New edition - 1st September 2021

AUDIT REPORT

EXPERTISE VEGANE EUROPE SAS
3 rue Auguste Rodin, Bât 23, F-28630 Le Coudray - France
www.certification-vegan.org

WARNING

This report is exclusively reserved for EXPERTISE VEGANE EUROPE SAS and the operator involved (subject of this report) in order to obtain the EVE VEGAN® certification mark.

It does not prejudge an effective certification and must not be passed on to third parties without prior authorisation.

Further information on the comments and conclusions of this report can be obtained from your certification officer.

TAB 1 - INTRODUCTION

OPERATOR IDENTIFICATION	
Client code :	**C22141**
Name of the company :	OPT BIO CO., LTD
Head office :	137-162 Gwahakdanji-ro, Sacheon-myeon, Gangneung-si, Gangwon-do, S. Korea
Audited site :	137-162 Gwahakdanji-ro, Sacheon-myeon, Gangneung-si, Gangwon-do, S. Korea

AUDIT DETAILS	
Date of assessment :	**17-août-22**
Start time :	09:00
End time:	18:00
Overall duration :	8 hours(2MD)

AUDIT SCOPE	
Service :	Certification according to the EVE VEGAN® standard
Activities subject to the audit :	Production of Cosmetics and Food Material

TYPE OF ACTIVITY	
Structure :	Mixed activity
Outsourcing :	Works as a subcontractor
Type of audit :	Initial check (with appointment scheduling)

AUDITOR	
Name and surname :	Byoung-Wook, An
Co-auditor(s) :	Man Taek, HAN

TAB 2 - PARTICIPANTS

Name, first name, job title	Opening Meeting	Document Review	Field inspection	Closing meeting
Young Seung, SA(Team Leader)	○	○	○	○
Min Jung, KIM(Assistant Reseachfer)	○	○	○	○
Sang Il, LEE(Director)	○			○
Min Chae, Kwak(Assistant Reseachfer)	○	○	○	○

TAB 3 - SCORING OF THE GRID	

Rating of requirements			
Results	**Status**	**Details**	**Points**
A	Full compliance	Grid criterion.	Adds 20 pts
B	Almost full compliance	Grid criterion.	Adds 15 pts
C	Low compliance	Grid criterion.	Adds 5 pts
D	Unfulfilled requirement	Grid criterion.	Removes 10 pts
N/A	Not applicable	Non-applicable to operator or activity.	Excluded from scoring

Results	
Total scoring	**Certification status**
Score less than 60%	Certification not approved. Request for compliance and mandatory follow-up of corrective actions according to the auditor's recommendations. Audit to be repeated to obtain the certification.
Score equal to or higher than 60%	Certification approved based on auditor's findings. A) No critical non-conformity detected: Certification delivered without request for mandatory compliance. B) Critical non-conformity detected: Request for compliance and mandatory follow-up of corrective actions prior to certification, within the deadlines indicated in the CAPA.

TAB 5 - RISK RATING TABLE

1) ASSESSEMENT OF RISKS OF ANIMAL ORIGINE

Ref.	Production conditions for products applying for certification	Result YES/NO	Score	Contamination possible crossover with... (detail substances of animal origin as well as their oils and derivatives)	Auditor's comments
	01. Raw material				
1.1	PRODUCTION LINE: Use of raw materials of animal origin.	NO	0		We found animal based glycerin from their raw material list, but they use NON_VEGAN dedicated production line. Therefore, there is no risk of cross-contamination.
1.2	PRODUCTION WORKSHOP (room): Use of raw materials of animal origin.	NO	0		We found animal based glycerin from their raw material list, but they use NON-VEGAN dedicated production line. Therefore, there is no risk of cross-contamination.
1.3	PRODUCTION SITE (factory): Use of raw materials of animal origin.	YES	30	Glycerin	During the reviewing material list of OPT BIO CO., LTD, We found Glycerin from their raw material list. The company use these materials in same building.
1.4	STORAGE AREA: Presence of ingredients of animal origin.	NO	0		The storage area for VEGAN materials are separated from NON-VEGAN materials. OPT BIO CO., LTD also operating to attach the NON-VEGAN label for every NON-VEGAN materials, so there are manage of separated from animal originated products. because there are use more less of animal raw materials.

	02. Finished products				
1.5	STORAGE AREA: Presence of finished products containing raw materials of animal origin.	NO	0		The storage area for VEGAN materials are separated from NON-VEGAN materials. OPT BIO CO., LTD also operating to attach the NON-VEGAN label for every NON-VEGAN materials, so there are manage of separated from animal originated materials.
1.6	PACKAGING AREA: Presence of finished products containing raw materials of animal origin.	NO	0		The packaging area for VEGAN finished products are separated from non-VEGAN finished products. OPT BIO CO., LTD also operating to attach the non-VEGAN label for every non-VEGAN finished products, so there are less possibility of contamination with raw materials of animal origin.
1.7	QUALITY CONTROL AREA : Presence of finished products containing raw materials of animal origin.	NO	0		The quality control area for non-VEGAN finished products are separated from VEGAN finished products. OPT BIO CO., LTD also operating to attach the non-VEGAN label for every non-VEGAN finished products, so there are less possibility of contamination with raw materials of animal origin.
1.8	SHIPPING AREA: Presence of finished products containing raw materials of animal origin.	NO	0		The shipping area for non-VEGAN finished products are separated from VEGAN finished products. OPT BIO CO., LTD also operating to attach the non-VEGAN label for every non-VEGAN finished products, so there are less possibility of contamination with raw materials of animal origin.
1.9	RETURN AREA: Presence of finished products containing raw materials of animal origin.	NO	0		The return area for non-VEGAN finished products are separated from VEGAN finished products. OPT BIO CO., LTD also operating to attach the non-VEGAN label for every non-VEGAN finished products, so there are less possibility of contamination with raw materials of animal origin.
		Total	30	/260pts	

	RESULTS	Total	**30**	
		Scoring		*Do not modify: Automatic filling with the quotation grid*
1	Low risk	< 60 pts		**X**
2	Minor danger	> 60 pts		
3	Major danger	> 130 pts		
4	Priority risk	> 200 pts		

Information: Any rating level obtained does not constitute a denial of certification.

