **Acceptable** |
| 5 | A.3.3 | Procedure for cleaning protective garments shall be established and implemented.<br>**The SOP for laundry has been by external agency M/s SFATEC for washing with contract verified and valid till 8/8/2022 on annual basis found to be documented with all the requirements been addressed in the contract copy as per the standard requirements. The audit was conducted 8/6/2020 for the laundry services on virtual and records available on file in format number VH/HR-F/19 on weekly basis. The microbiology swab test report for the apron was also conducted on 2/6/2022 and available for review.** | **Acceptable** |

| Quality Management | | | |
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| **No** | **Requirement Number** | **Question/Notes** | **Answer** |
| 1 | B.1.1 | Senior management shall have a process for reviewing the Quality System and performance indicators, at a minimum annually.<br>**The senior management review of Quality System and performance indicators was conducted on 29th March 2022 with minutes of meeting documented in VH/TL/F-05. The MRM meeting are conducted twice per year. The objective as part of KPI results were referred in VH/KPE/01. One of the objective as part of performance indicator has been documented in the KPI results doc number VH/KPI/01 dated 1/3/2016 which was for machinery breakdown max 80 minutes and which was maintained at 45 mins and was tracked on monthly basis. The details of such objectives are discussed in the MRM meeting which was verified for 29th March 2022.** | **Acceptable** |
| 2 | B.1.2 | Quality shall not report directly to Operations, or other areas that pose a conflict of interest; to ensure that quality decision making remains distinct and independent.<br>**The current organizational chart as per Quality manual verified in page 46. Quality department is reporting to the senior VP - Quality of the company and not to operation as per the current structure verified in VHPL-FSM-01 dated 2/3/2022 rev 05.** | **Acceptable** |
| 3 | B.1.3 | There shall be a procedure to ensure access to the facility by visitors is controlled.<br>**The visitor policy has been documented in the VH/QAD/SOP/024 dated 2/11/2020 with related to other are captured with records like the visitors sign off, providing bandages and GMP form filling up which are done and documented. The visitor's sign off record are available in the register which are maintained at the security with last entry for visitors was done on 19/5/2022 from pest control company.** | **Acceptable** |
| 4 | B.2.1 | Personnel shall have the appropriate qualifications; and have adequate training, experience, and education necessary to perform identified job functions.<br>**The HR policy which is included in the CSR policies and procedure manual VHPL-CSR-1 rev 06 dated 4/4/2022. The written job description for the Head- Quality with reference to educational qualification, work experience, technical skills and any additional skills have been documented as part of induction record reference number VH/HR/F-01 dated 20/8/2020 for senior chemist dated 9/5/2022. The annual performance review are done on HR format HR-APP-01 including the Skill matrix competency: VH/QAD/SOP/030 rev 04, dated 01.01.2021 for each employee which was also documented.** | **Acceptable** |

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| 5 | B.2.2 | Quality personnel shall have established roles and responsibilities.<br>**The Quality personnel roles and responsibilities for Microbiologist defined in the VH/JD/QCMB-01 dated 6.12.2018 rev 01.** | **Acceptable** |
| 6 | B.2.3 | There shall be defined supervisor training and responsibilities.<br>**The supervisor training and responsibilities are defined in the roles and responsibility which was verified for production executive and supervisor as per VH/JD/004.** | **Acceptable** |
| 7 | B.2.4 | All personnel, including temporary staff and contractors, shall be trained in appropriate policies and procedures.<br>**The training SOP has been documented as per VH/QAD/SOP/016 rev 08 dated 12/1/2022 which captures all the details in the format for training. The training need identification with annual training plan available in format VH/HR/F-02. The facility has planned 13 trainings in year 2021 and all were found completed. Also, the training planned for year 2022 was verified and 13 numbers which 5 trainings were completed.**<br><br>**Some of the examples were as follows for in-house training;**<br>**a) GMP training to staff on 24/1/2022 & 25/1/2022 attended by 176 staff,**<br>**b) FSSC Food safety awareness on 21/3/2022 to 23/1/2022 attended by 175 staff.**<br><br>**In this SOP the following procedures were defined: Induction process for new employees, basic GMP training and specific job-related training, annual training frequency for both types of training, document update training and confirmation process. The GMP training also included food safety, allergens and food defence topics. The training needs identification has been identified for Quality department through responsibility matrix for various activity has been documented.** | **Acceptable** |
| 8 | B.2.5 | Refresher training shall be conducted at least annually for all personnel.<br>**The training for PCQI has been imparted and documented with certificate number 2899178e dated 29/10/2018. The refresher training was imparted on May 20, 21st on Food safety internal auditor training which was verified.** | **Acceptable** |
| 9 | B.2.6 | There shall be an assessment of learning following training to document effectiveness.<br>**The training evaluation report are for the year 2022 which was verified with total of 13 trainings have been up-dated. The details for training was verified in the form training evaluation format number VH/HR-F-18 and complete within one week time verified for FSSC 22000 dated 22/3/2022.** | **Acceptable** |
| 10 | B.2.7 | Training and assessment records shall be maintained. | **Acceptable** |
| 11 | B.3.1 | Crisis Management procedures (Back-Up Plan or Disaster Recovery Plan) shall be developed to address any critical situations that occur such as natural disasters, catastrophic events and any other emergency situations (e.g.; power outage, fires, Information Technology (IT) failure, tampering, pathogen outbreak, etc.) that threaten to harm the organization.<br>**The detailed crisis management plan for the Doc no VHPL/CMP-01 rev 08 dated 10/8/2021. The details of the current contact number and role have been documented with back up identified in the plan with crisis team identified. The records of the annual fire safety mock drill conducted on 12/04/2022, done by external agency M/s Reliance Fire Protection Engineers in VH/FDR/01.** | **Acceptable** |
| 12 | B.3.2 | Provisions shall be in place for backup to critical systems in the event of main power failure. Written procedures for recovery from power failure shall be established.<br>**The details of the power failure are addressed in crisis management procedure page 30 of 55. In case of power failure power back generator of 250 KvA has been documented and maintained.** | **Acceptable** |
| 13 | B.4.1 | There shall be a product identification system to ensure raw materials, packaging, work in progress and finished product are clearly identified during all stages of receipt, production, storage and dispatch.<br>**# Checked the SOP VH/QAD/SOP/057 for product identification and traceability.** | **Acceptable** |
| 14 | B.4.2 | Procedures shall be established and implemented to ensure individual product lots or batches are uniquely identified.<br>**Lot Numbers Assigned for individual finished products lot and uniquely identified.** | **Acceptable** |
| 15 | B.4.3 | Finished Product Lot or Batch Number shall be traceable to the customer (one forward) and to the suppliers of raw materials and packaging (one backward). | **Acceptable** |
| 16 | B.4.4 | Records showing product traceability shall be available. | **Acceptable** |

