



IND-EXPO CERTIFICATION LIMITED

INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME

STAGE II AUDIT REPORT

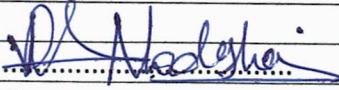

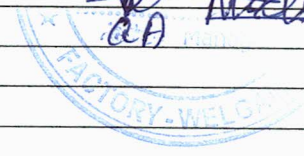
ISO 22000:2018

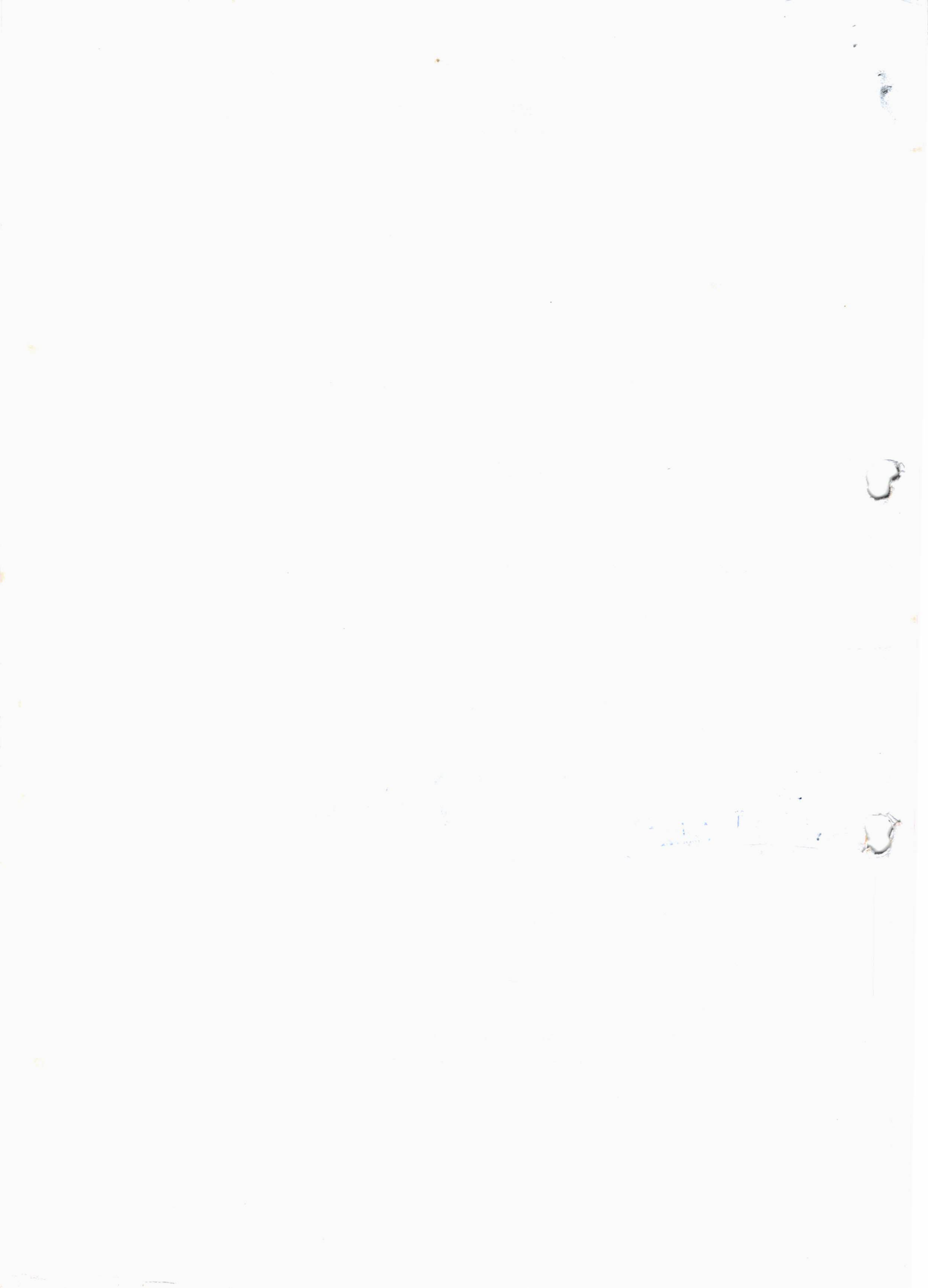
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**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
STAGE II AUDIT REPORT – ISO 22000:2018**

