DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place, Suite 5900 Detroit, MI 48207 313-393-8100	2/18-3/5/2021, 3/16/2021 FEI NUMBER 1819470

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kenneth A. Whitehead, Vice President IPM Operations

FIRM NAME	STREET ADDRESS
Eli Lilly and Company	1555 S. Harding St.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46285	Sterile Human Drug 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

Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.

A. Personnel Monitoring

1. Scientific rational could not be provided for holding aseptic personnel to Grade B specifications (b) (4) NMT (b)(4) CFU, chest NMT (b)(4) CFU) during personnel monitoring even though they are performing interventions inside the Grade A area. This was noted in 100% of the batches reviewed. Grade A specifications are only used for set-up and high-risk interventions (task-related – (b) (4) CFU, task-related forearms (b)(4) CFU) In the table below the interventions are categorized as either (b) (4)' or '(b) (4)'. (b) (4) ventions (b) (4) of the RABs (b) (4) while (b) (4) interventions can be performed using the RAB (b) (4). A critical (b) (4) intervention would be an intervention which required monitoring (b) (4) . Some examples include:

Batch	Date	Personnel	Intervention category	Type
D349899 Etesevimab	12/7/20	(b) (6)	260, 113X, 117X	(b) (4) interventions
	12/8/20		113X	(b) (4) intervention
	12/8/20		273, 274	Both (b) (4) and (b) (4) interventions
D340792 Bamlanivimab	12/3/20		610X, 113X	Both (b) (4) and (b) (4) interventions
	12/3/20		274 (2x), 126	(b) (4) interventions
	12/3/20		271 (2x), 274	Both (b) (4) and (b) (4)

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Batch	Date	Personnel	Intervention category	Type
				interventions
	12/3-4/20	(b) (6)	274, 280	(b) (4) interventions
D065359 Glucagon FINJ 1mg 1mL	4/5-6/20		125 (5X), 130 (3X), 126 (4X), 117X (2X), 116X, 251 (4X), 271 (33X), 260, 128, 256, 258, 270	Both (b) (4) and (b) (4) interventions
	4/5-6/20		611X (2X), 271 (4X), 251, 603X, 272, 260, 259, 609X, 125 (6X), 418X (5X), 419X, 611X (2X)	(b) (4) and (b) (4) interventions
	4/5/20		113X, 115X, 125, 271	(b) (4) and (b) (4) interventions
	4/5/20		514X, 418X	(b) (4) interventions
	4/5/20		271 (3X), 250	(b) (4) interventions
	4/5/20		125 (2X), 603X, 258, 271 (29X), 126, 251	(b) (4) and (b) (4) interventions
	4/6/20		126 (3X), 125(3X), 117X, 418X, 412X, 526X (3X)	(b) (4) and (b) (4) interventions
	4/6/20		133, 262	(b) (4) and Critical (b) (4) interventions
D299479 Bamlanivimab	8/26-27/20		113X, 271 (2X), 272	(b) (4) and (b) (4) interventions
	8/26/20		254, 271 (2X), 272, 123	Critical (b) (4), (b) (4) and (b) (4)
	8/27/20		126, 280 (2X), 272, 274	(b) (4) interventions
	8/27/20		274 (2X), 253X	(b) (4) interventions
D321280 Etesevimab	10/10-11/20		119X, 272 (9X)	(b) (4) interventions
	10/11/20		254, 271	Critical (b) (4) and (b) (4) interventions
	10/11/20		113X (2X)	(b) (4) intervention

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Batch	Date	Personnel	Intervention category	Type
	10/11/20	(b) (6)	113X (2X)	(b) (4) intervention
D336907	11/19/20		113X	(b) (4) intervention
Bamlanivimab	11/19-20/20		113X, (b) (4) R (2X)	(b) (4) intervention
	11/19-20/20		250, 251 (b) (4) (b) (4)	(b) (4) and (b) (4) interventions
	11/19-20/20		260, 280, 162, 262	(b) (4) and Critical (b) (4) interventions
	11/20/20		(b) (4) (5X), 113X (2X)	(b) (4) interventions

In addition, EM personnel are held to grade B specifications even though they need to breach the Aseptic Grade A area in order to perform EM activities. Management stated they consider environmental monitoring not as an intervention but as an aseptic manipulation.

