099 F Auditreport e

Organisation/client:	"PHARM SCALE" d.o.o.
Street:	ul Ćehaje bb
Postcode / Town:	BiH - 75350 Srebrenik
Client audit manager:	Senad Bećirović
Order number:	3330/3HPG/A0
Audit objective:	Determination of compliance with standards
Audit criteria:	ISO 22000:2018 / ISO 22003-1; TÜV Thüringen certification procedure and applicable regulations; documentation of the organisation's management system
Audit type:	Certification audit – Stage 2
Audit date:	09-10.03.2026.
Scope:	Production of food supplements
EA/IAF industry/category:	K
Non-applicability of standard requirements:	-
Number of employees:	6
Multi-site certification:	• Not applicable
Lead Auditor:	Tanja Baker ISO 22000:2018 / ISO 22003-1; K
Auditor:	-
Technical expert:	-
Trainee:	-
Other persons accompanying the audit:	-
Documents applicable to the audit report:	• Audit plan • Appendix to the audit report (remains with the certification body):

Audit plan	• The audit plan dated 27.02.2026; version 1 was implemented without changes.
Audit result:	• As a result of the audit objectives achieved, the issuance of the certificate is recommended.

Changes to the application review data are documented in the audit report or customer data sheet.

17.03.2026.	Tanja Baker
Creation date	**Lead Auditor**
Date of approval	**Approval of the certification body**

Notes on the procedure, evaluation of the audit, distribution list, confidentiality, property rights, restrictions, responsibilities

The audit result was determined by an on-site assessment of the organisation, including interviews with management and employees, inspection of documents and observation of processes using a sampling procedure.

An audit as a sampling procedure cannot examine every detail of the management system. Due to the sampling nature of an audit, it should be noted that nonconformities or weaknesses may exist that were not identified during the audit. The audit is based on a sampling procedure of available information. Any need for improvement identified in a specific area or process should always be reviewed by the organisation in other areas as well.

The certification body of TÜV Thüringen e.V. checks and evaluates the potential for improvement, nonconformities (deviations) and corrections/corrective measures. If necessary, the certification body may make new determinations as a result of the audit.

The auditors' findings and thus the audit result do not release the organisation from its responsibility to ensure continuous compliance with the standard requirements and legal requirements. Responsibility for the ongoing effective operation of the management system always remains solely with the audited and certified organisation.

If changes to the management system, structures or scope occur during the period of validity of the certificate, the organisation is obliged to notify the certification body of these changes immediately.

This report is sent to the certification body or bodies, to the accreditation body upon request, to the members of the audit team and to the organisation's audit representative. Appendices to the audit report are used for the certification decision and remain with the certification body. All documents (including this report) relating to this audit and certification process are treated as confidential by the audit team and the certification body. The certification body retains ownership rights to this audit report.

1. Summary assessment

Based on the documents reviewed and the processes audited, the audit concluded that the management system was assessed as complete effective in accordance with the underlying standard requirements.

The prerequisites for maintaining and further developing the management system are comprehensively given.

The management system is capable of meeting applicable requirements and delivering expected results.

The management system is capable of ensuring compliance with applicable statutory, regulatory and contractual requirements.

The process of conducting internal audits complies fully with the requirements of the standard. Management review is carried out fully in accordance with the standard.

2. Potential for improvement of the organisation's management system

Personnel are trained in SOPs and hygiene practices, but additional refresher training could strengthen adherence to FSMS procedures and enhance overall awareness of potential hazards.

3. Corrective measures on nonconformities from previous audits

Not applicable. Certification audit.

4. Nonconformities

Non-critical nonconformity

No

Critical nonconformity

No

5. Positive aspects

- Effective Implementation of HACCP and operational controls
- Good hygiene practices in production areas, production and packaging areas are clean and well maintained.
- High level of traceability
- Well documented and maintained records
- Employees involved in production activities show good understanding of hygiene rules, operational procedures and their responsibilities regarding food safety.
- Management commitment to food safety

6. Information on the organisation

6.1 Description of the organisation and its core activities:

"PHARM SCALE" d.o.o. is a small enterprise engaged in the production of food supplements. It has implemented a Food Safety Management System in accordance with the requirements of ISO 22000:2018.

The company’s core activities include the production, packaging, labeling and distribution of food supplements intended for human consumption. All processes are carried out under controlled conditions to ensure food safety, product quality and compliance with applicable regulatory requirements. Management is actively involved in ensuring the effective implementation and maintenance of the system. The organization operates at the location Ćehaje bb, Srebrenik, Bosnia and Herzegovina.

