DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	7/22/2024-7/26/2024
	FEI NUMBER 3009736169

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Oriol Argemi Febrer, Managing Director

FIRM NAME	STREET ADDRESS
Laboratorios Grifols, S.A.	Passeig Fluvial 24
CITY, STATE, ZIP CODE, COUNTRY Parets Del Valles, Barcelona, 08150 Spain	TYPE ESTABLISHMENT INSPECTED Drug Manufacturing Facility

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 I OBSERVED:

OBSERVATION 1

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your standard operating procedure #(b) (4) entitled "ALARMAS CRÍTICAS DE AUTOCLAVES" [Autoclaves, Critical Alarms, IG] is not detailed enough to include the steps during the autoclave malfunction when the (b) (4) is allowed to be transferred to another autoclave to continue sterilization cycle, when sterilization cycle can be stopped manually and when sterilization cycle is acceptable despite increased (b) (4) stage of the sterilization cycle. For example:
a) on November 11, 2022, the autoclave had a (b) (4) in a (b) (4) during the (b) (4) stage of sterilization of (b) (4) lot#(b) (4), the cycle was stopped, and (b) (4) was moved from autoclave (b) (4) to (b) (4). This lot was released on February 24, 2023.
b) On March 14, 2023, sterilization cycle for (b) (4) lot#(b) (4) was manually stopped by the operator (b) (6), (b) (7)(C) without any explanation documented.
c) On April 25, 2023, the (b) (4) stage exceeded allowed time of (b) (4), and was documented as (b) (4) on the autoclave sterilization printout for (b) (4) lot#(b) (4) due to autoclave malfunction. This lot was released on June 20, 2023.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 07-26-2024 05:18:38	7/26/2024

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OBSERVATION 2

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing.

Specifically,

(b) (4) uses (b) (4) amount depending on (b) (4) and requires additional calculation if it is not (b) (4). Calculation of (b) (4) was not documented on the batch records for all lots manufactured on lines (b) (4) and (b) (4) from May 28, 2020 to July 22, 2024.

OBSERVATION 3

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically,

(b) (4), your raw materials, and finished product, (b) (4) are tested for Endotoxin. (b) (4) reagent preparation is required for the Endotoxin test. Review of Endotoxin testing records for the raw materials and batches manufactured from May 28, 2020 to July 22, 2024 found that preparation of this solution is not documented.

OBSERVATION 4

Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used.

Specifically,

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Your initial cleaning validation, protocol Version 1 approval date October 17, 2017 and subsequent, current validation, protocol Version 2 effective date May 11, 2022 for line (b) (4), (b) (4) and (b) (4) that are not dedicated to manufacturing (b) (4), require (b) (4) of the (b) (4). However, there are no written procedures that would describe (b) (4) performed for these (b) (4) that are used to prepare (b) (4) or (b) (4) batches of the above (b) (4) in each (b) (4).

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Irina Gaberman, Investigator

X Irina Gaberman
Investigator
Signed By: 1300222798
Date Signed: 07-26-2024
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DATE ISSUED
7/26/2024

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 judgment, 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."