DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	3/1/2022-3/24/2022* FEI NUMBER 3012104093

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jason E. McGuire, Global Quality Director

FIRM NAME	STREET ADDRESS
Fagron Compounding Services	8710 E 34th St N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wichita, KS 67226-2636	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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

a. On 3/7/22 we observed a pre-production cleaning video from 3/1/22 of the ISO 5 Horizontal laminar flow hood in fill (b)(4) room (b) (4) where the inside back of the hood was not cleaned prior to producing Moxifloxican Lot # (b) (4) .

b. On 3/7/2022 we visually observed the cleaning of the ISO 5 Horizontal laminar flow hood in fill (b)(4) room (b) (4) where the inside back of the hood was not cleaned prior to producing Norepinephrine Bitartrate 32 mcg/mL (8mg/250mL) 250mL Bag Lot # (b) (4) .

c. On 3/4/22 we observed the (b) (4) clean video from 1/20/22 and the (b) (4) cleaning video from 3/1/22 of Fill (b)(4) room (b) (4) an ISO 7 Cleanroom where the side of a wall protrusion, the wall above, behind, and below the ISO 5 hood, a stainless-steel protruding box on the wall, and the floor area under the pump cart was not cleaned.

d. On 3/1/22 we observed a (b) (4) beaker with an aluminum foil cover placed into the ISO 5 hood from a cart in the ISO 7 area Fill (b)(4) room (b) (4) that was not sanitized prior to being placed in the hood and remained covered with foil for the duration of the vial filling process of Triamcinolone

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	Anthony J Ladner, Investigator Alan M Barker, Investigator	X Anthony J Ladner Investigator Signed By: Anthony J. Ladner -S3 Date Signed: 03-2 -2022 13:58:38	3/24/2022

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acetonide 40 mg/mL Inj Susp PF 1mL SDV Lot C274-000025377.

OBSERVATION 2

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

No equipment qualification was performed at your facility upon relocation of equipment. The (b) (4) used for (b) (4) was decommissioned at the (b) (4) and transferred to (b) (4) on or around January of 2020. The (b) (4) from this (b) (4) is used in the production of Sodium Thiosulfate 25% at your facility.

The Master batch record for Sodium Thiosulfate 25% solution states (b) (4) temperature should be above (b) (4) once it is (b) (4) bag however the asset number ((b) (4)) for the (b) (4) used to (b) (4) is not recorded in the batch record as shown in Batch Lot # (b) (4) produced (b) (4). Furthermore, your procedure FSS-SOP-0335, Use, Cleaning and Operation of the (b) (4), mentions a program for the (b) (4) that (b) (4) to (b) (4) but does not mention a program for (b) (4) to (b) (4). It is not proceduralized in the batch record or SOP on how the operators should (b) (4) the (b) (4). This process of (b) (4) has been used in the production of approximately (b) (4) batches of Sodium Thiosulfate 25% which were in turn used to make approximately (b) (4) batches of Sodium Thiosulfate 25% PF Inj Soln 50mL Single-Dose Vials since January of 2020.

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OBSERVATION 3

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

Specifically,

A. On 03/04/2022 we observed two technicians dump vials that were used for a personnel media fill operator qualification into a bin prior to performing final inspection of the vial. This process causes agitation of the vials prior to the inspection and could disturb microbial growth in the vial and inhibit detection of organisms. Procedure FSS-SOP-0341, Training Course Plan- Media Fill Inspection, does not mention how technicians should perform inspections on vials, only that the technician "inspects all Acceptable and Integral rejects to verifies [sic] any (b) (4) and (b) (4)". This procedure is used for identifying positive growth units from Operator Qualifications and Process Simulation Media Fills.

B. On 03/04/2022 we observed technicians check for (b) (4) on vials that were used for a media fill operator qualification by holding them up towards the lighting positioned near the ceiling of a (b) (4) warehouse. In addition two lights in the warehouse were not working and the background the vials were held up to was mostly brown cardboard boxes on the warehouse shelves.

C. There is no documentation/procedure/change control to initiate additional preventive maintenance added on 1/6/2022 for the (b) (4) or for using a (b) (4) to measure the (b) (4) placement during labeling operations for the Avastin Solution for Injection, 2.5 mg/0.1 mL. 0.12mL Fill repackaged product.

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OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

There is no testing of the preservative content in the multiple dose injectable drug products at time of release. The following injectable solutions contain preservatives:

Sodium Citrate 4% Inj Soln 30mL Multiple-Dose Vial Injection contains (b) (4) as a preservative

Sodium citrate 4% Gentamicin 320mcg/mL Inj Soln 30mL MDV contains (b) (4) as a preservative

Phenol in (b) (4) Inj Soln, 6%, 10-mL Multiple-Dose Vial contains (b) (4) as a preservative

OBSERVATION 5

The establishment of laboratory control mechanisms including any changes thereto, are not reviewed and approved by the quality control unit.

Specifically,

On 03/02/2022 it was observed that lab notebooks used to record temperature and incubation times of Environmental Monitoring samples and media fills are not routinely reviewed by the quality unit. The lab notebooks for incubator (b) (4) (b) (4)) and (b) (4) ((b) (4)) have not been

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reviewed by QA prior to January of 2021. Furthermore, documentation fields in the lab books were blank and marked for correction; fields left blank and marked for correction included date reviewed by, temperature of incubator, date which media was incubated or removed from incubator, activity performed, and write overs that were not corrected.

OBSERVATION 6

Your outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B because they (a) are not used to compound drug products that appear on the drug shortage list in effect under section 506E of the Act and (b) do not appear on a list developed by FDA of bulk drug substances for which there is a clinical need.

Specifically,

You produced the following products:

1. Glycopyrrolate 0.2 mg/mL (API) 1 mg per 5 mL in a 5 mL syringe (produced (b) (4))
2. Glycopyrrolate 0.2 mg/mL (API) 0.6 mg per 3 mL in a 5 mL syringe (produced (b) (4))

***DATES OF INSPECTION**

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	Anthony J Ladner, Investigator Alan M Barker, Investigator	X Anthony J Ladner Investigs or Signed By: Anthony J. Ladner -83 Date Signed: 03-2 -2022 13:58:38	3/24/2022

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3/01/2022(Tue), 3/02/2022(Wed), 3/03/2022(Thu), 3/04/2022(Fri), 3/07/2022(Mon), 3/08/2022(Tue), 3/09/2022(Wed), 3/10/2022(Thu), 3/22/2022(Tue), 3/23/2022(Wed), 3/24/2022(Thu)

X Alan M Barker
Investigator
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13:58:38

DATE ISSUED
3/24/2022

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."