NATRACOL
NATURAL FOOD COLOURS

ROHA
USA

January 25, 2013

To Whom It May Concern:

Please note that Roha adheres to the following system of Product Lot numbering:

- For FDA approved dyes & lakes:

  AN#### – 6 Digit alphanumeric lot numbers provided by Food Drug Administration (FDA)

- For all other products shipping from our facility located in St. Louis, MO:

  USYYMMXXXX – **US** means the product is being distributed by our plant in the United States. **YY** is the year of manufacturing. **XX** is the month, in which the batch was generated and **NNNN** is the 4-digit batch number.

Michael A. Huber
Supervisor-Quality Control & Regulatory
Roha USA LLC

coloring the future

ROHA USA LLC
5015, Manchester Avenue, St. Louis, MO 63110, USA.
Tel : +1-314-289-8300 **Fax** : +1-314-531-0461 **Email:** rohausa@rohadyechem.com **Website:** www.rohadyechem.com

March 19, 2013

To whom it may concern:

ROHA USA meets the requirements of the 2002 Bioterrorism Act. and its facility located in St. Louis, MO is registered as follows:

Roha U.S.A., L.L.C.: 13427256732

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ROHA
A JJT Group company
INNOVATING FOR YOU. WITH YOU.

May 18, 2017

Food Safety Modernization Act Statement

To Whom It May Concern,

ROHA USA LLC hereby declares that we act in accordance to the Food Safety Modernization Act. ROHA USA LLC is an active participant in the Global Food Safety Initiative and is certified SQF 7.2 Level III. ROHA USA LLC has the appropriate quality management systems in place to prevent any biological, chemical and physical hazards.

Sincerely,

Sarah Bettes
Regulatory Control
ROHA USA LLC

This information is being provided as a guide, with the data that we have available to us at this time. Regulations can change or be revised and we always recommend that you confirm the regulatory status of any food ingredient directly with the proper local governing agency.

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February 14, 2014

Social and Environmental Responsibility

Dear Customer,
Roha USA LLC and its parent company Roha Dyechem Ltd. Pvt. take great care in ensuring that our manufacturing processes impact the environment as little as possible. Both facilities maintain strict recycling programs and are responsible with regard to the elimination of any hazardous and/or chemical waste.

Roha USA LLC also introduced a motion sensing light systems, so that energy is only consumed when it is needed and have reduced the amount of paper products that we use by installing air powered hand dryers and electronically filing most records.

Additionally, Roha Dyechem Ltd. Pvt. has established two major renewable energy resources: wind power and solar power. With these two energy projects Roha Dyechem Ltd. Pvt. is essentially Carbon negative. More information on Roha's global energy initiatives can be found at our website
http://www.rohadyechem.com/environment.htm

Michael Huber
Regulatory Coordinator
ROHA USA LLC

Roha USA, LLC
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A JJT Group company
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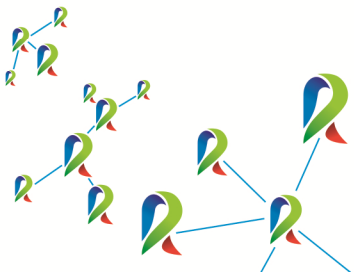
May 1, 2015

Ethical Sourcing Commitment

To Whom It May Concern,

Roha USA LLC hereby declares that through its document raw material approval process, Roha USA LLC scrutinizes every potential vendor and does not purchase products that have been manufactured by slave labor, or through manufacturers who pollute and destroy the environment. Roha USA LLC is committed to ensure that it leaves as small a footprint as it possibly can.

Michael A. Huber
Regulatory Support
Roha USA LLC



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Roha dichem Pvt Ltd, Roha

Audit Report

Food Safety Management System Certification FSSC 22000 Version 3 – Food Manufacturing ISO/TS 22003:2007

Audit Type	Surveillance
Audit Date(s) on-site	14/08/2015
Previous Audit Type	Surveillance
Previous Audit End Date	15/08/2014
Scope of certification	

Audit Team	Name	DNV GL ID #
Lead Auditor	Sushama Bhandare	SUSB

DNV·GL

Roha Dichem P Ltd

Management Summary Report

Organisation Details	
Organisation name of audited site	Roha Dichem P Ltd
FSSC Company number	0000
Key contact e-mail address	Kishor.ingale@rohagroup.com
Number of FTE	149
Other certified standards in addition to FSSC	☐ IFS Food ☐ ISO 9001 ☐ BRC Food (or IOP) ☐ SQF Code ☒ No other standard
Actual number of HACCP studies	2
Effective on site audit duration (man-days)	1
On-site Audit Time Justification Note: do not change this texts	On-site Audit time is compliant with FSSC requirements – see approved Quote calculation
Standard	☒ FSSC Manufacturing - ISO 22002-1:2009 ☒ FSSC Additional requirements ☒ ISO 22000
Scopes of standards	☐ C Processing 1 (perishable animal products) ☐ D Processing 2 (perishable vegetal products) ☐ E Processing 3 (ambient stable products) ☒ **L (Bio)chemical manufacturing**
FSSC 22000 product sector(s)	L2
Overview key changes since last audit	All the issues of last surveillance audit has been addressed.

