DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax:(513) 679-2772 Industry Information: www.fda.gov/oc/industry	01/13/2015 - 02/03/2015* FEI NUMBER 3005472652

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Judith Z. Minogue, RPh

FIRM NAME	STREET ADDRESS
Spoonamore Drug Co Inc	4014 Dutchmans Lane
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Louisville, KY 40207	sterile drug producer

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 the system for monitoring environmental conditions.

Specifically, **There are no records for monitoring the pressure differential limits between the (b) (4) ISO 5 laminar flow hoods and the ISO 7 Buffer/IV Prep Room or between the Buffer/IV Prep Room and the ISO 8 Anteroom. There are pressure gauges on (b) (4) ISO 5 laminar flow hoods, but no pressure gauges have been installed for monitoring the air pressure between the ISO 7 and ISO 8 areas.**

B. No environmental monitoring samples are taken from the curtain door between the ISO 7 I.V. Prep Room and the ISO 8 anteroom.

OBSERVATION 2

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically,

A. There is no stability test data to support the 120 day beyond use date assigned to Tri-Mix 30-2-20 injection lot 20141208@24, Tri-Mix 30-1-20 injection lot 20141218@38 and Tri-Mix 15-1-10 injection lot 20141125@37.

B. There is no stability test data to support the 180 day beyond use date assigned to Bi-Mix 30-1 injection lot 20141222@34.

C. There is no test data to support the 180 day beyond use date assigned to Vancomycin beads lot 20141022@23 or lot 20140827@23.

D. There is no test data to support the 180 day beyond use date assigned to Tobramycin beads lot 20141106@23.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kathleen Dant Culver, Investigator/Drug Preapproval Manager Kathleen Dant Culver	02/03/2015

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OBSERVATION 3

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically, **sterility testing is not performed on each lot of vancomycin or tobramycin beads prior to release. For example, there was no sterility testing of lot 20141022@23 of vancomycin beads or lot 20141106@23 of tobramycin beads prior to release.**

OBSERVATION 4

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

Specifically, **Microbial effectiveness testing has not been performed for Tri-Mix 30-2-20, Tri-Mix 30-1-20, Tri-Mix 15-1-10 or Bi-Mix 30-1 multi dose injection products.**

OBSERVATION 5

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

Specifically, **Media fills are currently performed with (b) (4) , but a recent lot of Tri-Mix 30-2-20, lot 20141208@24, was (b) (4) of product.**

OBSERVATION 6

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

Specifically, **A sporicidal agent is not routinely used to disinfect the (b) (4) ISO 5 hoods used for aseptic processing.**

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OBSERVATION 7

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

Specifically, **On 1/13/15, the operator in the clean room was not wearing sterile coveralls when making lot 20150113@15, a sterile injectable product.**

*** DATES OF INSPECTION:**
01/13/2015(Tue), 01/14/2015(Wed), 01/15/2015(Thu), 01/16/2015(Fri), 01/20/2015(Tue), 01/21/2015(Wed), 01/22/2015(Thu), 01/26/2015(Mon), 01/27/2015(Tue), 02/03/2015(Tue)

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