

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

FDA/CBER/OCBQ/Division of Manufacturing and Product Quality
10903 New Hampshire Avenue, Silver Spring, MD 20993
Attention: Carolyn Renshaw, Building 71, Room 4042
Telephone: (240) 402-7343

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

23-27, 30-31 Jan 2023

FEI NUMBER

3011160795

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Raquel Fortunato, Chief Executive Officer

FIRM NAME

Genlbet Biopharmaceuticals SA

STREET ADDRESS

Avenida da Republica

CITY, STATE AND ZIP CODE

2780-157 Oeiras, Portugal

TYPE OF ESTABLISHMENT INSPECTED

Drug Substance/Drug Product 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

There are no written procedures for production and process controls designed to assure that the have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, there is insufficient data to support the maximum target batch size, hold time, and process control parameters for the manufacture of .

a. The executed batch sizes for the process performance qualification do not represent the maximum target batch size of as per the current approved master batch record, .

b. There is insufficient data to ensure that the uniformity of the formulated containing within the is maintained throughout the hold time and during the .

c. The operating ranges specified during manufacturing are not optimized. For example, an specification for stages are not specified in the manufacturing batch record. Current operating ranges for respectively.

d. There is no detection device to ensure that the is free of contamination.

e. The supplier for respectively), used for the steps during the manufacturing of , allows the presence of particles . A toxicological assessment was not performed to evaluate the safety of the while using the , which are not particulate-free.

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EMPLOYEE(S) NAME AND TITLE (Print or Type)

Kathleen R. Jones, Biologist
Unncc Ranjan, Consumer Safety Officer
Miriam Ngundi, Consumer Safety Officer

DATE ISSUED

01/31/2023

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f. There are no equipment logs for the (b)(4) and the usage and cleaning history of these pieces of equipment are not readily available.

Observation 2

Equipment cleaning processes are inadequate. Specifically:

a. The cleaning validation study ((b)(4), Cleaning Validation Summary Report) performed on (b)(4) contact equipment does not ensure removal of the (b)(4). Specifically:

i. (b)(4) was not performed to ensure that the product is removed from the difficult to clean areas.

ii. (b)(4) was not assessed.

iii. The cleaning validation did not include the maximum lot size of (b)(4).

b. (b)(4) hold time is not representative of the (b)(4) manufacturing process, which includes (b)(4) that equipment are exposed to the Grade (b)(4) environment after cleaning (b)(4).

c. (b)(4) hold time is not representative of the (b)(4) manufacturing process, which includes a hold (b)(4) manufacturing (b)(4) decontamination.

Observation 3

Decontamination is incomplete or not adequately demonstrated to ensure prevention of cross-contamination. Specifically:

a. A decontamination study was not performed to evaluate the effectiveness of (b)(4), which is used to decontaminate (b)(4) parts, against (b)(4).

b. (b)(4), Report on the Cleaning Validation Strategy and Results did not evaluate the material of construction of all equipment or (b)(4) materials including (b)(4).

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(b)(4)
(b)(4), and a risk assessment was not performed to justify not evaluating these materials of construction, which includes (b)(4) equipment or (b)(4) materials.

Observation 4

Written procedures for decontamination, cleaning, and maintenance of equipment are deficient regarding sufficient details to protect equipment from contamination prior to use. For example:

- a. (b)(4)
(b)(4), do not specify the duration that equipment may be exposed to the environment after cleaning (b)(4).
- b. (b)(4), Cleaning Validation Summary Report, does not specify how the -- hold time is determined.
- c. Protocols governing decontamination of -- containing equipment that -- the manufacturing suites are deficient regarding sufficient details such as the (b)(4) locations in order to prevent contamination.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."