Management Summary Report

Registered Complaints on food safety and legal issues	There is a full proof mechanism to capture the complaints and investigate the same. Corresponding action plans are implemented. There is a considerable reduction in complaints as compared to last year and no serious issue pending

Transfer from other Certification Body

Previous CB	NA
Certificate Number and	NA
Expiry date	NA

List of Participants during opening and closing meeting

Name	Function	Meeting Attendance	
		Opening	Closing
Mr. S.N. Jadhav	VP Operations	X	X
Mr. Kishor Ingale	Head QA	X	X
Mr. D .M .Gadekar	Manager QC	X	X
Mr. Z. I. Dhanse	Manager QA/QC	X	X
Mr. KR Rao	Manager Eng services	X	X
Mr. J. K. Ingle	Manager Production Plant 3	X	X
Mr. S D. Shelar	Manager Production R section	X	X
Mr.Saroj Kumar Singh	Section head, Spray dryer	X	X
Mr. G. D. Singh	Section head Production	X	X
Mr. Sanjay Singhania	Head BSR	X	X

Management Summary Report

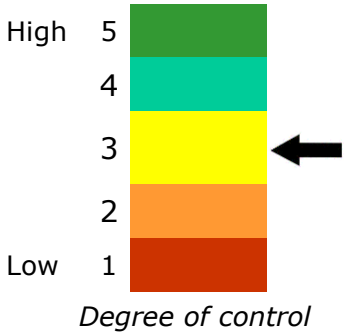
Mr. ParthaSarathi	Manager RM stores	X	X
Mr.Dilip Chaudhary	Manager Instrumentation/electrical	X	X
Mr.Sanjay Patil	Manager HSE	X	X
Mr Pramod Butala	Manager QA	X	X
Mr Dhanjay Singh I	Section head LST	X	X
Miss Trupti More	In charge training	X	X

Roha Dichem P Ltd

Management Summary Report

Focus Area Results

Focus Area 1 – PRP monitoring



Positive indications

- Good infrastructure
- Well trained team for monitoring PRP implementation

Main areas for improvement

- PRP monitoring need improvement in areas like Stores and packing with respect to personal behaviour, cleaning and sanitation, upkeep of facility and working environment
- PLEASE REFER TO LIST OF FINDINGS FOR FURTHER DETAILS.

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Management Summary Report

Overall Summary

Key points observed during the audit not included in the Focus Areas

Positive indications

- Committed team with strong support from top management.
- Well documented system
- 100% legal compliance.

Main areas for improvement

- The laboratory instruments and their detection capacity need to be reviewed for better reliability on results obtained.
- Pest control activity need further improvement with respect to supervision on technicians and data analysis
- Basic mapping of skills and education for the employees need to be established in a better manner.
- PLEASE REFER TO LIST OF FINDINGS FOR FURTHER DETAILS.

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Management Summary Report

Audit Findings and Compliance Status

Summary from the Audit:

Number of Non-Conformities identified during this audit:		3
Total number of Category 1 (Major) Non-conformities:	0	
Total number of Category 2 (Minor) Non-conformities:	3	
Number of Observations identified during this audit:		4
Number of Opportunities for Improvement identified during this audit:		0
Status of corrective actions for Non-conformities from previous audit was reviewed.		
Number of Non-conformities still not closed from previous audits:		0

Notes:

1) ***For details of Non-Conformities, Observations and Opportunities for Improvement, see attached 'List of Findings')***
2) ***See* "Definition of findings and conditions for handling of non-conformities"**

Focus Areas for Next Audit (suggested):

- *Free text Focus Area 1*

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Management Summary Report

Verified elements of the standard

Effectiveness of processes for Management Review and Internal audits	Management Review process is described in Customer focus & Management review RDC/QPM/ QD-002. Internal Audits are described in Internal Audit & site inspection RDC/QPM/ QD -014. Last round of internal audit was conducted on 9/7/2015. Last MRM was done on 14th May2015. The management review covers all the requirements of QMS & FSMS and tracking mechanism for the objectives has been found to be satisfactory. However refer List of finding for objective tracking. Results of internal, external & customer audits are discussed in detail and corrective actions are planned. The internal audits are done in 2 parts. Monthly inspection for hygiene and six monthly audits for FSMS & QMS system. Internal audits are done by competent auditors (trained by external agency) and corrective actions are taken. The overall process of management review and internal audits is found to be satisfactory.
Effectiveness of process for handling of customer and/or stakeholder complaints, including effectiveness of implemented identified corrective actions	Customer complaint, feedback & satisfaction process is described in Customer related process RDC/QPM/QD-007, Customer complaint RDC/QPM/QI/QAD-008, Customer sample process RDC/QPM/QI/QAD-009. There were total 11 complaints till date related to shortage of material and packaging defect. The complaint analysis and the corrective actions were found to be satisfactory.
The management system documentation has been changed to reflect changes in the organization.	Overall documentation is described in Procedure for Documents and Record Keeping RDC/QPM/QD-005. Management system documentation has been found be satisfactory.

