

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160 orabioinspectionalcorrespondence@fda.hhs.gov		DATE(S) OF INSPECTION 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 Laboratorios Grifols, S.A.		STREET ADDRESS 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 Irina Gaberman, Investigator Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 07-26-2024 05:18:38 X	
DATE ISSUED 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,					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Irina Gaberman, Investigator </td> <td style="width: 40%; vertical-align: top;"> DATE ISSUED 7/26/2024 Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 07-26-2024 05:18:38 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Irina Gaberman, Investigator	DATE ISSUED 7/26/2024 Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 07-26-2024 05:18:38
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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 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."