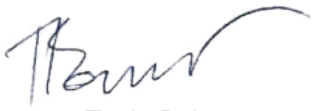
099 F Auditreport e

Organisation/client:	"PHARM SCALE" d.o.o.
Street:	ul Ćehaje bb
Postcode / Town:	BiH - 75350 Srebrenik
Client audit manager:	Senad Bećirović
Order number:	3330/3HPP/A0
Audit objective:	Determination of compliance with standards
Audit criteria:	ISO 22716; TÜV Thüringen certification procedure and applicable regulations; documentation of the organisation's management system
Audit type:	Certification audit – Stage 2
Audit date:	07.03.2026.
Scope:	Production of cosmetic creams
EA/IAF industry/category:	-
Non-applicability of standard requirements:	-
Number of employees:	6
Multi-site certification:	• Not applicable
Lead Auditor:	Tanja Baker ISO 22716
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 26.02.2026.; 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.



18.03.2026.	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

The organization maintains an approved supplier list and verifies supplier documentation.
Improvement could include implementing periodic supplier performance evaluations based on delivery reliability and raw material quality.

3. Corrective measures on nonconformities from previous audits

Not applicable. Certification audit.

4. Nonconformities

Non-critical nonconformity

No

Critical nonconformity

No

5. Positive aspects

- Production processes for cosmetic creams well organized and performed according to documented procedures.
- Good awareness of employees for hygiene requirements and GMP principles.
- Batch production records and traceability documentation are properly maintained.
- Established procedures for handling nonconforming products, complaints and product recalls.
- Equipment maintenance and calibration activities are documented and regularly performed.
- Commitment to continuous improvement, supported by internal audits and management reviews.

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 cosmetic creams. The company has implemented Good Manufacturing Practices in accordance with the requirements of ISO 22716:2007.
The company’s core activities include the manufacture, filling, packaging, labeling and distribution of cosmetic creams intended for consumer use. All production processes are carried out under controlled conditions in order to ensure product quality, safety, hygiene and compliance with applicable regulatory requirements for cosmetic products.
Management is actively involved in ensuring the effective implementation, maintenance and continual improvement of the GMP system, providing the necessary resources, supervision and training to employees.
The organization operates at the location Ćehaje bb, Srebrenik, BiH where production, storage and quality control activities related to cosmetic creams are performed.

6.2 Description of site conditions:

The organization operates from a single site where all activities related to the production of cosmetic creams are carried out. The facility includes designated areas for the receipt and storage of raw materials and packaging materials, production, filling and packaging operations, storage of finished cosmetic products and administrative activities.
The production area is well maintained, clean and equipped with the necessary infrastructure to support hygienic manufacturing of cosmetic products. Site conditions support the application of Good Manufacturing Practices.
The premises are organized in a way that minimizes the risk of contamination, mix ups and cross-contamination, while ensuring a logical workflow between different stages of production.
From an environmental and occupational health and safety perspective, the activities carried out at the site are considered low environmental impact operations, primarily involving mixing, filling and packaging of cosmetic formulations. The facility operates in accordance with applicable occupational health and safety requirements, and employees are provided with appropriate protective clothing and hygiene equipment.
The facility operates with standard energy consumption typical for small scale cosmetic production, mainly associated with production equipment, ventilation systems and lighting. The company operates one production shift.

From an information security perspective, access to the production and storage areas is restricted to authorized personnel only. The facility applies controlled access procedures, and certain areas are additionally monitored through video surveillance systems to ensure protection of products, materials and company property.

6.3 Temporary locations/projects:

The organisation has no temporary locations/projects.

6.4 Description of resources used:

During the audit, it was confirmed that “PHARM SCALE” d.o.o. has provided and maintains the resources necessary for the effective implementation of GHP in accordance with ISO 22716:2007.

The organization operates with a small but competent team of employees responsible for the management and execution of activities related to raw material handling, cosmetic cream production, filling, packaging, storage and administrative functions. Personnel interviewed during the audit demonstrated awareness of hygiene requirements and GMP principles relevant to their responsibilities.

The production process is supported by equipment suitable for cosmetic manufacturing, including mixing and homogenizing equipment, weighing devices, stainless steel mixing vessels, dosing and filling equipment and packaging machines. The equipment is designed and maintained in a manner that supports hygienic operation, cleaning and maintenance.

The facility is supplied with necessary utilities, including water, electricity and drainage systems.

6.5 Regulatory and legal requirements:

- Law on General Product Safety, Official Gazette of BiH no. 102/09
- Law on Consumer Protection in Bosnia and Herzegovina, Official Gazette of BiH no. 25/06, 88/15
- Law on Chemicals, Official Gazette of BiH no. 52/10
- Law on Market Surveillance in Bosnia and Herzegovina, Official Gazette of BiH no. 45/04, 44/07, 102/09
- Law on Indirect Taxation (VAT), Official Gazette of BiH no. 9/05, 35/05, 100/08, 33/17
- Law on Internal Trade, Official Gazette of FBiH no. 40/10, 79/17
- Law on Environmental Protection, Official Gazette of FBiH no. 15/21
- Law on Waste Management, Official Gazette of FBiH no. 33/03, 72/09, 92/17
- Law on Occupational Safety, Official Gazette of FBiH no. 79/20
- Law on Protection from Fire, Official Gazette of FBiH no. 64/09

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	09.02.2026.	
☒	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, packaging area, storage areas for raw materials, packaging materials and finished products, quality control area, administrative area.
The scope of the Good Manufacturing Practices ISO 22716:20707 system of “PHARM SCALE” d.o.o. is: “**Production of cosmetic creams**.”
The GMP system applies to the entire production facility, including all areas necessary for the manufacture, filling, packaging, storage and distribution of cosmetic products.
The system covers the following categories of processes:
Management processes include management responsibility and commitment, quality management, internal control and audits, management of deviations and nonconformities, corrective and preventive actions and documentation control; Basic (operational) processes include supplier selection and approval; receipt and control of raw materials and packaging materials; storage of raw materials and packaging; weighing and preparation of formulations; manufacturing of cosmetic products; filling and packaging operations; product labeling; storage of finished products, distribution and delivery; Supporting processes include personnel training and competence management; water quality control; cleaning and sanitation of premises and equipment; pest control measures; waste management; equipment maintenance and calibration of measuring devices; premises and equipment hygiene control; traceability and product recall procedures; and management of returned products and complaints.

The following processes are outsourced:

- calibration of laboratory and production equipment
- specialized maintenance of processing and packaging equipment
- waste collection and disposal 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:

The company’s management was informed that the certificate confirms conformity with the standard and may be used for marketing and communication purposes.

The certification mark is used as follows:

The company’s management was informed that the certification mark may be used for marketing and communication purposes.

Distribution list:

- Organisation
- Certification body