TAB 5 - AUDIT GRID

Item N°	Requirements	*Scoring method*	A	B	C	D (Major)	Score	Pts	NA	Auditor's comments	Corrective Actions OR CAPA Report N° if score is D
1) RESPONSABILITIES AND MANAGEMENT											
1.1	EVE VEGAN® referent(s) (operator statement) are responsible for the quality monitoring of the operator's products.	*Interview the manager(s) and staff.*	The declared referents and their activities comply with the obligations of the certification.	The declared referents and their activities comply with the obligations of the certification. However, important persons have not been reported.	The declared referents and their activities are too little coherent with the obligations of the certification. A modification of the referents is necessary.	The declared referents are neither legitimate nor entitled to manage a certification file. Situation at risk.	A	20	0	We had conducted the interview with Young Seung, SA / VEGAN Management team Leader. He is the project manager of EVE VEGAN operating system, and had a right to access the every process of Production, logistic, storage and quality control to manage the entire VEGAN management system. We could check EVE VEGAN referents organization chart for each of VEGAN related critical activities (Attach#1). The appointed VEGAN referents are as follows 1. EVE VEGAN management team leader: Young Seung, SA / Management team leader 2. Facilities Management Dept Sang Yong, LEE / team leader 3. Production team: Soon Sub, Beon / Production team 4. Quality control team Min Chae, KWAK / Management team leader 5. Laboratory Sang Il, LEE / Chief of laboratory	
1.2	EVE VEGAN® referent(s) are known to the whole company as certification officer(s).	*Interview the manager(s) and staff.*	Reported referrers are well identified by all staff.	Reported referrers are only partially identified by staff. Information is provided following certification (supporting evidence).	Reported referrers are only partially identified by staff. No information is provided.	Reported referrers are not identified by staff. No information is provided.	A	20	0	Information of EVE referents was distributed in the factory through the information board.	
1.3	EVE VEGAN® referent(s) are aware of their responsibility for monitoring the evolution of the Compliance Referential (evolving reference frame).	*Interview the manager(s) and staff.*	The declared referents have a good understanding of the evolving nature of the repository.	The declared referents have a partial understanding of the evolving nature of the repository.	*Scoring not allowed.*	The declared referents have an unsatisfactory knowledge of the repository. Insufficient preparation.	A	20	0	The company has distributed EVE VEGAN related regulation in 'Compliance Referential' to relevant staffs through regular training. According to 'Training procedure (OPT-QE-20E)', the company must conduct the training once a year. The company had conducted training on June, December of 2021, and had conducted the training as follows: 1) Training on 2022.07.28 This training include the contents for following things. 1) General concept of EVE VEGAN 2) EVE VEGAN regulation in the compliance referential The training had been conducted for every EVE Referents. Effectiveness of the training had been evaluated through test sheet.	
1.4	Employees involved in production are informed about the EVE VEGAN® certification process and demonstrate a good understanding of the minimum requirements (including temporary workers).	*Interview the manager(s) and staff.*	Employees are informed of the certification process. Their level of knowledge is satisfactory.	Employees are informed by the employer. However, the level of knowledge needs to be improved (training adapted to their position).	Employees are not informed. The operator has planned to do so following certification (supporting evidence).	Employees are not informed of the certification process. No training is planned.	A	20	0	The company has distributed EVE VEGAN related knowledge by below 2 ways: 1) Regular EVE VEGAN training: conducted on 2022.07.28 for every staffs. 2) EVE VEGAN instruction in processing area	
1.5	All of the operator's products meet EVE VEGAN® requirements, even if they are not systematically certified by the operator.	*Interview the manager(s) and staff.*	All of the operator's products comply with the requirements.	A majority of products comply with the requirements. Between 50% and 99% of the products.	A minority of products comply with the requirements. Between 1% and 49% of products.	*Scoring not allowed.*	A	20	0	There is only one animal based raw material: Glycerin. And the company rarely use this material as natural ingredient manufacturer. Therefore, 99% of current products is comply with EVE VEGAN regulation.	