Holding personnel who breach the aseptic grade A area to Grade B specifications resulted in inadequate trending of personnel monitoring data. The following aseptic personnel who performed activities in the Grade A area had a result of 1 CFU during personnel monitoring. These counts were not trended as the results were held to Grade B specifications:

- Environmental monitoring of aseptic personnel (b) (6)) received 1 CFU on (b) (4) (b) (4) at 19:48. (b) (6) was performing EM activities during the aseptic filling of D259974, CT974601, LY3303560, 600mg/50mL vial. The 1 CFU was not trended.
- Environmental monitoring of aseptic personnel (b) (6)) received 1 CFU on (b) (4) (b) (4) at 10:50. (b) (6) was performing EM activities during the aseptic filling of D336908, VL791002, LY3819253, 700mg/20mL vial. The 1 CFU was not trended.
- Environmental monitoring of aseptic personnel (b) (6) received 1 CFU on (b) (4) (b) (4) at 9:28. (b) (6) was performing EM activities during the aseptic filling of D349901, VL795002, LY3832479, INJ 700mg/20mL vial. The 1 CFU was not trended.

- Environmental monitoring of aseptic personnel (b) (6) received 1 CFU on (b) (4) (b) (4) at 9:20. (b) (6) was performing EM activities during the aseptic filling of D350585, CT20601, LY3074828, INJ 15mL vial. The 1 CFU was not trended.

2. Monitoring is not taking place after critical interventions as required by 1698-FORM-19-005.
   - Operator (b) (6) was supposed to be monitored for (b) (4) and forearms upon completion of intervention (b) (4)- (b) (4) Assembly – Front during the execution of batch D065359 (Glucagon) on (b) (4).
   - Operator (b) (6) was supposed to be monitored for (b) (4) and forearms upon completion of intervention (b) (4)– (b) (4) assembly during the execution of batch D321280 (Etesevimab) on (b) (4) .
   - Operator (b) (6) was supposed to be monitored for (b) (4) and forearms upon each of the following interventions: (b) (4)- (b) (4) assembly – Back and (b) (4) (b) (4) Assembly – Front during the execution of batch D336907 (Bamlanivimab) on (b) (4) .
   - Operator (b) (6) was supposed to be monitored for (b) (4) and forearms upon completion of intervention (b) (4) – (b) (4) assembly during the execution of batch D299479 (Bamlanivimab) on (b) (4) . Only (b) (4) were tested.

   The above monitoring did not take place. No deviations were written.

3. Personnel monitoring is not always performed after the aseptic connection.

4. Scientific justification was not provided for personnel monitoring during aseptic filling. Per your Aseptic Personnel Monitoring for Parenteral Products Operations procedure personnel who do not perform set-up or critical interventions are monitored (b) (4) during each batch filling operation. During a shift, aseptic operators gown and de-gown multiple times within a day and on the same shift without additional personnel monitoring. When they are monitored is not based on the activities they perform. Aseptic personnel can perform various interventions and environmental monitoring within the Grade A area.

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B. The following discrepancies were noted during the qualification of the aseptic B103 vial filling line:

1. The (b) (4) alarm time delay (between Grade B to Grade D transition) and the (b) (4) alarm time delay (between Grade B to Grade C gown room/airlock) for pressure differentials are not based on scientific rational. The firm had only two DP alarms in the last year in the B103 aseptic vial filling area.