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Management Summary Report

	Last audit findings are closed.
Progress of planned activities and objectives are monitored by management to ensure continual improvement	The FS & Quality objectives are planned and monitored. However, refer list of findings for objective tracking. Some of the examples of verified documents / records ☐ Spray dryer ☐ Evaluation of supplier RDC/QPM/QI/PUR-001 ☐ Preservation Of Products RDC/QPM/QI/STR-002 ☐ Deviation control RDC/QPM/QI/QAD-029 ☐ Corrugated boxes inspection RDC/QPM/QI/QAD-023 ☐ Loading of container Truck/tempo RDC/QPM/QI/DES-006 ☐ Calibration of weighing balance ICS 429 RDC/QPM/QI/ENGG-002 ☐ Calibration of pH meter RDC/QPM/QI/ENGG – 006 ☐ Product Stability Analysis RDC/QPM/QI/QAD-011
Effectiveness of the management system to ensure the organisation is capable to meet applicable statutory, regulatory and contractual requirements	The statutory & regulatory compliances were found. The applicable requirements are properly tracked. Refer list of regulatory requirements from the FSSC 22000 auditor statement

Roha Dichem P Ltd

Management Summary Report

Results and Conclusion per clause of the normative standard				
ISO 22000:2005 Clauses	**Audit Findings**			**Comment**
	Major	**Minor**	**Obs.**	
Food Safety Management System(4.0)				
Summary: The FSMS requirements are written in Roha Dyechem Management System Manual (ISO 9001 & FSSC 22000) RDC/QPM/QM – 001, *18.04.2013, v2*. The manual covers scope for all colours (solid & liquid) manufactured at site. There are no outsourced processes related to product. Specifications and Controls on outsourced services are identified in the respective SOP. The numbering system for documentation has been streamlined				
1 Introduction, scope	☐	☐	☐	
4.1 General requirements	☐	☐	☐	Complies. Scope, Outsourced services are identified properly. There is no outsourced process.
4.2 Documentation requirements				Complies. Procedure for Documents and Record Keeping RDC/QPM/QD-005, 08.06.2013, version 3
4.2.1. Documentation requirements - General	☐	☐	☐	
4.2.2. Control of documents	☐	☐	☐	
4.2.3. Control of records	☐	☐	☐	
Management responsibility(5.0)				
Summary: Management commitment is demonstrated. There is a uniform communication observed amongst the team members. Mr.Kishor Ingale is identified as Food Safety Team Leader and the food team consists of Production Head, Reaction Head, Purchase Head and HR Head. Following objectives are identified. ▪ 5% reduction in energy consumption (Fuel, Electricity) ▪ 0% food safety complaints (no foreign matter and product out of specification) ▪ Inventory management to be minimal Management Review Meeting report (14/5/2015) when the objectives were changed were available. The tracking is done for 4 months of data. Management Review frequency is once is 6 months. Electricity failure and accidental spillage of product & improper process reactions are identified as emergency situation				
5.1 Management Commitment	☐	☐	☐	Company's senior management commitment is evidenced through continuous participation during discussion, desire to address customer requirements. The management is well versed with the resource requirements and has plans for further improvement.

