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	7/30/2019-8/14/2019* FEI NUMBER 3006412304

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

FIRM NAME	STREET ADDRESS
KRS Global Biotechnology, Inc	791 Park of Commerce Blvd Ste 600
CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33487-3633	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

The quality control unit lacks the responsibility and authority to approve and reject all components, drug product containers, in process materials and drug products.

Specifically,

A. Your Quality Unit released and distributed (b) (4) batches of sterile drug products that failed sterility testing. OOS 1910 documents the sterility failure for L-ASPARAGINASE, COMPOUNDED STERILE 10,000 IU/VIAL LYOPHILIZED, Lot 07022018@1 and OOS 2037 documents the sterility failure for NOREPINEPHRINE 8MG ADDED TO 5% DEXTROSE 250 ML BAG (PF), Lot 03122019@10. (b) (4) vials of L-ASPARAGINASE, COMPOUNDED STERILE 10,000 IU/VIAL LYOPHILIZED, Lot 07022018@1 and (b) (4) bags of NOREPINEPHRINE 8MG ADDED TO 5% DEXTROSE 250 ML BAG (PF), Lot 03122019@10 were released and distributed.

B. Your Quality Unit released (b) (4) sterile drug batches when Too Numerous to Count (TNTC) bacteria were identified from Port(b) (4) in your firm's (b) (4) system on 04/25/19. Port(b) (4) and Por(b) (4) which are part of a (b) (4), are used in the production of sterile drug products. Your Quality Unit failed to conduct a thorough investigation to determine a root cause, assess the impact on batches produced on 04/25/19, and take corrective and preventative actions.

C. Your Quality Unit released approximately (b) (4) batches of sterile drug products when mold, Aspergillus sp. and Chrysonillia sp., were cultured on environmental monitoring (EM) in multiple Clean Rooms and multiple ISO 5 LAFWs and BSC hoods from 08/14/18 to 08/27/18. The following Out-of-Specification (OOS) reports document the EM during this period: 1927,

AMENDMENT 1

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1929, 1931, 1932, and 1934. Your Quality Unit failed to conduct thorough investigations to determine a root cause, assess the impact on batches released, and take corrective and preventative actions.

D. Your Quality Unit released (b) (4) batches of sterile drug products produced on (b) (4) located in ISO 5 Clean Room (b) (4) 03/19/19 when mold was identified on (b) (4) EM for (b) (4) on 03/19/19. OOS 2032 documents the EM results for 03/19/19. Your Quality Unit failed to conduct a thorough investigation to determine a root cause, assess the impact on batches released, and take corrective and preventative actions. (b) (4) vials of CARNITINE (L) COMPOUNDED 170 MG/ML INJ 27 ML, Lot 03192019@2, and (b) (4) vials of METHYLCOBALAMIN, COMPOUNDED SOLN 1 MG/ML INJ 30 ML, Lot 03192019@8 were released and distributed.

E. (b) (4) cleanings were not performed as per you firm's procedure *P-Prod-009, Sterile Compounding Area Cleaning and Disinfecting,* when non-viable particle excursions were documented in your firm's monitoring system, (b) (4), on 08/13/18, 08/22/18, 08/24/18, 09/19/18, 09/28/18, and 10/17/18 occurred in ISO 5 Clean Room (b) (4) and after maintenance was performed during the installation of new equipment in Room (b) (4) on 08/13/18. In addition, your Quality Unit failed to perform investigations when the non-viable particle out-of-specifications occurred in ISO 5 Clean Room (b) (4) (b) (4) batches produced on these dates were released for distribution.

OBSERVATION 2

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

Specifically,

A. Smoke studies performed 07/12/19 are deficient for the following reasons:
   - Smoke studies do not demonstrate operational processes which includes IV bags, vials, and syringes inside LAFWs, BSC hoods, and the (b) (4) (b) (4) located in room (b) (4)

AMENDMENT 1

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- The dynamic smoke study conducted in ISO 5 Clean Room (b)(4) with the (b) (4) (b) (4), does not demonstrate laminar airflow. Turbulent airflow is documented.
- The dynamic smoke study conducted in ISO 5 Clean Room (b) (4) with the (b) (4) (b) (4), does not demonstrate laminar airflow. Turbulent airflow is documented.
- The smoke studies demonstrating the transfer of (b) (4) (b) (4) to the (b) (4) are deficient as they do not show the flow of smoke over the vials.

