

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

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderly Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 8/22/2016-8/31/2016*
	FEI NUMBER 3006412304

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Riccardo D. Roscetti , President & CEO

FIRM NAME KRS Global Biotechnology, Inc	STREET ADDRESS 791 Park Of Commerce Blvd Ste 600
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CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33487-3633	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:**

**OBSERVATION 1**

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

Specifically,

- A. During the (b) (4) vial filling operation of Hydroxocabalamine 5mg/mL, lot 08232016@3 in the (b) (4) the aseptic technician (b) (4) (b) (4) (b) (4) was observed (b) (4) the (b) (4) (b) (4) The same technician failed to perform fingertip sampling (b) (4) which is not in accordance with SOP 03-08.01 3/16 "Gloved Fingertip Sampling."
- B. The (b) (4) used in the cleanrooms to disinfect stoppers (b) (4) (b) (4) are not sterile.
- C. Bottles of sterile (b) (4) were observed inside the ISO 5 hoods during aseptic operations and after cleaning the classified areas. The exterior surfaces of these bottles are not re-sanitized after removal from the sterile package and continuous use.
- D. The media fills performed in 2015 as per SOP 03-07.01 1/14 "Personnel Aseptic Media Fill Verification" were limited to (b) (4) This scenario does not represent worst case conditions. In addition, documentation was not adequate in that it lacked:
  - a. Incubator used and temperature readings

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- b. The results of the positive controls
  - c. The lot number and expiration date of the media (not always recorded)
  - d. Environmental and fingertip sampling
- E. The media fills performed in (b) (4) as per SOP 03-07.01 "Personnel Aseptic Media Fill Verification" revised on 3/9/16 requires (b) (4).  
 However, documentation lacked:
- a. Lot number of vials and stoppers used
  - b. Total number of vials actually filled and incubated
  - c. Incubator used and temperature readings
  - d. The results of the positive controls
  - e. Environmental and fingertip sampling
- F. The equipment media fills performed on (b) (4) to validate the (b) (4) (b) (4) as per SOP PRO-006 (b) (4) Media Fill" was not adequate in that only (b) (4)
- G. No validation and media fill has been performed for the lyophilization process used for injectable drug products such as L-Asparaginase 10,000 IU/Vial and no documentation of the lyophilization (b) (4) is included in batch records.
- H. The (b) (4) used to sterilize stoppers, glassware, (b) (4), tools and drug products such as Carnitine 75 mg/mL vials have not been adequately validated. The (b) (4) Validation performed between 1/26/16 and 7/25/16 for the (b) (4) was not adequate for the following reasons:
- a. Installation and operational qualifications of the (b) (4) were not performed prior to the validation of the sterilization (b) (4)

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- b. The validation was limited to (b) (4) (b) (4) (b) (4) used to sterilize stoppers (b) (4) and other compounding supplies, and the (b) (4) used to sterilize all glassware have not been validated.
- c. The (b) (4) were not established and documented for the (b) (4). SOP 07-34.01 01/14 "Sterilization by (b) (4) ) does not specify (b) (4) (b) (4) to be used for the different components, supplies and products.
- d. Appropriate (b) (4) (b) (4) the product to (b) (4) .
- I. Batch production records (Formulation sheets) for (b) (4) sterilized drug products do not document the (b) (4) used and the (b) (4) to confirm sterilization (b) (4) .
- J. (b) (4) are (b) (4) are not recorded, (b) (4) , and incubation results are not properly recorded and reviewed. For example, a review of Form 03-43A.01 04/14 " (b) (4) Log" for the period of 5/17-26/2016 showed that (b) (4) for sterilization (b) (4) from 5/19-5/24/16 did not show the date of reading and the initials of the person who documented the results after incubation. In addition, (b) (4) sterilized on 5/24-26/16 were inconclusive because they were incubated for too long until 6/6/16. These results had not been reviewed by the Pharmacist in Charge or the Quality Unit, a Variance Investigation was not opened, and corrective and preventive action was not taken.
- K. SOP 07-35.01 07/14 "Depyrogenation" does not include (b) (4) and the (b) (4) . In addition, there is no documentation to show that sterilization and depyrogenation (b) (4) used for vials and glassware are reviewed and approved (b) (4) before release to production to ensure (b) (4) . Also, the

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media used to incubate (b) (4) to the depyrogenation (b) (4) of vials and glassware from 7/10/16 to present expired on 5/6/16.