5.2 Food Safety Policy	☐	☐	☐	Since the company was certified to various food schemes, there has been awareness about food safety although not about FSSC scheme. There is a display at relevant locations. People were able to track the policy to their area of work and how they contribute in maintaining the policy.
5.3 FSMS Planning	☐	☐	☐	Evidenced. HACCP Plan, Internal Audit, FSMS Verification describes overall monitoring and verification activities.
5.4 Responsibility & Authority	☐	☐	☐	Documented in Procedure for Responsibility & Authority RDC/QPM/ QD -021
5.5 Food Safety Team Leader	☐	☐	☐	Mr.Kishor Ingale is appointed as Food Safety Team Leader by management. He has total experience of 26 years and has been with the organization for 2 years.
5.6 Communication				Internal communication is uniform owing to size of the organization. External communication, which is mainly with customers, suppliers and with statutory requirements, is found to be effective. There are no customer complaints from last 2 years.
5.6.1. External communication	☐	☐	☐	
5.6.2. Internal communication	☐	☐	☐	
5.7 Emergency Preparedness & response	☐	☐	☐	Emergency preparedness is written in Quality & Food Safety Manual. Power failure and accidental spillage of raw material & improper process reactions are identified as emergency situation. Control plan exists and verified during the audit.
5.8 Management Review				Performed as per Procedure for Management Review Meeting. Covers all the parameter. The frequency is twice in a year. Last Management review was done on 14th May 2015.
5.8.1. Management review – General	☐	☐	☐	
5.8.2. Review input	☐	☐	☐	
5.8.3. Review output	☐	☐	☐	
Resource Management (6.0) Since the organization started implementation of FSSC, resource requirements in the form of finance, man-power & their training has been provided. Training is mainly associated with the on job activities. Use of external training is limited only to training for FSTL. The company has annual budget for resource, and infrastructure requirements.				
Summary: >				
6.1 Provision of resources	☐	☐	☐	Procedure for Human Resource describes the resource allocation and training requirements.
6.2 Human resources				Training calendar for year 2014 is in place with hit ration of 93%. Training effectiveness is verified by their respective HOD which is linked to their annual performance. Overall found to be a very
6.2.1. Human resources – General	☐	☐	☐	
6.2.2. Competence, awareness and training	☐	☒	☐	

				streamlined process.
6.3 Infrastructure	☐	☐	☐	Infrastructure and work environment related requirements are addressed in GMP Expectation, RDC/QPM/QD003-11
6.4 Work Environment	☐	☐	☐	As above

Product realization(7.0)

Summary: Pre-requisite program:
GMP expectations document describes the PRP applicable to the organization. The plant is essentially a chemical reactor plant, hence the PRP are designed area wise. The plant is well aerated and secured. Pest Control activities are performed by a third party Pest Control of India dated 14th February 2014. The FSMS verification plan covers PRP verification on weekly & monthly basis. All the main audit findings associated with PRP have been taken care off.

Hazard Analysis:
The methodology for determining OPRP & CCP is documented in HACCP Plan. The method consists of identifying hazards (B, C, P) from sources like Equipment, Environment, Improper Process Conditions, Human activities and material in the area. Based on hazard assessment technique, significant hazards are identified and control measures determined. The control measures are then assessed through the 7 parameters to determine OPRP & CCP. Described in Hazard Analysis – OPRP, CCP Haccp Plan, control plan RDC/QPM/QD-003-5. Corrections and corrective actions are well identified. The record verification period was from Feb 2013 till date of the audit. The organization has identified following OPRP & CCP.

	What	**Limit**	**Monitoring Records**
OPRP 1	Cleaning of membrane	Not required	RDC/QAD/QR-016
OPRP 2	Cleaning of zero filter	Not required	RDC/QAD/QR-017
OPRP 3	Cleaning of air filter unit in HAG (Hot air generator)	Not required	RDC/QAD/QR-018
OPRP 4	pH measurement for the Process control	Not required	RDC/QAD/QR-019
OPRP 5	Screening and magnet process for the compactor unit	Not required	RDC/QAD/QR-020
OPRP 6	Cleaning of zero filter used in filtration of natural food colours like Beet root powder, Apo caroteneal	Not required	RDC/QAD/QR-021
CCP 1	Reaction: Dye intermediate (DI)& Subsidiary Dye(SD) /un- reacted residues & impurities	Dye intermediate & Subsidiary Dyes Not more than RDC specification RDC/QPM/QD-003-5	RDC/PRD/QR-004 RDC/QAD/QR-001 (QA Analysis report)
CCP 2	Sifter: Extraneous non- ferrous material in the product.	Foreign particle should retained over 40 mesh screen	RDC/PRD/QR-004.3 (Plant log sheet)

CCP 3	Metal Detector: Extraneous metals like ferrous non-ferrous & SS.	Ferrous and non-ferrous 3.0 & 3.5 mm & S.S 4.5 mm	Log sheet no. RDC/PRD/QR- 004.5

The traceability (up – and downstream) is complete.

The management of non-conforming products is also evidenced and found satisfactory. The documented recall plan is tested by the organization and is evaluated.

