DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	08/11/2014 - 08/28/2014* FEI NUMBER 3003316042

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Roy D. Katz, Compounding Pharmacist & Owner

FIRM NAME	STREET ADDRESS
Custom RX LLC, dba Custom RX Compounding Pharmacy	6519 Nicollet Ave S. Richfield Professional Bldg Ste 201
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Richfield, MN 55423	Producer of Drugs

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

The operations relating to the manufacture, processing, and packing of penicillin are not performed in facilities separate from those used for other drug products for human use.

Specifically, your firm uses non-dedicated space and equipment to produce penicillin antibiotics. From 1/1/2013 - 8/19/2014 you have compounded [redacted] Amoxicillin, Clavulanic Acid products, [redacted] Amoxicillin products, and [redacted] Ampicillin product. These products were produced in the same space as other drug products for human or animal use.

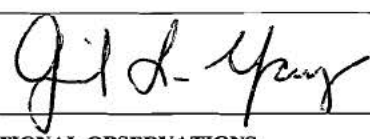
Additionally, you do not have procedures in place for addressing the production of penicillin antibiotics such as, but not limited to, cleaning procedures, verification all drug residues have been eliminated, specific instructions for handling powders, and specific equipment to use.

OBSERVATION 2

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically, your production area was not maintained in a clean and sanitary condition. This area is used in the production of Methylene Blue Solution, Amphotericin Loxasperse Capsule for Inhalation, Gentamicin Loxasperse Capsule for Inhalation, Chlorambucil, hormone-containing products, and thyroid-containing products. I observed unsanitary conditions as well as items that are not easily cleanable on 8/11 & 8/19/2014:

- Dust, powder, and debris were observed on your non-classified ventilation hood used for weighing and producing suspensions, creams and transdermal products.
- Your non-classified ventilation hoods used for encapsulation contained tape with apparent residue.
- Powder and rust were observed on the scale used for compounding suspensions, creams, and transdermals.
- The alcohol cleaning solution spray used to clean production areas was observed unlabeled.
- The alcohol cleaning solution used for scoopula storage between powder products was observed unlabeled.
- Tape with apparent residue was observed on the capsule machine during the encapsulation of Anastrozole 0.5mg Capsules.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	April L. Young, Investigator 	08/28/2014

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- The plastic mold used for encapsulation had apparent discoloration.
- Powder and rust were observed on the scale used for compounding capsules.
- The vacuum used on the encapsulation equipment appeared worn and not easily cleanable.
- The plastic scraper used for encapsulation was scratched and appeared not easily cleanable.
- Dust and apparent residue covered the keyboard adjacent to the encapsulation machines. Operators touch the keyboard prior to mixing powders manually.

OBSERVATION 3

In-process materials are not tested for identity, strength, quality, and purity and approved or rejected by the quality control unit during the production process.

Specifically, you do not perform in-process testing for your Methylene Blue Solution. You did not perform product testing on your distributed lot 07082014:65@20 which consisted of (b) (4) units of a 3mL solution of Methylene Blue 500mcg/mL packaged into 5mL syringes.

OBSERVATION 4

In-process specifications are not consistent with drug product final specifications.

Specifically, you do not have documentation on the intended use for your Methylene Blue Solution. You have not established in-process specifications for this product which would be consistent with final product specifications. On 7/8/2014, you prepared (b) (4) units of a 3mL solution into 5mL syringes of Methylene Blue 500mcg/mL under lot 07082014:65@20 without in-process specifications.

OBSERVATION 5

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

Specifically, you have no procedures or processes in place to prevent microbiological contamination during the production of your Methylene Blue Solution. This includes distributed lot 07082014:65@20 which consisted of (b) (4) units of a 3mL solution of Methylene Blue 500mcg/mL packaged into 5mL syringes.

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OBSERVATION 6

Written procedures are not established that describe the tests to be conducted on appropriate samples of in-process materials of each batch.

Specifically, your production instructions are inadequate for Methylene Blue Solution. Your production records do not include instructions for sampling and testing and do not include specific instructions for bioburden testing. You distributed Methylene Blue 500mcg/mL lot 07082014:65@20 which consisted of (b) (4) units of a 3mL solution packaged into 5mL syringes. This lot was distributed without testing such as bioburden testing.

OBSERVATION 7

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

Specifically, you do not have testing data or documentation to support the beyond use dating you apply to drug products you distribute. For example, you have not performed stability testing for Methylene Blue Solution with a beyond use date of 180 days, Amphotericin Loxasperse Capsule for Inhalation with a beyond use date of 90 days, and Gentamicin Loxasperse Capsule for Inhalation with a beyond use date of 180 days.

OBSERVATION 8

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically, you have not established specifications for drug products you distribute including Amphotericin Loxasperse Capsule for Inhalation, and Gentamicin Loxasperse Capsule for Inhalation. Drug product specifications have not been established for yeast and mold counts, freedom from *Pseudomonas aeruginosa*, absence of bile-tolerant Gram-negative bacteria, and absence of other objectionable microorganisms.

OBSERVATION 9

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

Specifically, you do not perform product testing for Gentamicin Loxasperse Capsule for Inhalation and Amphotericin

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Loxasperse Capsule for Inhalation prior to distribution. Testing such as, but not limited to, conformance to appropriate yeast and mold counts, freedom from *Pseudomonas aeruginosa*, absence of bile-tolerant Gram-negative bacteria, and absence of other objectionable microorganisms was not performed for Gentamicin Loxasperse Capsule for Inhalation lot 02202014:47@3, or Amphotericin Loxasperse Capsule for Inhalation lot 08082013:87@37 prior to distribution.

*** DATES OF INSPECTION:**
08/11/2014(Mon), 08/12/2014(Tue), 08/19/2014(Tue), 08/28/2014(Thu)

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