1. NAME OF ORGANIZATION : Rockland Distilleries (Pvt) Ltd
2. ADDRESS OF HEAD OFFICE : 7E, Ovitamulla, Thotupola Road, Welgama, Thittapattara
3. ASSESSMENT SITE/S : Same as 2
4. CONTACT DETAILS :
4.1 Name : Ms. V.P.A. Nadeeshani Designation : Quality Assurance Manager
4.2 Tel : 0334551486 Mobile : 0767795806 Fax :
4.3 E-mail : athila.nadeeshani@rockland.lk
5. NO. OF EMPLOYEES : 57
6. APPLICABLE STANDARD : ISO 22000:2018
7. FILE NO. : IMSC-FSMS-
8. NACE CODE / SUBCATEGORY :
9. SCOPE OF CERTIFICATION : Activities pertaining to manufacturing of alcohol based beverages and hand sanitizers
10. CONFIRMATION FOR SCOPE OF CERTIFICATION :
The scope is confirmed.
 Signature
 CA

11. DATE OF AUDIT & Time : 18/09/2020
12. TYPE OF AUDIT : Stage II
13. AUDIT TEAM :
Mr. Aruna Amaradasa Team Leader
Ms. Buddhika Sajeewani Team Member
Mr. Mohamed Asif Observer



**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
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The objectives of this audit were:

- to confirm that the management system conforms with all the requirements of the audit standard;
- to confirm that the organization has effectively implemented the planned management system;
- to confirm that the management system is capable of achieving the organization's policy and objectives on food safety

15. AUDIT CRITERIA :ISO 22000:2018, ISO 19011:2018, Relevant regulatory requirements

16. ANY DEVIATIONS FROM THE AUDIT PLAN AND REASONS: None

17. ANY SIGNIFICANT ISSUES IMPACTING ON THE AUDIT PROGRAMME: None

18. SIGNIFICANT CHANGES, IF ANY, THAT AFFECT THE MANAGEMENT SYSTEM OF THE COMPANY SINCE THE LAST AUDIT TOOK PLACE : None

19. AUDIT FINDINGS :**19.1 Context of the Organization (4 of ISO 22000):****Understanding the organization and its context (4.1 of ISO 22000):**

Organization has determined the external and internal issues that are relevant to purpose and strategic direction to achieve the expected results from the food safety management system. The organization is also having a mechanism to monitor and review those issues.

Understanding the needs and expectations of interested parties (4.2 of ISO 22000):

Organization has identified interested parties that can affect the food safety management system. The requirements of these interested parties have been determined by the organization. Organization has a system of monitoring and reviewing information of those interested parties.

Determining the scope of the food safety management system (4.3 of ISO 22000):

Organization has determined its scope based on the external and internal issues, the requirement of the interested parties, the product and services offered as well as the requirements of the ISO 22000:2018 standard.

Food safety management system (4.4 of ISO 22000):

Organization has established, implemented and maintained the food safety management system including the processes needed and its interaction. Organization has applied all the processes

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required throughout the organization with required input and expected output. The organization also has established required monitoring and measurement mechanism and assigned responsibilities and authorities for each requirement.

19.2 Leadership (5 of ISO 22000):**Management commitment (5.1 of ISO 22000):**

The top management has demonstrated the leadership and commitment with respect to food safety management system and was aware about their responsibilities to maintain an effective food safety system as per the food safety policy and food safety objective established compatible with company context and the strategic direction of the company.

They also committed to promote risk-based thinking throughout the organization and have taken steps to adequately provide recourses required and interested in achieving business objectives with continual improvement of established food safety objectives.

Policy (5.2 of ISO 22000):**Establishing the food safety policy (5.2.1 of ISO 22000):**

Company has established, implemented and maintained a food safety policy that can prove satisfactory application of applicable requirements and achievement of continual improvement.