7.1 Planning and realization of safe products – General	☐	☐	☐	>
7.2 Prerequisite Programmes (PRP)	☐	☐	☒	
7.3 Preliminary steps to enable hazard analysis				
7.3.1. Preliminary steps to enable hazard analysis – General	☐	☐	☐	
7.3.2. Food safety team	☐	☐	☒	
7.3.3.1. Raw materials, ingredients and product-contact materials	☐	☐	☐	
7.3.3.2. Characteristics of end products	☐	☐	☐	
7.3.4. Intended use	☐	☐	☐	
7.3.5.1. Flow diagrams	☐	☐	☐	
7.3.5.2. Description of process steps and control measures	☐	☐	☐	
7.4 Hazard Analysis				
7.4.1. Hazard analysis - General	☐	☐	☐	
7.4.2. Hazard identification and determination of acceptable levels	☐	☒	☐	
7.4.3. Hazard assessment	☐	☐	☐	
7.4.4. Selection and assessment of control measures	☐	☐	☐	
7.5 Establishing operational PRPs	☐	☐	☐	
7.6 Establishing HACCP Plan				
7.6.1. HACCP Plan	☐	☐	☐	
7.6.2. Identification of critical control points (CCPs)	☐	☐	☐	

7.6.3. Determination of critical limits for critical control points	☐	☐	☐	
7.6.4. System for the monitoring of critical control points	☐	☐	☐	
7.6.5. Actions when monitoring results exceed critical limits	☐	☐	☐	
7.7 Updating preliminary information & documents specifying PRP & HACCP Plan	☐	☐	☐	>
7.8 Verification Planning	☐	☒	☒	Verification of the PRPs not found effective. Eg. 1. Paint peel off noticed in areas like Unloading bay-anti room, above conch no.1, above conveyor of Sapal packing machine, above steel belt after the refiner, M S mesh painted in the crumb dumping hopper & on the cables above exit of cooling tunnel in TML. 2. Unprotected tubelight near vibro sifter of NML sieve. 3. Part of the paste transfer inclined conveyor & horizontal conveyor is open. 4. Expired food grade grease & oil found being used. Eg. "Klubersynth UH1 14-222" Mfg. Feb 12 Shelf life 24 months, "Kluberoil 4 UH 1 - 220N" Mfg.June 12, BBD-22.06.14, "Kluberoil 4 UH 1-68N" Mfg. Mar 13, BBD-28.03.15 5. The results for retest done for positive results of hand swabs has not been recorded for further clearance. Verification over the units of measurements used in calibration of instruments needs to be strengthened further.
7.9 Traceability System	☐	☐	☐	
7.10 Control of Non conformity				>
7.10.1. Control of nonconformity – Corrections	☐	☐	☐	
7.10.2. Corrective actions	☐	☐	☐	
7.10.3.1. Handling of potentially unsafe product – General	☐	☐	☐	
7.10.3.2. Evaluation for release	☐	☐	☐	
7.10.3.3. Disposition of nonconforming	☐	☐	☐	

products				
7.10.4. Withdrawals	☐	☐	☐	
Validation, Verification & Improvement of FSMS (8.0)				
Summary: The organization complies with the Statutory and legal requirements. The organization also carries out the Performance measurement and monitoring. Records are available. The internal audits carried out at regular intervals. Results of Internal audits are used as a tool for improvement of organization's activities. Audit Reports are presented in MRM at regular intervals, method, follow-up - achievement of policy commitments and relevant objectives are evidenced and found satisfactory. Improvement (including corrective actions are evidenced.				
8.1 Validation, verification and improvement of the food safety management system - General	☐	☐	☐	
8.2 Validation of control measures	☐	☐	☐	
8.3 Control of monitoring & measuring	☐	☐	☐	
8.4 FSMS Verification				
8.4.1. Internal audit	☐	☐	☒	
8.4.2. Evaluation of individual verification results	☐	☐	☐	
8.4.3. Analysis of results of verification activities	☐	☐	☐	
8.5 Improvement.				
8.5.1. Continual improvement	☐	☐	☐	
8.5.2. Food safety management system updating	☐	☐	☐	
Additional requirements FSSC 22003:2007				
1 Specifications for services The organization shall ensure that all services (including utilities, transport and maintenance) which are provided and may have an impact on food safety.	☐	☐	☐	Services Including Utilities, Maintenance and Transportation are well controlled and integral part of Food Safety Management System. Compliance to same has been verified on regular basis. The Organization has inventory of relevant regulatory and Statutory requirements related to food safety. All the legislation requirements are Implemented including Raw Material, Packing Material and Finished Product

1.1 Shall have specified requirements.				All the said requirements are integral Part of Food Safety Management System. Updating as per new FSSR-2011.
1.2 Shall be described in documents to the extent needed to conduct hazard analysis.				All the said requirements are integral Part of Food Safety Management System
1.3 Shall be managed in conformance with the requirements of technical specification for sector PRPs.				All the said requirements are integral Part of Food Safety Management System and Technical specifications for PRP`s also observed
2 Supervision of personnel in application food safety principles.	☐	☒	☐	The supervision over policy implementation not effective. Mangesh Bhagat (Powder packing) was found wearing religious pendant and have not shaved properly.
2.1 The organization shall ensure the effective supervision of personnel in the correct application of food safety principles and practices commensurate with their activity.				The supervision over policy implementation not effective. Mangesh Bhagat (Powder packing) was found wearing religious pendant and have not shaved properly.
3 Specific regulatory requirements	☐	☐	☐	Legal requirements also observed specially related to product.
4 Management of inputs	☐	☐	☐	Management input also observed as a Minutes of Meeting and including, previous MRM points, Complaints, Nonconformities observed ,Customer feedbacks and raw material changes and if new product design developed and accordingly doing the risk assessment

