DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DPMA VI Attn: Christopher Downey, Ph.D., Division Director 10903 New Hampshire Avenue; White Oak Building 51/Room 2269 Silver Spring, MD 20993-0002 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	September 12, 13, 15 – 18, 2025
	FEI NUMBER 3013580641

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Prof. Vladas Algirdas Bumelis, Chairman of the Board CEO	
FIRM NAME Biotechnologinės farmacijos centras Biotechpharma UAB	STREET ADDRESS Mokslininku str. 4
CITY, STATE, ZIP CODE, COUNTRY Vilnius, LT-08412, Lithuania	TYPE ESTABLISHMENT INSPECTED Drug Substance Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Observation 1

Equipment used during the (b) (4) drug substance manufacturing operations occurring in the manufacturing building (b) (4) at your facility are not adequately designed to ensure the prevention of contamination of equipment or product by environmental or processing conditions that would be expected to have an adverse effect on product quality. Specifically,

On September 13, 2025, during the (b) (4) step of the (b) (4) drug substance manufacturing process for batch (b) (4) performed in building (b) (4) room (b) (4) we observed a high level of condensation on the floor, on the (b) (4) pipes, and on the (b) (4) (b) (4) tank containing the (b) (4) bag. The presence of condensation does not allow detection of leakage from the (b) (4) bag.

Observation 2

Preventive maintenance procedure for equipment is inadequate. Specifically,

On September 15, 2025, during the discussion of the procedures related to preventive and routine maintenance, the head of quality indicated that document MNP-001, titled Preventive and Routine Maintenance, revision 10, effective March 18, 2025, describes the timing for preventive maintenance notification, preventive maintenance due date, and preventive maintenance due date extension. However, this information could not be found in document MNP-001 or in any other document.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Melissa D. Ray -S Digitally signed by Melissa D. Ray -S Date: 2025.09.18 03:13:56 -04'00' Andrea Franco -S Digitally signed by Andrea Franco -S Date: 2025.09.18 03:19:31 -04'00'	Melissa Ray, PhD, Microbiologist Andrea Franco, PhD, Pharmaceutical Scientist	September 18, 2025

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Observation 3

Your disinfectant efficacy study is inadequate. Specifically,

Qualifications of (b) (4) (report VLP-FR-8020) and (b) (4) (report VLP-FR-8453) conducted on February 3, 2014 and December 11, 2023, respectively, were performed without the use of clean room isolates.
According to Document QCP-091, Qualification and Evaluation of Antimicrobial Efficacy of Disinfectants, revision 3, effective date June 20, 2025, and version 0, effective date July 4, 2013, disinfectant efficacy studies should include at least (b) (4) most commonly detected and identified microorganisms in clean controlled production facilities.

Observation 4

Your environmental monitoring program is deficient. Specifically,

On September 17, 2025, during the (b) (4) drug substance filling operations for batch (b) (4) occurring in the manufacturing building (b) (4) room (b) (4) we observed the operator performing post-operation personnel monitoring. The fingerprint collection of the operator was not conducted properly (*e.g.,* without rolling on the contact plate).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Melissa D. Ray -S Digitally signed by Melissa D. Ray -S Date: 2025.09.18 03:15:34 -04'00' Andrea Franco -S Digitally signed by Andrea Franco -S Date: 2025.09.18 03:20:17 -04'00'	Melissa Ray, PhD, Microbiologist Andrea Franco, PhD, Pharmaceutical Scientist	September 18, 2025