

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
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

08/04/2014 - 08/08/2014

FEI NUMBER

3010166880

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert Simpson, President and CEO

FIRM NAME

LeeSar, INC

STREET ADDRESS

2727 Winkler Ave

CITY, STATE, ZIP CODE, COUNTRY

Fort Myers, FL 33901-9358

TYPE ESTABLISHMENT INSPECTED

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

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

- a) The gauge used to monitor pressure differentials between the ISO7 clean room (where components and drug products are staged and loaded into the ISO 5 classified area) and ISO8 ante room (where gowning occurs) is not monitored daily during production.
- b) Airflow studies were not performed under static or dynamic conditions to verify that processing equipment do not alter or impede the unidirectional cascade of air from the HEPA filters to the ISO 5 classified area where sterile drug products are manipulated.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, the environmental monitoring program is deficient. The program does not include monitoring of: daily surface or viable air sampling within the ISO 5 classified areas during production; non-viable particles in the ISO 5 classified areas under dynamic conditions; or personnel monitoring.

OBSERVATION 3

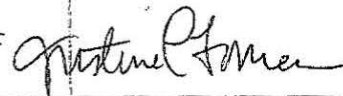
Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically, non-sterile gowns are used during aseptic operations including loading of components and vials into the ISO 5 IV classified area. Additionally gowns are reused throughout the day.

SEE REVERSE
OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Justine C. Tomasso, Investigator



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OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, no media fills or process simulations have been performed under the most stressful or challenging conditions.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, documentation regarding cleaning and disinfection of the ISO 5 classified area is incomplete. For example cleaning records of the ISO 5 classified area were unavailable for:

- IV Station used to produce Lidocaine 2% 2mL in 3mL syringe on 5/7/2014;
- IV Station used to procedure Heparin 10000 units added to 1000mL 0.9% NaCl bag on 6/13/2014; or
- IV Station used to procedure Azithromycin 500mg added to D5W 250mL on 7/25/2014.

OBSERVATION 6

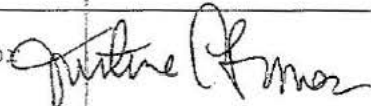
Each lot of components, drug product containers, and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, sterile drug products and components (i.e. IV bags, syringes) are used during aseptic production without obtaining or reviewing the manufacturer's certificate of analysis to ensure specifications are met.

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