FSSC Manufacturing ISO/TS 22002-1:2009

Requirement	NA	OK	Major	Minor	Obs.	Summary:
			See List of findings for details			
1 Scope	☐	☐	☐	☐	☐	
4 Construction and Layout of Buildings						The building is constructed of concrete material, with acid proof material whereever required. The site is well secured, located in industrial area. External sources of contamination been considered in hazard analysis. There are no potential sources of hazards as the site is individually located in the chemical zone. The
4.1 General Requirement	☐	☒	☐	☐	☐	
4.2 Environment	☐	☒	☐	☐	☐	
4.3 Location of establishment	☐	☒	☐	☐	☐	

						access to the site is restricted and only authorized persons are allowed to the site. Roads and yards are well constructed and maintained. Vegetation tended. Parking area is in side of the admin office. FSMS verification plan consists of verification of infrastructure. The organization fulfills all the requirements of the clause 4 and carried out necessary repair work mentioned during initial site visit.
5. Layout of premises workspace						The plant has uniform flow of direction. Since it's a chemical process, it follows a closed loop system. Essentially being a chemical plant, majority of the equipments are of fixed nature, except reactor & dryer, the plant has pipelines of stainless steel. There is dedicated place for storage of raw material. The WIP material is stored in silos in closed conditions. The on-line testing laboratory is restricted for physico-chemical analysis. The main testing lab is located in admin building away from the production plant. The laboratory performs all analysis (except for pathogen testing). There are no temporary storage facilities. The facility provides easy cleaning operations.
5.1General requirements	☐	☒	☐	☐	☐	
5.2 Internal design, layout and traffic patterns	☐	☒	☐	☐	☐	
5.3 Internal structures and fittings	☐	☒	☐	☐	☐	
5.4 Location of equipment	☐	☒	☐	☐	☐	
5.5 Laboratory facilities	☐	☒	☐	☐	☐	
5.6 Temporary/mobile premises and vending machines	☐	☒	☐	☐	☐	
5.7 Storage of food, packaging	☐	☒	☒	☐	☐	
6. Utilities – air, water, energy						The utilities consist of Water, boiler, air. The water is municipality water and only softening treatment is done so that it meets IS 10500 requirements. (Verified water quality records MICRO-2013-20/01). All lights are covered and found to be in sound condition providing adequate lighting. During day time, natural lighting is used. There are no compressed air / gases used. 6.4 The ventillation in the packing room was not found adequate. 6.6 Lighting in RM storage area is not
6.1 General requirements	☐	☒	☐	☐	☐	
6.2 Water supply	☐	☒	☐	☐	☐	
6.3 Boiler chemicals	☐	☒	☐	☐	☐	
6.4 Air quality and ventilation	☐	☐	☐	☒	☐	
6.5 Compressed air and other gases	☐	☒	☐	☐	☐	
6.6 Lighting	☐	☐	☐	☒	☐	

Management Summary Report

						adequate. Few of the lights at production junction were not functional.
7. Waste disposal						Waste disposal consists of mainly liquid waste which comes out as process waste. This is directly connected to Effluent Treatment Plant of the industrial area. However, testing is done before discharging. Found to be compliant with the requirements of Maharashtra State Pollution control board requirements. For other waste, covered collection bins are kept identified as dry waste. Overall, waste disposal activity was in compliant.
7.1 General requirements	☐	☒	☐	☐	☐	
7.2 Containers for waste and inedible or hazardous substances	☐	☒	☐	☐	☐	
7.3 Waste management and removal	☐	☒	☐	☐	☐	
7.4 Drains and drainage	☐	☒	☐	☐	☐	
8. Equipment suitability, cleaning and maintenance						Food grade lubricants are used. The preventive maintenance plan is followed. There is an objective on reducing the energy consumption. The breakdown is mainly due to power failure. There is a metal detector before packing identified as CCP. Calibration program is well followed.
8.1 General requirements	☐	☒	☐	☐	☐	
8.2 Hygienic design	☐	☒	☐	☐	☐	
8.3 Product contact surfaces	☐	☒	☐	☐	☐	
8.4 Temperature control and monitoring equipment	☐	☒	☐	☐	☐	
8.5 Cleaning plant, utensils and equipment	☐	☒	☐	☐	☐	
8.6 Preventive and corrective maintenance	☐	☒	☐	☐	☐	
9. Management of purchased materials						The purchasing activity is done by Purchase team from corporate. The COA for each material comes with every consignment and in coming tests are also being done. (The stage 1 audit findings are closed. However, refer the finding for a supplier missing in performance evaluation and incoming inspection
9.1 General requirements	☐	☒	☐	☐	☐	
9.2 Selection and management of suppliers	☐	☒	☐	☐	☐	
9.3 Incoming material requirements (raw/ingredients/packaging)	☐	☒	☐	☐	☐	
10. Measures for prevention of cross contamination						Practically, being a closed loop process, there are no chances of cross contamination, except for the raw material heating process where raw material containers are heated in warm water, there might be chances of cross contamination from water. The process is very tight looped.
10.1 General requirements	☐	☒	☐	☐	☐	
10.2 Microbiological cross contamination	☐	☒	☐	☐	☐	
10.3 Allergen management	☐	☒	☐	☐	☐	
10.4 Physical contamination	☐	☒	☐	☐	☐	
11. Cleaning and sanitizing						Overall cleaning and sanitizing activity is found to be compliant. Hygiene checklist is used for
11.1 General requirements	☐	☒	☐	☐	☐	