Item N°	Requirements	*Scoring method*	A	B	C	D (Major)	Score	Pts	NA	Auditor's comments	Corrective Actions OR CAPA Report N° if score is D
2) REQUIREMENTS STATEMENTS											
2.1	The company adress are according to the EVE VEGAN® statement or the transmitted file (head office, production locations, product storage included).	*Interview the manager(s) and staff.*	The declared addresses are correct and complete.	The declared addresses are incomplete.	The declared addresses are partially incorrect.	The declared addresses are incomplete and incorrect.	A	20	0	The Address of head office, production locations, product storage are complete, and same as reported to EVE [OPT BIO CO., LTD] 137-162 Gwahakdanji-ro, Sacheon-myeon, Gangneung-si, Gangwon-do, S. Korea	
2.2	The operator shall not use any external subcontractors for part of its production, packaging, bottling, in particular for the products concerned by the certification. Otherwise, the operator has informed EVE for approval.	*Interview the manager(s) and staff.*	The operator does not use any external subcontractors. OR The operator uses subcontracting for products not concerned by the certification.	The operator subcontracts for certified products. This information has been provided.	*Scoring not allowed.*	The operator subcontracts for certified products. This information was not provided.	A	20	0	The company doesn't have any subcontractor.	
2.3	Declared formula sheets (finished product) are available on the production site.	*Check if there is a register and if the elements are in conformity with the file.*	The sheets exist and are accessible.	The sheets exist but are difficult to access	*Scoring not allowed.*	There is no archiving. OR Register not accessible during the check.	NA	0	1	This is not applicable to company as this is company's initial factory audit and they have no certified product.	
2.4	Finished products checked during the audit comply with the EVE VEGAN® statement or transmitted documentation.	*Carry out a random check on 2 to 3 products.*	The controlled elements are in conformity.	*Scoring not allowed.*	*Scoring not allowed.*	One or more non-conformities found during this check.	NA	0	1	This is not applicable to company as this is company's initial factory audit and they have no certified product.	
2.5	Technical data sheets of declared raw materials are available on the production site.	*Check if there is a register and if the elements are in conformity with the file.*	The sheets exist and are accessible.	*Scoring not allowed.*	*Scoring not allowed.*	There is no archiving. OR Register not accessible during the check.	NA	0	1	This is not applicable to company as this is company's initial factory audit and they have no certified product.	
2.6	Raw materials checked during the audit comply with the EVE VEGAN® statement or transmitted documentation.	*Carry out a random check on 2 to 3 products.*	The controlled elements are in conformity.	*Scoring not allowed.*	*Scoring not allowed.*	One or more non-conformities found during this check.	NA	0	1	This is not applicable to company as this is company's initial factory audit and they have no certified product.	
2.7	The declared packaging corresponds to the EVE VEGAN® declaration.	*Carry out a random check on 2 to 3 products.*	The controlled elements are in conformity.	*Scoring not allowed.*	*Scoring not allowed.*	One or more non-conformities found during this check.	NA	0	1	This is not applicable to company as this is company's initial factory audit and they have no certified product.	
2.8	The use of the label is in accordance with the EVE VEGAN® guidelines (logo, displayed conformity level, registered products, leaflets).	*Visual verification of labels and communication supports.*	The controlled elements are in conformity.	*Scoring not allowed.*	*Scoring not allowed.*	One or more non-conformities found during this check.	NA	0	1	This is not applicable to company as this is company's initial factory audit and they have no certified product.	

Item N°	Requirements	*Scoring method*	A	B	C	D (Major)	Score	Pts	NA	Auditor's comments	Corrective Actions OR CAPA Report N° if score is D
3) LAB TESTS & ANIMALS											
3.1	(Live animals): The operator does not carry out any tests on live animals for legal obligations.	*Interview the manager(s) and staff.*	The operator does not perform this type of test, whatever the product.	The operator performs this type of test only for non-certified products. The operator is able to transmit the products and protocols concerned.	The operator performs this type of test only for non-certified products. The operator is not able to transmit the products and protocols concerned.	The operator carries out this type of test. OR The operator is not able to answer on the subject.	A	20	0	After We interviewed and conduct the site audit, We could know that OPT BIO CO., LTD didn't conduct any IN-VIVO tests for Q.C inspection. Instead of IN-VIVO, The company conduct the tests through testing tools like pH Meter, Hardness, viscosity, by using the related testing tools. (Attach #3)	
3.2	(Live animals): The operator does not carry out any tests on live animals for product research and development (carried out on the company's own initiative or on its behalf, or by parties over which the company exercises effective control).	*Interview the manager(s) and staff.*	The operator does not perform this type of test, whatever the product.	The operator performs this type of test only for non-certified products. The operator is able to transmit the products and protocols concerned.	*Scoring not allowed.*	The operator carries out this type of test. OR The operator is not able to answer on the subject.	A	20	0	After We interviewed and conduct the site audit, We could know that OPT BIO CO., LTD didn't conduct any IN-VIVO tests for Q.C inspection. Instead of IN-VIVO, The company conduct the tests through testing tools like pH Meter, Hardness, viscosity, by using the related testing tools. (Attach #3)	
3.3	(Live animals): The operator shall not perform any tests on live animals for placing on the market in a foreign country.	*Interview the manager(s) and staff.*	The operator does not perform this type of test, whatever the product.	The operator performs this type of test only for non-certified products. The operator is able to transmit the products and protocols concerned.	*Scoring not allowed.*	The operator carries out this type of test. OR The operator is not able to answer on the subject.	A	20	0	The company doesn't conduct any animal test for their product by themselves. However, their client may perform the animal test. This is not related with EVE VEGAN certified product, and has a protocol to prevent any cross-contamination from it.	
3.4	(Animal derivatives): The operator does not perform any in-vitro tests for legal obligations.	*Interview the manager(s) and staff.*	The operator does not perform this type of test, whatever the product.	The operator is currently carrying out this type of test. He is able to communicate the protocols.	The operator is currently carrying out this type of test but the operator is not able to transmit the products and protocols concerned.	The operator carries out this type of test. OR The operator is not able to answer on the subject.	A	20	0	The company doesn't conduct any animal test for their product by themselves. However, their client may perform the animal test. This is not related with EVE VEGAN certified product, and has a protocol to prevent any cross-contamination from it.	
3.5	(Animal traction): The operator shall not use any means of delivery which makes use of animal traction. (At least within the limits of his legal responsibilities. Please note that this criterion does not apply to raw materials).	*Interview the manager(s) and staff.*	The operator does not use this mode of transport or delivery.	This criterion is currently subject to monitoring by the operator because of its possibility (supporting evidence).	This criterion is not being monitored despite the possibility.	The operator mainly uses animal traction.	A	20	0	The company didn't use the Animal transaction about their entire activities in the factory.	