*Inadequate validation of the sterilization (b) (4) is a repeated observation from the FDA-483 issued on 3/17/2014.*

**OBSERVATION 2**

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

Specifically, the suitability and efficacy of disinfecting agents and cleaning procedures have not been assessed and approved to ensure potential contaminants are adequately removed from surfaces in the ISO 5, ISO 7 and ISO 8 classified areas of the cleanrooms. For example,

- A. Your SOP 02-04.01 rev. 01/14 "Sterile Compounding Area Cleaning and Disinfecting" states to use (b) (4) cleaning agents and (b) (4) but it does not specify the required contact time, frequency, and rotational schedule.
- B. A sporicidal disinfectant is not used in the ISO 5 hoods. The firm reportedly uses (b) (4) (b) (4) as a sporicidal agent (b) (4) (b) (4) (b) (4) but according to this product's specification sheet, (b) (4) is not a sporicidal disinfectant.
- C. Cleanroom Cleaning Form 02-04B.01 01/14 "Sterile (b) (4) Cleaning and Maintenance Log for IV Rooms and Ante Areas" reviewed from July 2016 through August 25, 2016 did not document the (b) (4) cleaning agent used to confirm usage of the appropriate disinfectant and (b) (4). In addition, there are no documented explanations for not performing (b) (4) cleaning during the following periods as follows:
  - a. Cleanroom (b) (4) from 7/5-7/18/2016
  - b. Cleanroom (b) (4) from 8/4-8/20/2016
  - c. Cleanroom (b) (4) from 8/8-8/20/2016

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d. Corridor <sup>(b)(4)</sup> from 8/3-8/20/2016

- D. <sup>(b)(4)</sup> mop heads and buckets are not dedicated for ISO 5 & ISO 7 rooms and surfaces (i.e. walls, ceiling or floors) and the <sup>(b)(4)</sup> sterilization <sup>(b)(4)</sup> for the mop heads has not been validated. On 8/22/16, non-dedicated wet and used cleanroom mops were observed inside a bucket in the ISO 8 corridor; this was not in accordance with section XII.F of SOP 02-04.01 which requires mops to be hung vertically and buckets to be inverted to allow drying. On 8/30/16 the clean plastic buckets stored on a shelf were observed with dirt residue and rust looking particles.
- E. The design of the trash cans in the ISO 5 and ISO 7 cleanrooms is not adequate in that they have lids that have to be pushed down with hands to throw away trash such as wipes and packaging components. In addition, these lids were not properly cleaned and sanitized as several of them were observed dirty and stained during compounding operations.
- F. The following compounding equipment in the ISO 5 and ISO 7 cleanrooms was observed not properly maintained, cleaned and sanitized after the rooms were reportedly cleaned:
- a) ISO 7 Cleanroom <sup>(b)(4)</sup>:
    - i. A <sup>(b)(4)</sup> that looked rusty and with peeling paint was being used in the ISO 5 hood during formulation of a sterile drug product on 8/22/16.
    - ii. The <sup>(b)(4)</sup> light fixtures containing <sup>(b)(4)</sup> fluorescent lights each inside the ISO 5 hood <sup>(b)(4)</sup> were missing their cover making it difficult to clean.
    - iii. The air vent cover below the surface of the ISO 5 hood was observed with rust.
  - b) ISO 5 Cleanroom <sup>(b)(4)</sup>:
    - i. <sup>(b)(4)</sup> placed on a shelf was observed dirty, rusty and with peeling paint.
    - ii. The control panel to turn on the motor and lights of the ISO 5 hood where the <sup>(b)(4)</sup> <sup>(b)(4)</sup> is housed was observed stained and dirty.
    - iii. The air vents along the edge of the hood surface in the <sup>(b)(4)</sup> ISO 5 hood were observed dirty with dried product spills.
    - iv. The light fixture inside the ISO 5 hood containing <sup>(b)(4)</sup> tubular fluorescent lights/exposed wiring was missing its cover making it difficult to clean.

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**OBSERVATION 3**

*Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.*

Specifically, the following deficiencies were observed during the walk-thru inspection on 8/22/16:

- A. The differential pressure readings of each ISO 5 and ISO 7 cleanroom are only monitored and documented (b) (4) and not throughout aseptic compounding operations.
- B. The differential pressure reading of the ISO 7 corridor adjacent to the ISO 8 corridor is not monitored and recorded daily. During compounding operations on 8/22/16, the gauge labeled as "Corridor (b) (4)" (without a calibration sticker) was observed reading "0" PSIG and no corrective action had been taken. It was later reported that the tubing leading to the gauge was pinched and it was fixed on the same day. It was also observed that the sliding door between the ISO 7 anteroom and ISO 8 corridor does not close completely.
- C. A ceiling tile above the (b) (4) in ISO 5 cleanroom (b) (4) was observed not properly seated on its frame due to plastic tubing improperly installed from the ceiling to the (b) (4).
- D. The qualification of the ISO 5 Cleanroom (b) (4) did not include smoke studies to demonstrate HEPA filtered laminar airflow over the partially stoppered filled vials transferred from the (b) (4) to the (b) (4) across the room.
- E. A ceiling tile directly above the (b) (4) in the ISO 8 Prep room was observed missing during the (b) (4) process of glass vials with (b) (4).
- F. Two bottom wall tiles in ISO 7 Cleanroom (b) (4) and adjacent to the ISO 8 corridor were observed not properly seated on their frame thus creating a gap.