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11.2 Cleaning and sanitizing agents and tools	☐	☒	☐	☐	☐	monitoring and verification. GMP & GHP program is documented in GMP. All the stage 1 points are implemented.
11.3 cleaning and sanitizing programmes	☐	☒	☐	☐	☐	
11.4 Cleaning in place (CIP) systems	☐	☒	☐	☐	☐	
11.5 Monitoring sanitation effectiveness	☐	☒	☐	☐	☐	
12. Pest control						Pest management is carried out approved contractor and controlled by the organization. Pest management Responsible is HR department. There were no incidences of pest control seen during the audit. All the records are mentioned in Pest Control Monitoring Sheet The trends are verified on quarterly basis. Being chemical industry, the incidences of pest are very minimal.
12.1 General requirements	☐	☐	☐	☐	☐	
12.2 Pest control programmes	☐	☒	☐	☐	☐	
12.3 Preventing access	☐	☒	☐	☐	☐	
12.4 Harbourage and infestations	☐	☒	☐	☐	☐	
12.5 Monitoring and detection	☐	☒	☐	☐	☐	
12.6 Eradication	☐	☒	☐	☐	☐	
13. Personnel hygiene and employee facilities						Personal hygiene consists of wearing of an apron, mask while entering the production area. The clothing by workers was found to be satisfactory. Hand wash facilities are available at 3 places in the plant. Annual medical examination is carried out as per the directives of the Regulatory authorities is carried out for all food handlers. Jewellry policy, visitor protocol, Medicine policy exists.
13.1 General requirements	☐	☒	☐	☐	☐	
13.2 Personnel hygiene facilities and toilets	☐	☒	☐	☐	☐	
13.3 Staff canteens and designated eating areas	☐	☒	☐	☐	☐	
13.4 Workwear and protective clothing	☐	☒	☐	☐	☐	
13.5 Health status	☐	☒	☐	☐	☐	
13.6 Illness and injuries	☐	☒	☐	☐	☐	
13.7 Personal cleanliness	☐	☒	☐	☐	☐	
13.8 Personal behaviour	☐	☒	☐	☐	☐	
14. Rework						There is no rework during the production at any stage. However, if product goes out of specs, then process adjustment is done to bring back the product to normal accepted values. Traceability and handling of rework / reprocessing was found to be satisfactory.
14.1 General requirements	☐	☒	☐	☐	☐	
14.2 Storage. identification and traceability	☐	☐	☐	☒	☐	
14.3 Rework usage	☐	☒	☐	☐	☐	
15. Product recall procedures						Ideally product recall is not applicable as product does not reach to common consumer. It is for institutional sale for beverage industry only. Hence, withdrawal process is defined, in which all key contacts, their details are mentioned. The procedure for Handling of non conforming

						product describes the type of action to be taken on the product
15.1 General requirements	☐	☒	☐	☐	☐	
15.2 Product recall requirements	☐	☒	☐	☐	☐	
16. Warehousing						The finished product is securely stored in epoxy coated storage tanks till the product is transported in the mobile road tankers. The warehouse is well identified and separate places are designated. The initial visit finding for proper warehousing has been closed effectively.
16.1 General requirements	☐	☒	☐	☐	☐	
16.2 Warehousing requirements	☐	☒	☐	☐	☐	
16.3 Vehicles, conveyances and containers	☐	☒	☐	☐	☐	
17. Product information/consumer awareness						The company brochures and information are in line with the product specifications.
17. Product information	☐	☒	☐	☐	☐	
18. Food defence, biovigilance and bioterrorism						The security system is capable of handling such issues. Close circuit cameras installed at the plant .
18.1 General requirements	☐	☒	☐	☐	☐	
18.2 Access controls	☐	☒	☐	☐	☐	