Item N°	Requirements	*Scoring method*	A	B	C	D (Major)	Score	Pts	NA	Auditor's comments	Corrective Actions OR CAPA Report N° if score is D
4) CONTROL OF HAZARDS											
4.1	There is a system of hazard analysis and critical control points for ensuring hygiene and preventing cross-contamination. (Manufacturing flow chart, Good Hygiene Practices, control and acceptance criteria table, etc.).	*Assessing the existence of good practice monitoring and its regular control*	There is a documented risk analysis system in place that is consistent with good business practice.	The risk analysis system exists. However, the procedure can be improved on critical points.	*Scoring not allowed.*	There is no satisfactory procedure or system of analysis. OR Register not accessible during the audit.	A	20	0	The company has a system of hazard analysis and critical control points for ensuring hygiene and preventing cross-contamination. The company use the documents below as a tools to control the hazard. **1. Bulk management procedure [OPT-QE-32F]** 1) "Storing the animal based product with animal label in the dedicated storage area to prevent any contamination to EVE VEGAN product" is mentioned in the procedure. **2. Packaging material storage procedure [OPT-QE-30F]** 1) "Storing the animal based packaging material with animal label in the dedicated storage area to prevent any contamination to EVE VEGAN packaging material" is mentioned in the procedure. **3. Packaging procedure [OPT-QE-33F]** 1) "temporary store the EVE VEGAN bulk product in dedicated area" is mentioned in the procedure. 2) "Use of dedicated packaging facility for animal based product" is mentioned in the procedure. **4. Finished product storage procedure [OPT-QE-34F]** 1) "Storing the animal based product with animal label in the dedicated storage area to prevent any contamination to EVE VEGAN product" is mentioned in the procedure. **5. Raw material storage procedure [OPT-QE-28F]** 1) "Storing the animal based raw material with animal label in the dedicated storage area to prevent any contamination to EVE VEGAN raw material" is mentioned in the procedure. **6. Manufacturing procedure [OPT-QE-31F]** 1) "Use of dedicated production tools, container, facilities for manufacture of animal based product" is mentioned in the procedure.	
4.2	The operator shall be subject to regular audits by external bodies. For example IFS, BRC, ORGANIC, ISO etc.).	*Verification of quality certificates or inspection reports over the last few months.*	The operator is regularly audited by external bodies. He is able to provide certificates and reports.	The operator is regularly audited by external bodies. He is not able to provide evidence on the day of the audit (documents not accessible, out of date.).	The operator is not audited by any external body.	*Scoring not allowed.*	A	20	0	The company is regularly audited for ISO9001, ISO14001, EFfCI GMP by outside organization; GSC.	
4.3	There is a written procedure for the withdrawal and recall of non-compliant (or potentially consumer-at-risk) finished products. This procedure includes at least a technical procedure, a crisis team, alert instructions, legal sources and a communication plan.	*Evaluate the written procedure. Ask about the number of annual withdrawals and recall.*	There is a procedure for managing withdrawals or recalls that includes crisis managers, alert contacts, communication plan.	Scoring not allowed.	*The procedure exists, however it is incomplete or unsatisfactory.*	There is no satisfactory written procedure. OR Register not accessible during the audit.	A	20	0	The company has documented recall and withdrawal procedure [OPT-QE-52F] to include communication plan and crisis management. The company didn't have actual case of recall. However, the company had conducted mock recall on 2022.06.16 to check validation of their internal recall system.	

4.4	There is a written procedure for the management of incorrect raw materials when they are received (including packaging materials) **or a control plan to find out non compliant substances.**	*Evaluate the written procedure. Ask about the number of annual non-compliances.*	There is a procedure for managing non-conforming products that includes corrective measures for each problem.	The procedure exists, however it is incomplete or unsatisfactory.	*Scoring not allowed.*	There is no satisfactory written procedure. OR Register not accessible during the audit.	A	20	0	The company has a written procedure for managing incorrect raw materials / products **(OPT-QE-50F).** This procedure contain the corrective measures for each problem. There was no actual case of incorrect raw materials / products on 2022.	
4.5	There is a written procedure for pre-checking the admissibility of any new raw material or supplier with EVE VEGAN® criteria. The procedure describes the associated checks (application for certificates, certificates of origin, questions for exotic products, etc.).	*Evaluate the written procedure and its relevance with respect to the requirements.*	There is a written procedure for due diligence of a new ingredient or supplier with certification.	The procedure exists, however it is incomplete or unsatisfactory.	*Scoring not allowed.*	There is no satisfactory written procedure. OR Register not accessible during the audit.	A	20	0	The company has a written procedure of raw material selection and supplier audit **(OPT-QE-27F)**. the procedure include EVE VEVEGAN supplier evaluation criteria (Cross-contamination prevention, animal test, animal exploitation), and EVE VEGAN raw material selection.	
4.6	There is a written procedure for cleaning and disinfection including: responsibilities, products used, areas to be cleaned, objectives, frequency of cleaning, documentation requirements (including external providers).	*Interview the manager(s) and staff.*	There is a written procedure for cleaning and disinfection. Regular monitoring of cleaning frequencies and conditions.	There is a written procedure. The procedure or frequency of cleaning can be improved.	There is no written procedure, only regular cleaning. Need to set up a documentary follow-up.	There is no written procedure or proof of regular cleaning.	A	20	0	The company has written **Cleaning procedure [OPT-QE-17E]** and this procedure mention following things: 1) Cleaning with VEGAN detergent is mentioned in the procedure. The company only use botanical based raw material in the factory, so there is no cross-contamination prevention cleaning procedure for the company.	
4.7	There is a pest control plan consistent with the production activity and hazards.	*Interviewing staff without checking the details of the plan in place (this is outside the scope of the certification).*	There is a protocol for pest management.	There is no protocol for pest management. However, no risks could be identified.	There is no protocol for managing pests despite a proven risk.	*Scoring not allowed.*	A	20	0	The company has well organized pest control procedure **(OPT-QE-19E)**, and manage does things internally. The company has following things for the record of pest control. 1) record for effectiveness of pest control system. I recommend the company improve following things for better implementation. 1) Establish the layout to identify location of pest control tools. 2) Detail analysis with trend of pest. 3) Eligibility management of person in charges of pest control.	