Communicating the food safety policy (5.2.2 of ISO 22000):

Food safety policy was available and maintained as documented information. Policy was communicated, understood and applied at all levels within the organization and communicated to relevant interested parties.

Organizational roles, responsibilities and authorities (5.3 of ISO 22000):

Top management has delegated responsibility and authority for relevant personals via verbally. Appointment letters has been issued.

19.3 Planning (6 of ISO 22000):**Actions to address risks and opportunities (6.1 of ISO 22000):**

Company has determined the issues under clause number 4.1 and the requirements under 4.2 of this standard and as determine the risk and opportunities that are arising during the planning of foods safety management system. These include enhance desirable effects and prevention and reduction of undesired effect while achieving the improvements. The planning also ensures integration and implementation of action in to its FSMS processes with evaluation of effectiveness.

Objectives of the food safety management system and planning to achieve them (6.2 of ISO 22000):

Food safety objectives have been defined and established and are in line with the strategic direction. The organization is also having a mechanism to monitor and measure the food safety objectives. They have analyzed and reviewed the achievements of objectives of the food management system at the management review meeting.

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
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Organization has a mechanism to determine the changes required to food safety management system and carryout the same by planning, while considering the need for change and its expected results while ensuring the integrity of FSMS.

19.4 Support (7 of ISO 22000):**Resources (7.1 of ISO 22000):****General (7.1.1 of ISO 22000):**

The organization has been determined and provided the resources needed for the establishment, implementation, maintenance, update and continual improvement of the FSMS.

People (7.1.2 of ISO 22000):

Organization also has provided personnel required to effectively implement the FSMS and the activities related to FSMS.

Infrastructure (7.1.3 of ISO 22000):

Company has provided buildings, space for its intended operation with required utilities such as electricity, water, and information and communication technology.

Work Environment (7.1.4 of ISO 22000):

Company has provided necessary environment operation for combination of both physical and human requirement. Company has provided adequate ventilation and light for the operation. Company also complies with the sanitary requirements for staff and the visitors. General cleanliness of the environment also has been ensured.

Externally developed elements of the food safety management system (7.1.5 of ISO 22000):

Company has established maintained and updated externally developed elements such as PRPs, Hazards analysis and the hazard control plan. Those specifically adapted to the processes and products by the food safety team.

Control of externally provided processes, products or services (7.1.6 of ISO 22000):

Company has developed criteria for the evaluation of external providers of processes. Supplier evaluation questionnaire is available.

Competence (7.2 of ISO 22000):

Personnel hygiene and FSMS Trainings have been provided and effectiveness of training given has been evaluated.

Awareness (7.3 of ISO 22000)

The organization has given awareness to all the staff members on food safety.

Communication (7.4 of ISO 22000):**General (7.4.1 of ISO 22000):**

The company has identified and planned internal and external communication relevant to FSMS.

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The company has communicated effectively sufficient information with external interested parties.

Internal Communication (7.4.3 of ISO 22000):

The company has developed effective communication system with related to food safety impact. Food safety team has informed changes in timely manner.

Documented Information (7.5 of ISO 22000):**General (7.5.1 of ISO 22000):****Creating and updating (7.5.2 of ISO 22000):****Control of documented information (7.5.3 of ISO 22000):**

Company has identified documented information required by the standard and documents required to be applied for effectiveness of FSMS. Company has established a documented information control system for both documents and records. Including distribution, retrieval, storage and preservation, control of changes, retention and disposition. All external documents required has been identified and controlled.

19.5 Operation (8 of ISO 22000):**Operation planning and control (8.1 of ISO 22000):**

Company has planned, implemented and controlled the processes required to control the service and product provision. Company has established relevant criteria for the processes and the acceptance of service and products. As well as organization has controlled planned changes and it has noticed they have been reviewed the consequences of unintended changes and actions has taken to mitigate the same.