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Conclusion / Next Step

- *All findings were agreed with Management as being a true record of the facts observed. In the closing meeting the general conclusions and non-conformities were presented and discussed*
- *The audit plan was followed without major changes.*
- *The analysis of cause and the actions taken in respect of the nonconformities identified at the previous audit were reviewed and were found to be effective in dealing with the issues raised. As such, all previous nonconformities are now closed, as per attached "List of Finding" (LOF).*
- *Except for the non-conformities listed in the "List of findings", the management system was found to be in compliance with the standard*
- *The lead auditor recommends the organisation for continuation to certification.*

Statement of confidentiality

The contents of this Report, including any notes and checklists completed during the Audit will be treated in strictest confidence, and will not be disclosed to any third party without the written consent of the customer, except as required by the appropriate Accreditation Authorities.

Accredited Unit

Name of the accredited legal entity	**DNV GL Business Assurance B.V.**
Address of the accredited legal entity	**Zwolseweg 1, 2994 LB, Barendrecht, The Netherlands**

Disclaimer

A management system audit is based on verification of a sample of available information. Consequently there is an element of uncertainty reflected in the audit findings. Also if no non-conformities were identified this does not mean that they do not exist in audited and/or other areas. Prior to awarding or renewing certification this report is also subject to an independent DNV GL internal review which may affect the report content and conclusions.

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Statement of confidentiality

Distribution

This report will be sent to the Organisation's Contact Person, hardcopy or electronic as agreed with the organisation and to the DNV GL Technical Review responsible as/if required by the DNV GL process, an Electronic copy will be kept in DNV GL File.

Annexes

- ✓ Audit Plan (AP)
- ✓ Periodical Audit Program (PAP)
- ✓ List of findings (LOF)
- ✓ PAP

Definition of findings and conditions for handling of non-conformities

Definition of findings:

Major (Category 1):

- A failure to fulfil one or more requirements of the Management System that raises doubt about the capability of the management system to achieve the expected food safety outcomes in the Food chain or to effectively control the process for which it was intended
- A situation which raises significant doubt that products will meet specified requirements (serious or imminent threat to public health or a non-compliance with a food safety regulatory requirement)
- A group of category 2 non-conformities indicating inadequate implementation or effectiveness of the system relevant to an element of the standard.
- A category 2 non-conformity that is persistent (or not corrected as agreed by the organisation) shall be up-graded to category 1.

Minor (Category 2):
A lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that products or services will meet requirements. Overall system requirement is defined, implemented and effective.

Observation
An observation is not a non-conformance, but something that could lead to a non-conformance, if allowed to continue uncorrected; or an existing condition without adequate supporting evidence to verify that it constitutes a non-conformance.

Opportunity for Improvement
Opportunities for improvement relates to areas and/or processes of the organisation which may meet the minimum requirement of the standard, but which could be improved.

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Conditions for handling of non-conformities:

The standard deadline to respond to NCs is max. 28 days for Major NCs and 3 Months for Minor NCs. Within this timeframe the following is expected to be performed by the organization:

- Immediate action(s) to eliminate the non-conforming situation (if relevant for the NC)
- Root cause analysis to identify corrective actions to prevent recurrence of the NC
  - With regard the Major NCs, the proposed Corrective Actions Plan, including corrections, shall be sent to the Team Leader within 14 days following this audit
- Implement corrective actions and verify the effectiveness of action(s)
- Fill in the pertinent part of the List of Findings and submit to DNV GL - BUSINESS ASSURANCEs Team Leader with relevant supporting documentation as evidence (when applicable)

Within the max. timeframe and as a prerequisite before a certificate can be issued the following conditions apply:

- Major NCs: Evidence of root cause analysis and effectively implemented corrections and corrective actions shall be provided within 28 days. If the CA cannot be concluded within the 28 days period, the corrective action plan must include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented, maximum within 3 months of the audit.
- Minor NCs: Corrective Action Plan, including corrections, shall be sent to the Team Leader within 3 months. The implementation of planned actions will at latest be verified during next audit.

Response deadline for Re-certification: Where the certificate expires within the 3 months period a shorter deadline will be set to ensure proper follow-up and renewal of the certificate within the expiry date. This is to provide for the continual validity of certification. If the expiry date is exceeded without the process being finalised, the current certificate is not allowed to be extended and will be regarded suspended until renewal of the certificate.

There is no obligation to investigate or respond formally to an Observations or Opportunity for Improvement. However to support an effective certification process DNV GL - BUSINESS ASSURANCE recommends that Observations are also considered and responded to by the Organisation.

DNV GL - BUSINESS ASSURANCE will normally perform an on-site follow-up when Major NCs are issued. For Minor NCs follow-up is normally performed as a desk review based on received documentation.

Insufficient responses to NCs or lack of corrective actions may be grounds for suspension or withdrawal of a certificate.