

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Detroit District Office: 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 1/14/19 - 1/18/19, 2/8/2019
	FEI NUMBER 3011967886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Raymond R. Carlson, Owner

FIRM NAME RC Outsourcing LLC	STREET ADDRESS 102 E. Water St.
CITY, STATE AND ZIP CODE Lowellville, OH 44436-1117	TYPE OF 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) (WE) OBSERVED:

OBSERVATION 1

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

- a. Your firm failed to follow the formula worksheet for the compounding of Vancomycin HCl USP 1mg/0.1ml lot no. 03092018. Per the worksheet instructions the specified pH range should be (b) (4) however the reported pH value for this lot was 6.97. This lot was associated with two complaints your firm received on 4/2/18 for cloudiness in the drug after thawing. Your firm's investigation into these complaints attributed the observed cloudiness to vancomycin precipitating out of solution from the high pH value observed during production.
- b. Your firm's Quality review failed to observe this pH OOS event prior to lot release on 3/9/18.
- c. You did not implement adequate CAPA's to address the failure of your firm's quality unit to observe this pH OOS event.

OBSERVATION 2

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

Specifically,

Your firm has not provided adequate data in the form of published literature or test studies which support the BUD/Expiration dates for products produced.

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- Cefuroxime 1mg, 1ml syringe & 10ml vial, (45 day BUD)
- Moxifloxacin 1.5mg, 0.1ml/1ml syringe, (45 day BUD)
- Vancomycin 1mg, 2mg, & 25mg, 1ml syringe & 15ml dropper (45 day BUD)

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm failed to conduct an investigation for the 70 syringe defect complaints your firm received between April 1, 2017 and December 31, 2018. Syringe defect categories included:

- bent needle
- dull needle
- clogged needle
- stuck plunger
- empty syringe

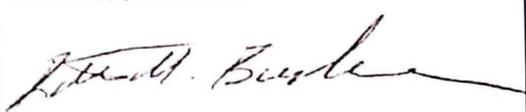
OBSERVATION 4

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,

Your firm did not conduct identity and strength (potency) testing of each lot for the following drug products produced at your facility:

- Cefuroxime 1mg
- Moxifloxacin 1.5mg
- Vancomycin 1mg
- Vancomycin 2mg

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-Vancomycin 25mg

In addition, the following tests were also observed not having been performed:

Testing for pH of each lot was not performed for the following sterile injectable drug product produced at your facility:

-Cefuroxime 1mg

Testing for subvisible particulate of each lot was not performed for the following sterile injectable drug products produced at your facility:

- Cefuroxime 1mg
- Moxifloxacin 1.5mg
- Vancomycin 1mg
- Vancomycin 2mg

Sterility testing of each lot was not performed for the following sterile drug products produced at your facility:

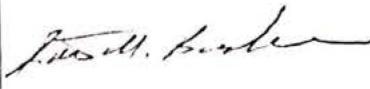
- Cefuroxime 1mg
- Moxifloxacin 1.5mg
- Vancomycin 1mg
- Vancomycin 2mg

THIS IS A REPEAT OBSERVATION

OBSERVATION 5

The accuracy, sensitivity and reproducibility of test methods have not been established and documented.

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Your firm's process for conducting the in-house sterility test has not been verified as being suitable for its intended use in the sterility testing of Dexamethasone 400mcg, Lidocaine 1%, Phenylephrine 1.5%, Phenylephrine 2.5%. Further, the in-house sterility testing process is not detailed in a formal procedure.

OBSERVATION 6

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

Specifically,

Active air sampling is not performed daily during production activities.

****THIS IS A REPEAT OBSERVATION*****

OBSERVATION 7

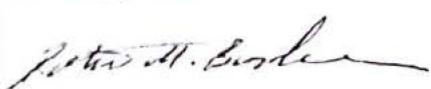
Specific identification tests are not conducted on components that have been accepted based on the suppliers report of analysis.

Specifically,

Your does not perform on identity test on all incoming lots of bulk active pharmaceutical ingredients (API's). The following bulk API's are used in the production of drug products at your facility.

- Moxifloxacin Hydrochloride USP
- Dexamethosone Sodium Phosphate USP
- Tobramycin Sulfate USP
- Phenylephrine Hydrochloride USP
- Vancomycin Hydrochloride USP

OBSERVATION 8

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You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, you compound drug products that:

- a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
- b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include;

- Dexamethasone 400 mcg/0.1 mL syringe for injection
- Moxifloxacin 0.150 mg/0.1 mL syringe for injection
- Vancomycin 1 mg/0.1 mL syringe for injection
- Vancomycin 2 mg/0.1 mL syringe for injection
- Vancomycin 25 mg/mL – 10 mL dropper

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