

PharmaHemp d.o.o., Koprška ulica 106C, SI-1000 Ljubljana, Slovenija		Pharma  Hemp®
QUALITY SELF-DISCLOSURE		
Issue date:	Expiration date:	Code: VPR1-VOD-GEN-001
		Revision No.: 01
		Appendixes: /
Author: Tine Lavrič	Reviewer: Martina Korenčan	Approver: Tine Lavrič

1. GENERAL INFORMATION

Company Name	PharmaHemp d.o.o
Company address	Koprška 106C, SI-1000 Ljubljana, Slovenia
Facility Address	Cesta v Gorice 8, SI-1000 Ljubljana, Slovenia
Website	www.pharma-hemp.com
Scope of service	- Supply, processing and distribution: raw materials, bulk, finished products (custom and private label) with or without phytocannabinoids (food supplements, cosmetic products). - Laboratory testing - quantitative determination of cannabinoids. - Research and Development services. - Regulatory support.

2. CERTIFICATIONS

Standard / certificate	Certified since
ISO 22716:2007 – Cosmetics - Good Manufacturing Practice (GMP) – Guidelines on Good Manufacturing Practices	15.10.2019
Ecogea - Organic, Natural-organic	29.07.2019
Kosher KLBD	20.03.2020
ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories	22.10.2020
ISO 22000:2018 - Food Safety Management Systems – Requirements for any organization in the food chain	27.04.2021
GMP - Food supplements - Good Manufacturing Practice for Food Supplements	27.04.2021
HACCP - Hazard Analysis Critical Control Point - GENERAL PRINCIPLES OF FOOD HYGIENE CXC 1-1969, Rev. 2020	27.04.2021
ISO 9001:2015 - Quality management systems	17.06.2021

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3. QUALITY

3.1 Quality system

Activity	Yes
Is there a written description of the quality policy and quality rules?	x
Is there a written description of the general competence, impartiality and confidentiality?	x
Have written procedures for records management and retention been generated?	x
Are all retained GMP records filed in archive storage and backed-up?	x
Is access to documents controlled?	x
Are documents periodically reviewed and updated according to written procedure?	x
Are internal audits carried out at regular intervals?	x
Are there procedures for complaint management?	x
Are there procedures to control the change to all document types?	x
Does the change control program include process, equipment and software changes?	x
Does the quality unit approve all changes to documents, equipment, product, materials and facilities, as applicable?	x
Are there written procedures for the management of corrective and preventive actions and CAPA database?	x
Are there written procedures for the management of deviations and investigations?	x
Is there a procedure that describes product recall?	x

3.2 Quality Control

Activity	Yes
Are there written procedures for quality control and release of incoming materials and final products?	x
Are there specifications defined for quality control purposes?	x
Are incoming materials inspected for their required specifications?	x
Is there any written proof of release issued before the incoming materials are further processed?	x
Are there any sampling instruction?	x
Is it ensured that reserve samples are stored in sufficient quantities so that follow-up inspections can be done at any time?	x
Are the existing analytical procedures sufficient to ensure that each batch satisfies the specifications with regard to quality, purity and identity?	x
Are the current specifications always available for the staff involved?	x
Is there a written procedure for "out-of-specification" results?	x
Do the analysis certificates indicate which product they refer to?	x

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4. PRODUCTION

4.1 General

Activity	Yes
Are there written procedures for the control and monitoring of production processes to ensure that the product conforms to its specifications?	x
Do production records require documentation of specific major equipment used?	x
Are critical steps independently verified by a second person?	x
Are all production deviations reported and critical deviations investigated?	x
Are changes to the process or equipment documented and approved by the Quality Unit?	x

4.2 Organization and personnel

Activity	Yes
Do all employees have job descriptions on file?	x
Is there a written training program for employees?	x
Is training of employees documented prior to their participation in regulated activities?	x
Is there a policy on employee hygiene?	x
Is there a Quality Assurance (QA) function and Quality Control (QC) described in written procedures?	x

4.3 Facilities

Activity	Yes
Are facilities used for production, logistics and quality control appropriate size, construction and location to facilitate cleaning, maintenance and proper operations?	x
Has facilities adequate space for placement of equipment and materials to prevent mix-ups?	x
Are there written procedures for sanitation of the facilities that include schedules, methods, equipment and materials to be used?	x
Is there adequate lighting, sewage and refuse disposal, washing and toilet facilities?	x
Is there an established Pest Control Program?	x
Is there a monitoring system for temperature and humidity with deviation alert?	
Has the purified or better quality water system been validated?	x
Has the HVAC system been validated?	x
Does the facility have a backup power system?	x
Has the facilities and refrigerators temperature and humidity monitoring system and real-time alerts?	x

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4.4 Equipment

Activity	Yes
Are all major equipment and instruments appropriately identified?	x
Are critical pieces of equipment qualified prior to use?	x
Is equipment calibrated and included in a calibration schedule?	x
Are calibration standards traceable to certified standards?	x
Is equipment designed to prevent contamination of product from lubricants, heating fluids, coolants or other substances?	x
Are there written procedures for equipment in place?	x
Are there written procedures for equipment inspection, qualification, calibration, cleaning and preventive maintenance?	x

4.5 Materials and logistics

Activity	Yes
Is there written procedures for the acceptance of incoming materials?	x
Are incoming materials evaluated by inspection, testing or other activities prior to release?	x
Are there designated storage areas for quarantine, release, return/reject materials?	x
Are there written instructions for the packaging process?	x
Are product shipments tracked to ensure traceability of product?	x