

Pharmahemp d.o.o., Kopraska ulica 106C, SI-1000 Ljubljana, Slovenija		
SUPPLIER TESTING SERVICES ASSESMENT		
Issue date:	Expiration date:	Code: VPR2-VOD-GEN-010
		Revision No.: 01
		No. pages: 6
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In accordance with the GMP guidelines, raw materials and packaging materials can be accepted on the basis of the supplier's analytical certificate only if the technical requirements, experience and knowledge of the supplier are determined, the supplier's assessment is performed and test methods agreed with the supplier.

INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

- Please complete all pages of a questionnaire.
- If the process complies with the written requirements, mark at each point of the standard ☐ Yes.
- If the process doesn't comply with the written requirements, mark at each point of the standard ☐ No.

Company Name	
Name	
Laboratory Address	
Telephone No.	
Email	
Type of Business	
Scope of service the company provides or will provide	
Date	
Signature	

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I. QUALITY MANAGEMENT SYSTEM	
1. Have written procedures for records management and retention been generated?	☐ Yes ☐ No
2. Are all retained laboratory records filed in archive storage and backed-up?	☐ Yes ☐ No
3. Is access to documents controlled?	☐ Yes ☐ No
4. Are documents periodically reviewed and updated according to written procedure?	☐ Yes ☐ No
5. Are there procedures in place describing the process for receipt, review and evaluation of complaints (whether oral, electronic or written)?	☐ Yes ☐ No
6. Are there procedures to control the change to all document types?	☐ Yes ☐ No
7. Does the change control program include process, equipment and software changes?	☐ Yes ☐ No
8. Does the quality unit approve all changes to documents, equipment, product, materials and facilities, as applicable?	☐ Yes ☐ No
9. Are there written procedures for the management of corrective and preventive actions?	☐ Yes ☐ No
10. Are there written procedures for the management of deviations and investigations?	☐ Yes ☐ No
11. Is there a procedure that describes product recall activities?	☐ Yes ☐ No
12. List company Quality Management Systems (GxP).	☐ Yes ☐ No
13. Number of certification or regulatory agency audits in the last two years and date of last inspection?	☐ Yes ☐ No
14. Date of last self-inspection / audits?	☐ Yes ☐ No

II. LABORATORY ORGANIZATION AND PERSONNEL	
1. Are laboratory activities undertaken impartially?	☐ Yes ☐ No
2. Is the laboratory in the company structure listed as independent unit?	☐ Yes ☐ No
3. Number of employees in laboratory?	
4. Do laboratory employees have CV's and job descriptions on file?	☐ Yes ☐ No
5. Is there a written training program and an annual compliance training for employees working in laboratory?	☐ Yes ☐ No
6. Is training of employees documented prior to their participation in regulated activities?	☐ Yes ☐ No

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III. LABORATORY PREMISES	
1. Are the buildings and facilities used for laboratory testing appropriate size, construction and location to facilitate cleaning, maintenance and proper operations?	☐ Yes ☐ No
2. Has laboratory HVAC system (Heating, Ventilation, and Air Conditioning)?	☐ Yes ☐ No
3. Has the HVAC system been validated?	☐ Yes ☐ No
4. Do you monitor temperature, humidity?	☐ Yes ☐ No

IV. LABORATORY EQUIPMENT	
1. Are all major equipment and instruments appropriately identified?	☐ Yes ☐ No
2. Are critical pieces of equipment qualified prior to use (IQ, OQ, PQ)?	☐ Yes ☐ No
3. Is laboratory equipment calibrated and included in a calibration schedule?	☐ Yes ☐ No
4. Are there written procedures for equipment inspection, qualification, calibration, cleaning and preventive maintenance?	☐ Yes ☐ No
5. Are there written procedures for equipment in place?	☐ Yes ☐ No
6. Specify basic laboratory equipment.	

V. MATERIALS	
1. Is there written procedures for the acceptance of incoming laboratory materials?	☐ Yes ☐ No
2. Are incoming laboratory materials evaluated by inspection, testing or other verification activities prior to release?	☐ Yes ☐ No
3. Are all your material manufacturer's or supplier's qualified?	☐ Yes ☐ No
4. Are there designated storage areas for quarantine, release and reject materials?	☐ Yes ☐ No
5. Are retention samples taken of the product and materials, as applicable?	☐ Yes ☐ No

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VI. LABORATORY OPERATIONS	
1. Are there written test methods and are they validated/qualified, as applicable?	☐ Yes ☐ No
2. Are there written procedures and/or protocols that address laboratory operations, including sample handling, data generation and control?	☐ Yes ☐ No
3. Is there a process for evaluation and handling of Out-of Specification (OOS) results?	☐ Yes ☐ No
4. Are primary reference standards obtained from an officially recognized source?	☐ Yes ☐ No
5. Is there a written procedure for handling and controlling reagents, media and buffers?	☐ Yes ☐ No
6. If an in-house primary standard is used, has appropriate testing been performed to qualify such standard?	☐ Yes ☐ No
7. Do you ensure full laboratory data traceability?	☐ Yes ☐ No
8. Has laboratory software been validated?	☐ Yes ☐ No
9. Do you perform interlaboratory comparisons, if yes, indicate the date of the last comparison?	☐ Yes ☐ No

VII. TESTING METHOD						
No.	ID of the document describing the testing method	Characteristic or parameter tested	Description of test (type of test, test principle or technique)	Range of testing	Items tested (materials, products)	Method qualification completed by PharmaHemp (signature, date)
1.						
2.						
3.						
4.						

SUPPLIER TESTING SERVICES QUALIFICATION	QA (signature, date)
YES / NO	

COMMENT: _____