

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

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 1/25/2016-2/9/2016* FEI NUMBER 3011967886
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Raymond R. Carlson , Owner, Pharmacist

FIRM NAME RC Outsourcing LLC	STREET ADDRESS 102 E Water St
CITY, STATE, ZIP CODE, COUNTRY Lowellville, OH 44436-1117	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

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

Specifically, the firm does not test each batch of injectable product for endotoxin.

OBSERVATION 2

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

Specifically, the firms media fill procedures SOP P1.1.2.3 indicate that a (b) (4) (b) (4) The firm failed to complete the (b) (4) media fill challenge during the last media fill challenge (b) (4)

OBSERVATION 3

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

Specifically, your firm failed to monitor differential pressure readings frequently during aseptic production. Differential pressure values are not recorded.

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joshua P Wireman, Generic Drug User Fee Amendments (GDUFA)	DATE ISSUED 2/9/2016
	<input checked="" type="checkbox"/> Joshua P Wireman Generic Drug User Fee Amendments (GDUFA) Signed by: Joshua P. Wireman-3	

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

Specifically,

A. The firm failed to provide documentation of its investigations into microbial counts which exceeded the firms environmental and personnel monitoring alert levels. The firm noted 8 CFUs for (b) (4) (sample # (b) (4) tested 12/4/15 which exceeds firm's alert level. The firm was unable to provide documentation regarding the handling of this deviation.

B. while temperature of the facility, refrigerator, and incubators as well as the humidity of the facility is monitored (b) (4) the firm does not have procedures in place to investigate deviations from specified ranges. The Daily Management Log indicated that the humidity of the label room, anteroom, and clean room was below the specified range the week of Jan 18. The firm failed to investigate these deviations.

OBSERVATION 5

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, the door leading from the (b) (4) room into the anteroom as well as the door leading from the anteroom into the clean room have gaps at the bottom approximately 1 inch in size.

OBSERVATION 6

Complaint files are not maintained. Specifically ***

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Specifically, The firm does not have a complaint procedure to properly investigate complaints. I reviewed the two Continuous Quality Improvement (QCI) sheets on file at the firm but the firm could not provide documentation for the handling these CQI sheets.

OBSERVATION 7

Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically, the (b) (4) electronic balance used to measure bulk drug substances and ingredients used in production of Dexamethasone 400mcg/0.1, Phenylephrine 1.50%, Phenylephrine 2.5%, Vancomycin 1mg/0.1ml, and Vancomycin 2mg/0.1ml product is not calibrated (b) (4) as instructed in SOP P3.8.1.4. The Balance Calibration Log L3.8.1.4 has not been completed.

OBSERVATION 8

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

Specifically, the following information is not found on your drug product labels:

- The statement, "Office Use Only," or the date the drug was compounded.

Examples of drug product labels that do not include this information:

- Cefuroxime 1 mg/0.1 ml – in Tb syringe
- Dexamethasone 400 mcg/0.1 ml – Tb syringe
- Ceftazidime 2.25 mg/0.1 ml – in Tb syringe
- Ceftazidime 4.5 mg/0.1 ml – in Tb syringe
- Vancomycin 1 mg/0.1 ml – Tb syringe
- Vancomycin 2 mg/0.1 ml – in Tb syringe
- Phenylephrine 1.5% - 1 ml in a 3 ml BD syr
- Phenylephrine 2.5% - in 15 ml (b) (4)

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Furthermore, the following information is not found on the container labels for some of the drug products you produce:

- The dosage form or route of administration.

Examples of container labels that do not contain this information:

- Cefuroxime 1 mg/0.1 ml – in Tb syringe
- Dexamethasone 400 mcg/0.1 ml – Tb syringe
- Ceftazidime 2.25 mg/0.1 ml – in Tb syringe
- Ceftazidime 4.5 mg/0.1 ml – in Tb syringe
- Vancomycin 1 mg/0.1 ml – Tb syringe
- Vancomycin 2 mg/0.1 ml – in Tb syringe
- Phenylephrine 1.5% - 1 ml in a 3 ml BD syr
- Phenylephrine 2.5% - in 15 ml (b) (4)

Annotations to Observations

Observation 1: Not annotated
 Observation 2: Not annotated
 Observation 3: Not annotated
 Observation 4: Not annotated
 Observation 5: Not annotated
 Observation 6: Not annotated

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Observation 7: Not annotated
Observation 8: Not annotated

***DATES OF INSPECTION**

1/25/2016(Mon),1/26/2016(Tue),1/27/2016(Wed),1/28/2016(Thu),2/09/2016(Tue)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Joshua P Wireman, Generic Drug User Fee
Amendments (GDUFA)

2/9/2016

DATE ISSUED

2/9/2016

X

Joshua P Wireman

Joshua P Wireman

Generic Drug User Fee Amendments (GDUFA)

Signed by: Joshua P. Wireman - S

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."