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| **Relevant Standard** | **ISO 9001:2015 GMP HACCP** |
| * Lead Auditor Please follow the client processes to prepared the following two forms * This audit programme is to be prepared by the Lead Auditor at the completion of the Stage 2 audit or the Recertification audit. It should be replicated in all subsequent surveillance visit reports. * Where an element(s) of the programme cannot be completed at a given visit the programme shall be amended and up-issued accordingly to ensure coverage at the following visit * Site visits are to be included in the programme with a clear indication as to the processes intended to be sampled. | |

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| Process Approach Details of process Map |
| Including input & output |
| **MP1 Business Management Process**  Understanding the organization and its context / Understanding the needs and expectations of workers and other interested parties / Scope of operations / the ISO 9001:2015 GMP and HACCP Codex Standard  Leadership and commitment / ISO 9001:2015 GMP and HACCP Codex Standard policy / Organizational roles, responsibilities and authorities / Consultation and participation of workers  Actions to address risks and opportunities and assessment of risks and opportunities / Determination of legal requirements and other requirements / Planning action  **MP2 Continual Improvement**  ISO 9001:2015 GMP and HACCP Codex objectives and planning to achieve them  **Performance evaluation:** Monitoring, measurement, analysis and performance evaluation / Internal audits / Management review  **Improvement:** Incident, nonconformity and corrective action / Continual improvement  **SP1 Support process- Admin / DCC**  **Support:** Resources / Competence / Awareness / Communication / Documented information  **COP1 Operation process**  Operational planning and control / Emergency preparedness and response  **The system cord process - Engineering inspection**  Received order -> Manpower input to project -> Engineering inspection -> Project handover.  **The system cord process -** **ISO 9001:2015 GMP and HACCP Codex Management training**  Received order -> Design training program -> Planning -> Lecture freelance selection -> Prepare training course -> Training |

**Process Audit Record**

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| **Process name:** | Organisational Context and Planning | **Process Owner** | Top Management |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| **Evidence to support audit conclusion (inputs/outputs/Process observations):**  **(4) Context of The organization**  **(4.1) Understanding the organization and its context**  **(4.2) Understanding the needs and expectations of interested parties**  **(4.3) Determining the scope of the quality management system**  **(4.4) Quality management system and its processes**  **(6.1) Action to address risks and opportunities**  FLEX ENGINE CO., LTD.  Address: 88/22 Moo 2 Nara Phirom, Bang Len, Nakhon Pathom Thailand  Meeting conducted at Office of FLEX ENGINE CO., LTD. audit conducted as per audit plan. Site tour made with ISO 9001:2015 GMP and HACCP Codex staff.  Member:   1. Mr. Tawatchai S. – CEO 2. Mr. Suntron R. – ISO Officer 3. Mr. Pisit S.- Engineering 4. Mrs. Marisa K.- ISO Staff & Document Control 5. Mr. Weerayut J. Sale & Marketing   **(4) Context of The organization**  **(4.1) Understanding the organization and its context**  **(4.2) Understanding the needs and expectations of interested parties**  **(6.1) Action to address risks and opportunities**  The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | **Document Title** | **Document No.** | **Established** | | Risks & Opportunities Management | QM-GMP-HACCP-01 | 31-01-2020 ISSUE 00 |   Procedures established where all activities required by the standard requirement have been addressed and fulfilled.  **(4.1) Understanding the organization and its context**  The organization has identified internal and external issues of processes in the business flowchart of company which are relevant to  • Purposes of the organization  • Strategic direction  • Affect ability to achieve the intended results of the quality management system   |  |  |  | | --- | --- | --- | | **Considering issues arising** | **Internal issued** | **Risks(R) or opportunities(O)** | | Product | Shortages of raw materials due to natural products | Risks | | Man | Employees lack skills And work expertise | Risks | | Material | -Raw material used from nature cannot control the quality.  -Raw material that are sometimes used by nature are scarce. | Risks | | Method | The method is not complicated but easily loss from work. | Risks |  |  |  |  | | --- | --- | --- | | **Considering issues arising** | **External issued** | **Risks(R) or opportunities(O)** | | Political | Products are controlled by Food and Drug Administration (FDA). The operation may not comply with the relevant regulations. | Risks | | Economic | This product has a clear customer. Currently, sales are not enough to meet demand. | Opportunities | | Social | The place of operation is small. No loud noise at work | Opportunities |   **(4.2) Understanding the needs and expectations of interested parties**  The organization had determined the interested parties and the requirements of these interested parties that are relevant to the QMS and GMP and HACCP fully identified follow this table:   |  |  |  | | --- | --- | --- | | **Interested parties** | **The needs and expectations** | **Issued** | | Owner | Performance is on target. | The performance did not meet the target. | | Employee | Stability and reasonable income | Inappropriate income | | Customer | Quality products Deliver on time and reasonable price | Product is not quality and not enough demand | | External provider | Consistent purchase | The external provider is less and is a purchase through auction | | Regulator | Compliance with relevant regulations | The product does not meet the standards of Food and Drug Administration (FDA). |   The company has established the monitor and review information about these interested parties issues at least once a year.  **(4.3) Determining the scope of the quality management system**  **QMS and GMP and HACCP registration scope:**  “Manufacturing of drinking, Herb Water, Vitamin Water, Flavour drink Water.” The scope of QMS was identified in Quality Manual and GMP and HACCP Manual.  Exclusion of ISO 9001:2015 GMP and HACCP requirement: 8.3 exclusion made to this activity due to there is no activities being  Exclusion of GMP & HACCP Codex Alimentarius:  No exclusion   |  |  |  | | --- | --- | --- | | Requirement | Document No. | Established | | Determining the scope of the QMS/GMP/HACCP | QM-GMP-HACCP-01 | 31-01-2020 ISSUE 00 |  * Scope of registration is defined in the manual. * Requirement 8.3 exclusion to the ISO9001:2015 requirement, mentioning in manual.   8.3: Food and Drug Administration – FDA (under Thai Food Act B.E. 2522) provides specification/ processing requirements and inspection requirements, and the organization do not need to develop the product, product under Food and Drug Administration – FDA (under Thai Food Act B.E. 2522).   * Procedures were referent to each ISO9001:2015 /GMP/ HACCP Codex Alimentarius requirement mentioned in the manual. * The “Business process” was established and defined in the manual, aiming at identifying the business overview.   **(4.4) Quality, occupational health and safety management system and its processes**  All processes needed for the QMS and OH&SMS included their interaction are identified in the Quality manual and GMP and HACCP Manual. | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Leadership | **Process Owner** | Mr. Tawatchai S. – CEO |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| **(5) Leadership**  **(5.1) Leadership and commitment**  **(5.1.1) General**  Top management’s FLEX ENGINE CO., LTD. demonstrated leadership and commit with respect to the QMS by   * Mr. Tawatchai S. – CEO / MR taking accountability for the effectiveness of the QMS GMP and HACCP. * Quality policy and Quality objectives were established by Mr. Tawatchai S. – CEO / MR and these matters are compatible with context and strategic direction of company also these matters were communicated throughout the bureau (Evidence see clause 5.2 and 6.2). * The organization already integrated QMS requirements into the bureau’s business flowchart, identified in the Quality GMP and HACCP manual. * Promoting the use of the process approach and risk-based thinking (Evidence see clause 6.1). * Resources were appropriate for implementation and maintenance of the QMS (Evidence   See clause 7.1).   * Communication the importance of effective quality management and of conforming to the QMS requirements (Evidence see clause 7.4). * Ensuring that the QMS system achieves its intended result through Management Review activity (Evidence see clause 9.3). * Engaging, directing and supporting persons to contribute to the effectiveness of the QMS (Evidence see clause 7.1.2). * Promoting improvement (Evidence see clause 10). * Supporting other relevant management roles to demonstrate their leadership as it applied to their areas of responsibility (Evidence see clause 5.3).   **(5.1.2) Customer focus**   * QMS GMP and HACCP procedure & Customer satisfaction surveys have been implemented to ensure that customer requirements are fulfilled. (Evidence see clause 8.1 and 9.1.2)   **(5.2) Policy**  **(5.2.1) Establishing the quality policy**  **(5.2.2) Communicating the quality policy**  **Quality Policy** was approved by Mr. Tawatchai S. – CEO and announced on January 31, 2020.  FLEX ENGINE CO., LTD., we are a manufacturer of drinking water that is clean, valuable, useful, hygienic and takes into account the safety of consumers and production under international standards ISO9001 GMP and HACCP.  **Quality Policy**   * Policy was established and complied with the specified requirements. * The policy was communicated throughout the bureau by meeting, posted on the information. The authorities acknowledged the policy.   **(5.3) Organizational roles, responsibilities and authorities**   * Organization Chart consists of all positions (4 layers):   CEO -> Managers -> Supervisor -> Staffs   * Job Descriptions were established for all positions and distributed to each department. * Mr. Tawatchai S. – CEO / MR take responsibility and authority for   + Ensuring that QMS conforms to the requirements of ISO9001:2015 standard.   + Ensuring that the processes are delivering their intended outputs.   + Reporting on the performance of the QMS and on opportunities for improvement, in particular to top management.   + Ensuring the promotion of customer focus throughout the organization.   + Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.   GMP/HACCP  Section 5 : Control of Operation  Management and supervision  GMP/HACCP team was appointed on Jan 31,2020, compose of :  Mr. Tawatchai S. – CEO  Mr. Suntron R. – ISO Officer  Mr. Pisit S.- Engineering  Mrs. Marisa K.- ISO Staff & Document Control  Mr. Weerayut J. Sale & Marketing  The team is qualified and capable of maintaining and improvement of the GMP/HACCP system  Management Commitment  • Policy was established and communicated throughout the company.  • Customer requirements were communicated to all personnel concerned.  • Management Review was planned to implement at least 1 time / year.  • Resources were appropriate for implementation and maintenance of the GMP/HACCP.  Policy  Policy is  “FLEX ENGINE CO., LTD., we are a manufacturer of drinking water that is clean, valuable, useful, hygienic and takes into account the safety of consumers and production under international standards ISO9001 GMP and HACCP” Announced on Jan 31,2020  Responsibility & Authority  • Organization Chart consists of all positions (4 layers):  CEO -> Managers -> Supervisor -> Staffs  • Job Descriptions were established for all positions and distributed to each department  Management Representative  GMP/HACCP MR  • Mr. Tawatchai S. – CEO has been appointed as the GMP/HACCP MR since Jan 31,2020.  • The MR has performed his work since the appointment date.  • CEO is the MR. His position was indicated in the organization chart and the responsibilities and authorities were mentioned in company’s organization chart established on Jan 31,2020.  Communication  • Internal communication was made through the use of “Notice Board”, circulation and meeting where appropriate.  • All personnel were fully aware of the GMP/HACCP information. | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Planning | **Process Owner** | Mr. Pisit S.- Engineering |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| **(6) Planning**  **(6.1) Action to address risk and opportunities**  The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | **Document Title** | **Document No.** | **Established** | | Risk Management in QMS GMP HACCP | QM-GMP-HACCP-01 | 31-01-2020 ISSUE 00 |   Procedures established where all activities required by the standard requirement have been addressed and fulfilled.  **Process Flowchart:**  1) Determined the scope of risks & opportunities management ->  2) Understand the organization and contexts for identified internal & external issues ->  3) Identified potential risks ->  4) Analysis types of risks (strategic, operation, financial, compliance) ->  5) Evaluated all potential risks (Likelihood x Severity) ->  6) Determined risk profiles ->  7) Determined actions to dress & considered opportunities for improvement ->  8) Monitor & measured result of actions ->  9) Reviewed overview of risks & opportunities management in management review.  The organization has identified internal and external issues of processes in the business flowchart of company which are relevant to  • Purposes of the organization  • Strategic direction  • Affect ability to achieve the intended results of the quality management system   |  |  |  |  | | --- | --- | --- | --- | | **Considering issues arising** | **Internal issued** | **Risks(R) or opportunities(O) evaluation** | **Actions to address risks and opportunities** | | Product | Shortages of raw materials due to natural products | Medium(R) | Procurement of additional raw material auction sources. | | Man | Employees lack skills And work expertise | Medium(R) | Let the chief give basic knowledge while working. | | Material | -Raw material used from nature cannot control the quality.  -Raw material that are sometimes used by nature are scarce. | Medium(R) | -Determine the source of raw materials.  -Procurement of raw material auction sources. | | Method | The method is not complicated but easily loss from work. | Medium(R) | Set a goal and follow up periodically. |  |  |  |  |  | | --- | --- | --- | --- | | **Considering issues arising** | **External issued** | **Risks(R) or opportunities(O) evaluation** | **Actions to address risks and opportunities** | | Political | Products are controlled by Food and Drug Administration (FDA). The operation may not comply with the relevant regulations. | High(R) | There is a request to register the FDA correctly. | | Economic | This product has a clear customer. Currently, sales are not enough to meet demand. | Opportunities | -Determine the source of raw materials.  -Procurement of raw material auction sources. | | Social | The place of operation is small. No loud noise at work | Opportunities |  |   The organization had determined the interested parties and the requirements of these interested parties that are relevant to the QMS GMP HACCP fully identified follow this table:  Risks and opportunities of the needs and expectations of interested parties   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Interested parties** | **The needs and expectations** | **Issued** | **Risks(R) or opportunities(O)** | **Actions to address risks and opportunities** | | Owner | Performance is on target. | The performance did not meet the target. | Medium(R) | Set a goal and follow up periodically. | | Employee | Stability and reasonable income | Inappropriate income | High(R) | Determination of clear returns And suitable for living expenses | | Customer | Quality products Deliver on time and reasonable price | Product is not quality and not enough demand | Low(R) | -Determine the source of raw materials.  -Procurement of raw material auction sources. | | External provider | Consistent purchase | The external provider is less and is a purchase through auction | Medium(R) | -Determine the source of raw materials.  -Procurement of raw material auction sources. | | Regulator | Compliance with relevant regulations | The product does not meet the standards of Food and Drug Administration (FDA). | High(R) | There is a request to register the FDA correctly. |   **Risks and opportunities of processes**   |  |  |  |  | | --- | --- | --- | --- | | **Processes** | **Issued** | **Risks(R) or opportunities(O) evaluation** | **Actions to address risks and opportunities** | | Sale | Sales did not meet the target. | Medium(R) | Targeting and follow periodically | | Production | Lost raw materials | Medium(R) | There is a check of raw materials between departments. | | QC | Product is not quality | Medium(R) | There is a standard of inspection and tested in every production process | | Warehouse | The amount of storage of raw materials and products does not match the stock card. | Medium(R) | There are checks stock raw materials and products every week. | | Warehouse | Product damage is caused by packaging that is not standardized by the seller. | Medium(R) | Set packing standards with seller | | Warehouse | Expertise of inspection staff (in the cabinet), such as arranging, placing products on pallets If there is a mistake, resulting in the relevant part to be malfunctioned or may have to fix the work, the work will be redundant. | Medium(R) | Create a manual for arranging products on pallets. | | HR | Employees do not have knowledge and understanding of the operation. | High(R) | Continuously develop employee training plans | | HR | Income and employee compensation are not clear. As a result, employees lack motivation to work. | High(R) | Announcement of methods of assessment and how to adjust the pay rate clearly | | HR | Employees do not have modern expertise. | Medium(R) | Internal training | | HR | The management system of the executives does not meet international standards. | Medium(R) | Regularly hold meetings between executives and employees to understand how they work. | | Purchasing | Lead time in the order is delayed and unclear. | Medium(R) | Plan the order in Sheet Google Drive and plan the import in the Discourse. | | Purchasing | Stock management is not enough to sell and keep up with customers' needs. | High(R) | Scheduled to check products in the system every week (Designated as Saturday) and use the database from the Price List as a basis for checking | | Purchasing | Availability of product claim information Makes no bargaining information | Medium(R) | Request information from the accounting department and let the depot notify the matter when QC from the cabinet immediately. And photographed as data | | Delivery | The product is broken during transportation. | Low(R) | Place the product with the weight to the bottom and put on the light weight. And arranged in the order of stores that are later in the inside before in the back |   Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of services  **(6.2) Quality objectives and planning to achieve them.**  Food safety objectives  The quality objectives and Food safety objectives are consistent with the quality policy and relevant to conformity of products and services and to enhancement of customer satisfaction.  Quality objectives / Food safety objectives and planning to achieve objectives were established.  Y2020   |  |  |  |  | | --- | --- | --- | --- | | Objectives | Action plan | Result | Corrective action | | % Target sales > 80% | Established | Jan-May 20 = 85%  - satisfied | - | | Number of complaints per month < 2 times | Established | Jan-May 20 = 0  - satisfied | - | | Customer satisfaction > 80% | Established | Jan-May 20 = 95%  - satisfied | - | | Buy products on schedule 100% | Established | Jan-May 20 = 100%  - satisfied | - | | Buy the product correctly 100% | Established | Jan-May 20 = 100%  - satisfied | - | | Recruiting employees to meet the needs 100% | Established | No recruitment request since Jan.-May 20 | - | | Provide training according to the training plan 100% | Established | Jan-May 20 = 100%  - satisfied | - | | Production efficiency > 80% | Established | Jan-May 20 = 95%  - satisfied | - | | % losing < 10 % | Established | Jan-May 20 = 1%  - satisfied | - | | % Product claims from customers < 0.5 % | Established | Jan-May 20 = 0%  - satisfied | - | | Average speed in solving problems for customers < 5 day | Established | No problems from customers since Jan.-May 20 | - | | Raw materials and products must be 100% accurate | Established | Jan-May 20 = 100%  - satisfied | - | | Damage caused by storage 0% | Established | Jan-May 20 = 0%  - satisfied | - |   (6.3) Planning of changes  The quality management system – QMS has not any changes.  **GMP/ HACCP : General**  **Section 1 : Objectives**  The Codex General Principles of Food hygiene  **Section 2 : Scope, Use and definition**  QM-GMP-HACCP Manual (QM-GMP-HACCP-01 ISSUE.00)- established and implemented.  Where all requirements contained in this manual  (1) Notification of Ministry of Public and Health where access would be made as below  <http://newsser.fda.moph.go.th/food2/Law.php>  (2) Codex Alimentarius Supplement to Volume 1B-1997; Annex to CAC/RCP-1 (1969), Rev.4 (2003): Recommended International Code of Practice-General Principle of Food Hygiene has been addressed in the manual.  Scope : From primary production to the final consumer  The scope was mentioned in the Manual above.  GMP & HACCP team consisting of management positions and defined in the Manual above.  Certification scope : Manufacturing of drinking, Herb Water, Vitamin Water, Flavour drink Water utilising the requirements of GMP/HACCP (Hazard Analysis and Critical Control Points)  **Product information and consumer awareness**   |  |  |  | | --- | --- | --- | | Requirement | Document No. | Established | | Product information and consumer awareness | QP-PD-01 Rev.00 | Jan 31,20 |   Procedures-same version previous the visit.  Procedure established where all activities required by the standard requirement have been addressed and fulfilled.    **Product information and consumer awareness**   |  |  |  | | --- | --- | --- | | Topic | Details | Results | | Product name | DRINKING WATER | OK | | Product characteristics | 100% RO | OK | | Product usage details | For Drinking | OK | | Packaging | Clear plastic bottle size as ordered by customers | OK | | Shelf-life | 2 years from the date of manufacture  (Production date Specify on the packaging) | OK | | Distribution characteristics | Sold as finish good for customers | OK | | Recommendations on the label | Storage: Should be stored in a clean place | OK | | Special distribution control | 1.Dust protection  2.Prevent Sun | OK | | Consumer groups | General consumer | OK | | Manufacturer and / or supplier information | FLEX ENGINE CO., LTD.  88/22 Moo 2 Nara Phirom, Bang Len, Nakhon Pathom Thailand | OK | | Net weight | According to customer orders | OK |   **Product information and consumer awareness**   |  |  |  | | --- | --- | --- | | Topic | Details | Results | | Product name | MEE HERB | OK | | Product characteristics | Herb Water, Vitamin Water, Flavour drink Water | OK | | Product usage details | For Drinking | OK | | Packaging | Clear plastic bottle size as ordered by customers | OK | | Shelf-life | 1 year from the date of manufacture  (Production date Specify on the packaging) | OK | | Distribution characteristics | Sold as finish good for customers | OK | | Recommendations on the label | Storage: Should be stored in a clean place | OK | | Special distribution control | 1.Dust protection  2.Prevent Sun | OK | | Consumer groups | General consumer | OK | | Manufacturer and / or supplier information | FLEX ENGINE CO., LTD.  88/22 Moo 2 Nara Phirom, Bang Len, Nakhon Pathom Thailand | OK | | Net weight | According to customer orders | OK |   **Section 5 : Control of operation**  Control of Food Hazards   |  |  |  | | --- | --- | --- | | Requirement | Document No. | Established | | Control of Food Hazards | QP-QC-01 Rev.00 | Jan 31,20 |   Procedures-same version previous the visit.  Procedure established where all activities required by the standard requirement have been addressed and fulfilled.  **HACCP Analysis:**  **Control Points**  Control points : All points are in control-OK (checked on audit date)   |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | No | Step | Hazard type | Hazards and causes / sources of danger | Risk  level | Decision tree | | | | CCP  (Y/N) | Corrective Action(s) | CCP  NO. | | Q1 | Q2 | Q3 | Q4 | | 1 | Receive raw material | Chemical | None | - | - | - | - | - | - | - | - | | Biological | Dirt that comes with bottle, such as Dust | Low | Y | Y | - | - | Y | There is a preliminary separation of cleaners from the supplier. | 1 | | Physical | None | - | - | - | - | - | - | - | - | | 2 | Storage raw material | Chemical | None | - | - | - | - | - | - | - | - | | Biological | Fungus | Low | Y | Y | - | - | Y | Storage in clean area and pest control | 2 | | Physical | None | - | - | - | - | - | - | - | - | | 3 | Raw material preparation | Chemical | None | - | - | - | - | - | - | - | - | | Biological | Dirt that comes with bottle, such as Dust | Low | Y | Y | - | - | Y | Primary cleaning and Machine automatic 100% cleaning | 3 | | Physical | None | - | - | - | - | - | - | - | - | | 4 | Washing | Chemical | Water used for washing | Low | Y | Y | - | - | Y | Sterilizing machine | 4 | | Biological | Dirt that comes with bottle, such as Dust | Low | Y | Y | - | - | Y | Primary cleaning and Machine automatic 100% cleaning | 5 | | Physical | None | - | - | - | - | - | - | - | - | | 5 | Filling | Chemical | None | - | - | - | - | - | - | - | - | | Biological | None | - | - | - | - | - | - | - | - | | Physical | None | - | - | - | - | - | - | - | - | | 6 | Packing | Chemical | None | - | - | - | - | - | - | - | - | | Biological | None | - | - | - | - | - | - | - | - | | Physical | None | - | - | - | - | - | - | - | - |   **The control at CCP :**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | CP/CCP | Process | Hazards and causes / sources of danger | CL: Critical Limits & Control Method | Results | | CCP1 | Receive raw material | Dirt that comes with bottle, such as Dust | -There is a preliminary separation of cleaners from the supplier refer to Purchasing: QP-PU-01 Rev.00.  -Inspection & Testing: QP-QC-01 Rev.00 | IQC Record: FM-QC-01 - OK  The control measure is acceptable. | | CCP2 | Storage raw material | Fungus | Storage in clean area and pest control  –Cleaning Procedure QP-GMP-05  -Maintenance of equipment and facilities: QP-MT-01 Rev.00  QP-MT-02 Rev.00  -Pest Control Procedure QP-GMP-07 Rev.00  -Preservation product: QP-WH-01 Rev.00 | -Cleaning Record: FM-GMP-05-01 – OK  -Equipment List Record FM-MT-01-01-OK  -Equipment History Record FM-MT-01-02  -Maintenance Record FM-MT-01-03  -Building Check Record FM-MT-02-01-OK  -Building Inspection Report FM-MT-02-02-OK  -Pest Control Record FM-GMP-07-01-OK  Stock material check record: FM-WH-01 – OK  The control measure is acceptable. | | CCP3 | Raw material preparation | Dirt that comes with bottle, such as Dust | Primary cleaning refer to Production planning & control: QP-PD-01 Rev.00 | Production order & control Record: FM-PD-01 - OK  The control measure is acceptable. | | CCP4 | Washing | Water used for washing | Through a Sterilizing machine refer to Production planning & control: QP-PD-01 Rev.00 | Production order & control Record: FM-PD-01 - OK  The control measure is acceptable. | | CCP5 | Washing | Dirt that comes with bottle, such as Dust | Primary cleaning refer to Production planning & control: QP-PD-01 Rev.00 | Production order & control Record: FM-PD-01 - OK | | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Human Resources | **Process Owner** | Mr. Tawatchai S. – CEO |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| **(7) Support**  **(7.1) Resources**  **(7.1.1) General**  **(7.1.2) People**  Resources are adequate for establishment, implementation, maintenance and continual improvement of the QMS GMP/HACCP as well as to meet customer requirements.  **(7.1.6) Organizational knowledge**  The organization had determined organizational knowledge through  -Policy  -Strategy  -Objective  -Service provision  -Obligation concern with the organization ex. Customer’s requirements, etc.  The organization had established training needs for every position by cover the organizational knowledge.  **(7.2) Competence**  **(7.3) Awareness**  The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | Document Title | Document No. | Established | | Recruitment & Training | QP-HR-01 | Jan 31,20 | |  |  |  |   Procedure established where all activities required by the standard requirement have been addressed and fulfilled.  New recruitment:   |  |  |  | | --- | --- | --- | | Position | Job description | Result | | QC Inspector | * Plan and conduct of inspection both materials & finished goods. * Establish inspection reports. * Prepare and conduct the parts approval process. * Control and calibrate all inspection & measuring devices. * Establish all working instruction. | Effective date on:  Jan 31,20 and alaiable. |   Knowledge, competence, awareness Management procedure was established and implemented to ensure the competence and awareness of people as well as the effective training system, Also the organizational knowledge include in training need plans respond to these requirements.  Sampling   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Training item | Date | Member | Result | Training record | | ISO9001:2015 Requirements  & Implementation Including  Risk Management in ISO 9001:2015  GMP/HACCP Requirements | March 21,20 | Mr. Tawatchai S.  Mr. Suntron R.  Mr. Pisit S.- Mrs. Marisa K.-  Mr. Weerayut J. | evaluated,  passed | Retain appropriate  documented  information  -OK | | ISO9001:2015 GMP//HACCP Internal audit | April 4,20 | Mr. Tawatchai S.  Mr. Suntron R.  Mr. Pisit S.- Mrs. Marisa K.-  Mr. Weerayut J. | evaluated,  passed | Retain appropriate  documented  information  -OK | | Hazard Analysis Critical Control Point requirements | March 28,20 | Mr. Tawatchai S.  Mr. Suntron R.  Mr. Pisit S.- Mrs. Marisa K.-  Mr. Weerayut J. | evaluated,  passed | Retain appropriate  documented  information  -OK |   The people competency is evaluated after probationary period and by the end of each year.  The evaluation criteria are:   * + Responsibility at work   + Result of work   + Capability   + Human Relations   The number and the qualification of the existing people are adequate. The training is sufficient for improving the people’s quality awareness.  (7.4) Communication   * Communication throughout the bureau by meeting, posted on the information boards of bureau   and company e-mail, such as Quality Policy, Quality objectives.  The communication educating employees in all parts of a system to understand the policy of the bureau to achieve its target of KPI. Preparation programs to achieve the goal. Communication documented information reviewed  Information of implementing of ISO 9001:2015 GMP/HACCP informed to these organization, e.g.   * January 31, 2020 Quality policy * January 31, 2020 – Quality objectives.   GMP/HACCP  Section 7 : Establishment: Personal Hygiene  Health Status/Illness and Injuries/Personal cleanliness/Personal behavior/Visitors  This section is controlled as per :  Personnel Hygiene control: QP-GMP-01- Rev.00  Training: QP-HR-01 Rev.00  Visitor plant visit report: FM-VT-01 Rev.00  Personal hygiene inspection records SP-GMP-02 Rev.00  Training plan: FM-HR-01 Rev.00  Training evaluation record: FM-HR-01-01 Rev.00  Training history of each staff: FM-HR-01-04 Rev.00  The above documents have been implemented (checked on audit date).  Sampling :  Personal hygiene inspection record dated May 2020 - results-Passed.  The medical examination for the infectious disease was done on May 2020  By Nakhon Pathom Hospital. Location: Bang Len, Nakhon Pathom.  Results : Hepatitis A, B, C : Not detected-OK.  Operator: Ms. Siriwan.- Swab test -OK  Interviewed Ms. Siriwan. and Mr. Jongon. for personal hygiene behavior, explained- OK  Medical examination report of Ms.Siriwan. and Mr. Jongon. on May 2020 was satisfactory (No infection).  The visitor plant visit report was provided to the auditor to fill on the audit day-OK  HACCP  Section 10 : Training  Awareness and responsibilities/training programmes/instruction and supervision/refresher training  This section is controlled as per :  Training: QP-HR-01 Rev.00  Training plan: FM-HR-01-01 Rev.00  Training evaluation record: FM-HR-01-03 Rev.00  Training history of each staff: FM-HR-01-04 Rev.00  The above documents have been implemented (checked on audit date).  Sampling the training :  (1) Training on Food hygiene practices.  Conducted in Feb 01, 2020 : Mr. Tawatchai S. – CEO, attended, evaluated and passed. Training record found-OK.  (2) The control at the CCPs  Conducted in Feb 01, 2020: Mr. Pisit S.- Engineering/Production attended, evaluated and passed. Training record found-OK.  (3) Training on Personal hygiene practices.  Conducted in Feb 03, 2020: Ms. Siriwan – Opeerator. attended, evaluated and passed.  Training record found-OK.  (4) Cleaning of packing equipment.  Conducted in Feb 03, 2020: Mr. Jongon – Operator, attended, evaluated and passed. Training record found-OK.  (5) Internal audit for HACCP/GMP system and principle of food hygiene  Conducted in April 04, 2020: Mrs. Marisa K.- ISO Staff & Document Control, Mr. Weerayut J. Sale & Marketing attended, evaluated and passed.  Training record found-OK  The routine supervision is done by Mr. Tawatchai S. – CEO -OK  New staff:  No new recruitment in this audit period.  The staff competency is evaluated after probationary period and by the end of each year. The evaluation criteria is :  - Responsibility at work  - Result of work  - Capability  - Human Relations  The number and the qualification of the existing staffs are adequate.  The infrastructure and equipment are sufficient for GMP/HACCP implementation.  The training is sufficient for improving the staffs’ quality and food safety awareness. | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Maintenance | **Process Owner** | Mr. Pisit S.- Engineering |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| (7.1.3) Infrastructure  The infrastructure is sufficient for QMS implementation. The organization has determined, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of services. The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | Document Title | Document No. | Established | | Breakdown and Preventive Maintenance | QP-MT-01 | Jan 31, 2020 Rev.00 | | Infrastructure | QT-MT-02 | Jan 31, 2020 Rev.00 |   Procedure established where all activities required by the standard requirement have been addressed and fulfilled. **Sampling** - Actual preventive maintenance infrastructure can done follow plan.   |  |  |  | | --- | --- | --- | | Maintenance | Record | Decision | | Water filter | Facilities and production equipment maintenance record : in May 2020 | OK | | Hand dryer | Facilities and production equipment maintenance record : in May 2020 | OK | | Exhaust fan | Facilities and production equipment maintenance record : in May 2020 | OK | | Sterilizer | Facilities and production equipment maintenance record : in May 2020 | OK | | Sink | Facilities and production equipment maintenance record : in May 2020 | OK | | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Documented information | **Process Owner** | Mrs. Marisa K.- ISO Staff & Document Control |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
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Sampling **-** Master list update established on   |  |  |  |  | | --- | --- | --- | --- | | Documented Title | Document No. | Established by | Document status | | Quality Manual | QM-GMP-HACCP-01 | January 31, 2020 – Rev.00 | up to date-OK | | Document & Record Control | QP-DCC-01 | January 31, 2020 – Rev.00 | up to date-OK | | Internal Audit | QP-MR-02 | January 31, 2020 – Rev.00 | up to date-OK | | Management Review | QP-MR-03 | January 31, 2020 – Rev.00 | up to date-OK | | Corrective Action | QP-MG-01 | January 31, 2020 – Rev.00 | up to date-OK | | Customer Inquiries Receive & Review | QP-MK-01 | January 31, 2020 – Rev.00 | up to date-OK | | Customer Compliant Response | QP-MK-02 | January 31, 2020 – Rev.00 | up to date-OK | | Customer Communication | QP-MK-03 | January 31, 2020 – Rev.00 | up to date-OK | | Recruitment & Training | QP-HR-01 | January 31, 2020 – Rev.00 | up to date-OK | | Production planning & control | QP-PD-01 | January 31, 2020 – Rev.00 | up to date-OK | | Cleaning Control | QP-GMP-05 | January 31, 2020 – Rev.00 | up to date-OK | | Inspection & Testing | QP-QC-01 | January 31, 2020 – Rev.00 | up to date-OK | | Control of nonconforming product: | QP-NC-01 | January 31, 2020 – Rev.00 | up to date-OK | | Measuring equipment control: | QP-CL-01 | January 31, 2020 – Rev.00 | up to date-OK | | Recalled products: | QP-RP-01 | January 31, 2020 – Rev.00 | up to date-OK |   **Documented information evidence**  **Retention:**   * Procedure was established and details all necessary activities required by the specified requirement. * The following documented information were sampled for effective control:  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Requirement | Documented information | Period | Retention | Result | | (6.1) Action to address risk  and opportunities | Risk assessment list | May 2020 | Keep 3 years | Found – OK | | (6.2) Quality objectives and planning  to achieve them. | Quality objectives result | May 2020 | Keep 3 years | Found – OK | | (7.2) Competence | Evidence of competence | May 2020 | Until employee leave. | Found – OK | | (7.1.3) Infrastructure | Evidence of maintenance | May 2020 | Keep 2 years | Found – OK | | (8.5.1) Control of construction and  service provision | Evidence of construction control | May 2020 | Keep 2 years | Found – OK | | (8.6) Release of products and services | Evidence of out-going inspection | May 2020 | Keep 3 years | Found – OK | | (9.1.2) Customer satisfaction | Evidence of customer satisfaction | May 2020 | Keep 2 years | Found – OK | | (9.2) Internal audit | Evidence of internal audit | May 2020 | Keep 3 years | Found – OK | | (9.3) Management review | Evidence of Management review | May 2020 | Keep 3 years | Found – OK |   Identification:  All documented information required in the system were identified in each procedure, e.g.   * Customer satisfaction * Management review   Storage:  Each documented information was kept in specific file, e.g.   * HR’s file, communication documented information were kept at HR section.   Preservation/Protection:   * Each section has full responsibility to keep the documented information in each files. * Loss protection, e.g.   + Documented information as evidence of recruitment kept at Personnel’s file and no other section can access the file, if they wanted to borrow they have to get permission from responsible person.   + Documented information as evidence of Management review kept at MR’s file and no other section can access the file, if they wanted to borrow they have to get permission from responsible person.   + Control at the CCPs kept at MR’s file and no other section can access the file, if they wanted to borrow they have to get permission from responsible person.   Documented information as evidence of Management review kept at QMR’s file and no other section can access the file, if they wanted to borrow they have to get permission from responsible person. | | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Calibration | **Process Owner** | Mr. Pisit S.- Engineering |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| 7.1.5 Monitoring and measuring resources  7.1.5.1 General  7.1.5.2 Measurement traceability  Calibration of monitoring and measuring devices is sufficient for QMS implementation. The organization has determined, provide and maintain the monitoring and measuring devices that have necessary for the operation of its processes and to achieve conformity of services. The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | Document Title | Document No. | Established | | Calibration Procedure | QP-CL-01 | Jan 31, 2020 Rev.00 |   Procedure established where all activities required by the standard requirement have been addressed and fulfilled. **Sampling** – Actual of calibration could be done follow plan.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Device No. | Device Name | Calibration Plan | Calibrated Date | Calibration  Results | | ORP Meter | ORP-200 | Cal-Passed : May 2020  Next due : May 2022 | External / 2 yearly | OK | | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Sales and Marketing | **Process Owner** | Mr. Weerayut J. Sale & Marketing |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| **8. Operation**  **8.2 Requirements for Products and Services**  **8.2.1 Customer Communication**  **8.2.2 Determining The Requirements for Products and Services**  **8.2.3 Review of The Requirements for Products and Services**  **8.2.4 Changes to Requirements for Products and Services**  **9. Performance Evaluation**  **9.1 Monitoring, Measurement, Analysis & Evaluation**  **9.1.2 Customer Satisfaction**  The organization had established documented procedures for determine, implement, monitor, measure, analyse and evaluate all processes – customer inquiries receiving and review, customer compliant response and customer satisfaction survey as follow;   |  |  |  | | --- | --- | --- | | Document Title | Document No. | Established | | Customer Inquiries Receive & Review | QP-MK-01 | January 31, 2020 – Rev.00 | | Customer Compliant Response | QP-MK-02 | January 31 2020 – Rev.00 | | Customer Communication | QP-MK-03 | January 31, 2020 – Rev.00 |   **Sampling**   1. Quotation No. AJ6306-0031 Rev.00, Date: June 10, 2020, Rev.00   Customer: ANRO   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Item | Product | Q’ty  (Pcs.) | Bottle | Color Code | | 1 | OC60 | 6,000 | 350-05 | 014 |   Prepared by: Ize  Approved by: Lek   1. Quotation No. AJ6306-0017 Rev.00, Date: June 4, 2020, Rev.00   Customer: Dubao   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Item | Product | Q’ty  (Pcs.) | Bottle | Color Code | | 1 | OC60 | 12,000 | 500-04 | 014 |   Prepared by: Ize  Approved by: Nook   1. Quotation No. AJ6306-0024 Rev.00, Date: June 9, 2020, Rev.00   Customer: ISTORE   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Item | Product | Q’ty  (Pcs.) | Bottle | Color Code | | 1 | OC | 2,400 | 350-02 | 019 |   Prepared by: Lukkana  Approved by: Lek   1. Quotation No. AJ6306-0050 Rev.00, Date: June 15, 2020, Rev.00   Customer: MEEHEARB   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Item | Product | Q’ty  (Pcs.) | Bottle | Color Code | | 1 | CL | 31,500 | 300-02 | 020 |   Prepared by: Ize  Approved by: Lek  **Customer Compliant Response**  This audit doesn’t found any customer compliant.  **Customer Satisfaction Survey**  **Ex.** Customer: ISTORE.   |  |  |  | | --- | --- | --- | | Description | Score  (Excellent to Rectify , 10 -> 4) | Total | | Coordination   * + Communication   + Facsimile contact   + E-mail correspondence   + Speediness in response   + Understanding of sale activity contents   + Follow up in coordination process | 30 | 25 | | Delivery   * + Punctual delivery   + Packing   + Transportation   + Shipment control   + Delivery when compared with others | 20 | 20 | | Quality   * + Proper technology usage   + Proper machine / tool usage   + Product quality   + Trouble shooting and prevention   + Product quality when compared with other | 50 | 50 | | Total Summary | | 95  (95%) |   Remark: Not found any comments or compliant in this surveying.  **GMP/HACCP**  **Recall procedure**:  The following procedures were established to control this process.  Recalled products: QP-RP-01 Rev.00  Receiving of customer complaints: FM-MK-02-01 Rev.00  Record of Product Recall: FM-RP-01-01 Rev.00  The above documents have been implemented (checked on audit date).  Since the establishment of the GMP/HACCP system, there is no product recall.  Verification record :  The re-call procedure was practice and verified during the system internal audit: June 2020.  The results were satisfactory and the procedure is still effective. | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Purchasing & Store | **Process Owner** | Mr. Pisit S.- Engineering |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| **(8) Operation**  (8.1) Operational planning and control  **(8.4) Control of Externally provided**  **(8.4.1) General**  **(8.4.2) Type and Extent of Control**  **(8.4.3) Information for External Providers**  (8.5) Construction and service provision  (8.5.1) Control of construction and service provision  (8.5.2) Identification and traceability  (8.5.4) Preservation  (8.5.6) Control of changes  (8.6) Release of products and services  (8.7) Control of nonconforming outputs  The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | **Document Title** | **Document No.** | **Established** | | Purchasing | QP-PU-01 | January 31, 2020 – Rev.00 | | Supplier Selection & Evaluation | QP-PR-01 | January 31, 2020 – Rev.00 | | Qulaity Control | QP-QC-01 | January 31, 2020 – Rev.00 | | Material Control | QP-MC-01 | January 31, 2020 – Rev.00 |   Procedures established where all activities required by the standard requirement have been addressed and fulfilled.  **Process Flow:**  PC calculate quantity of materials -> Issue P/R -> Select & Register new supplier (If hadn’t) -> Receive P/R and Issue P/O to supplier -> Incoming inspection when supplier delivered -> Reject to supplier (If mis-quality.) -> Receive material in warehouse –> Withdraw & balance stock when construction request.  **Sampling:**   * Purchased Requisition * P/R No.: 6306-022 * Issued date: June 17, 2020 * Requested by: Production * Requested Delivery Date: June 18, 2020 * Botle Cap. 30,000 ea * Purchased Order * P/O No.: FE 6306-022 * Issued date: June 17,2020 * Issued by Patohanee PU officer * Requested Delivery Date: June 18,2020 * Botle Cap. 30,000 ea * Original Tax Invoice from Supplier * Supplier name Bangkok Plaspack Co., Ltd. * Issued date: June 18, 2020 * Botle Cap 024 * Q’ty: 30,000 kgs. * New Supplier / Vendor Selection Form * Supplier name: United Pastic Packaging Co., Ltd. * Selected by consider from product quality, price, payment, quality management system and servicing which each evaluation item has score 10 points. * Results: Passed (45 points – 90%) * Approved Supplier List: ASL (QP-PU-01 Rev.00) * Register in June, 2020 * Supplier Performance Evaluation Record   Sampling check   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Supplier | Selection  record | Selection  result | Re-evaluation  record | Re-evaluation  result | | Bangkok Plaspack 99 | Y 2020 | This supplier was selected before start ISO system | June 2020 | score 100%-satisfied |   **Identification and Traceability**  The organization will identify receiving date on material packaging for FIFO including status of incoming inspection would be identified by stamping – QC Passed – on material packaging.  **Control of changes**  From sampling and interview responsibility persons, construction planning and control is not change for products and services provision.  **Control of Nonconforming Outputs**  This audit doesn’t found any nonconforming outputs from incoming inspection or other processes. | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Design & Development | **Process Owner** | exclusion |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | exclusion |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| 8.3 Design and development of products and services exclusion | | | |
| Conclusion of the overall effectiveness of the process Choose an item. | | | |

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| **Process name:** | Construction | **Process Owner** | Mr. Pisit S.- Engineering |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| **(8) Operation**  **(8.5) Production and service provision**  **(8.5.1) Control of Production and service provision**  **(8.5.6) Control of changes**  The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | **Document Title** | **Document No.** | **Established** | | Environment for the operation of process | QP-PD-01 | January 31, 2020 Rev.00 | | Quality Control | QP-QC-01 | January 31, 2020 Rev.00 |   Procedures established where all activities required by the standard requirement have been addressed and fulfilled.  **Process flow:**  Receive customer’s forecasted plan or delivery plan -> Check capacity -> Check materials -> Scheduled on production plan -> Issue work order -> Follow up and update construction status -> Prepare delivery -> Delivery to customer.  **Sampling:**   1. **work order no. MEEHERB BASIC**    * Issued date: June 16, 2020    * Customer order no.: June-04-20    * Requested by: Ice    * Q’ty: 31,500 .    * Delivery date: June 26, 2020   **Control of changes**  From sampling and interview responsibility persons, construction planning and control is not change for products and services provision.   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **(7.1.4) Environment for the operation of process**  **(8) Operation**  **(8.1) Operational planning and control**  **(8.5) Production and service provision**  **(8.5.1) Control of production and service provision**  **(8.5.2) Identification and traceability**  **(8.5.5) Post-delivery activities**  **(8.5.6) Control of changes**  **(8.6) Release of products and services**  **(8.7) Control of nonconforming outputs**  The procedures were established and implemented as follows:   |  |  |  | | --- | --- | --- | | Requirement | Document No. | Established | | Environment for the operation of process | QP-PD-01 Rev.00 | January 31, 2020 Rev.00 | | Quality control | QP-QC-01 Rev.00 | January 31, 2020 Rev.00 | | Control of nonconforming output | QP-NC-01 Rev.00 | January 31, 2020 Rev.00 |   Procedures-same version previous the visit.  Procedures established where all activities required by the standard requirement have been addressed and fulfilled.  **Sampling Operation control**  **Control of changes**  From sampling and interview responsibility persons, all operation control are not change for products and services provision.  **Process flow:**  Received order -> Planning -> Material Incoming -> Incoming inspection -> Material input -> Raw material preparation -> Washing -> Filling> Product -> Inspection -> Packing -> Storage -> Delivery.  The QMS/HACCP scope covers all production processes.  **Environment for the operation of process**  **GMP/HACCP-Work environment**  The company has declared the need of control work environment in the QM section where it is complied with specified ISO 9001:2015 GMP// HACCP requirements, Controls of insects and disease carrier animals and prepare PPE for personnel Hygiene control and personnel safety.  **Auditors observed Environment for the operation of process on site**  **-Sampling check regularly that PPE is used**  Ms.Jiraporn PD  Using PPE for personnel safety  1.Safety Shoes  2.Safety Hand gloves  3.Chemical protection mask  4.Mesh hat  - Personnel Hygiene control and Safety signs for reminder that PPE should be worn already shown in operation area.  **-Sampling check 5S at operation process**  1. Sort: sorting through all items in a location and removing all unnecessary items from the location-OK.  2. Set In Order: putting all necessary items in the optimal place for fulfilling their function in the workplace-OK.  3. Shine: sweeping or cleaning and inspecting the workplace, tools and machinery on a regular basis-OK.  4. Standardize: to standardize the processes used to sort, order and clean the workplace-OK.  5. Self-discipline: the developed processes by self-discipline of the workers. Also translates as "do without being told"-OK.  -5S have been implemented and results verified monthly, check evidence record in MAY 2020 -OK.  Environment for the operation of process was well controlled.  The current work environment status is acceptable (checked on audit date - OK).  **Operational planning and control, Production and service provision**  **Control of production and service provision, Identification and traceability**  **Release of products and services , Post-delivery activities**  Onsite visit:  On audit date: Auditor check actual operation process and inspection process, records evidence of each process compare their procedure Environment control for operation process: QP-PD-01 Rev.00, Production control: QP-PD-01 Rev.00 , Quality control: QP-QC-01 Rev.00 , Control of nonconforming output: QP-NC-01 Rev.00 .  Result all activities done same as standard and records of each process maintained – OK.  **Auditors observed key processes on site**   |  |  |  | | --- | --- | --- | | Key processes | Key processes operation method | Actual result | | Filling Process | Automatic Filling Machine in positive air presser room | - Operator done filling job follow work instruction standard no. QP-PD-01 Rev.00 - OK  - Operation record input to Production order & control Record: FM-PD-01-01 on audit date-OK. |   **Sampling production evidence**  -Customer: MEEHERB, Product: Herb Drinking Water, Quantity: 31,500., “Production order & control Record: FM-PD-01-01” on June 2020, records maintained-OK.  -Customer: ANRRO, Product: Drinking Water, Quantity: 6,000., “Production order & control Record: FM-PD-01-01” on May 2020, records maintained-OK.   |  |  |  | | --- | --- | --- | | Key processes | Key processes operation method | Actual result | | Packing | Automatic packing | - Operator done packing job follow work instruction standard no. QP-PD-01 Rev.00 - OK  - Operation record input to Production order & control Record: FM-PD-01-01 on audit date-OK. |   **Sampling production evidence**  - Customer: MEEHERB, Product: Herb Drinking Water, Quantity: 31,500., “Production order & control Record: FM-PD-01-01” on June 2020, records maintained-OK.  -Customer: ANRRO, Product: Drinking Water, Quantity: 6,000., “Production order & control Record: FM-PD-01-01” on May 2020, records maintained-OK.   |  |  |  | | --- | --- | --- | | Key processes | Key processes operation method | Actual result | | Inspection | - Cleanliness of each botle | - Operator done Inspection job follow work instruction standard no. QP-QC-01 Rev.00 - OK  - Inspection record input to Product inspection Record: FM-QC-01-01 on audit date-OK. |   **Sampling production evidence**  -Customer: MEEHERB, Product: Herb Drinking Water, Quantity: 31,500., “Production order & control Record: FM-PD-01-01” on June 2020, records maintained-OK.  -Customer: ANRRO, Product: Drinking Water, Quantity: 6,000., “Production order & control Record: FM-PD-01-01” on May 2020, records maintained-OK  **Post-Delivery activities**: Refer to contract,  Commercial Condition: None  Product warranty: 2 Years | | **Identification and traceability**   |  |  |  | | --- | --- | --- | | Product | Identification & Traceability | Result | | Drinking Water | Delivery date on June 18, 2020  Final inspection on June 16, 2020  Production process on June 15, 2020  Customer: ANRRO | OK |   All production and inspection data will keep for traceability data.  **Non-conforming products : No NC Product**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Part no. | Problem |  | Date | Defect q’ty | Action | Authority | Record | |  |  |  |  |  |  |  |  |   **HACCP**  **Section 4 : Establishment : Design and facilities**  Location/Premises and rooms/equipment/facility  This section is controlled as per :  Building and facility layout: QM-GMP-HACCP-01 ISSUE 00  Production Flow chart QM-GMP-HACCP-01 ISSUE 00  Glass equipment layout: QP-GMP-02 Rev. 00  Garbage storage layout: QP-GMP-04 Rev. 00  Pest control layout: QP-GMP-07 Rev. 00  The above documents have been implemented (checked on audit date).  Sampling :  - The plant is located independently, away from the contamination source.  - The production line is the one way process. So, the cross contamination is prevented.  - Floors, walls, ceilings, windows, doors, working surfaces are cleaned.  - Production drainage system is acceptable.  - The cleaning plan and procedure are implemented, sampling the cleaner Ms. Jiraporn – PD - OK  - There is no temporary premise or vending machine.  - The equipment is made of stainless steel and is ease of cleaning.  - Containers are identified.  - Drinking water is inspected 1 time/ year, sampling the inspection record of the year 2020 results-Passed.  - The toilet is located near the office, away from the production premise.  - No over head hoods are installed.  - Lighting is covered by the steel mess-OK  - Raw materials and packed products are stored securely and identified.  - First-In-First-Out is implemented- confirmed by the stock card.  **HACCP**  **Section 6 : Establishment :Maintenance and Sanitation**  Maintenance and cleaning/cleaning programmes/pest control systems/waste management  **Cleaning program :**  This section is controlled as per :  Cleaning Control: SP-GMP-05 Rev.00  Sampling :  Cleaning program for the year 2020, reviewed and approved on May 2020 and implemented-OK  **Pest control systems :**  This section is controlled as per :  Pest Control Systems: QP-GMP-07 Rev.00  Pest control layout: FM-GMP-07-01 Rev. 00  Pest inspection report: FM-GMP-07-01 Rev. 00  The above documents have been implemented (checked on audit date).  Sampling :  Pest inspection report dated May 2020 mentioned found the access of ants at the entrance to the production line. The area around was re-cleaned and the waste was empty. Inspected again on June 2020- result- satisfied.  Pest control layout was found and inspected monthly by Production.– qualified.  Monitoring: Rats, Flies, Fruit Flies, lizards and others.  No serious pest infestation- OK  **Waste Management :**  This section is controlled as per :  Waste Management: QP-GMP-04 Rev.00  Layout of waste storage location and the collection house: SD-GMP-04-01 Rev.00  The above documents have been implemented (checked on audit date).  Sampling :  The waste as well controlled.  The waste is disposed daily and transported out by the municipality Section.  **Section 8 : Transportation**  General/ Requirements/ Use and maintenance  This section is controlled as per :  Customer communication: QP-MK-01 Rev.00 - Order receiving and delivery.  Preservation product: QP-WH-01 Rev.00 - Stock control.  Inspection & Testing: QP-QC-01 Rev.00 - Control of quality of finished products  Production planning & control: QP-PD-01 Rev.00 - Packing and Stacking the products  Inspection record of driver, loaders and vehicles: FM-TR-01-01 Rev.00 - OK  Record of vehicle arrangement: FM-TRT-01-01 Rev.00 - OK  The above documents have been implemented (checked on audit date).  