Item N°	Requirements	*Scoring method*	A	B	C	D (Major)	Score	Pts	NA	Auditor's comments	Corrective Actions OR CAPA Report N° if score is D
5) QUALITY MANAGEMENT											
5.1	There is a complete traceability system. A traceability test can identify the raw materials and packaging used in the manufacture of a finished product.	*Carry out a traceability test on 1 to 3 finished products.*	The traceability test makes it possible to go back over all the stages, the proofs brought are complete, clear and satisfactory.	The traceability test allows you to go back through all the steps. However, it can be improved on certain critical points.	*Scoring not allowed.*	The traceability test does not make it possible to trace all the steps. Unacceptable result.	A	20	0	Each process and materials are available to trace as following things: Sampling item: Deep Sleep Oil (DSO-22001), manufactured on 2022-05-26 1) Manufacturing report: raw material name, raw material number, percentage, process, person in charge for weighing / manufacturing process, date, etc 2) COA for semi-finished product: manufacturing number, testing number, inspector, testing item, specification, result, date of approval, etc 3) Filling & packaging record: manufacturing number, date of process, facility, person in charge, information of sub-material, result, prechecklist, etc 4) COA for finished product: manufacturing number, testing number, inspector, testing item, specification, result, date of approval, etc	
5.2	The traceability system shall mention the person responsible for the control as well as the date and the result of the control.	*Assess the level of detail of the documents.*	The traceability system shall mention the persons responsible for the checks, the date and the result of the check.	The traceability system does not provide sufficient information on persons and/or date and/or type of control.	*Scoring not allowed.*	The traceability system does not mention any date and no one responsible.	A	20	0	I checked that process related record include person in charge and date of process.	
5.3	The traceability system and record keeping shall be appropriate to the nature and size of the operator's activity.	*Assess the level of detail of the documents.*	The level of detail of the traceability system is consistent with the type and size of production.	*Scoring not allowed.*	The level of detail in the documents is insufficient for the type and size of production.	*Scoring not allowed.*	A	20	0	The traceability system and its record was appropriate to the nature and size of the company's activity.	
5.4	The traceability system is secured and managed in such a way as to prevent any subsequent modification of the data.	*Evaluate the security applied to the recordings as a whole.*	The traceability system is secured so as to avoid any subsequent modifications.	The traceability system is only partially secured from subsequent changes.	There is no security of the traceability system. It is possible to modify the production documents at a later date.	*Scoring not allowed.*	A	20	0	The company store every documents and record in "Document storage drawer" in QC office.	
5.5	The traceability system mentions the EVE VEGAN® certification.	*Interview the manager(s) and staff.*	The traceability system mentions certification.	The traceability system mentions certification. However, this reference needs to be applied more widely or improved.	The traceability system does not mention certification.	*Scoring not allowed.*	A	20	0	The traceability system mention following things to prevent cross-contamination between VEGAN product and animal based product. 1) Insert the animal checklist in the label.	
5.6	The traceability system is subject to regular internal validation by the operator (e.g. in the form of an internal audit of procedures related to documents or associated registrations).	*Interview the manager(s) and staff.*	The traceability system is subject to regular validation.	The traceability system is subject to irregular or insufficient validation.	There is no regular monitoring of the traceability system.	*Scoring not allowed.*	A	20	0	The company had conducted mock traceability test on 2022.06.16 This include internal verification of traceability system and there was no history to conduct the mock traceability test.	

5.7	To verify the effectiveness and compliance with the requirements of the EVE VEGAN® Technical Referential, Internal audits of the manufacturing management methods and the quality management system are planned and conducted, by the competent personnel, at least once a year.	*Interview the manager(s) and staff.*	Internal audits are planned and carried out at least once a year, and corrective action plans are implemented.	Internal audits are planned and carried out at least once a year, but without a corrective action plan.	This is a first certification. Internal audits will be planned according to the results obtained in the initial audit.	No internal audits are planned or conducted.	A	20	0	The company has written procedure of internal audit (OPT-QE-59G). This internal audit mentioned following things: 1) Internal audit planning 2) Qualification of internal auditor 3) Conduct the internal audit annually. 4) Internal audit with EVE VEGAN checklist. The company had conducted internal audit on 2022.02.07 with VEGAN checklist and this include following things: 1) The internal audit had been conducted with EVE referents. 2) The audit include EVE VEGAN regulation 3) There was 2 non-conformities and these were corrected.	
5.8	Finished products that are required to display the statement "May contain traces of...". (incidental allergens) have readapted their product labeling to "Manufactured in a workshop that uses ..." to avoid confusion with the EVE VEGAN® certification.	*Interview the manager(s) and staff.*	Finished products have no obligations related to allergen regulations. OR Finished products have an obligation related to allergen regulations and these are in compliance with EVE requirements.	Finished products have an obligation related to allergen regulation. The indication does not comply with EVE requirements. Mention to be modified.	*Scoring not allowed.*	*Scoring not allowed.*	A	20	0	I could confirm that the company record 40 allergin based material in the list and manage them.	
5.9	The labelling of batches of semi-finished or finished products is carried out at the time of packaging. In the event that products are labelled at a later stage, temporarily stored products are identified with specific batch labelling.	*Interview the manager(s) and staff.*	Labelling of batches is carried out at the time of packaging. OR Labelling of batches is carried out after packaging. There is specific temporary identification.	Labelling of batches is carried out after packaging. Temporary identification is insufficient or needs to be improved.	Scoring not allowed.	Labelling of batches is carried out after packaging. There is no temporary identification.	A	20	0	The initial labelling was conducted on the Bulk product storage process. In this stage, the lot number of product was assigned with temporary label. After that, the company carry out the labelling of batches at the filling process (initial packaging).	
5.10	Quality controls are conducted on finished products before shipment. In the event of non-compliant finished products, they are temporarily stored in a dedicated area with a "non-compliant" label	*Interview the manager(s) and staff.*	There is a written quality control procedure. Products are inspected before shipment according to the expected quality criteria. For products checked as non-compliant, they are temporarily stored in a dedicated area and labelled "non-compliant"	There is a written quality control procedure. Products are inspected before shipment according to the expected quality criteria. For products checked as non-compliant, they are not temporarily stored in a dedicated area and not labelled as "non-compliant".	IThere is no written quality control procedure. However, products are inspected before shipment according to the expected quality criteria. Products inspected as non-conforming are not stored in a dedicated area and are not labelled as "non-compliant".	There is no written procedure for checking finished products before shipment	A	20	0	The company store the returned or non-compliant finished product at the dedicated storage area to prevent any contamination to VEGAN product. I checked that every non-compliant material is segregated from others.	