6.2 Description of site conditions:

The organization operates from a single site where all activities related to the production of food supplements are carried out. The facility includes designated areas for the receipt and storage of raw materials, production, packaging, storage of finished products, quality control activities and administrative offices.
The production area is well maintained, clean and equipped with the necessary infrastructure to support hygienic food processing. Site conditions support GMP, ensuring that raw material handling, processing and packaging take place under controlled and food safe conditions. The premises are organized to minimize the risk of cross contamination and to support an efficient workflow between different production stages.
From an environmental perspective, the activities of the organization have low environmental impact, as the production of food supplements do not have significant emissions or hazardous waste generation. Waste generated during production is managed in accordance with applicable regulations.
Regarding occupational health and safety, it is classified as a low to moderate risk activity, with main risks related to equipment operation, manual handling of materials and hygiene requirements. Appropriate safety and hygiene measures are implemented to protect employees.
In terms of energy use, the facility consumes energy mainly for operation of production equipment, laboratory instruments, lighting, ventilation and climate control. Energy consumption is considered moderate, typical for small scale food supplement production. The organization operates with 6 employees and production activities are carried out in one working shift.
Access to the production and administrative areas is controlled, allowing entry only to authorized personnel. Visitor access is registered and supervised.

6.3 Temporary locations/projects:

The organisation has no temporary locations/projects.

6.4 Description of resources used:

"PHARM SCALE" d.o.o. has identified and allocated the necessary resources to support the implementation and maintenance of the FSMS according to ISO 22000:2018.

Human resources consist of a small but well trained team responsible for overseeing and performing all stages of the process, including raw material handling, production, packaging, storage and administrative activities. The organization utilizes modern food processing equipment, primarily made of stainless steel, which supports hygienic and efficient operations throughout the production cycle. Equipment used in the production of food supplements includes mixing and blending equipment, weighing scales, stainless steel processing containers, dosing machines, capsule handling equipment and packaging equipment. The equipment is suitable for food contact applications and designed to facilitate cleaning, maintenance and hygienic operation.

Production facility is equipped with essential utilities, including water supply, electricity and drainage systems. These resources enable the organization to maintain appropriate production conditions and ensure consistent product quality and food safety.

6.5 Regulatory and legal requirements:

- Food Law, Official Gazette BiH 50/04
- Labeling regulations for ingredient declarations, nutritional information, allergen statements and product traceability under BiH food law
- Regulations on materials in contact with food, Official Gazette BiH 42/10
- Regulation on plastic materials and items intended to come into contact with food - Official Gazette BiH 66/17
- Registration of Food Supplements (FBiH)
- Regulation on maximum permitted quantities of certain contaminants in food - Official Gazette BiH 84/18
- Rulebooks and By-laws by Agency for Food Safety of BiH, Federal Ministry of Agriculture, Water Management and Forestry and Inspectorate of FBiH

6.6 Changes to the management system since the previous audit:

No.

6.7 Objective evidence:

The following objective evidences were given to the audit team during the audit:

	Evidence	Revision or date	Comment
☒	Extract from the commercial register or central trade register (or comparable evidence)	30.10.2025.	
☒	Organisational chart / Structure of the organisation's documentation	01.11.2025.	
☒	Top management policy	01.11.2025.	
☒	Scope of the management system	01.11.2025.	
☒	Latest management review (at least cover page, table of contents)	10.02.2026.	
☒	Results of the last internal audits	06.02.2026.	
☒	Information on the number and subject of complaints/grievances	No complaints	
☐	Relevant required permits, approvals, registrations – *if applicable*	n.a.	
☒	Description of the relevant processes – *if applicable*	01.11.2025.	
As well as other documents required by the standard ***(if more documents are required, please add them and delete those that do not apply)***			

Note: Confidential information in the objective evidence may be redacted.

7. Scope of the management system

The scope includes the following locations / functional areas:

Production area including raw material handling, weighing, mixing, capsule filling, drying and processing; packaging area which include blister packaging, capsule bottle filling, bottle capping, cartoning and labeling; storage areas fro raw materials, packaging materials, finished products, including freezer and ambient storage; quality control for product testing, moisture analysis and verification of raw materials and finished products; administrative area which includes management, documentation, record keeping, sales and logistical activities.

The scope of FSMS of “PHARM SCALE” d.o.o. is "**Production of food supplements**". It applies to the entire production facility including all areas necessary for safe production, handling and distribution of products.

The scope of certification covers all necessary processes of FSMS: management processes (strategic management, food quality and safety management, internal control and audits, risk and nonconformity management); basic (operational) processes including: supplier selection and approval; raw material and packaging receipt; raw material storage; dosing and preparation of formulations; food supplement packaging; product labeling; finished product storage; and distribution and delivery; supporting processes (PRP) including: employee training program; water control program; cleaning and disinfection program; DDD (pest control) measures program; allergen control program; waste management program; temperature calibration and control program; and traceability and product recall program.

The following processes are outsourced:

- Calibration of analytical and production equipment,
- Specialized maintenance of processing and packaging machines,
- Waste management services.

8. Complaints about the organisation's management system

There are no complaints about the company’s management system.

9. Use of the certification mark/certificate

During the final audit meeting, the organisation was informed in detail about the use of the certification mark and certificate in accordance with § 6 of the certification agreement. In this context, it was pointed out that the use of the certification mark and certificate must not give the impression of product certification or certification of areas outside the scope of application.

The certificate is used as follows:

It was explained to the company’s management that the certificate is primarily intended to demonstrate conformity with the standard and may be used for marketing and communication purposes

The certification mark is used as follows:

It was explained to the company’s management that the certification mark may be used for marketing and communication purposes.

Distribution list:

- Organisation
- Certification body