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| 17 | B.4.5 | Traceability exercises shall be conducted at least annually, on one finished product and one raw material, including product contact packaging.<br>**The onsite traceability challenge test conducted on site for the products which was as follows; Product name: Green coffee bean extract 50%, batch number VH/CBE-A/222-0034 batch size: 1000 kgs, Manufacturing date: April 2022, Expiry date: March 2025. Raw material used: Green coffee beans, Quantity received: 20,000 kgs on 22/3/2022 from Vidya Coffee Vehicle number KA 378834 against PO number: KHPL/PO-1733. Goods receive note number: CB2203361, tested on 22/3/2022, approved by QC - AR No: CBVH/21R361. Processing aid used 70% Ethyl alcohol. Ethyl alcohol purchased from KSBCL, AR No: VH21R404 dated 20/3/2022. Packing material: Primary packing with Food grade poly bags. 2000 kgs received on 25/3/2022 from M/s Shree Pla Pvt . Ltd. Vehicle number KA05 AH-1955 against PO number: VHPL/PO- 1741 dated 14/3/2022. Goods receive note number: 2203411 which is approved by QC- AR No: VH21R411. The Product is secondary packing with HDPE drums purchased from Time Technoplast Ltd., received quantity 500 Nos, against PO number: VHPL/PO-1777 dated 21/3/2022. The HDPE drums received on 31/3/2022, Goods receive note number: 2203423 which is approved by QC - AR number VH21R423. Total quantity obtained after processing 1010 kgs, Packed quantity 1000 kg (25 kg X40 drums), number of HDPE drums used is 40 numbers each containing 25kgs of product Total polybag used 18 kgs. 10 kgs material (milling stage loss 2.3 kgs, blending loss 0.9 kgs, shifting loss 2.8 kgs and rest used for QC 1.9 kgs. The mass balance 100 % with all records verified on file and completed within 90 minutes.** | **Acceptable** |
| 18 | B.5.1 | The methods and responsibilities for detection and control of nonconforming product, raw material, ingredient, work-in-progress, packaging during receipt, storage, processing, handling or delivery shall be documented and implemented. Associated records shall be maintained and available for review.<br>**The procedure for the control of non-conforming product has been documented as per VH/QAD/SOP/055 rev 2 dated 2/11/2020 with details filled up in non-conforming records verified but don't have any non-conforming reports on file. In this procedure the following topics were covered how to put OOS materials on hold and how to release them, roles and responsibilities for these procedures were in place, documentation forms to be used, decision to disposition has to be made by Manager-QA which were verified for non-conformance investigation checklist VH/QCF-13 B on file.** | **Acceptable** |
| 19 | B.5.2 | Storage areas for nonconforming product, materials, and equipment shall be clearly identified and separated in a manner that prevents inadvertent use.<br>**The non-conforming area has been identified and hold label are put on the product which are for material not meeting the specifications. The facility document the OOS for such nonconformance product which is identified. Quarantine areas for raw materials and finished products were clearly segregated in separate room which is locked and identified in the system.** | **Acceptable** |
| 20 | B.5.3 | Quarantine records shall include: | **Acceptable** |
| 21 | B.5.4 | Recall and withdrawal procedures shall be established and implemented.<br>**The mock recall procedure has been documented as per VH/QAD/SOP/22 rev 10 dated 1/4/2022. The mock recall conducted on 21/03/2022, for the product Aswanganda extract 1.5 % batch number VH/WSE/F221-1140 Qty 1000 kgs total time duration was 2 hrs with mass balance of 100% in place.** | **Acceptable** |
| 22 | B.5.5 | The effectiveness of the product withdrawal and recall system shall be reviewed, tested and verified at least annually.<br>**See comments B 5.4** | **Acceptable** |
| 23 | B.5.6 | Records of product withdrawals and recalls, mock recalls and traceability exercises shall be maintained. | **Acceptable** |
| 24 | B.6.1 | A document management program shall be established. It shall include a minimum the following:<br>**The SOP for document management program has been as per procedure VH/QAD/SOP/044 rev 03 dated 2/11/2020. Documents were organized by a numbering system, versions were indicated and the date when the document will be effective with blue colour for master copy and red colour for controlled copy. QA reviewed and approved documents. Obsolete documents were called back from the departments based on a list of copies.** | **Acceptable** |
| 25 | B.6.2 | Most recent revisions of documents are accessible to appropriate personnel and positions.<br>**The document accessibility has been maintained as per the procedure and all the documents were available for review on the day of audit.** | **Acceptable** |
| 26 | B.6.3 | Review of documents shall occur on a defined frequency, at least once every three years, unless otherwise justified.<br>**The review of the documents takes place every 2 years as per document revision record format number which is documented in the SOP.** | **Acceptable** |
| 27 | B.6.4 | Good Documentation Practices (GDP) shall be established and implemented. | **Acceptable** |

