DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	10/02/2023 - 10/06/2023 FEI NUMBER 1819470

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Matt Edwards, Sr. Vice President - Indianapolis Parenteral Operations

FIRM NAME	STREET ADDRESS
Eli Lilly and Company	Lilly Corporate Center
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Indianapolis, Indiana 46285	Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed. Specifically,

a. The (b) (4) stopper contact surfaces are not maintained as sterile. The (b) (4) (b) (4) Line (b) (4) located in building (b) (4) for (b) (4) drug product manufacture includes assembly of the (b) (4) (b) (4) stopper (b) (4) followed by the addition of (b) (4) (b) (4) (b) (4) stoppers. (b) (4) stoppering machinability testing is performed, followed by (b) (4) stoppers from the stoppering system, with cleaning/sanitization of the (b) (4) stopper contact surfaces, excluding the (b) (4) with (b) (4) (b) (4) % (b) (4) followed by (b) (4) The process as described provides a (b) (4) stopper component contact sanitized surface.

b. On 02 October 2023, setup of the (b) (4) for (b) (4) drug product manufacture included (b) (4) (b) (4) fill line equipment, with the (b) (4) equipment sanitized into Grade A (b) (4) from Grade C space. Good aseptic practice was not observed. Specifically,

i. The (b) (4) was mounted to the fill line, with the (b) (4) surface touched by sanitized gloved hand. Good aseptic practice was not followed, as handling of the (b) (4) equipment should have been limited to the handle, where the equipment could have been maintained in the (b) (4) in mounting, mitigating the touching of the (b) (4) surface.

ii. Observed was the touching of the non-sterile gown to a sanitized surface within the (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Wayne Seifert Qiao Bobo	Wayne Seifert, Senior Consumer Safety Officer Qiao Bobo, Division Director	10/06/2023

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Observation 2

A validation designed to prevent microbial contamination of drug products purporting to be sterile does not include adequate validation of the sterilization process. Specifically,

The (b) (4) sterile drug product (b) (4) that includes the (b) (4) approximately (b) (4) mm diameter (b) (4) is (b) (4) (b) (4) During validation, you indicated that a calibrated (b) (4) and (b) (4) was position at (b) (4) of the of the drug product (b) (4) with the (b) (4) (b) (4) The (b) (4) provides an entry point for (b) (4) best case, with the validation inadequate.

Furthermore, the (b) (4) drug product (b) (4) validation failed to evaluate both physically and biologically, the (b) (4) of the (b) (4) that may present a difficult position for (b) (4)

Observation 3

On 06 October 2023, observed for batch (b) (4) (b) (4) (b) (4) mg (b) (4) ml was the (b) (4) fill process in (b) (4) with (b) (4) drug product encrustation observed on the outside of all (b) (4) Although you indicated that potential root causes for the product encrustation is vibration and (b) (4) alignment, corrective measures are still pending. The drug product fill process has not been optimized.

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