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	08/24/2015 - 09/21/2015* FEI NUMBER 3011509553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edward J. Zatta, Managing Partner, Owner

FIRM NAME	STREET ADDRESS
RXQ Compounding LLC	340 W State St Unit 9
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Athens, OH 45701-1564	503B 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 WE OBSERVED:

Facilities and Equipment system

OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

1. On (b)(4) I (CTM), observed a third party contractor perform a smoke study of the clean room (ISO 7) and ISO 5 hood. During the smoke study, it appeared that the smoke (b)(4) (b)(4) Management and a representative from the third party contractor performing the smoke study confirmed. Two purportedly sterile products have been processed in the ISO 5 hood since the last certification: IC-Green 6.25mg/ml Ophthalmic Solution lot#08132015@1, processed on 8/13/15 (released and distributed) and Acetaminophen 10mg/ml Injectable lot#08212015@7, processed on 08/21/15 (on sterility test hold at time of inspection).

OBSERVATION 2

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.

Production system

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christopher T. Middendorf, Investigator Joshua P. Wireman, Investigator	09/21/2015

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	08/24/2015 - 09/21/2015* FEI NUMBER 3011509553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edward J. Zatta, Managing Partner, Owner

FIRM NAME	STREET ADDRESS
RXQ Compounding LLC	340 W State St Unit 9
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Athens, OH 45701-1564	503B Facility

OBSERVATION 3

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

Specifically,

1. Your firm currently performs (b)(4) types of aseptic processing: (b)(4) and a (b)(4) (b)(4)(b)(4) Media fills performed by personnel in the ISO 5 hood, do not simulate actual production or include the most challenging conditions and manipulations. For example, you have not performed a medial fill using the (b)(4) used to sterilize Acetaminophen 10mg/ml Injectable.

2. (b)(4) used by your firm is not intended for pharmaceutical use. During the inspection, we reviewed the label of a (b)(4) (b)(4)(b)(4) The label read in part, "...For research use only, not for in vitro diagnostic or for parenterals." This (b)(4) was used to (b)(4) sterilize Acetaminophen 10mg/ml Injectable lot#08212015@7, processed on 08/21/15 (on sterility test hold at time of inspection, intended for distribution).

3. The validation of the depyrogenation (b)(4) (used to depyrogenate finished product vials) and (b)(4) (used for (b)(4) sterilization of stopper, tools and other glassware) did not include (b)(4) and/or represent actual production conditions. For example:
a. You did not place a biological indicator (BI) within any vial during your validation for the depyrogenation of finished product vials.
b. During production, you (b)(4) but vials were (b)(4) during the depyrogenation study.
c. You did not place a BI within any package of material (stopper, forceps, glassware) during your validation of the (b)(4)

OBSERVATION 4

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

Specifically, employees do not wear eye protection during manufacturing activities in your clean room (ISO 7) and ISO 5 hood. On 8/27/15, I (CTM), observed employee gowning and a subsequent dynamic condition qualification of your clean room and ISO 5 hood. The employee was not wearing eye protection as required by your SOP 009, entitled, "Required Gard for Clean Room Access", section 9.2.2, which requires employees to don eye protection before entering the gowning area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christopher T. Middendorf, Investigator Joshua P. Wireman, Investigator JPW CTM	09/21/2015

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	08/24/2015 - 09/21/2015* FEI NUMBER 3011509553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edward J. Zatta, Managing Partner, Owner

FIRM NAME	STREET ADDRESS
RXQ Compounding LLC	340 W State St Unit 9
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Athens, OH 45701-1564	503B Facility

OBSERVATION 5

Batch production and control records do not include a description of drug product containers and closures used for each batch of drug product produced.

Specifically, you do not include lot numbers of containers or stoppers in product batch records.

Laboratory system

OBSERVATION 6

Test procedures relative to appropriate laboratory testing for sterility are not followed.

