

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 10/18/2021-10/29/2021*
	FEI NUMBER 3010166880

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
James R. Boswell Jr., CEO and President

FIRM NAME LEESAR, INC	STREET ADDRESS 2727 Winkler Ave
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CITY, STATE, ZIP CODE, COUNTRY Fort Myers, FL 33901-9358	TYPE ESTABLISHMENT INSPECTED 503B outsourcing facility
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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**

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

- A. Your firm failed to fully investigate an out of specification potency test result for Vancomycin 1.5g Lot (b) (4). On 10/26/2020, your contract laboratory reported a result of 89.4%, outside the specifications of (b) (4)%. You reported this failure as a major deviation in the risk assessment. The quality unit approved this product for release on 10/28/2020 without proper justification to the investigation and there was no additional follow up with any associated batches. This batch was distributed on 10/29/2020 and 10/30/2020.
  
- B. Your firm failed to identify and investigate an OOS potency test result for Vancomycin 1.25g Lot (b) (4) with a result of 89.8% on 09/08/2020 (specification (b) (4)%) and the product was approved for release by the quality unit on 09/08/2020 and on 09/18/2020. There was no investigation opened for this OOS result.
  
- C. Your firm failed to investigate failures of the compounding batch yields. The specification for intermediate batch yield is greater than or equal to (b) (4)% yield. Batches did not meet this specification, and were forwarded for visual inspection. No investigations were opened and the product was approved and released by the quality unit. Potency testing was not performed for these batches.
  - 1. Phenylephrine 40mg into 250mL NaCl IV Bags, Lot (b) (4) failed with 89%

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jennifer Lalama, Investigator Kayla V Sprague, Investigator - Dedicated Drug Cadre	Jennifer Lalama Investigator Signed By: Jennifer Lalama-S Date Signed: 10-29-2021 14:40:15  X	DATE ISSUED 10/29/2021

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yield and Lot (b) (4) failed with 79% yield. A certification of compliance, releasing the product for distribution, was issued by the quality unit on 04/23/2019.

2. Calcium Gluconate 1g into 50mL 0.9% NaCl IV Bags, Lot (b) (4) failed with 81% yield, Lot (b) (4) failed with 78% yield, and Lot (b) (4) failed with 87% yield. A certification of compliance, releasing the product for distribution, was issued by the quality unit on 04/29/2019.

**OBSERVATION 2**

Written procedures are not established that describe the tests to be conducted on appropriate samples of in-process materials of each batch.

Specifically, you have not validated the process(es), or equivalent, to demonstrate that the automated system could consistently compound IV bags and syringes within specification for potency over multiple lots and days.

**OBSERVATION 3**

The master production and control records are deficient in that they do not include a statement of theoretical yield and yield percentages.

Specifically,

- A. There are no calculations of final batch yield listed in master batch records. An intermediate batch yield is calculated prior to visual inspection. Once product is released or rejected from visual inspection there are no numbers reported in the batch record to include the final batch quantity and the number of rejected products to establish a final yield of finished products.
- B. Calculations used to determine the passing of visual inspection training are not inclusive of the actual number of correctly identified units. Specifically, false positive units are not accounted in

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current calculation; thus, affecting percent calculations and pass/fail status of training. Recalculation, with the consideration of false positives, revealed that operator <sup>(b) (6)</sup> does not meet the passing criterion; however, this operator is performing routine visual inspection on current batches of product.

**OBSERVATION 4**

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically, the following product was compounded and not identified on your report dated June 2021.

- Calcium Gluconate 1 gm

**OBSERVATION 5**

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

- The dosage form and strength
- A list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient.

Examples of your drug product labels that do not contain this information:

- Azithromycin 500 mg added to Dextrose 5% 250 mL (2 mg/mL)
- Diltiazem 125 mg added to Dextrose 5% 100 mL (1 mg/mL)
- Heparin 5,000 units added to NaCl 0.9% 500 mL (10 units/mL)

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- Heparin 10,000 units added to NaCl 0.9% 1000 mL (10 units/mL)
- Hydromorphone 50 mg added to NaCl 0.9% 250 mL (0.2 mg/mL)
- Oxytocin 30 units added to NaCl 0.9% 500 mL (0.06 units/mL)
- Phenylephrine 40 mg added to NaCl 0.9% 250 mL (160 mcg/mL)
- Phenylephrine 1 mg/10 mL in 10 mL syringe (100 mcg/mL)
- Succinylcholine 120 mg/6 mL in 10 mL syringe (20 mg/mL)
- Succinylcholine 100 mg/5 mL in 10 mL syringe (20 mg/mL)
- Vancomycin 1.25 g added to NaCl 0.9% 250 mL (5 mg/mL)
- Vancomycin 1.5 g added to 0.9% NaCl bag 250 mL (6 mg/mL)

**\*DATES OF INSPECTION**

10/18/2021(Mon), 10/19/2021(Tue), 10/20/2021(Wed), 10/21/2021(Thu), 10/22/2021(Fri),  
 10/29/2021(Fri)

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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."