2. Scientific justification for the position of the permanent non-viable monitors in the critical adjacent grade A areas was not provided. The permanent non-viable monitors are not positioned near operator activity. Instead the NVP monitors are positioned approximately (b) (4) where activity takes place. Indianapolis Parenteral Manufacturing Environmental Monitoring – Rationale for the cNVPM Probe Locations states "(b) (4) " There is no data to support an acceptable level of non-viable particulates are being generated from personnel/activities which takes place in the critical adjacent area.

3. Non-viable monitoring at working level is performed (b) (4) with a (b) (4) monitor in the critical adjacent grade A area. PEM-218 Vial Filling and (b) (4) Syringe Filling, formulation Manufacturing and Equipment Preparation, dated 2020, states Vial Filling and (b) (4) area will be monitored for total particulate air during operation (b) (4) for NMT (b) (4) . During review of the last dynamic annual monitoring, it was confirmed that although a batch was running in the closed RABS unit, there was no activity (i.e. set-up or interventions) taking place in the critical adjacent grade A area where the monitoring was taking place.

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OBSERVATION 2

Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed.

Specifically,

A. Individual RAB (b) (4) on the aseptic vial line are not tracked. The firm stated the (b) (4) are replaced every (b) (6) while (b) (4) integrity testing is performed (b) (4) . Failures in (b) (4) integrity are not considered deviations and are not investigated. Numerous (b) (4) failures were found in the Deviation Observation log:

Observation #	Date	Line
TR 40209421	08 FEB 21	B103 Vial Filling
TR 40208503	06 FEB 21	B103 Vial Filling
TR 40192846	17 DEC 20	B103 PFS
TR 40188205	06 DEC 20	B103 Vial Filling
TR 40184073	20 NOV 20	B103 PFS
TR 40174573	23 OCT 20	B103 PFS
TR 40174245	21 OCT 20	B103 Vial Filling
TR 40167253	22 SEP 20	B103 PFS
TR 40164233	21 SEP 20	B103 Vial Filling
TR 40047970	12 JUL 19	B103 Vial Filling

(b) (4)

Due to the high rate of failed RABS (b) (4) Tests occurring since September 2020 on the PFS and the Vial Filling lines in B103, a trend report was initiated on 16 Dec 20. This trend is still awaiting investigation.

B. The monitoring of the RAB (b) (4) is not based on the interventions performed with the (b) (4). On 2/23/21, the FDA investigators watched EM personnel sample the RABs (b) (4) at the end of production. We observed contact plates being used to monitor the fingertips on one side of the (b) (4) The (b) (4) gloves can be used in either direction, based on the intervention performed.

C. You filed a FAR regarding deviation TR40190443 dated 12/14/2020 for a cluster of glass breakage/cracked vial events. Your investigation is inadequate including the following reasons:

1. You did not adequately evaluate the scope or impact during this investigation. Specifically, you did not perform adequate retain reviews of the potentially impacted batches nor did you trend all batches filled on this line, B103.

2. You performed an engineering study to simulate glass vial breakage event(s). You did not document a protocol for this engineering study defining elements such as number of runs and your results (counts and severity/characterization of broken vials). Your engineer stated operators were present during this study to ensure forces applied simulated how the operators actually loaded the trays on the line. However, no documentation was captured to support the operator's attendance during the study. This event specifically impacts Bamlanivimab, EUA 90/94 which are filled in 20mL vials.

D. You receive glass vials as well as other components from "high risk" vendors. You established glass vial suppliers as high risk since they are primary packaging components. Your incoming glass vial inspections have failed and rejected numerous lots of these incoming vials for critical defects including (b) (4) defects. Investigations/vendor complaints are issued, however, no definitive root causes are established via vendor investigations. Follow up and/or review of vendor investigations are not always documented. Root causes routinely identify (b) (4) samples without scientific justification.

E. You do not consider the quality impact to previously inspected batches nor do you open a deviation if an operator fails requalification for manual or semi-automated visual inspection.

OBSERVATION 3

Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes.