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| 28 | B.6.5 | Electronic records and signatures, if used shall be included in the document management program and shall be compliant with regulatory requirements (e.g. 21 CFR Part 11, and § B.6.1).<br>**All documents are in hard copy.** | **Not Observed** |
| 29 | B.6.6 | Record management shall be documented and implemented.<br>**The record control procedure has been documented in section VH/QAD/SOP/044 rev 03 dated 2/11/2020.** | **Acceptable** |
| 30 | B.6.7 | Record retention policy shall be defined and implemented.<br>**Previous CAR # 2834928-2: Implemented.**<br><br>**The revised SOP # VH/QAD/SOP/034 section 5.7. Also reference record VH/QA-F-11 also verified for implementation.** | **Acceptable** |
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| Corrective and Preventive Action (CAPA) | | | |
|---|---|---|---|
| **No** | **Requirement Number** | **Question/Notes** | **Answer** |
| 1 | C.1.1 | A corrective and preventive action (CAPA) program to facilitate resolution of food safety and quality issues shall be established and implemented.<br>**The SOP for CAPA VH/QAD/SOP/043 rev 4 dated 2/11/2020. The Quality Head is responsible for handling the CAPA for its approval and respective department for implementation of the plan.** | **Acceptable** |
| 2 | C.1.2 | A documented procedure shall exist for CAPA investigation requirements. Quality shall be responsible for managing and approving all CAPAs.<br>**The details of the report for the CAPA form VH/QC-F-13A verified which is same to that of NCR report which was verified. The details for nature of findings, root cause analysis and closure of CAPA was verified for the internal audit conducted on 18/12/2020 reference IA/03/NCR/02. The details for the CAPA log are maintained in the CAPA handling log for all findings during audits, routine work and addressed in register form which is maintained.** | **Acceptable** |
| 3 | C.2.1 | Complaint Management Program shall be defined, and include roles and authorities, both internal and external. Complaint investigations shall be conducted by qualified personnel.<br>**The market complaint procedure has been documented in VH/QAD/SOP/029 rev 02 dated 2/11/2020.** | **Acceptable** |
| 4 | C.2.2 | Records of customer complaints and any associated investigations shall be maintained.<br>**The customer complaint register reference number VH/QC-F-04 was verified. The last complaint investigation form for one of the product Lycopene 20% oil, batch number: VH/TE-O/F220-0009, manufacturing date: April 2020, expiry date: March 2022 reference ID number VHPL/COM-03, received on 27/05/2020, Complaint details: Breakage of plastic cap of aluminum cans during the transport, complaint closed on 27/05/2020 details of investigation report followed by dual signature by concerned department and verified/closed by QA department. No complaints in the year 2021 and 2022.** | **Acceptable** |
| 5 | C.2.3 | Where required by regulations in the country of manufacture and distribution, procedures for adverse event reporting shall be established and implemented. The adverse event either discovered by or reported to the operation shall be reported to the USFDA or applicable regulatory agency. Appropriate regulatory documents shall be provided to the regulatory agency.<br>**The adverse handling procedure VH/QAD/SOP/054 rev 03 dated 2/11/2020.** | **Acceptable** |
| 6 | C.3.1 | Procedures for internal audit program including methods and responsibilities for scheduling and conducting internal audits shall be documented and implemented.<br>**The procedure for internal audit VH/QAD/SOP/011 rev 5 dated 1/4/2021. The frequency of internal audit based on risk based as per the format schedule which is VH/TL/F16 with all the various department been addressed. The risk-based approach has been documented to cover the internal detail in the schedule audit plan for internal audits with Quality head responsible for conducting the audit.**<br>**The last internal audit was conducted 27/4/2022 for all the departments with 3 non-conformances raised during the audit which was raised 1 packing and 1 QC department which was verified and closed. The internal audit trend analysis also have been documented and analyzed for improvement.** | **Acceptable** |

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| 7 | C.3.2 | Staff conducting internal audits shall be trained on internal audit procedures and shall be independent of the function being audited.<br>**Previous CAR # 2834928- 3: Implemented**<br>**The internal auditor training was conducted on May 20th and 21st, 2021 available with certificate and training on the file also verified. Interview was conducted with staff trained and found to be satisfactory.** | **Acceptable** |

## Supplier Qualification

| No | Requirement Number | Question/Notes | Answer |
|---|---|---|---|
| 1 | D.1.1 | Supplier/Material Qualification Program shall be established and documented.<br>**Previous CAR # 2834928-4: Implemented**<br>**The procedure has been amended as per approving criteria based on this filled questioner received from the supplier in vendor approval procedure VH/QAD/SOP/037 rev 8 dated 25/3/2022. The new vendor questionnaire has been filled vendor name M/s Jaycee Agro Products India Pvt Ltd. which was conducted on 2/6/2022 for all supply of herbal extracts.** | **Acceptable** |
| 2 | D.1.2 | Sources of any product or component that are brokered, or contract manufactured by the facility shall be identified.<br>**The source of manufacture of a product are analyzed and documented. Manufacturer information are now available in pre audit questionnaire and supplier approved list as part of the approved vendor / Supplier list which was verified.** | **Acceptable** |
| 3 | D.1.3 | A Supplier assessment schedule shall be documented and approved and shall be managed by Quality.<br>**The in-house ID testing for material is on green coffee bean extract 40%, batch number VH/CBE-40/F220-0921, report date: 02/02/2021 with report code: AR-21-IR-008427-01-01 which was verified.** | **Acceptable** |
| 4 | D.1.4 | Where required, a Foreign Supplier Verification Program (FSVP) shall be established and implemented.<br>**The supplier are based in the country so no imported material are used.** | **Not Observed** |
| 5 | D.2.1 | Purchasing controls shall be documented and implemented and shall include provisions to only purchase or obtain services from an approved supplier.<br>**Previous CAR # 2834928-5 : Dropped**<br>**The approved vendor list as per VH/PUR/F-07 rev 03 dated 25/3/2022 with details of purchases and contact details has been documented."the requirement was removed, therefore the CAR is dropped" but was combined with another requirement.** | **Acceptable** |
| 6 | D.3.1 | Inspection and receipt of goods, including components, raw materials, product labels and packaging shall be documented and implemented, and shall include provisions to confirm that only approved suppliers were used.<br>**The sampling procedure for inspection of goods are documented in VH/QCD/SOP/004 rev 04 dated 2/11/2020 The details for the raw materials and packing material also verified.** | **Acceptable** |
| 7 | D.3.2 | A system shall be established to determine if all incoming goods and materials specifications have been met.<br>**The specification are documented for the raw material and tested accordingly which was verified for green coffee beans (Arabica) VH/QC/RMS-33 dated 16/1/2020. The details of the supplier as per analytical reference number (AR) EUINBA-00097365 dated 17/7/2021 checked for identification, foreign matter and caffeine content qty 24610 kgs and approved on 1/2/2021. Similarly, for packaging material, LDPE bags as per specification number VH/PM-SP/02 dated 25/8/2021 which was verified and documented.** | **Acceptable** |
| 8 | D.3.3 | A carrier inspection procedure for receiving and shipping shall be established and implemented.<br>**The vehicle inspection programme as per procedure VH/STR/F-01 dated 1/10/2019. The outbound vehicle are also checked for the dispatch of material and each drums are sealed with tamper sealed which are recorded in the form which was verified.** | **Acceptable** |
| 9 | D.3.4 | Raw materials or components shall be sampled, examined and released prior to use in production.<br>**The processing aid are also tested which was verified for solvent ethyl alcohol as per specification format number VH/ET-SP/01, dated 01/01/2021 which was verified.** | **Acceptable** |
| 10 | D.3.5 | Packaging and labeling materials shall be visually examined and reviewed against the supplier's invoice to determine conformance with specifications.<br>**The packaging and labelling are implemented as per the customer specifications which was verified in the BPR and traceability exercise.** | **Acceptable** |