Sampling :  Vehicle plate number : 5111  The storage condition in the container (floor, wall and doors) is inspected daily, sampling audit date of vehicle plate number 0428- record found and results-OK  **HACCP**  **Section 9 : Product Information and consumer awareness**  Lot identification/production information/labelling/consumer education  This section is controlled as per :  Production planning & control: QP-PD-01 Rev.00 - Identification and traceability of products.  Product description and objectives  The above documents have been implemented (checked on audit date).   |  |  |  | | --- | --- | --- | | Topic | Details | Results | | Product name | DRINKING WATER | OK | | Product characteristics | 100% RO | OK | | Product usage details | For Drinking | OK | | Packaging | Clear plastic bottle size as ordered by customers | OK | | Shelf-life | 2 years from the date of manufacture  (Production date Specify on the packaging) | OK | | Distribution characteristics | Sold as finish good for customers | OK | | Recommendations on the label | Storage: Should be stored in a clean place | OK | | Special distribution control | 1.Dust protection  2.Prevent Sun | OK | | Consumer groups | General consumer | OK | | Manufacturer and / or supplier information | FLEX ENGINE CO., LTD.  88/22 Moo 2 Nara Phirom, Bang Len, Nakhon Pathom Thailand | OK | | Net weight | According to customer orders | OK |   8.5.3) Property belonging to customers or external providers  (8.5.4) Preservation  GMP/HACCP  Section 5 : Control of Operation  Incoming material requirements/packaging  The procedures were established and implemented as follows:   |  |  |  | | --- | --- | --- | | Requirement | Document No. | Established | | Warehouse Management | QP-WH-01 Rev.00 | Jan 31, 2020 |   Procedure-same version previous the visit.  Procedures established where all activities required by the standard requirement have been addressed and fulfilled.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Product | Identified | Protect | Balance q’ty | Result | | Meeberb | Product label  Meeherb  Quantity: 100 Pack | Keep in cleaness area | 100 pack – same as stock card | protect and safeguard - OK | | Drinking Water | Product label  Wink  Quantity: 1000 Pack | Keep in cleaness area | 1000 pack – same as stock card | protect and safeguard - OK |   Stock card used for control and check stock balance monthly.  Sampling check on audit date  Product stock is stored securely and identified by layout and name. | | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

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| **Process name:** | Performance evaluation & Improvement | **Process Owner** | Mr. Tawatchai S. – CEO |
| **KPI Measurements(s)** | See in process “Objectives and planning to achieve them” | **Auditor (if applicable)** | Dr.Kittsopon |
| **Documentation reviewed** | See in “Evidence to support audit conclusion (inputs/outputs/Process observations)”. | | |
| **Equipment** | None | | |
| |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **(9) Performance evaluation**  **(9.1) Monitoring, measurement, analysis and evaluation**  **(9.1.1) General**  Company determine Monitoring, measurement, analysis and evaluation through activities customer satisfaction (Evidence see clause 9.1.2), analysis and evaluation, internal audit and management review.  **(9.1.3) Analysis and evaluation**  The organization had analyzed and evaluated data and information from monitoring and measurement such as   * + Conformity of products (Evidence see clause 8.7)   + Customer satisfaction (Evidence see clause 9.1.2).   + Performance of QMS (Evidence see clause 9.2).   + Effectiveness of actions taken of risks and opportunities (Evidence see clause 6.1).   (9.2) Internal audit  (10.2) Nonconformity and corrective action  The following procedures were established to control this process.   |  |  |  | | --- | --- | --- | | **Document Title** | **Document No.** | **Established** | | Internal audit | QP-MR-02 | January 31, 2020 – Rev.00 | | Corrective & Preventive Action | QP-MG-01 | January 31, 2020 – Rev.00 |   Procedures established where all activities required by the standard requirement have been addressed and fulfilled.  The organization has established the procedure to ensure that the internal audit is carried out according to the requirement of the QMS. GMP HACCP  Audit Plan, Audit schedule, Checklist, Report, Corrective Action Request form are being used as planned. The internal audit was planned to implement at once a year.  The internal audits were effectively implemented by the qualified auditor team.  Qualified internal auditors for ISO 9001:2015 GMP HACCP  None of auditors audit his / her own work.  Checklist for cover all the requirement and activity were prepared.  Year 2020 Internal audit set up on June 06, 2020 covered all processes. None of CARs was raised.  Sampling audit records:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Audit section | Audit date | Auditor (Section) | Result | Action | | Top Management | June 06, 2020 | Eng. | NC = 0 | - | | QMR | June 06, 2020 | Eng | NC = 0 | - | | Sales | June 06, 2020 | Purchasing | NC = 0 | - | | Purchasing | June 06, 2020 | Production Control | NC = 0 | - | | Production Control | June 06, 2020 | QC | NC = 0 | - | | QC | June 06, 2020 | QMR | NC = 0 | - | | Production | June 06, 2020 | QMR | NC = 0 | - | | Maintenance | June 06, 2020 | Sale | NC = 0 | - | | HR | June 06, 2020 | QC | NC = 0 | - |   All processes were audited. Audit report was done on dated: June 06,2020  Qualified internal auditors are as below  1) Mr. Tawatchai S. – CEO  2) Mr. Suntron R. – ISO Officer  3) Mr. Pisit S.- Engineering  4) Mrs. Marisa K.- ISO Staff & Document Control  5) Mr. Weerayut J. Sale & Marketing  (9.3) Management review  **(9.3.1) General**  The organization has established the management review system and planned to implement at least once a year.  **(9.3.2) Management review inputs**  The Agenda Management review in Y2019 on June 12, 2020 covers all QMS’s GMP HACCP requirements;   * The Status of actions from previous management review * Initial Management review * Changes in external and internal issues that are relevant to the QMS. * No change relevant to the QMS * Information on the performances and effectiveness of the QMS. * Follow-up actions from previous management reviews (If had.) * Customer satisfaction and feedback from relevant interested parties   Customer satisfaction survey, No customer complaint   * The extent to which quality objectives have been met   All KPIs achieved target   * Process performance and conformity of products and service   Quality report shown that company achieved customer requirements  Process performance follow KPI   * Nonconformities and corrective actions * Result of internal audit (None of CARs was raised.) * Status of preventive and corrective actions * Monitoring and measurement result   Customer satisfaction, analysis and evaluation, internal audit, management review   * Audit result   Result of internal audit (December, 2019)   * The adequacy of resources * The effectiveness of action taken to address risk and opportunities * Opportunities for improvement   **(9.3.3) Management review outputs**  The management decision had made, including:   * improvement of the effectiveness of the QMS GMP HACCP and its processes, * Conclusion no need for changes to the QMS GMP HACCP, and * resource needs   The review covered all topics required. Relevant persons attended and the top management attended.  The management review was effectively conducted by the management team, including the Top management.  Management review report was done on: June 2020  (10) Improvement  (10.1) General  (10.3) Continual improvement  Continual improvement through the use of quality policy (Evidence see clause 5.2), quality objectives (Evidence see clause 6.2), audit result (Evidence see clause 9.2), analysis and evaluation (Evidence see clause 9.1.3), Nonconformity and corrective action (Evidence see clause 10.2) and management review (Evidence see clause 9.3). | | | | |
| Conclusion of the overall effectiveness of the process Process / Audit Area satisfactory | | | |

**Use of Registration Marks and Logos**

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| **Use of Registration Mark (if used) is in accordance with the Rules of Registration** | | N/A |
| <<Provide a brief summary of use if required>> | | |