The following discrepancies were noted during the review of media fills and batch records which were executed on the B103 vial filling line. Products aseptically filled on this line include but are not limited to Ramucirumab, Glucagon, (b) (4) , Olaratumab,(b) (4) , (b) (4) , Bamlanivimab, and Etesevimab. Specifically,

A. Media Fills

1. Interventions performed during media fills do not reflect routine production. The firm normalizes the number of inherent interventions obtained for the entire year to determine the number of interventions performed per(b) (4) vials. They do not trend the frequency/type of interventions occurring per batch. For (b) (4) media fills performed annually on the vial filling line, the firm only performs the(b) (4) inherent interventions.

2. Adequate justification was not provided to support of how the conditions simulated during your Fill Duration Challenge – NLT (b) (4) in Media fill MF0116 – MF0271, D291263 is reflective of routine manufacturing.

3. Fatigue is not adequately challenged. Filling Operator Extended Personnel Shift was listed as being challenged for 14 hours, 9 minutes (Protocol Required Challenge NLT(b) (4)) during MF0273, Batch D256292 per APS Summary report, effective July 6, 2020. An

aseptic operator's shift is (b) (4) . The media fill D256292 did not support the operator working on the aseptic line for 14 hours, 9 minutes. Management confirmed the operator did not have to work on the aseptic fill line for the entire time they are challenging fatigue. They stated they do not consider the time the operator is working in the aseptic B103 vial filling line during the fatigue challenge, instead the monitor the length of the operators shift, regardless of where they are working. As performed by the firm, the fatigue challenge does not ensure the operator maintains aseptic technique even when they are fatigued.

B. Aseptic Processing

1. SOP 001-005056 General Aseptic Practices and Techniques for Parenteral Filling and Manufacturing Operations, v22, dated 12/16/19, section 5.7.2 states "All aseptic personnel must use the appropriate (b) (4) terminal within the aseptic area to log in and log out from the areas identified within the applicable (b) (4) ". Management stated they use an electronic entry/exit log for tracking the number of people who work in the B103 aseptic vial line, however they do not use this electronic system to reconcile who is in the room during production. This log is not controlled. Operators can make adjustments to this log to alter the number of persons in the room when people forget to log in/out. What is documented in the batch record does not correlate to what is listed in the electronic log. For example:
   a. During the execution of D349899, VL795002, LY3832479 starting on (b) (4) :
      - (b) (6) did not sign into the log but is recorded as performing set-up of the line at 11:24 am and is documented as leaving at 11:27 am.
      - (b) (6) is documented as performing setup activities at 11:11 am and 11:23 am but according to the electronic entry/exit log, he did not sign into the aseptic fill line area until 3:22 pm.
      - (b) (6) is documented as performing 3 interventions on 12/7/20 at (b) (4) (b) (4) yet according to the electronic log, (b) (6) was not documented being in the aseptic fill vial line for the entirety of the run.
   b. During the execution of D308778, VL701991, LY3819253 dated (b) (4)

- (b) (6)) is documented as performing interventions at (b) (4) (b) (4) but according to the electronic entry/exit log, (b) (6) did not sign into the aseptic fill line area until 5:52 pm.

c. Environmental Monitors are not logged into the electronic entry/exit log, even though they are in the aseptic area and performing EM on the line.

2. Not all activities performed in the aseptic area are documented. The firm does not document who and when aseptic manipulations are performed (i.e. addition of stoppers, environmental monitoring).

3. The firm did not have scientific justification for removing some coded interventions from their (b) (4) system used to document interventions during production. These interventions were still occurring (although at low frequency). No rational could be provided as to why interventions occurring less frequent were kept while some interventions occurring at higher frequencies were removed.

4. Quality oversight of the aseptic B103 vial filling line is not documented. 001-004190 Responsibilities of Personnel Working in Indianapolis Parenteral Manufacturing states under QA Responsibilities in section 2.3.6, *"Must ensure its regular presence in all operational areas"*. No documentation was provided to support you perform quality oversight of aseptic filling.