| Food Safety | | | |
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| **No** | **Requirement Number** | **Question/Notes** | **Answer** |
| 1 | E.1.1 | A multidisciplinary team that includes personnel responsible for quality, production, technical, and other relevant functions in the company shall be established.<br>**The team remains the same as per Food safety VH/TL/F01 dated 2/8/2021. The food safety team is multidisciplinary and the dedicated person Quality Head has been specifically nominated as the food safety (HACCP) team leader having 10 years and has been trained in PCQI and Food safety training. The other members of the team are from quality, operations (production and Engineering), purchase, Human resource, Stores and quality executive. The team members have good educational back ground and experience of the product.** | **Acceptable** |
| 2 | E.2.1 | A food safety plan (e.g. HACCP, Food Safety Plan) specific to the manufacturing site shall be established and implemented.<br>**The details of alcoholic Extracts of Green coffee bean 50% / Ashwagandha (Withania Somnifera), Tulsi (Holy Basil leaves) Turmeric (Curcuma Longa) water extracts of Mucuna Pruriens and Clove (Syzgium Aromaticum. The product specifications are taken from legislative/regulatory documents. Product flow chart is adequately descriptive and has been reviewed and verified on 2/8/2021 by the HACCP team. The products manufactured are the solvent extracted concentrates and spray dried. Currently the product being manufactured is Green coffee bean extract 50 % which was verified. The Food safety plan was reviewed once per year and next due is on 2/8/2022.** | **Acceptable** |
| 3 | E.2.2 | There shall be a current and verified process flow diagram covering the scope of the food safety plan.<br>**Verified the flow chart for the flow diagram for green coffee extract 40% in doc number VH/TL-F01 and for curry leaf extract VH/TL-F01 dated 2/8/2021 respectively.** | **Acceptable** |
| 4 | E.2.3 | Hazards that are known or can be reasonably expected to occur shall be considered and identified for each type of product manufactured, processed, packed, or held at the facility at each step of the operation, and for other inputs.<br>**Hazard analysis for all the steps identified in the flow chart has been done and consists of possible Biological, Chemical and Physical hazards. They have also identified quality hazards. Risk assessment has been done by the Food safety team. They have used various sources for the data on risk assessment and have also used their personal experience and available knowledge in the industry.** | **Acceptable** |
| 5 | E.2.4 | Hazard evaluation shall be conducted for each identified hazard. A combined hazard analysis is acceptable for different packaging sizes of the same product.<br>**The hazards have been evaluated for significance and the high-risk areas were identified correctly. The HACCP studies have identified control points for monitoring- Spray drying of the products Inlet temperature 190 Deg C to 210 Deg C and outlet temperature 90 to 100 Deg C Monitoring at Every one hour The HACCP study has identified other controls as 1. Extraction with solvent such as Ethanol (96%)- and Checks for foreign matter and filtration using press filter, 2. Distillation of solvent and concentrated mass- Solvent residue- Distillation under vacuum 3. Purification / Enrichment and final distillation, Solvent residue - Distillation under vacuum. HACCP plan which includes the identified critical hazards and their monitoring plans, including corrective actions in case of deviations and also verification plans. Verification planning: The verification of proper application of all PRP's has been carried out as per the identified frequencies in the individual procedures and records maintained to make sure the hazards are reduced to accepted level with records verified.<br>In addition, the packgaing material also have been included in the hazard analysis.** | **Acceptable** |
| 6 | E.2.5 | Controls to prevent or significantly minimize hazards shall be identified, established and implemented.<br>**Verification activities have been reviewed periodically by the QA Manager and also by the senior management at management reviews. Three CCPs have been identified.<br>1. Filtration after extraction: 0.5- micron mesh size to eliminate particles more than 0.5 micron. Filter checks are done after each batch 1000 kgs.<br>2. Drying spray/vacuum are temperature limits 190-210 Deg C /10 minutes per cycle<br>3. Metal detection after sifting and before final packing: Fe- 0.8 mm; NFe- 1.0 mm and SS 1.2 mm. Metal detector check is done after each batch of 1000 kgs.<br>The verification activities have been completed and results are communicated to food safety team. CCP's have been verified as per the HACCP plans which was done by the HACCP team and documented.** | **Acceptable** |