B. (b) (4) (b) (4) in Room (b)(4) are placed under non-HEPA filtered air during prior to transfer to the

OBSERVATION 3

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.

Specifically,

A. Your firm failed to determine a root cause, perform an assessment of additional batches that may be affected, and take preventative and corrective actions for out-of-specifications (OOS) found during environmental monitoring (EM) from 07/16/18 to 05/22/19. The following OOS reports document the EM excursions: 1908, 1911, 1919, 1920, 1937, 1938, 1942, 1945, 1949, 1955, 1960, 1963, 1965, 1966, 1968, 1969, 1972, 1979, 1985, 1986, 1989, 1990, 1995, 2003, 2005, 2006, 2007, 2008, 2014, 2015, 2019, 2033, 2057, 2059, 2075. Organisms included, but were not limited to the following: Nectria sp., Eurotium sp., Candida albicans, Chrysonillia sp., Rhizopus sp., and Bacillus sp.

B. Your firm failed to determine a root cause, perform an assessment of additional batches that may be affected, and take preventative and corrective actions for the following out-of-specifications (OOS) found during sterility testing from 07/02/18 to 05/13/19. The following OOS reports documents the sterility failures: 1917, 1933, 1936, 1950, 1957, 1961, 1996, 1998, 1999, 2012, ~~2014,~~ 2022, 2023, 2024, 2025,

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2035, 2044, 2052, 2056, 2077. Organisms included, but were not limited to the following: Bacillus circulans, Bacillus cereus, Proprionibacterium acne, and Nigrospora sp.

C. Your firm failed to perform an investigation when HEPA filter failures occurred for hoods #310 and #610 during certification on 07/01/19.

D. Your firm failed to perform an investigation when an Out-of-Tolerance for the (b) (4) (b) (4) during calibration on 07/26/16 and 05/25/18 for your firm's (b) (4) system.

E. Your firm failed to take corrective and preventative actions when a Biological Indicator (BI) failure was documented for the (b) (4) . The (b) (4) , is used for the depyrogenation of (b) (4) used in production and final product vials. Specifically, OOS reports 1980, 2011, 2036, and 2049, dated 11/02/18, 01/30/19, 03/15/19, and 04/09/19, respectively, indicate BI failure was due to technician error without identifying organism. In addition, the (b) (4) was not validated to depyrogenate (b) (4) until (b) (4) from (b) (4) lots (b) (4) were released for use in finished drug products.

F. Mold was identified on gloved finger-tip sampling on 07/18/19. No OOS investigation was opened though investigation memo is attached to CAPA 19-008. The lot was rejected, and the root cause was identified as a possible contamination from outer IV bag packaging. There was no assessment on the impact to other batches and training was not documented.

OBSERVATION 4

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

Specifically,

A. ISO 5 Clean Roo (b) (4) and ISO 5 Clean Room (b) (4) have ceiling tiles and light fixtures that are Non-HEPA filtered. For example, non-HEPA tiles are located above the (b) (4) in ISO 5 Clean Room (b) (4) and non-HEPA tiles located immediately next to the (b) (4) in ISO 5 Clean Room (b) (4)

B. The July 2019 Clean Room Inspection Report states room certifications were conducted "at-rest." Clean Rooms (b) (4) contain automated equipment.

C. The door remains open from the non-classified prep area to ISO 8 Prep Room (b) (4) The room certification

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was performed with the door closed.

D. All ISO 8 rooms including Prep (b) (4) and the ISO 8 corridor have unfiltered air entering the rooms. Depyrogenated vials and glassware used in the production of sterile drug products are stored in Prep room (b) (4) and hand-washing occurs in the ISO 8 corridor.
E. The (b) (4), hood certifications **does not state the certification was** ~~were not~~ performed under dynamic conditions.