OBSERVATION 4

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

Specifically, your vision inspection process is inadequate. You depend on this inspection process to reject critical and major defects including but not limited to units presenting with (b) (4) (b) (4) , etc. Your visual inspection processes are used to inspect numerous

finished products filled in buildings 103, 105 and 107 including but not limited to: Cyramza, BLA 125477, approved 2014; Bamlanivimab, EUA 90/94; Portrazza, BLA125547, approved 2015.

A. Your visual inspection training qualification requires operators to appropriately reject (b)(4)% of the (b)(4) to pass and has not established a lower limit regarding major defects.

B. Your (b)(4) visual inspection (b)(4) are inadequate. Your (b)(4) have not been characterized to ensure operators can reliably, repeatedly and accurately reject defective units. For example, you have not measured the size of each type of defect embedded in the (b)(4) to ensure you understand the relationship between defect size and operator capability.

C. You have established one visual inspection (b)(4) which is used to qualify operators during their initial visual inspection qualification effort. You reuse this one visual inspection defect (b)(4) (b)(4) times within approximately a (b)(4) period. Using one (b)(4) may allow operators to acclimate to the (b)(4) and does not present operators with worst case conditions.

D. You do not challenge fatigue on (b)(4) basis regarding your visual inspection training program.

E. You do not require periodic requalification of incoming vial visual inspection operators using simulated inspection conditions. Operators are trained initially using your incoming vial test (b)(4) and are not required to requalify using your incoming vial inspection test (b)(4) after this initial qualification effort. Your incoming visual inspection process is used to inspect incoming vials to include 3mL - 50mL vial sizes.

F. You have established one visual inspection training (b)(4) regarding incoming vial inspection. This incoming vial inspection (b)(4) harbors (b)(4) critical defects including but not limited to (b)(4) (b)(4) and approximately (b)(4). These critical defects do not present worst case conditions to

incoming visual inspectors. Your incoming visual inspection process is used to inspect incoming vials to include 3mL through 50mL vial sizes.

OBSERVATION 5

The written stability program for drug products does not include reliable, meaningful and specific test methods.

The firm has not ensured that the methods used during the stability testing of Bamlanivimab or Etesevimab are stability indicating even though these methods are being used to support expiry dates. Management confirmed they do not review peak purity or (b) (4) during any (b) (4) studies performed at this facility. For example, the firm is currently using Method (b) (4) for the determination (b) (4) (b) (4) to determine the current expiry date of Bamlanivimab. Reviewing the ongoing (b) (4) studies being performed by the firm, large discrepancies in (b) (4) were noted during the following (b) (4) conditions: (b) (4)

These discrepancies have not been investigated. In addition, the firm does not ensure that degradation peaks are not forming under the main peak of interest or the matrix peak.

OBSERVATION 6

Representative samples are not taken of each shipment of each lot of components and drug product containers for testing or examination.

Specifically,

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A. Your firm has not qualified the process of (b) (4) samples). Verification of the accuracy from the vendor against samples collected in (b) (4) has not been performed. This applies to (but is not limited to) glass components and API used in the manufacture of Bamlanivimab, Ramucirumab, and Glucagon.

B. Your sample sizes are inadequate regarding discrete units such as glass vials. You pull (b) (4) glass vials per incoming lot when the lot size is over (b) (4) units. I observed (b) (4) samples pulled for inspection from an incoming lot of over (b) (4) vials. Glass vials are supplied from a high risk vendor. Your incoming glass vial visual inspection processes are used to inspect vial sizes ranging from approximately 3mLs – 50mLs. Glass vials in this range are used in numerous finished products filled in buildings 103, 105 and 107 including but not limited to: Cyramza, BLA 125477, approved 2014; Bamlanivimab, EUA 90/94; Portrazza, BLA125547, approved 2015.

OBSERVATION 7

The establishment of laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically, The PR&D Development laboratory located in B314, used for lot release of clinical batches, stability testing and method validation do not perform reconciliation of injections performed in the laboratory. Only the sequences turned in for review, are evaluated.

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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."