Pre-requisite programmes (PRPs) (8.2 of ISO 22000):

Organization has established, maintained and updated PRPs to facilitate the prevention and reduction of contaminants in the product, product processing and work environment. They have identified the applicable statutory, regulatory requirements when establishing PRPs and maintained a monitoring plan for verification of the PRPs. Organization has retained documented information.

However following deviations were identified: -

Cleaning of following areas are not adequate. (NC 1)

- a) Cobwebs have been observed at the conveyor from bottle washing machine to SACMI filler machine.
- b) Certain area of bottle store.

Lids of manhole of vat at manufacturing area have not been locked at the time of audit and also cleaning of lid is not adequate. (NC 2)

Medical declaration of employees is not par with the food hygiene regulation. (NC 3)

Insceticutor at bottle washing machine is closed to process floor. (OB 1)

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Fire wood has been located close to bottle issuing area. That may lead to cross contamination. (OB 2)

Letter of confirming suitability for food has not been taken for certain packing material (OB 3)

Ex: - Cap

It is difficult to trace FIFO process at bottle store area. (OB 4)

Certain areas of wall have been damaged due to handling of pallet. (OB 5)

Glass wool of ceiling at bottle store area is damaged heavily. This may lead to cross contamination. (OB 6)

Traceability system (8.3 of ISO 22000):

Mechanism of traceability relation of lots of received to end product is effective.

Emergency preparedness and response (8.4 of ISO 22000):**General (8.4.1 of ISO 22000):****Handling of emergencies and incidents (8.4.2 of ISO 22000):**

A procedure has been established, implemented to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain.

Hazard Control (8.5 of ISO 22000):**Preliminary steps to enable hazard analysis (8.5.1 of ISO 22000):****General (8.5.1.1 of ISO 22000):**

Hazard analysis, preliminary documented information has been collected, maintained and updated by the food safety team leader.

Characteristics of raw materials, ingredients and product contact materials (8.5.1.2 of ISO 22000):

Characteristics of raw material have been described. Physical, chemical and biological food hazards documented.

Characteristics of end products (8.5.1.3 of ISO 22000):

Organization has identified the characteristic of end products to extent needed to conduct the hazard analysis.

But Certain information given in the label is not accurate. (OB 7)

Ex: - 100% Pure Aged Coconut Arrack

Intended use (8.5.1.4 of ISO 22000):

Intended use of products has been addressed in the food safety manual.

Flow diagrams and description of processes (8.5.1.5 of ISO 22000):

**INTEGRATED MANAGEMENT SYSTEMS CERTIFICATION SCHEME
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Flow diagrams available for processes, which covered the entire steps from raw material receiving to the end product dispatch and the control measures.

On-site confirmation of flow diagrams (8.5.1.5.2 of ISO 22000):

The flow diagrams accuracy is verified by food safety team after onsite conformation and records are maintained.

Description of processes and process environment (8.5.1.5.3 of ISO 22000):

Company has maintained layout of premises with processing equipment and product flows.

Hazard analysis (8.5.2 of ISO 22000):**General (8.5.2.1 of ISO 22000):**

Food safety team has conducted a hazard analysis, based on the preliminary information to determine the hazards that need to be controlled.

Hazard identification and determination of acceptable levels (8.5.2.2 of ISO 22000):

Organization has identified and documented all the food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment. Also they have taken appropriate control measures to control the impact to FSMS.

Hazard assessment (8.5.2.3 of ISO 22000):

Organization has identified and evaluated the each food safety hazard with likelihood of its occurrence, the severity of its adverse health effects. It is kept as documented information.

Selection and categorization of control measure(s) (8.5.2.4 of ISO 22000):

Company has identified CCPs and OPRPs from the significant hazards. Control measures have taken to prevent or reduce the CCPs and OPRPs. Documented evidences are available.

Validation of control measure(s) and combinations of control measures (8.5.3 of ISO 22000):

Food safety team has ensured that the control measures taken, its capability to achieve intended control the significant hazards. Verification methods were defined clearly for CCPs, PRPs and OPRP's. Reviewing documents, external lab testing, calibration and internal audits have been used as verification methods. Monitoring records are verified by the responsibility holders.