Specifically (b)(4) (b)(4) used to perform finished product sterility testing were not incubated at the correct temperature. Your firm performs (b)(4) finished product sterility testing (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) During the inspection I (CTM), observed apparent (b)(4) (b)(4) for the finished product sterility testing of Acetaminophen 10mg/ml lot# 08212015@7 in the same incubator - the temperature was ~ 35°C. Your SOP #016, entitled, "Sterile Compounding Finished Preparation Testing", section 9.1.5 reads in part, "Sterility methods must follow the USP <71>." USP <71> specifies an incubation temperature of (b)(4) for (b)(4)

OBSERVATION 7

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

Specifically, you did not perform sterility testing before distributing IC-Green 6.25mg/ml Ophthalmic Solution lot#08132015@1. Although the product is stored frozen. the BUD is 45 or less days from the date of manufacture, and the total volume of product manufactured was (b)(4) (b)(4) units produced), you did not compound this lot pursuant to a prescription for a single patient.

Quality system

OBSERVATION 8

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

Specifically, you did not open an investigation per your SOP 008 entitled, "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer" when the refrigerator used to store drug products was out of established limits. According to the SOP, the temperature range of the refrigerator is 2-8C. Section 9.1.5 of the SOP reads, "If the observed temperature of

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	08/24/2015 - 09/21/2015* FEI NUMBER 3011509553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edward J. Zatta, Managing Partner, Owner

FIRM NAME	STREET ADDRESS
RXQ Compounding LLC	340 W State St Unit 9
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Athens, OH 45701-1564	503B Facility

the drug product refrigerator or freezer does not fall within the designated range, drug products must be removed immediately and placed in an alternate, properly calibrated drug product refrigerator or freezer. QA/QC shall be notified and if necessary, an OOS incident shall be issued." A review of the temperature log for the refrigerator revealed the refrigerator was operating out of established limits on the following days:

- 6/5/15, operating temperature was -4C
- 6/8/15, operating temperature was -1C
- 6/29/15, operating temperature was 20C

Packaging and Labeling system

OBSERVATION 9

The batch production and control records are deficient in that they do not include copy of labeling.

Specifically, you did not retain a sample of all labels used for the following products:
a. IC-Green 6.25mg/ml Ophthalmic Solution, lot#08132015@1 batch record does not include a sample of the unit label or the container label
b. Acetaminophen 10mg/ml Injectable, lot# 08212015@7 batch record does not include a sample of the unit label

Additionally, you did not follow your OSD #16, entitled, "Product Label Information per Current USP", which requires,
(b)(4)

OBSERVATION 10

The labels and containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and (B).
Specifically,
The following information is not found on some of your drug product labels:

1. The established name of the drug.
2. The statement of quantity or volume, as appropriate.
3. The storage and handling instructions.
4. The inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

Furthermore, the following information is not found on or in the containers for some drug products you produce:

1. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1800FDA1088 <http://www.fda.gov/medwatch and 1800FDA1088>.

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

- Acetaminophen 10 MG/ML Injectable
- IC-Green 6.25 MG/ML OPH SOLN

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christopher T. Middendorf, Investigator Joshua P. Wireman, Investigator	09/21/2015

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	08/24/2015 - 09/21/2015* FEI NUMBER 3011509553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edward J. Zatta, Managing Partner, Owner

FIRM NAME	STREET ADDRESS
RXQ Compounding LLC	340 W State St Unit 9
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Athens, OH 45701-1564	503B Facility

- Lidocaine/Prilocaine 2.5%, Gabapentin 6%, Meloxicam 0.2%

*** DATES OF INSPECTION:**
08/24/2015(Mon), 08/25/2015(Tue), 08/26/2015(Wed), 08/27/2015(Thu), 09/21/2015(Mon)

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Christopher T. Middendorf, Investigator Joshua P. Wireman, Investigator	09/21/2015

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 judgement, 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."