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| 7 | E.3.1 | The facility shall have a documented and implemented Environmental Monitoring Program.<br>**Reviewed the # SOP/MB/003 dated 31.10.2018 Environmental monitoring in place. The facility carry out the microbiology pathogen testing for air and water including the drain pathogen testing which is documented in environmental monitoring program F8.2.4-10-05 for Salmonella and Listeria checks. The report for zone 4 is documented in VH/QC-F-55 on monthly basis with records available 1/4/2021 on file.** | **Acceptable** |
| 8 | E.4.1 | The facility shall have a documented and implemented allergen control program.<br>**Allergen monitoring program has been documented vide Allergen control policy VH/QAD/SOP/038, issue:02, revision: 5, dated: 01/01/2021.** | **Acceptable** |
| 9 | E.4.2 | Production records and documents, batch sheets formulas, labels, etc. shall clearly identify the presence of allergens.<br>**No allergen are handled however they have separate area identified for allergens in case of any R&D samples received at the facility for safety reason.** | **Acceptable** |
| 10 | E.4.3 | Allergenic ingredients and allergen containing bulk and finished products shall be identified.<br>**See comments in E 4.2.** | **Acceptable** |
| 11 | E.4.4 | Allergen containing ingredients, Work-In-Process (WIP), rework and finished product shall be controlled.<br>**See comments E 4.2.** | **Acceptable** |
| 12 | E.4.5 | Allergen management control program shall include documented cleaning procedures.<br>**No allergenic material handled at the site.** | **Acceptable** |
| 13 | E.5.1 | Sanitation controls shall be defined and documented to mitigate product risk.<br>**Cleaning procedures have been developed as per regulatory guidelines and verified by the food safety team by using daily or weekly general cleaning checklist (HR-F-06). Verified the details for the May 2022 on file.** | **Acceptable** |
| 14 | E.5.2 | Standard Sanitation Operating Procedures (SSOPs) shall have procedures that include methods, frequencies and chemicals to be used when cleaning areas; and include how the cleaning shall be documented and maintained.<br>**The cleaning and sanitation team operate after finishing a lot of 500 Kgs for a thorough clean of the production line. Cleaning procedures have been developed as per regulatory guidelines and using Daily or weekly General cleaning checklist (HR-F-06) verified by the food safety team and recorded.** | **Acceptable** |
| 15 | E.5.3 | Documents, records, and check sheets for cleaning and sanitation shall be maintained. | **Acceptable** |
| 16 | E.5.4 | A master sanitation schedule (MSS) shall be developed and utilized for the monitoring and recording of cleaning and sanitizing activities.<br>**Master sanitation schedule was verified as per plant wise on system.** | **Acceptable** |
| 17 | E.5.5 | Pre-operational Inspection (prior to the start of each stage of the process, i.e. weighing, mixing, packaging) shall be documented and maintained.<br>**Pre-operational clearances of equipment and rooms were adequately performed to prevent cross-contamination risk.** | **Acceptable** |
| 18 | E.5.6 | Manufacturing operations shall be conducted using adequate sanitation principles. | **Acceptable** |
| 19 | E.5.7 | Sanitation procedures shall be verified.<br>**The master sanitation schedule along with cleaning validation protocol VH/CV/001 with records for cleaning validation microbiology count was available for review.** | **Acceptable** |
| 20 | E.6.1 | Exposed product, processing vessels, ingredients in use and work-in-process (WIP) shall be adequately covered or protected to reduce the risk of contamination. | **Acceptable** |
| 21 | E.6.2 | There shall be a documented program, including policies and processes for the management of glass and brittle plastic.<br>**Monthly glass/hard plastic audits are evident and observations are recorded in glass register VH/QC-F-14 done on monthly basis conducted on 24/3/2022. No glass incidents to date. Staff well trained in process and mock incident has taken place for training. No glass containers are used to pack products.** | **Acceptable** |
| 22 | E.6.3 | Sieves, filters, and screens shall be used where appropriate and shall be properly managed.<br>**The sieve used is 40 mesh size which integrity test are conducted and recorded in the BMR report for each batch.** | **Acceptable** |
| 23 | E.6.4 | Blades where used shall be controlled and inspected.<br>**No blade are used in the facility.** | **Not Observed** |



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| 24 | E.6.5 | Foreign material detection systems (e.g. x-ray, magnets, filters or metal detection) shall be in place to minimize the potential for foreign material product contamination.<br>**The facility has a metal detector system in place to challenge the metal pieces. The facility has considered a metal detector as a CCP and the critical limit has been defined for Ferrous - 0.8 mm, Non-Ferrous -1.0mm, and Stainless Steel 1.5 mm spherical balls. The facility has to keep the monitoring records for each product in each BMR. Auditor reviewed the standard test pieces test certificate use for verification during the virtual tour.** | **Acceptable** |
| 25 | E.6.6 | Controls for use, storage, and disposal of pallets and porous materials shall be established.<br>**The facility is not handling any wooden pallets.** | **Not Observed** |
| 26 | E.7.1 | Food and non-food chemicals shall be approved for use, securely stored, clearly identified, and used by trained personnel.<br>**Validation carried out on set up of new equipment with machine manufacturers verified as per document VH/CV/001 for various machine. Trends show satisfactory results of the cleaning process. No chemicals are used for cleaning the machinery but only hot water. The machinery is washed with hot water and sanitized using 70% Ethanol. The facility is using chemicals such as a solvent for extraction purposes. All the solvents were stored in separate tanks with restricted access. The facility is not using any other chemicals on site.** | **Acceptable** |
| 27 | E.7.2 | Food Defense<br>**Food defense SOP # VH/QAD/SOP/55 version 01 dated 25/3/2022. The facility is also certified to FSSC 22000 and maintained the Food defense process.** | **Acceptable** |

## Facilities

| No | Requirement Number | Question/Notes | Answer |
|---|---|---|---|
| 1 | F.1.1 | A master site plan or facility diagram/floor plan shall be on file, readily available for review during the inspection, and accurately reflect the current layout of the building including but not limited to: | **Acceptable** |
| 2 | F.1.2 | All facilities shall be of adequate size, construction, and design for their intended use.<br>**Previous CAR# 2834928-6 : Implemented.**<br>**The facility is now maintained and paint peeling off the walls in the packaging material storage area adjacent to the window exhaust causing potential cross contamination of stored packgaing material are now repaired and addressed.** | **Acceptable** |
| 3 | F.1.3 | Product shall be separated and protected from any operations that could cause contamination. | **Acceptable** |
| 4 | F.1.4 | Procedures and processes shall be established to separate different product types including but not limited to foods, human food by-products, cosmetics, dietary supplements and pharmaceuticals across manufacturing, packaging, labeling, holding and storage areas. | **Acceptable** |
| 5 | F.1.5 | Working areas shall have adequate access and space; aisles shall be clear to allow for personnel to perform their duties and protect against contamination or mix-ups.<br><br>**FINDING: Working areas do not have adequate access and space.** The working area in the raw material dispensing area and the storage of materials were touching the walls with no adequate access and space. | **Minor NC*** |
| 6 | F.1.6 | Walls, floors, doors, windows and ceilings shall be kept in good repair and shall allow for appropriate cleaning.<br>**Previous CAR # 2834928-7 : Implemented**<br>**The wall corner edges near the dryer equipment was maintained and repaired which was verified during the onsite tour.**<br><br>**FINDING: Walls, floors, doors, windows and ceilings are not kept in good repair.** New Finding: The ceiling in the plant #2 extraction unit was found to be having deposit of dust and dirt which was not cleaned maintained properly. | **Minor NC*** |
| 7 | F.1.7 | Bathrooms shall be provided and be of adequate number and at appropriate locations. Bathrooms shall be kept clean and shall not be a potential source of contamination. | **Acceptable** |
| 8 | F.1.8 | Hand washing facilities shall be constructed and located in appropriate areas to ensure personnel employ proper hand washing. | **Acceptable** |
| 9 | F.1.9 | Appropriate change rooms shall be available and provide adequate storage of personal effects. | **Acceptable** |
| 10 | F.1.10 | There shall be a documented process for the design and qualification of facilities and equipment. | **Acceptable** |

