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	10/16/2017-10/23/2017* FEI NUMBER 3006412304

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

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:
Facilities & Equipment System

OBSERVATION 1

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically,

A. (b) (4) cleaning. Your firm was unable to provide documentation (such as protocol and report) for the (b) (4) cleaning validation of the Water for Injection (WFI) system. Your (b) (4) clean process includes a (b) (4) and (b) (4), but there is no data showing that these parameters are achieved throughout the entire system (from skid to POU) by the (b) (4) system. You do not have written procedures to include process parameters, acceptance criteria, and verification of (b) (4) completion.

B. Chemical cleaning. You do not have written procedures for the chemical sanitization (including approved sanitizer, concentration, application, and acceptance criteria) that is occasionally used as a corrective action for the water system.

The WFI water has been used to make drug preparations such as Phenylephrine HCl/Tropicamide 2.5%/1% and Magnesium Chloride hexahydrate/ selenium/ calcium gluconate, and has been used since mid-2015.

C. Records. You were unable to provide records for the maintenance, cleaning, sanitizing, and inspection of the Water for Injection (WFI), deionized (DI) water, and laboratory water systems.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer Lalama, Investigator	X Jennifer Lalama Investigator Signed By: Jennifer Lalama -S Date Signed: 10-23-2017 12:50:54	10/23/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	10/16/2017-10/23/2017* FEI NUMBER 3006412304

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Riccardo D. Roscetti, CEO & President	
FIRM NAME KRS Global Biotechnology, Inc	STREET ADDRESS 791 Park of Commerce Blvd Ste 600
CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33487-3633	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Also, you do not have written procedures requiring that these records must be maintained.

Laboratory System

OBSERVATION 2

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 open out of specification (OOS) (or out of trend (OOT)) investigations for microbial contamination that was detected in samples collected from your WFI water system since 2016.

1. Sample WFI06082017: microbial contamination was detected but no OOS/OOT was initiated
2. Sample WFI01252017: microbial contamination was detected but no laboratory worksheet was available (or equivalent documentation that contained actual microbial counts) and no OOS was initiated.
3. Sample WFI02092017: microbial contamination was detected but no laboratory worksheet was available (or equivalent documentation that contained actual microbial counts) and no OOS was initiated.
4. Samples 04172017 and 01132017: no laboratory worksheet (or sterility test worksheet) was available for these dates where potential for growth was identified due to water system alarms

B. Your firm failed to open an OOS investigation for microbial contamination that was detected on

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	10/16/2017-10/23/2017* FEI NUMBER 3006412304

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Riccardo D. Roscetti, CEO & President	
FIRM NAME KRS Global Biotechnology, Inc	STREET ADDRESS 791 Park of Commerce Blvd Ste 600
CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33487-3633	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

your negative control plates for analysis of WFI samples. Examples of such occurrences include:

1. Sample WFI04172017: where the negative control plate count is >100 cfu
2. Sample WFI08032017: where the negative control plate count is 40 cfu

OBSERVATION 3

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

A. Your firm failed to adequately investigate potentially hazardous organisms biochemically. When an organism was detected, further identification was pursued through gram staining and microscopy, and assigned a classification; however, the organism was not identified to the genus and species level.

B. Your firm failed to run a negative/system control to assure all systems/media were performing properly during testing of water samples.

1. Sample LB04202017A: no negative/system control (b) (4) was analyzed along with the water sample.
2. Sample LB04182017A: no negative/system control (b) (4) was analyzed along with the water sample.

C. Your firm does not collect and trend water analysis so that comprehensive review may aid in preventing microbial growth.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jennifer Lalama, Investigator X Jennifer Lalama Investigator Signed By: Jennifer Lalama -S Date Signed: 10-23-2017 12:50:54	10/23/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	10/16/2017-10/23/2017*
	FEI NUMBER 3006412304

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Riccardo D. Roscetti, CEO & President	
FIRM NAME KRS Global Biotechnology, Inc	STREET ADDRESS 791 Park of Commerce Blvd Ste 600
CITY, STATE, ZIP CODE, COUNTRY Boca Raton, FL 33487-3633	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

D. Your firm did not collect samples directly from product containers.

***DATES OF INSPECTION**

10/16/2017(Mon), 10/17/2017(Tue), 10/18/2017(Wed), 10/19/2017(Thu), 10/23/2017(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer Lalama, Investigator	X Jennifer Lalama Investigator Signed By: Jennifer Lalama -S Date Signed: 10-23-2017 12:50:54	10/23/2017