Hazard control plan (HACCP/OPRP plan) (8.5.4 of ISO 22000):**General (8.5.4.1 of ISO 22000):**

Organization has implemented, maintained and documented a hazard control plan including food safety hazards, critical limits, monitoring procedure, action criteria for correction, responsibility and authority and record of monitoring.

Determination of critical limits and action criteria (8.5.4.2 of ISO 22000):

Company has identified CCPs or OPRPs for the manufacturing process and taken action to control the impact to FSMS.

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Company has established monitoring systems for CCPs and OPRPs. And defined frequency, responsibilities & authorities and evaluation of results have been documented.

Actions when critical limits or action criteria are not met (8.5.4.4 of ISO 22000):

Company has specified corrections and corrective actions when critical limits and action criteria not meet.

Implementation of the hazard control plan (8.5.4.5 of ISO 22000):

Company has implemented and maintain document of hazard control plan.

Updating the information specifying the PRPs and the hazard control plan (8.6 of ISO 22000):

Preliminary information was noted updating when necessary. When characteristics of materials and ingredients, characteristics of end products, intended use and flow diagram.

Control of monitoring and measuring (8.7 of ISO 22000):

Company has provided adequate monitoring and measuring activities related to PRPs and hazards control plan.

Verification related to PRPs and the hazard control plan (8.8 of ISO 22000):**Verification (8.8.1 of ISO 22000):**

Company has defined purpose, methods, frequencies and responsibilities for verification activities.

Analysis of results of verification activities (8.8.2 of ISO 22000):

Food safety team has conducted an analysis of result of verification results has used to evaluate performance of FSMS.

Control of product and process nonconformities (8.9 of ISO 22000):**General (8.9.1 of ISO 22000):****Corrections (8.9.2 of ISO 22000):**

Product deviated from the hazard control plan have been identified and controlled with regard to their use and release.

Corrective Actions (8.9.3 of ISO 22000):

Appropriate actions have been specified to identify and eliminate the cause of detected nonconformity. Documented information is maintained.

Handling of potentially unsafe products (8.9.4 of ISO 22000):**General (8.9.4.1 of ISO 22000):****Evaluation for release (8.9.4.2 of ISO 22000):**

Company has identified and established a process to evaluate and disposition of non-conforming products.

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Appropriate actions have been specified to identify and eliminate the cause and detected non conformity. Documented information is maintained.

Withdrawal/Recall (8.9.5 of ISO 22000):

Company has ensured the timely withdrawal of lots of end products that have been identified as potentially unsafe, where it's identified as potential unsafe. Company Has procedure for a procedure for handling recalled products.

19.6 Performance evaluation (9 of ISO 22000):**Monitoring, measurement, analysis and evaluation (9.1 of ISO 22000):****General (9.1.1 of ISO 22000):**

Company has determined what needs to be monitored and measured, the methods for monitoring, measurement, analysis.

Analysis and evaluation (9.1.2):

Company has a procedure and method to evaluate PRPs and hazards control plan, internal and external audit results.

Internal Audit (9.2 of ISO 22000):

Internal audit has been conducted as per the requirements defined in the procedures and planned intervals.

Management Review (9.3 of ISO 22000):**General (9.3.1 of ISO 22000):****Management review input (9.3.2 of ISO 22000):****Management review output (9.3.3 of ISO 22000):**

Management review has been done.

19.7 Improvement (10 of ISO 22000):**Nonconformity and corrective action (10.1 of ISO 22000):**

Company has taken necessary actions to addressed nonconformities and corrective actions have been implemented for such nonconformities. Company has retained documented information as evidence of the nature of the NC and any subsequent action taken and results of corrective action taken.

Continual improvement (10.2 of ISO 22000):

Company is committed to continually improve the effectiveness of the management system through the use of food safety policy, food safety objectives, audit results, analysis of data, management review, and corrective implementation.

Update of the food safety management system (10.3 of ISO 22000):

FST was evaluated planned intervals by top management and established PRPs and hazard control plan was updated at planned intervals.