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| 11 | F.2.1 | Equipment shall be 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. | **Acceptable** |
| 12 | F.2.2 | All product production and packaging equipment shall meet food sanitary design requirements. These shall be installed in such a manner as to permit proper operation and access for cleaning and inspection. | **Acceptable** |
| 13 | F.2.3 | Utensils shall be designed and constructed to withstand the environment in which they are used and shall not degrade upon exposure to components, process materials, and cleaning agents. | **Acceptable** |
| 14 | F.2.4 | Equipment and utensils shall protect components and dietary ingredients from contamination by any source. | **Acceptable** |
| 15 | F.2.5 | Automated, mechanical, or electronic equipment shall be functioning properly and be adequately designed. | **Acceptable** |
| 16 | F.3.1 | Grounds shall be properly maintained. | **Acceptable** |
| 17 | F.3.2 | The exterior of the facility shall be constructed and maintained to facilitate the production of product that meets customer and regulatory food safety and quality requirements. | **Acceptable** |
| 18 | F.3.3 | Water that comes in contact with a product contact surface or used as a product component shall meet regulatory requirements for drinking water in the country of sale and shall not cause contamination to the product.<br>**Water used in production is treated to eliminate the minerals using softner and ion exchange process Then RO water is subjected to UV light exposure. However, water treated with Ion exchange softener is used for boiler. Water is analysed daily in house for microbiology (TVC, TFC, Coliform, e-coli, Salmonella, Staph. Aureus, pseudomonas Aeruginosa pH, Hardness in terms of conductivity) (recorded in format No: VH/QC-F-49, rev: 03, dated 2020-07-01) and once in a year by Eurofins laboratory (NABL accredited lab) for potability test analysis as per IS 10500:2012. The report number AR-22-IR-025585-01 dated 2022-03-22 is on record was viewed.** | **Acceptable** |
| 19 | F.3.4 | Water delivery systems shall be constructed, designed and maintained to prevent contamination of the product.<br>**The facility has now included the plumbing and water diagram for the RO, DM, and purified water storage tanks. The staff has been trained accordingly and records maintained with the organization on file.** | **Acceptable** |
| 20 | F.3.5 | Testing shall be conducted to demonstrate that the water supply is potable and that potability is maintained. | **Acceptable** |
| 21 | F.3.6 | The facility shall demonstrate that ice and steam supplies are potable and that potability is maintained.<br>**No ice and steam used in the product related manufacturing in the facility.** | **Not Observed** |
| 22 | F.3.7 | Plumbing shall be of adequate size and design for intended usage. | **Acceptable** |
| 23 | F.3.8 | Sewage and waste disposal shall be properly plumbed from the facility and shall not provide a potential source of contamination to areas including, but not limited to, contact surfaces, products, components, and water supplies.<br>**Waste water with local regulations and ETP water as per Karnataka state pollution control board norms consent order no AW-331099 and valid till 30/9/2031 which was verified. The waste disposal procedure are followed and documented. The plant generate only cleaning chemical which is send to common effluent treatment plant located in the industrial area** | **Acceptable** |
| 24 | F.3.9 | Floor drainage shall be adequate. | **Acceptable** |
| 25 | F.3.10 | Backflow and cross-connection prevention devices shall be installed to protect potable water supplies. | **Acceptable** |
| 26 | F.3.11 | Adequate heating, ventilation and airflow shall be provided in all areas to maintain proper environmental and sanitary conditions for ingredients, finished product, equipment, and packaging materials. | **Acceptable** |
| 27 | F.3.12 | Airborne contaminants shall be minimized. | **Acceptable** |
| 28 | F.3.13 | Process gases and compressed air that are used and contact dietary ingredients, components, and contact surfaces shall be controlled so as not to cause contamination.<br>**No process gas and compressed air are used in the facility and product.** | **Not Observed** |
| 29 | F.3.14 | Adequate lighting shall be provided in all production and examination areas, including warehouses.<br>**The light intensity is checked and recorded in the form VH/MT-F-07 which was verified for May 2022 on file.** | **Acceptable** |
| 30 | F.3.15 | Lighting that is suspended or located above areas where materials or equipment are exposed shall be safety-type, or the facility shall be constructed in a manner that will protect these areas from contamination with glass. | **Acceptable** |
| 31 | F.3.16 | Temperature and humidity control equipment shall be of adequate design for its intended function and shall be operating properly.<br>**Temperature and humidity log maintained in VH/QC/F-27-09 verified for packing section of milling room done three times per day and recorded.** | **Acceptable** |
| 32 | F.3.17 | Waste treatment and disposal shall be adequate and shall not provide a source of potential contamination. | **Acceptable** |