Item N°	Requirements	*Scoring method*	A	B	C	D (Major)	Score	Pts	NA	Auditor's comments	Corrective Actions OR CAPA Report N° if score is D
6) STORAGE											
6.1	The building(s) and facilities housing the storage of raw materials and finished products are clean and in good condition (sanitary condition, waste, odours, dust, humidity, mould).	*Evaluation of storage conditions.*	The storage area is clean and in good condition.	Clean storage area. However an old condition requiring renovation.	Insufficiently clean area requiring overhaul.	Unacceptable state of cleanliness resulting from non-compliance with cleaning procedures.	A	20	0	The raw material storage area is managed cleanly with good condition. Even for dust collector and ceiling, We could not find any dirt.	
6.2	EVE VEGAN® raw materials and non-compliant raw materials are stored separately (dedicated area) and individually identified (VEGAN or NON-VEGAN labeling depending on the majority configuration).	*Evaluation of storage conditions.*	The storage complies with the requirements: dedicated area and individual identification.	Storage is separate. However, the items are not identified individually.	Storage is mixed. However, the elements are identified individually.	Storage is mixed and items are not identified individually.	B	15	0	The storage space in the raw material warehouse is physically separated from Non-VEGAN raw materials. The company displayed the instruction tag of 'Animal based raw materials storage area" . The company didn't individually attach the "VEGAN" label for each of raw material. However, they plan to use it after finishing the product certification process of EVE VEGAN.	
6.3	EVE VEGAN® packaging and non-compliant packaging are stored separately (dedicated area) and individually identified (VEGAN or NON-VEGAN labeling depending on the majority configuration).	*Evaluation of storage conditions.*	The storage complies with the requirements: dedicated area and individual identification.	Storage is separate. However, the items are not identified individually.	Storage is mixed. However, the elements are identified individually.	Storage is mixed and items are not identified individually.	B	15	0	The storage space in the packaging material warehouse is physically separated from Non-VEGAN packaging materials. The company displayed the instruction tag of 'Animal based packaging materials storage area" . The company didn't individually attach the "VEGAN" label for each of packaging material. However, they plan to use it after finishing the product certification process of EVE VEGAN.	
6.4	EVE VEGAN® finished products and non-compliant finished product are stored separately (dedicated area) and individually identified (VEGAN or NON-VEGAN labeling depending on the majority configuration).	*Evaluation of storage conditions.*	The storage complies with the requirements: dedicated area and individual identification.	Storage is separate. However, the items are not identified individually.	Storage is mixed. However, the elements are identified individually.	Storage is mixed and items are not identified individually.	B	15	0	The storage space in the finished products warehouse is physically separated from Non-VEGAN finished products. The company displayed the instruction tag of 'Animal based finished products storage area" . The company didn't individually attach the "VEGAN" label for each of finished product. However, they plan to use it after finishing the product certification process of EVE VEGAN.	

Item N°	Requirements	*Scoring method*	A	B	C	D (Major)	Score	Pts	NA	Auditor's comments	Corrective Actions OR CAPA Report N° if score is D
7) MANUFACTURING SITE											
7.1	The building(s) housing the manufacture of the products are clean and in good condition.	*Overall visual check.*	Building(s) clean and in good condition.	Old building(s) however clean and in good condition.	Old and dilapidated building(s). High risk of humidity or pest invasion.	Unacceptable state. Result of a lack of maintenance or renovation.	A	20	0	The building was totally new, and it was entirely clean.	
7.2	The technical installations dedicated to the manufacture of the finished products are clean and in good condition.	*Overall visual check.*	Area and equipment clean and in good condition.	Clean area and equipment. However in a dilapidated state requiring renovation.	Insufficiently clean area requiring a revision of the hygiene protocol.	Unacceptable state. Result of a lack of maintenance or renovation.	A	20	0	The production facilities were entirely clean and in good condition.	
7.3	The production equipment is exclusively reserved for EVE VEGAN® products (incl. production line, filters, sieves and utensils). The tools are labelled and stored in such a way that the risk of contamination is avoided.	*Interview referrers and staff. Assess the risks of contamination of the equipment.*	The production material is exclusively reserved for EVE VEGAN® products.	Production equipment is not reserved (mixed). However, a specific and satisfactory cleaning plan is in place.	Production equipment is not reserved (mixed). The cleaning plan is not satisfactory or needs improvement.	Production equipment is not reserved (mixed) and there is no cleaning plan.	A	20	0	The company use following production equipment as a VEGAN dedicated production facility and tools. 1) Weighing tools 2) Weighing container 3) washing tools 4) Filling facility 5) Packaging facility 6) Manufacturing facility.	
7.4	The facilities dedicated to the manufacture of finished products do not report any lubrication that may come into contact with the finished product (non-animal origin where applicable).	*Interview the manager(s) and staff.*	The technical installations do not report any lubrication.	Some of the installations report lubrication. The substances used are not of animal origin.	Some of the installations report lubrication. The substances used may be of animal origin, but under no circumstances may they come into contact with the finished products.	Some of the installations report lubrication. These greases can come into contact with the finished products. The substances used are of animal origin or without proof to the contrary.	A	20	0	The company don't use any lubrication. When filling the product, it is managed in a manual way.	
7.5	Production and storage areas are secured to prevent unauthorized access and malicious acts.	*Interview the manager(s) and staff.*	Production areas are secured (access badge, alarm, reception control, for example).	The production areas are secured but there are still unprotected areas.	The production areas as a whole are insufficiently secured.	No security. Unacceptable situation due to the risks of the surrounding environment.	A	20	0	The visitor from outside must record their personal information before enter the processing area, and be with the staffs of company.	
RESULTS											

