DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/29/2025-5/9/2025* FEI NUMBER 3010166880

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John E. Streger, President and CEO

FIRM NAME	STREET ADDRESS
LEESAR, INC	2727 Winkler Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Myers, FL 33901-9358	503B Outsourcing 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
There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Your firm failed to fully investigate an out of specification pH test result for Azithromycin 500mg in a 250mL Dextrose 5% IV Bag campaign comprised of Lot# (b) (4), (b) (4) and (b) (4) prior to release and distribution. On 04/22/2025, your contract laboratory reported the pH result at 7.2, outside your established specification range of (b) (4). Your quality unit opened investigation UDR2025-02 on 04/22/2025 and reported this failure as a major deviation in the risk assessment. The contract laboratory retested this product on 04/25/2025 and reported a passing pH result at 7.0 under a different specification range of (b) (4) This change to the specification was discovered during the inspection and presented to your quality unit who was unaware of the change. Your firm reported this specification range was inadvertently changed by the contract laboratory. Your quality unit has not completed the investigation into this out of specification deviation but approved the aseptically produced drug product for release on 04/25/2025 and these batches were distributed on 04/25/2025.

****This is a repeat observation from the previous inspection conducted 10/18-29/2021.**

OBSERVATION 2
The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Your quality unit is not following written procedure 6-8 rev 03 *Quality Events and Investigations Management Process* dated November 16, 2021, that defines how deviations are handled and investigated

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kayla V Sprague, Investigator X Kayla V Sprague Investigator Signed By: Kayla V. Sprague -S Date Signed: 05-09-2025 15:15:36	5/9/2025

at your firm. This procedure describes how you classify deviations as minor, major and critical based on the possible process impact and product quality. The subsequent investigation is then conducted based on that classification. The following examples are deviations where the quality unit failed to properly classify the deviation as per your written procedure:

i. UDR 2024-07 dated December 02, 2024, is the investigation for the OOS reported air samples taken on November 26, 2024, in the ISO 7 compounding areas that was classified as minor in the risk assessment. This deviation as per your procedure should be categorized as a major deviation.

ii. UDR 2023-12 dated August 17, 2023, is the investigation of the potency OOS for the finished compounded drug product Oxytocin 30U added to 0.9% NACL 500mL bag Lot# (b) (4) classified as minor in the risk assessment. This deviation as per your procedure should be categorized as a critical deviation.

iii. UDR 2023-13 dated September 21, 2023, is the investigation for the OOS active air samples taken on September 09, 2023, in the ISO 5 containment cell that was classified as major in the risk assessment. This deviation as per your procedure should be categorized as a critical deviation.

B. Your firm uses written procedure 6-27 rev 01 *Quality Assurance Program* dated November 06, 2020, to describe your quality program including your finished product testing and specifications for your aseptically produced drug products but it has not been reviewed or updated since 2020 and does not reflect the current operations at your firm. For example, as stated in this program potency testing is performed on (b) (4) but as of September 2023 your firm is only conducting potency testing for new product stability studies. Additionally, the finished product specifications described in this procedure is not current for your aseptically produced drug products. For example, your firm has been aseptically producing Dexmedetomidine HCL 20mcg (4mcg/mL) in 0.9% NACL syringes since September 2024 but it is not mentioned here.

OBSERVATION 3

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically, your firm does not maintain written records for annual product reviews conducted for your

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aseptically produced drug products including but not limited to:

- Amiodarone 900mg added to Dextrose 5% 500mL bag
- Azithromycin 500mg added to Dextrose 5% 250mL bag
- Diltiazem 125mg added to Dextrose 100mL bag
- Heparin 5000U added to 0.9% NACL 500mL bag
- Heparin 10000U added to 0.9% NACL 500mL bag
- Hydromorphone 50mg added to 0.9% NACL 250mL bag
- Lidocaine 2% (60mg/mL) 2mL repacked in 3mL syringe
- Norepinephrine 8mg added to 0.9% NACL 500mL bag
- Oxytocin 30U added to 0.9% NACL 500mL bag
- Phenylephrine 40mg added to 0.9% NACL 250mL bag
- Phenylephrine 100mcg/mL in 10mL syringe
- Succinylcholine 20mg/mL repacked in 110mL syringe
- Vancomycin 1.25g added to 0.9% NACL 250mL bag
- Vancomycin 1.5g added to 0.9% NACL 250mL bag

OBSERVATION 4

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 firm does not have a change control program or written procedure to define and describe how your firm will properly document and evaluate changes within your processes including but not limited to changes within your manufacturing operations, product specifications or standard operating procedures/programs. For example, on 08/19/2022 the finished product pH specifications for *Azithromycin 500mg added to Dextrose 5% 250mL bag* were changed from (b) (4) to (b) (4) but there is no change control documentation describing the justification and implementation of this change.

***DATES OF INSPECTION**

4/29/2025(Tue), 4/30/2025(Wed), 5/01/2025(Thu), 5/02/2025(Fri), 5/05/2025(Mon), 5/09/2025(Fri)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kayla V Sprague, Investigator

X Kayla V Sprague
Investigator
Signed By: Kayla V. Sprague -S
Date Signed: 05-09-2025
15:15:36

DATE ISSUED
5/9/2025

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."