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| 33 | F.4.1 | Control measures shall be established to prevent pests and animals from entering facility. | **Acceptable** |
| 34 | F.4.2 | A pest control program shall be established and implemented.<br>**The company has an annual pest control contract with Rentokil-PCI verified number 36785 dated 2022-06-01 and valid till 2023-06-1. The contract covers rodents and crawling insects and lizards. Only external baits are used. Once in fortnight inspections are carried out by the contractor and results were recorded on Pest control analysis report- Activity report & Pest Control Register dated 2021-03-16. The company also monitors in-house and records in house monitoring format no: VH/HR-F-08 once in fortnight for rodent and In-house monitoring format no: VH/HR-F-11 daily for rodents and cockroaches. Mr. K U is trained by an external agency "Food safety works". On 2020-12-18. No issues highlighted through monthly trending reports. Pest control chemicals are not stored on site.** | **Acceptable** |
| 35 | F.4.3 | Pest control devices and chemicals shall be properly managed.<br>**Pest control devices were working properly and do not pose any risk of product contamination. The entry points to all units are now covered with Flexible curtains with metal doors to prevent an entry by birds or rodents.**<br>**The pest control map dated 10/8/2021 rodent traps - 35, insect light killers -26 which was verified. The last detailed report dated 23/3/2022 was verified on the documents.** | **Acceptable** |
| 36 | F.5.1 | Procedures and programs shall be established for maintaining equipment.<br>**All the measuring gauges and weighing scales used in production, QC , Stores & maintenance are been listed in a formalized Master list of Measuring & Monitoring Devices, where all the range, least count, operating range, calibration frequency, calibration standard are been mentioned. - Process monitoring is done using data logging system where temperature and Vacuum are being monitored online and with digital display against every process equipment. These instruments are calibrated externally and records maintained.** | **Acceptable** |
| 37 | F.5.2 | All equipment, utensils, utilities, parts and tools shall be included in the PM program | **Acceptable** |
| 38 | F.5.3 | Equipment and utensil surfaces shall be corrosion-resistant, made of non-toxic materials. These shall be inspected at routine intervals for signs of wear and damage.<br>**The material used are SS 316 grade which for 5KL reactor with MS jacket was verified on file.** | **Acceptable** |
| 39 | F.5.4 | Procedures shall be defined for equipment taken out for maintenance.<br>**The preventive maintenance and records for the burning hours of the UV lamp. The records are documented in VH/EWL/001 dated 2/4/2022. Training provided on the change to staff which was on 21/4/2022 with RO water log: VH/RO-L/01 which are also documented.** | **Acceptable** |
| 40 | F.5.5 | Maintenance, inspection, cleaning and sanitation records shall be maintained for each piece of equipment.<br>**The breakdown maintenance register VH/MAIN/F-04 dated 14/5/2022 was verified on file.** | **Acceptable** |
| 41 | F.5.6 | A maintenance shop shall be in a defined area within the facility. | **Acceptable** |
| 42 | F.6.1 | A calibration program shall be established and implemented.<br>**Calibration details were reviewed during the audit for the equipment which are used for monitoring the processes**<br>**1.Digital Temperature indicator with sensor – FCS make, Range 0 deg C to 200 deg C id no. VH/PRO/03 fitted on Manufacturing plant 1, Extractor 03 (P1E4) Calibration done by BLR Techno Solutions - Certificate number BLR 22/O/430-64 dated 2022-03-02 and valid till 2023-02-28.**<br>**2. Pressure Gauge Make -Delta Range - 0-21 kg/cm2 ID - VH/PRO/97 Location --Manufacturing plant 2, Extractor 03 (P1E4) Certificate Number - BLR22/O/430-67 Cal Date – 2022-03-01 and Due Date - 2023-02-28 Done by BLR Techno Solutions were verified.** | **Acceptable** |
| 43 | F.6.2 | Equipment, instrument, and control devices that impact product compliance to quality and regulatory requirements shall be calibrated.<br>**The metal detector checks are done on M/s Target innovations ferrous, non-ferrous and SS as per model GFMD-75 done on 16/5/2022 and next due date 15/5/2023 on file. The calibration certificate for metal detector report number 132 dated 31/7/2021 and next due date 30/7/2022 was verified.**<br>**The autoclave records for calibration from external agency M/s Alphs Linear private limited dated 7th August 2021 with certificate number ALPL/VHPL/PC/AV/08-21/01 and valid till 6/8/2022 on file.** | **Acceptable** |
| 44 | F.6.3 | Calibration record requirements shall be defined. | **Acceptable** |
| 45 | F.6.4 | Quality shall review and approve all processes and procedures for calibrating equipment, instruments, and control devices. | **Acceptable** |
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## Production and Process Controls

| No | Requirement Number | Question/Notes | Answer |
|---|---|---|---|
| 1 | G.1.1 | Production and process controls to ensure product consistently meets specifications and is produced according to manufacturing procedures shall be established and implemented. | **Acceptable** |
| 2 | G.1.2 | Manufacturing processes shall be designed to produce a product that consistently meets specifications and as specified in the manufacturing procedures. | **Acceptable** |
| 3 | G.1.3 | Procedures for the collection of representative samples to verify compliance with specifications shall be established and implemented. | **Acceptable** |
| 4 | G.1.4 | Procedures for control of packaging and labeling operations shall be established and implemented. | **Acceptable** |
| 5 | G.1.5 | The packaging integrity and function shall adequately protect the product. | **Acceptable** |
| 6 | G.1.6 | Where label information is the responsibility of the facility, procedures for development, review and revision of labels shall be established and implemented.<br>**The procedure for label control and issuance documented in VH/QAD/SOP/051 with details of label reconciliation log F-03 verified on file.** | **Acceptable** |
| 7 | G.2.1 | Controls for rework and reprocess operations shall be established and implemented.<br>**The procedure for rework and reprocessing as per standard requirement as per procedure VH/QAD/SOP/053 were available for review.** | **Acceptable** |
| 8 | G.3.1 | Procedures for setting specifications for in-process product, and finished product shall be established and implemented.<br>**The specification are documented for the raw material and tested accordingly which was verified for green coffee beans (Arabica) VH/QC/RMS-33 dated 16/1/2020.** | **Acceptable** |
| 9 | G.3.2 | Botanical components shall be identified.<br>**The in-house ID testing for material is on green coffee bean extract 40% which was verified.** | **Acceptable** |
| 10 | G.3.3 | All blends shall be identified for both incoming and finished products.<br>**No blend are received in the facility.** | **Not Observed** |
| 11 | G.4.1 | Procedures shall be established and implemented to ensure product is not released until all release criteria have been met and release is authorized.<br>**The product release criteria are defined as per the product release report. Release criteria were checked using the product the traceability exercise was carried out on. All control steps identified in the process relevant SOPs had to filled out and signed off by quality manager, including analytical results and absence of contaminants tested externally by third approved lab on file.** | **Acceptable** |
| 12 | G.4.2 | Finished product compliance testing requirements shall be established.<br>**Finished product analysis report format No: VH/QA-F-05, Product name: Curry leaf extract batch number: VH/CRE/F222-0007 qty 900 kgs mfg date: April 2002 expiry date March 2024. Tested for id test by TLC, appearance, odour, particle size, bulk density, Assay for Chlorogenic acid and Caffeine by HPLC, pH, Turbidity, LOD, Solubility, Total solvent residue by GCMS, Total heavy metals by ICPMS, Microbiology parameters: TPC, Yeast and mould, Total coliforms, S. aureus, P. aeruginosa, Salmonella spp and E.coli results was verified.** | **Acceptable** |
| 13 | G.4.3 | CoA and/or Certificate of Compliance (CoC) shall be made available for all finished raw materials sold.<br>**Raw material used: Green coffee beans, Quantity received: 20,000 kgs on 22/3/2022 from Vidya Coffee Vehicle number KA 378834 against PO number: KHPL/PO-1733. Goods receive note number: CB2203361, tested on 22/3/2022, approved by QC - AR No: CBVH/21R361. Processing aid used 70% Ethyl alcohol. Ethyl alcohol purchased from KSBCL, AR No: VH21R404 dated 20/3/2022. Packing material: Primary packing with Food grade poly bags. 2000 kgs received on 25/3/2022 from M/s Shree Pla Pvt . Ltd. Vehicle number KA05 AH-1955 against PO number: VHPL/PO- 1741 dated 14/3/2022. Goods receive note number: 2203411 which is approved by QC- AR No: VH21R411.** | **Acceptable** |
| 14 | G.4.4 | Procedures for the collection of reserve or retain samples for each lot of finished product shall be established and implemented.<br>**Procedures shall be established for the collection of reserve or retain samples for each lot of finished material has been addressed in VH/QAD/SOP/018 dated 31/10/2018.** | **Acceptable** |
| 15 | G.4.5 | Procedures for the control of returned products shall be established and implemented.<br>**The policies are documented as per the returned goods VH/QAD/SOP/031 dated 31/10/2018 verified.** | **Acceptable** |