	Pts	NA
TOTAL AUDIT SCORE	**745**	**6**
SCORING RATE	98%	

TAB 7 - AUDIT CONCLUSION

RESULTS	
Do not modify: Automatic filling with the audit grid	
Total of the audit :	**745**
Scoring rate :	**98%**

1.CONCLUSIONS OF THE AUDITOR :	
Total of minor non-conformities (Note C)	**0**
Total of major non-conformities (Note D)	**0**

The facilities had been established to only deal with natural botanical ingredient.
Because of that, the factory was highly familiar with VEGAN regulation, so there was just few risk of cross-contamination.
EVE VEGAN operating system is also established to prevent any contamination from animal based material.
Therefore, the company is full of qualification to produce VEGAN products in their facilities.

2.POINTS OF VIGILANCE DURING NEXT AUDIT

There is no production record for VEGAN product.
The efficiency of EVE VEGAN operating system must be reviewed again on next audit.

3. RECOMMANDATIONS	
Additional Audit	☐
Unannounced Audit	☐

NA

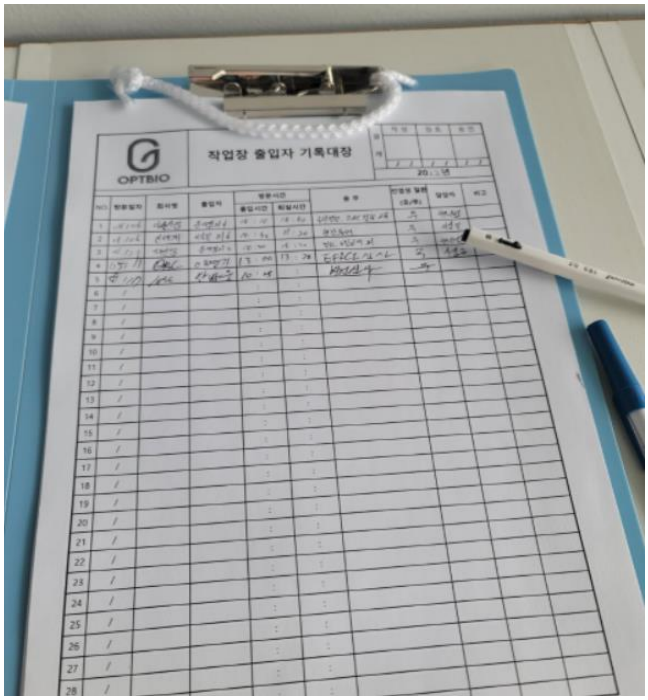
4. AUDITOR OPINION

Positive opinion. Attention only the products present on the certificate can be sold with the label

ANNEX
Add here the related documents

Authorisation to be obtained in advance for taking **relevant photos** of the site, etc.

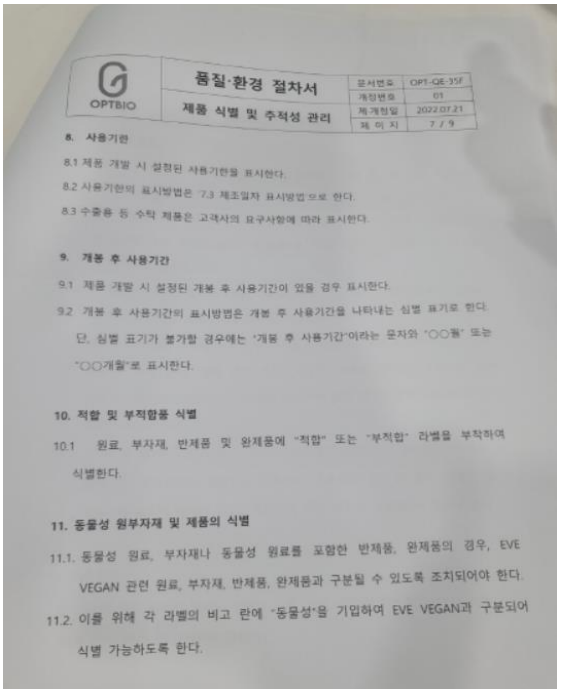
Indicate here the list of annexes, or insert here the annexes.




동물성 반제품 및 완제품은 1층 보관


동물성 전용


Chamber 101



OPTBIO

품질·환경 절차서

제품 식별 및 추적성 관리

문서번호	OPT-QE-35F
개정번호	01
제·개정일	2022.07.21
페 이 지	7 / 9

8. 사용기한

8.1 제품 개발 시 설정된 사용기한을 표시한다.

8.2 사용기한의 표시방법은 7.3 제조일자 표시방법으로 한다.

8.3 수출용 등 수탁 제품은 고객사의 요구사항에 따라 표시한다.

9. 개봉 후 사용기간

9.1 제품 개발 시 설정된 개봉 후 사용기간이 있을 경우 표시한다.

9.2 개봉 후 사용기간의 표시방법은 개봉 후 사용기간을 나타내는 심벌 표기로 한다. 단, 심벌 표기가 불가할 경우에는 "개봉 후 사용기간"이라는 문자와 "○○월" 또는 "○○개월"로 표시한다.

