

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

DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax: (510)337-6702	DATE(S) OF INSPECTION 2/25/2019-3/20/2019*
	FEI NUMBER 3015134033

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eghomware J. Igbinovia, RPh, Owner

FIRM NAME ACRX Specialty Pharmacy Inc	STREET ADDRESS 3200 Soaring Gulls Dr Ste 101
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CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89129-2198	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products
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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 established.

Specifically, on 02/26/2019 during the production of sterile products I observed the following:

- A) Multiple exists and entries from the cleanroom, to attain supplies from classified and unclassified zones without disinfecting or changing garbing.
- B) Sterile clothing (suit & gloves) used to clean and disinfect the clean-room was not replaced prior to production of sterile drug products.
- C) Supplies used to manufacture sterile products were left inside of the ISO5 LAFH in a manner which could disrupt unidirectional airflow.
- D) Sterile (b) (4) was opened and refilled during production.
- E) Sterile wipes used during sterile production were observed open on a cart inside the anteroom and (b) (4) zone.

On 03/06/2019 I observed the following:

- A) Sterile garbing hanging next to the clean room for reuse, per the PIC.

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- B) Equipment used to depyrogenate glassware has never been qualified or calibrated.
- C) Equipment used in (b) (4) sterilization has never been qualified or calibrated.
- D) Dynamic smoke studies have not been conducted.
- E) Media fills are conducted (b) (4) but do not include the most challenging process performed.
- F) (b) (4) studies have never been conducted to qualify the (b) (4) sterilization process. For example:
Rx (b) (6) Rx(b) (6) , Rx(b) (6) and Rx(b) (6) for Biotin 10 MG/ML IM Injectable, formula ID (b) (4) is (b) (4) sterilized by (b) (4) . (b) (4) studies have never been conducted per the PIC and no data to qualify this process was provided.

OBSERVATION 2

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

Specifically,

- A) Environmental monitoring of ISO classified zones is conducted on a (b) (4) basis only.
- B) Pressure differentials between classified and unclassified areas are not monitored daily.

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C) Personnel monitoring is conducted using samples taken from the gloved hands of employees following sterile drug production on a (b) (4) basis only.

D) Alarm systems to monitor for potential breaches in air quality are currently not employed. For example, I observed a sliding door between the ISO8 classified ante-room and unclassified zone that was held open during sterile drug production on 02/26/2019 to gather supplies.

OBSERVATION 3

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Extended BUD's are established for multiple products without the appropriate data. For example:

- 1) Glutathione 200mg/ml Inj: 180 days.
- 2) Hydroxocobalamin 25mg/ml Inj: 180 days

Sterility and potency data was observed for these products however no other data was provided.

Accelerated studies were either not conducted or data was not provided after multiple requests, that demonstrates there are no degradant products formed or potency altered under such conditions.

Furthermore, I observed ingredient stock solutions used in multiple Vita-B Complex formulations. These stock solutions are used for multiple products, requiring multiple extractions during extended use. For example:

- 1) Calcium Gluconate MDV 10% Inject Solution; lot #: 12102018@15; 180 days.

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- 2) Magnesium Chloride Hexahydrate MDV 20% Inject Solution; lot #: 01242019@10; 158 days.
- 3) Aminocaproic Acid 250MG/ML Inject Solution; lot #: 02112019@5; 44 days.
- 4) Niacinamide (MDV) 200MG/ML Inject Solution; lot #: 02072019@18; 30 days.
- 5) Thiamine HCL 250MG/ML Inject Solution; lot #: 02202019@6; 22 days.
- 6) Hydroxocobalamin 25MG/ML Inject Solution; lot #: 01182019@1; 120 days.
- 7) Riboflavin 10 MG/ML Inject Solution; lot #: 02062019@19; 30 days.