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20. KEY PERSONNEL INTERVIEWED :

Name:	Designation	Responsibilities
Asiri Wickramasinghe	QAO	Monitoring and documentation
Rukshan Rathnayake	Manufacturing Manager	Overall res of manufacturing
Chamika Jayasekara	ME	Engineering activities
Wenuri Ranasinghe	QAO	Documentation
Amanda Rathnayaka	QAO	Documentation
V.P.A Nadeeshani	QA Manager	Quality Assurance and compliance

21. APPLICABLE LEGAL REQUIREMENTS: Food Act, Food Hygiene Regulation, Factory Ordinance, CEA regulations

22. ANY UNRESOLVED ISSUES: None

23. OVERALL CONCLUSION OF THE AUDIT

Audit is based on a sampling process of the available information at the point of auditing and the audit methods used were interviews, observation of activities and review of documentation and records. With consideration to the findings identified on the report the overall conclusions of the audit are as follow:

- The management system documentation demonstrated conformity with the requirements of the audit standard and provided sufficient structure to support implementation and maintenance of the management system. YES NO
- The organization has demonstrated effective implementation and maintenance /improvement of its management system. YES NO
- The organization has demonstrated the establishment and tracking of Appropriate key performance objectives and targets and monitored progress towards their achievement. YES NO
- The internal audit program has been fully implemented and demonstrates effectiveness as a tool for maintaining and improving the management system. YES NO
- The management review process demonstrated capability to ensure the continuing suitability, adequacy and effectiveness of the management system. YES NO
- Throughout the audit process, the management system demonstrated overall conformance with the requirements of the audit standard. YES NO

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24. MAJOR NON-CONFORMITIES: None

25. MINOR NON-CONFORMITIES:

01. Cleaning of following areas are not adequate. (8.2.4 i)
- a) Cobwebs have been observed at the conveyor from bottle washing machine to SACMI filler machine.
 - b) Certain area of bottle store.
02. Lids of manhole of vat at manufacturing area have not been locked at the time of audit and also cleaning of lid is not adequate. (8.2.4 j)
03. Medical declaration of employees is not par with the food hygiene regulation. (8.2.4)

26. OBSERVATIONS:

01. Insceticutor at bottle washing machine is close to process floor. (8.2.4 b)
02. Fire wood have been located close to bottle issuing area. Tats may lead to cross contamination. (8.2.4 b)
03. Letter of confirming suitability for food has not been taken for certain packing material (8.2.4 f)
Ex: - Cap
04. It is difficult to trace FIFO process at bottle store area. (8.2.4 g)
05. Certain areas of wall have been damaged due to handling of pallet. (8.2.4 h)
06. Glass wool of ceiling at bottle store area is damaged heavily. This may lead to cross contamination. (8.2.4 h)
07. Certain information given in the label is not accurate. (8.5.1.3 f)
Ex: - 100% Pure Aged Coconut Arrack

27. RECOMENDATION FROM AUDIT TEAM:
(Strike off which is not relevant)

The audit team concludes that the organization has / ~~has not~~ established and maintained its management system in line with the requirements of the standard and demonstrated the ability of the system to systematically achieve agreed requirements for products / services within the scope and the organization's policy and objectives.

Therefore the audit team recommends that, based on the results of this audit and the system's demonstrated state of development and maturity, management system certification be:

Granted / ~~continued~~ the certification subjected to the completion and subsequent verification of corrective action for all ~~major~~/minor non conformities raised / ~~Suspended~~ until satisfactory corrective action is completed.

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• This page is for internal purposes only.

10. RECOMMENDATION BY AUDIT TEAM :

Recommended for the certification subject to the verification of the corrective action taken for raised NCRs


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Signature of Team Leader

2020/09/18
.....
Date


.....
Signature of Team Member -1

.....
Date

.....
Signature of Team Member - 2

.....
Date

11. RECOMMENDATION BY CERTIFICATION MANAGER:

All NCRs have been closed, hence recommended for certification


.....
Signature of Certification Manager

2020/10/28
.....
Date

12. APPROVAL FOR SUBMISSION TO THE CERTIFICATION COMMITTEE:

Approved


.....
Signature of Director

2020/10/28
.....
Date

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