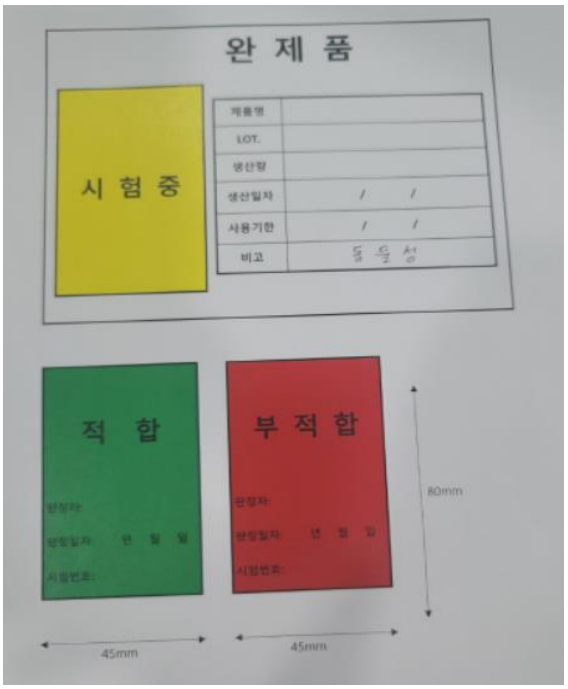
10. 적합 및 부적합품 식별

10.1 원료, 부자재, 반제품 및 완제품에 "적합" 또는 "부적합" 라벨을 부착하여 식별한다.

11. 동물성 원부자재 및 제품의 식별

11.1. 동물성 원료, 부자재나 동물성 원료를 포함한 반제품, 완제품의 경우, EVE VEGAN 관련 원료, 부자재, 반제품, 완제품과 구분될 수 있도록 조치되어야 한다.

11.2. 이를 위해 각 라벨의 비고 란에 "동물성"을 기입하여 EVE VEGAN과 구분되어 식별 가능하도록 한다.



완 제 품

시 험 중

제품명	
LOT.	
생산량	
생산일자	/ /
사용기한	/ /
비고	동물성

적 합

완정자:

완정일자: 년 월 일

시험번호:

부 적 합

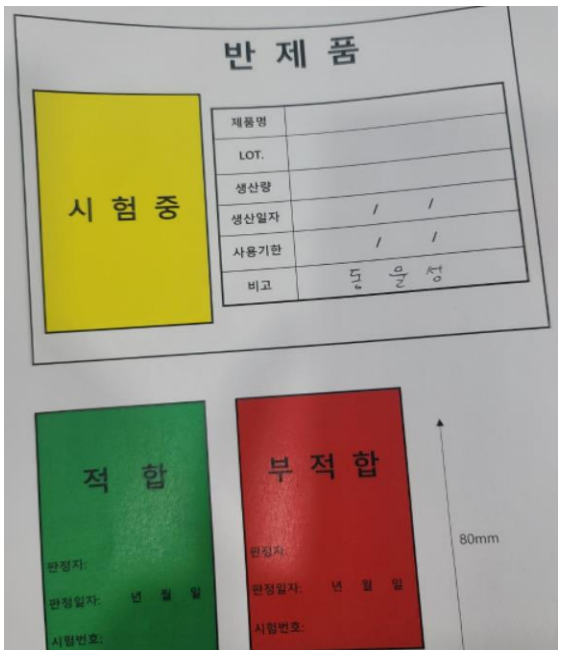
완정자:

완정일자: 년 월 일

시험번호:

80mm

45mm 45mm



반 제 품

시 험 중

제품명	
LOT.	
생산량	
생산일자	/ /
사용기한	/ /
비고	동물성

적 합

완정자:

완정일자: 년 월 일

시험번호:

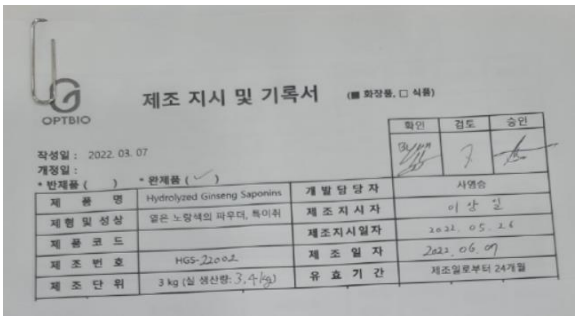
부 적 합

완정자:

완정일자: 년 월 일

시험번호:

80mm



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제조 지시 및 기록서 (■ 화장품, □ 식품)

확인	검토	승인
	7	

작성일 : 2022. 03. 07

개정일 :

* 반제품 ( ) * 완제품 (✓)

제 품 명	Hydrolyzed Ginseng Saponins	개 발 담 당 자	사영승
제형 및 성상	옅은 노랑색의 파우더, 특이취	제 조 지 시 자	이 상 길
제 품 코 드		제조지시일자	2022. 05. 26
제 조 번 호	HGS-22002	제 조 일 자	2022. 06. 07
제 조 단 위	3 kg (실 생산량: 3.4kg)	유 효 기 간	제조일로부터 24개월


OPTBIO
VEGAN

Audit EVE VEGAN sign-off sheet V01.18

COMPANY : OPT BIO CO., LTD.

Audit de	Labelling ☑ .... unannounced check ☐ .... reappointment ☐	
Date	2022. 8. 17	Duration :
Lead Auditor	Byoung Wook, AN	Signing :
Co-auditor(s)	Han mun taek	Signing :

First and last name	Fonction	Signing
Young seung SA	Team leader	
Min Jeong KIM	Assistant Researcher	
Sang Il LEE	Director	
MIN CHAE KWAK	Assistant researcher	
HYeonJeong KIM	Assistant researcher	