OBSERVATION 4

The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically,

You are currently using an off the shelf program with lot tracking functionality. However, you have not instituted a data entry or report procedure to ensure that Rx information is cross referenced to specific lots. Multiple requests to track specific lot information via Rx information could not be performed by the PIC or the assistant Pharmacist. No specific lot could be identified for the Rx's requested. For example:

1. Rx (b) (6) for 1250 ml of Glutathione 200MG/ML Injection, dispensed on or about 08/07/2018.

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- 2. Rx(b) (6) for 300 ml of Myer's Cocktail Injection, dispensed on or about 09/14/2018.
- 3. Rx (b) (6) for 300 ml of Ascorbic Acid 500MG/ML Injection, dispensed on or about 01/21/2019.

OBSERVATION 5

Written procedures for cleaning and maintenance fail to include maintenance and cleaning schedules, description in sufficient detail of methods, equipment and materials used, description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance, instructions for protection of clean equipment from contamination prior to use and parameters relevant to the operation.

Specifically,

There were no cleaning SOP's to review which demonstrate actual procedures utilized. A generic, commercially available template SOP was provided but lacked any supporting information that would reflect actual practices at your firm as described by the PIC.

Cleaning practices observed on 02/26/2019 prior to sterile drug production were not reflected in SOP #: 3.020 "Cleaning and Maintenance of The Clean Room Facility". Furthermore, the PIC confirmed on 02/26/2019 and 02/28/2019 that most SOP's at the facility have not been modified to reflect actual practices at the firm.

OBSERVATION 6

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

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Specifically, sterility and endotoxin testing are not conducted on finished sterile drug products. For example:

1. Rx (b) (6) Vitamin B Complex (SMS-14Days) Injectable Solution, lot #'s: 01032019@11 & 01032019@3; produced on 01/03/2019 using formula ID: (b) (4).
2. Rx (b) (6) Glutathione (MDV) 200 MG/ML Injectable Solution, lot #: 01142019@20; produced on 01/14/2019 using formula ID: (b) (4).
3. Rx (b) (6) Vitamin B Complex (LIPO-V) Injectable Solutions, lot #: 01082019@4; produced on 01/08/2019 using formula ID: (b) (4).

OBSERVATION 7

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

Specifically, potency testing is not conducted on finished drug products prior to release. For example:

1. Rx (b) (6) Vitamin B Complex (SMS-14Days) Injectable Solution, lot #'s: 01032019@11 & 01032019@3; produced on 01/03/2019 using formula ID: (b) (4).
2. Rx (b) (6) Glutathione (MDV) 200 MG/ML Injectable Solution, lot #: 01142019@20; produced on 01/14/2019 using formula ID: (b) (4).
3. Rx (b) (6) Vitamin B Complex (LIPO-V) Injectable Solutions, lot #: 01082019@4; produced on 01/08/2019 using formula ID: (b) (4).

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OBSERVATION 8

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

Specifically, all compliant files were requested. Provided were two complaints over the past 12 months. The PIC stated that prior to 2018 a complaint file was not maintained. Review of the two complaints compiled demonstrated that complaints received are not investigated or reviewed by the PIC. Pertinent product information such as lot number is not provided. For example:

CC#1: Nature of problem "Black Specs Formed" does not provide lot, expiration, results or product name. No investigation was conducted nor explained why none was needed. The Completed/Reviewed By and date sections were left blank

OBSERVATION 9

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

Specifically, finished non-sterile drug products are not tested for the presence of microorganisms. For example:

1. Rx (b) (6) Lidocaine/Tetracaine/Prilocaine 27%:7%:2.5% Cream, lot #: 01082019@26; produced on 01/08/2019 using formula ID: (b) (4), with log ID 27771.

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2. Rx (b) (6) Tadalafil 40MG Troche, lot #: 01232019@2; produced on 01/23/2019 using formula ID: (b) (4), with log ID (b) (4).
3. Rx (b) (6) Benzocaine/Lidocaine/Tetracaine 20%: 8%:4% Cream, lot #: 01242019@2; produced on 01/24/2019 using formula ID: (b) (4), with log ID (b) (4)

***DATES OF INSPECTION**
2/25/2019(Mon), 2/26/2019(Tue), 2/27/2019(Wed), 2/28/2019(Thu), 3/01/2019(Fri), 3/06/2019(Wed), 3/07/2019(Thu), 3/20/2019(Wed)

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