OBSERVATION 5

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

Specifically,

A. HEPA filters located in Clean Rooms (b) (4) and in the ISO 5 LAFW and BSC hoods are sprayed directly with cleaning agents during cleaning procedures. In addition, surfaces other than the hoods and tables, are not wiped after being sprayed.
B. On 08/01/19, I observed an operator use one sterile wipe to clean an ISO 5 LAFW, then wipe down a stainless-steel table (upper and lower shelves), and then clean another ISO 5 hood.
C. Your firm lacks antimicrobial effectiveness testing of cleaning agents used in the ISO 5 areas.
D. (b) (4) water used in the dilution of the firm's cleaning agents, (b) (4) and (b) (4) are not sterile. These products are used in the ISO 5 rooms and hoods.
E. Spray bottles used to store (b) (4) and (b) (4) are non-sterile. These bottles are maintained in the ISO 5 and ISO 7 Clean Rooms during production.

OBSERVATION 6

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

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Specifically,

A. The firm's (b) (4) validation performed 07/2015 to 07/2016 is deficient. The Phase 1&2 **summary** report **memo** dated ~~09/28/15~~ **09/22/15** lacks supporting data. There is not an assessment and final report for Phase 3. The Quality Unit failed to review and approve the validation report for Phase 1&2. The non-sterile water produced by the (b) (4) system is used for the production of sterile drug products and for the dilution of cleaning agents used in the ISO 5 areas.
B. There is no validation for the firms (b) (4) water system. (b) (4) water is non-sterile and is used for the dilution of cleaning agents used in the ISO 5 areas and production of non-sterile drug products.

OBSERVATION 7

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

Specifically,

- Your firm did not continuously monitor differential pressures in the ISO 5 Clean Room (b) (4) from 07/01/18 to 07/25/19.
- Your firm did not continuously monitor non-viable particles in ISO 5 Clean Room (b) (4) from 10/25/18 to 07/25/19; ~~and~~ ISO 7 Clean Room (b) (4) from 07/01/18 to 07/25/19; and ISO 7 Clean Room (b) (4) from 07/01/18 to 08/01/19. In addition, your firm does not continuously monitor non-viable particles in ISO 5 laminar airflow hoods and BSC hoods.
- Your firm lacks scientific rationale for the limited environmental surface monitoring during compounding operations.

OBSERVATION 8

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

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Specifically, on ~~08/01/19~~ **07/31/19**, a crack in the light cover in laminar airflow workbench (LAFW) #530 and a dirty/rusted HEPA grate in BSC Hood #568 was observed.

OBSERVATION 9

Routine calibration of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

ISO 5 LAFW and BSC hoods are not always recertified when moved from one room to another. Examples include, but are not limited to the following:

- Hood 568-not recertified after movement Clean Room (b) (4) o Clean Roo (b) (4) n 07/12/19.
- Hood 303-not recertified after movement from Clean Roo (b) (4) to Clean Room (b) (4) on 08/03/18
- Hood 903- not recertified after movement from Clean Room (b) (4) to Clean Room (b) (4) on 07/12/19.

OBSERVATION 10

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, your firm's Quality Unit failed to perform and complete quality complaint investigations. Investigations often lacked the following: an investigation, Quality Unit approval, a root cause, an assessment of related complaints, an assessment of the lot affected, and corrective and preventative actions. Examples from 2018 and 2019 include, but are not limited the following:

- CAR #740-MF
- CAR #454
- CAR #358
- CAR #419

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- CAR #263 and #264
- CAR-00-687
- CAR-00-681
- CAR-00-666
- CAR-00-547
- CAR-00-473
- AE-19-001

OBSERVATION 11

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, your firm has failed to perform stability testing on sterile drug formulas and non-sterile drug formulas. Examples include, but are not limited to the following sterile and non-sterile drug products:

- CARNITINE (L) 170MG/ML INJ 27 ML, COMPOUNDED, Lot 05152019@9
- METHIONINE/INOSITOL/CHOLINE, COMPOUNDED 25/50/50MG/ML INJ 30 ML, Lot 04252019@6
- ALPHA LIPOIC ACID (PF) COMPOUNDED 25 MG/ML INJ 30 ML, Lot 05292019@7
- ASCORBIC ACID (TAPIOCA SOURCE) (PF) COMPOUNDED 500 MG/ML INJ 50 ML, Lot 06182019@4
- KETAMINE IN 0.9% SODIUM CHLORIDE (PF) 5 ML FILL IN 6 ML SYRINGE, COMPOUNDED 10 MG/ML(1%) SYRINGE 5ML, Lot 03212019@20
- DEXAMETHASONE SODIUM PHOSPHATE, COMPOUNDED 24 MG/ML INJ 5 ML, Lot 05222019@8
- FENTANYL CITRATE IN 0.9% SODIUM CHLORIDE (PF) COMPOUNDED, 100 ML FILL IN 150 ML IV BAG 25 MCG/ML IV - 100ML, Lot 06142019@22
- NEOSTIGMINE METHYLSULFATE (PF), 5 ML FILL IN 6 ML SYRINGE, COMPOUNDED

AMENDMENT 1

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1 MG/ML SYRINGE 5ML, Lot 06122019@18

- BENZO/LIDO/TETRACAINE TOPICAL, COMPOUNDED, 20%-8%-4% CREAM, Lot 07312019@33
- HUMAN CHORIONIC GONADOTROPIN ODT, COMPOU%-NDED 500 UNITS TABLET, Lot 02202019@28
- HUMAN CHORIONIC GONADOTROPIN ODT, COMPOUNDED 500 UNITS/TABLET 500 UNITS ODT, Lot 05172019@22
- LIDOCAINE/TETRACAINE, COMPOUNDED 20%/7% OINTMENT, Lot 06242019@41

OBSERVATION 12

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm does not perform potency testing prior to release for any non-sterile drug formulations. Examples include, but are not limited to the following non-sterile drug products:

- BENZO/LIDO/TETRACAINE TOPICAL, COMPOUNDED, 20%-8%-4% CREAM, Lot 07312019@33
- HUMAN CHORIONIC GONADOTROPIN ODT, COMPOU%-NDED 500 UNITS TABLET, Lot 02202019@28
- HUMAN CHORIONIC GONADOTROPIN ODT, COMPOUNDED 500 UNITS/TABLET 500 UNITS ODT, Lot 05172019@22
- LIDOCAINE/TETRACAINE, COMPOUNDED 20%/7% OINTMENT, Lot 06242019@41

OBSERVATION 13

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

Specifically, non-sterile (b) (4) produced by your firm is used in the production of non-sterile drug

AMENDMENT 1

products. The system used in the production of the (b) (4) water is not validated and the (b) (4) water is not tested to USP prior to use. Examples include, but are not limited to the following:

- MANNAWAY ANTIGEN, COMPOUNDED 100 MCG/ML 1ML TOP SOLN, Lot 04152019@30
- STAINZYME, COMPOUNDED 1 ML FILL IN 3 ML DROPTAINER 100 MCG/ML TOPICAL SOLU, Lot 04152019@31
- PROTEASE PPA 1897, COMPOUNDED 1 ML FILL IN 3 ML DROPTAINER 100 MCG/ML TOPICAL SOLU, Lot 04152019@54
- CAREZYME, COMPOUNDED 1 ML FILL IN 3 ML DROPTAINER 100 MCG/ML TOPICAL SOLU, Lot 04152019@33

OBSERVATION 14

The container labels of your outsourcing facility's drug products are deficient.

Specifically, information to facilitate adverse event reporting is not included on all container labels. The information required includes:

- www.fda.gov/medwatch
- 1-800-FDA-1088

Drug products lacking the required information include, but are not limited to:

- MANNAWAY ANTIGEN, COMPOUNDED 100 MCG/ML 1ML TOP SOLN, Lot 04152019@30
- STAINZYME, COMPOUNDED 1 ML FILL IN 3 ML DROPTAINER 100 MCG/ML TOPICAL SOLU, Lot 04152019@31
- PROTEASE PPA 1897, COMPOUNDED 1 ML FILL IN 3 ML DROPTAINER 100 MCG/ML TOPICAL SOLU, Lot 04152019@54
- CAREZYME, COMPOUNDED 1 ML FILL IN 3 ML DROPTAINER 100 MCG/ML TOPICAL SOLU, Lot 04152019@33

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