## Laboratory Controls

| No | Requirement Number | Question/Notes | Answer |
|---|---|---|---|
| 1 | H.1.1 | Procedures shall be established and implemented for laboratory operations.<br>**The documented procedure for laboratory operation is covered in procedure which verified as per VH/QAD/SOP/079 rev 01 dated 2/11/2020.** | **Acceptable** |
| 2 | H.1.2 | The laboratory and laboratory personnel shall not serve as points of potential contamination within the facility.<br>**The in house laboratory is equipped for chemical analysis as per the laboratory safety procedure VH/QAD/SOP/081 rev 1 dated 2/11/2020. The facility microbiology laboratory on the site which is separate from the production building and properly controlled as per the safety requirements.** | **Acceptable** |
| 3 | H.1.3 | Methods of testing and examination used to confirm specifications shall be defined.<br>**The sampling plan procedure doc VH/QCD/SOP/111 dated 2/11/2018 verified. The details for the same are approved by Quality department for sampling for chemical analysis. The reduced testing programme as per VH/QAD/SOP/046 has also been documented. Microbiological specifications and sampling plans shall be established which was verified in VH/QCMB/SOP/51. The microbiological test method are defined in microbiological testing for TPC, E.coli, Salmonella, Pseudomonas and other pathogens with details of testing which are defined in the procedure for microbiological sampling and details maintained in VH/QCMB/SOP/01, 02 and 03 respectively with USP 40 NF 35 followed.**<br>**The autoclave records for calibration from external agency M/s Alphs Linear private limited dated 7th August 2021 with certificate number ALPL/VHPL/PC/AV/08-21/01 and valid till 6/8/2022 on file.** | **Acceptable** |
| 4 | H.1.4 | All test methods developed in house or standard methods that have been modified or used outside their scope shall be validated.<br>**The test method are validated as per procedure VH/VMP/01 rev 04 dated 1/4/2021.**<br>**The analytical method validation test for Analytical method validation for solvent residue using GC/MS as per VH/RS/MB/18/01 dated 18/4/2018. The validation procedure included Linearity, system suitability, Limit of detection, Limit of quantification, repeatability, intermediate precision, robustness, Accuracy - Spiked recovery. Reference standard pure 1000 mg of ethanol reference number used as internal standard purchased from M/s Lab chem services which was verified.** | **Acceptable** |
| 5 | H.1.5 | Where required by the regulations in the country of manufacture and distribution, a stability testing program to support product shelf life shall be established.<br>**The procedure for stability studies testing for finished products are conducted as per VH/QAD/SOP/010 rev 06 dated 2/11/2020. The stability is checked as per ICH guidelines accelerated and long term studies on file.** | **Acceptable** |
| 6 | H.1.6 | Shelf life and stability studies data shall be available (e.g. stability study results, stability summary report, etc.). For contract manufacturers, where stability studies are performed by brand owner, contract manufacturer shall have proof of stability (e.g. stability data or stability summary report) on file to support quality release of final dietary ingredient.<br>**Stability study conducted for both Normal and Accelerated type. Normal study details : Studies conducted for description, LOD, Assay, Microbiology parameter like TPC, TYMC, Total coliforms, E.coli, Salmonella, S.aureus and P. aeruginosa at the interval of initial, 3rd month, 6th month, 9th month 12th month, 18th month, 36th month and 48th month which is recorded in the format number: QC-SBRT- 01, revision 07, rev. date: 20/06/2020 which was verified.**<br>**One of the example for completed stability study was verified for product Holy basil extract 2.5% batch number VH/HBE/F216051 mfg date April 2016 and expiry March 2019 on file. Also** | **Acceptable** |

| Warehouse and Distribution | | | |
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| **No** | **Requirement Number** | **Question/Notes** | **Answer** |
| 1 | I.1.1 | Procedures for warehouse and distribution shall be established and implemented.<br>**The warehousing and distribution checks are done and documented as VH/QAD/SOP/028 and VH/QAD/SOP/035 has been maintained.** | **Acceptable** |
| 2 | I.1.2 | Raw materials, ingredients, packaging and finished products shall be secured and protected in storage. | **Acceptable** |
| 3 | I.1.3 | Appropriate precautions shall be implemented to prevent contamination by microorganisms, chemicals, filth, or other extraneous materials. | **Acceptable** |
| 4 | I.1.4 | Equipment including but not limited to freezers and refrigerators that are used to hold components or dietary ingredients shall be functioning properly and adequately designed.<br>**Not in use.** | **Not Observed** |

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| 5 | I.1.5 | Procedures for inventory control shall be established and implemented.<br>**Procedures for inventory control shall be established and implemented. The facility maintained inventory transfer with details of the inventory maintained in the excel sheet. The details of material requisition for the finished goods handed material requisition slip was verified. The inventory are taken on monthly basis and recorded with challenge test are done on weekly basis as the system of record keeping is manual and documented.** | **Acceptable** |
| 6 | I.1.6 | Procedures for holding and distribution operations shall be established and implemented. | **Acceptable** |
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| GMP Registration Policies | | | |
|---|---|---|---|
| **No** | **Requirement Number** | **Question/Notes** | **Answer** |
| 1 | J.1.1 | Prompt and thorough access shall be granted to the auditor during the NSF audit. | **Acceptable** |
| 2 | J.1.2 | Documents requested during the NSF audit shall be provided in a timely manner. | **Acceptable** |
| 3 | J.1.3 | The NSF GMP Registered Facility Mark shall not be used on materials, ingredients, components, or finished products. | **Acceptable** |
| | | | |

* Represents nonconformances.




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