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**OBSERVATION 4**

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

Specifically,

- A. SOP 03-06.01 04/15 "Surface Sampling Procedures" is not followed in that surface samples of the (b) (4) are not taken (b) (4). Also, surface samples taken in th (b) (4)
- B. Raw data (i.e. sample collection date & time, taken before or after cleaning, incubation temperature & time, and reading date) for environmental monitoring of surface and viable air in the (b) (4) for the 2016 1<sup>st</sup> and 2<sup>nd</sup> Quarter reports and thereafter was not available. On 8/29/16, dried out media plates and strips for surface, air and fingertip samples collected between 8/13 and 8/24/16 were observed inside (b) (4) Incubator A and there was no documentation showing when they were placed in the incubator and why they had not been read after their required incubation time.

**OBSERVATION 5**

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

Specifically,

- A. The face masks and plastic shields worn by aseptic technicians during sterile compounding operations in the ISO 5 hoods and ISO 5 cleanrooms are not sterile.

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- B. SOP 05-04.01 04/15 “Sterile Compounding Hand Hygiene and Garbing Procedure” and Form 05-04A.01 (b) (4) are not adequate in that:
- a. There was no demarcation line in the anteroom to divide the clean and dirty areas as specified in the SOP.
  - b. SOP does not specify hand washing procedure. A sink and (b) (4) different soaps were observed in the ISO 8 corridor: non-antimicrobial hand soap, (b) (4) (b) (4) however, according to the SOP (b) (4) hand washing.
  - c. Donning sequence of sterile gown, face mask and shield, and sterile gloves is not clearly described and consistently followed by technicians. For example, a technician (b) (6), (b) (7)(C) was observed donning non-sterile gloves before donning sterile gown; the same technician (b) (6), (b) (7)(C) was observed another day donning sterile gloves prior to donning sterile gown; another technician (b) (6), (b) (7)(C) was observed donning sterile gown with bare hands. (b) (6), (b) (7)(C) also allowed the pants to touch the floor on the dirty side of the newly established demarcation line in the anteroom.
  - d. Wrapped gowning items stored in open bins in an ISO 8 prep room are not wiped and sanitized prior to entering them into the ISO 7 gowning area. A ceiling tile was observed missing in the ISO 8 prep area.

**OBSERVATION 6**  
*The labels of your outsourcing facility’s drug products are deficient.*

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

a) The statements "This is a compounded drug" and "Not for resale."  
Example(s) of drug product labels that do not contain this information:

- Anastrozole, Compounded 0.5 mg capsule
- Naltrexone 4.5 mg Tablet

b) The statement "Office Use Only."  
Example(s) of drug product labels that do not contain this information:

- Rocuronium Bromide, 10 mg/mL
- Glycopyrrolate 0.2mg/mL (PF)
- L-Asparaginase 10,000 iu
- L-Carnitine 170 mg/mL
- Hydroxycobalamin 1 mg/mL
- Methylene Blue 10 mg/mL
- Naltrexone 4.5 mg Tablet

c) The address of applicable outsourcing facility.  
Example(s) of drug product labels that do not contain this information:

- Rocuronium Bromide, 10 mg/mL
- Glycopyrrolate 0.2mg/mL (PF)
- Methylene Blue (PF) 10mg/mL (1%) Injectable
- L-Carnitine 75 mg/mL Injectable

d) The established name of the drug.  
Example(s) of drug product labels that do not contain this information:

- Human Chorionic Gonadotropin 10,000 iu/Hydroxo B12

e) The storage and handling instructions.

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Example(s) of drug product labels that do not contain this information:

- Anastrozole, Compounded 0.5 mg capsule
- Naltrexone 4.5 mg Tablet

f) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient, is not found on your product labels.

Example(s) of drug products labels that do not contain this information:

- Anastrozole, Compounded 0.5 mg capsule
- Rocuronium Bromide, 10 mg/mL
- Glycopyrrolate 0.2mg/mL (PF)
- L-Asparaginase 10,000 iu
- L-Carnitine 170 mg/mL
- Hydroxycobalamin 1 mg/mL
- Methylene Blue 10 mg/mL
- Human Chorionic Gonadotropin 10,000 iu/Hydroxo B12 5mg
- Ascorbic Acid 500mg/mL (PF)
- Lidocaine 4%/Tetracaine 0.5%/Epinephrine 0.18%
- Naltrexone 4.5 mg Tablet

**\*DATES OF INSPECTION**

8/22/2016(Mon), 8/23/2016(Tue), 8/24/2016(Wed), 8/25/2016(Thu), 8/26/2016(Fri), 8/29/2016(Mon), 8/30/2016(Tue), 8/31/2016(Wed)

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