DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	7/29/2025-8/8/2025* FEI NUMBER 3012104093

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Deborah McHugh, Vice President, Quality North America

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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your firm produces and releases drugs made after failed media fills and before successful revalidation of the aseptic processes. For example, on 3/7/2025, your firm documented suspected growth in (b)(4) media fill vials for study (b) (4) which was to validate the aseptic production process for Methylprednisolone Acetate 80mg/mL Injection suspension preservative free 1mL (single dose vials). Your firm was unable to subculture the material in the vials when attempted and the observed particulate could not be identified as the samples were inadvertently discarded. No root cause could be determined. Your firm manufactured (b) (4) batches of the Methylprednisolone Acetate drug product after the failing media fill results were obtained. Three of the (b) (4) lots were released for customer distribution (lot (b) (4) (BUD: 7/9/2025), lot (b) (4) (BUD:7/9/2025), and lot (b) (4) (BUD:8/6/2025)). Media fill deficiencies were noted during the 2024 FDA inspection.

B. Your aseptic process simulations (media fills) are inadequate for the following reasons:
   - Your media fill records are not accurate. Your firm reconciles the number of media fill units produced and incubated via a (b) (4) process. The pre and post incubation weights and calculated number of media fill units should be consistent. Your firm documents pre and post incubation weights in the official media fill batch records and also

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	Sean R Marcsisin, Investigator	X Sean R Marcsisin Investigator Signed By: Sean R. Marcsisin -S Date Signed: 08-08-2025 12:46:56	8/8/2025

in an unofficial spreadsheet kept by the responsible group. On 8/5/2025, I reviewed data from the unofficial spreadsheet and official media fill batch records for lots (b) (4) , and (b) (4) The media fill batch records indicated no discrepancies in the pre and post incubation weight checks for the above lots The spreadsheet indicated there were weight discrepancies and that there were unaccounted media fill units for the above lots (b) (4) and (b) (4) missing units respectively). No deviations have been initiated for the noted discrepancies. Additionally, I observed that you routinely document the pre incubation weights in the post incubation sections of the associated batch records. The above media fills were conducted to validate your 3 mL Dropper Bottle, 3 mL Syringe Mitomycin Ophthalmic Injection Solution, and 7 mL Dropper Bottle aseptic production processes.

- Your media fills are not representative of your aseptic processes. For example, the unplanned interventions conducted during media fills for the Avastin Injection filling process include (b) (4) failure, (b) (4) kit tubing leak and cleanup, needle replacement, and (b) (4) replacement. Interventions that are conducted during Avastin aseptic filling, such as removal of fallen/jammed syringes from the ISO-5 filling area or removal of jammed syringe plungers, have not been challenged nor part of your media fill program.

C. Your firm does not ensure first pass air is not disrupted in critical production areas. The following were noted during the current inspection:

- On 7/30/2025, I observed the filling of Avastin Injection (1.25 mg/0.05 mL) lot (b) (4) (BUD: 12/27/2025). Operators were observed to reach directly over the syringe plunger (b) (4) four times at approximately 11:36 pm, 11:38 pm, 11:39 pm, 11:40 pm (time on video) to retrieve forceps for syringe/plunger interventions. The (b) (4) contained syringe plungers that make direct product contact when inserted into the syringes during the fill process. Additionally, an operator reached directly over open syringes within the ISO-5 enclosure/critical fill area at 11:39 pm. Your firm does not track filled trays and

cannot determine which syringe trays were impacted by the observed interventions. Additionally, your firm did not reject fill material and components within the filling enclosure after I observed the operator reach over and disrupt first pass air with their body/gowning.

- I reviewed the video footage from production of Succinylcholine Chloride 20mg/mL injection syringes lot (b) (4) (BUD: 11/8/2025) from 7/19/2025 in Fill (b) (4) The operator in the ISO-5 hood filling syringes was observed to pass the viable air sampling equipment directly over unfilled empty syringes at 11:37 am (time on video). The impacted syringes were not cleared/rejected and subsequently filled with drug product.

- On 8/1/2025, I observed the production of Oxytocin 30 U Injection Solution in 500 mL 0.9 % NaCl IV bags lot (b) (4) (BUD: 11/8/2025) in Fill room (b) (4) The operators were observed filling IV bags within the ISO-5 hood where first pass air was blocked by production materials pushed up against the HEPA filters.

D. Your firm does not adequately place, and control tools utilized during aseptic production of Avastin Injection. For example, on 7/30/2025, I observed the following during the aseptic filling of Avastin Injection (1.25 mg/0.05 mL) lot (b) (4) (BUD: 12/27/2025:
   - An operator removed sterile scissors from the (b) (4) bag and placed them on the deck of the filling enclosure. The scissors were then utilized to open the syringe plunger bags without being sanitized during line setup.
   - Operators must reach over the syringe plunger (b) (4) (blocking first pass air) to retrieve the forceps.

E. Your firm does not open sterilized ISO-5 filling equipment components in ISO-5 classified areas. I reviewed the 07/15/2025 video for the (b) (4) filling line setup for Avastin Injection (1.25 mg/0.05 mL) lot (b) (4) . The operator was observed to open the (b) (4) bag and

expose both the syringe plunger (b) (4) bowl and associated track in the ISO-7 area of the cleanroom. The equipment was not sanitized after installation and was subsequently utilized to fill lots (b) (4) and (b) (4) (BUDs 12/12/2025).

F. Your firm's airflow pattern analyses (smoke studies) of critical ISO-5 production environments are inadequate for the following reasons:

I. Your firm's smoke studies dated 27JULY2024, for the evaluation of air flow and first pass air during filtration of bulk parent batch material from (b) (4) bags into 10 L bags show non-unidirectional airflow when the bags are positioned parallel to the HEPA filters. Smoke is turbulent and appears to enter the ISO-5 filling area from the surrounding ISO-7 area at approximately 4:27-4:50 minutes. Your firm optimized the 10 L bag position in the video as shown at approximately 4:54 minutes by angling the bags to approximately (b) (4) in relation to the HEPA filters. Additionally, the bags shown in the associated smoke study video dated 27JULY2024, do not contain any liquid, which is non-representative of the production process. On 7/30/2025, I observed operators produce 10 L bags of Phenylephrine 0.1mg/mL solution drug product lot (b) (4) with the 10 L bags in the non-optimized position, parallel to the HEPA filters. Product in the 10 L bags is not subsequently (b) (4)/sterilized. The 10 L bags from lot (b) (4) were utilized to fill Phenylephrine 0.1mg/mL preservative free injection solution 10 mL syringes for lots (b) (4) and (b) (4) (BUDs 1/19/2025 ad 1/20/2026 respectively).

II. Your firm lacks smoke studies for the evaluation of airflow and first pass air during Avastin vial (b) (4) for aseptic repackaging operations, a process that was observed on 7/30/2025 for Avastin Injection (1.25 mg/0.05 mL) lot (b) (4) (BUD:12/27/2025).

III. For the (b) (4) Avastin filling line (b) (4) perimeter airflow video dated 07MAY2020, smoke is turbulent and can be seen flowing back up towards the HEPA filters in the video at

approximately 0.48-0.56, 1:04-1:07, 1:13, 1:32, 2:04-2:06, 2:21, 2:34-2:47, 3:43, and 3:58 minutes. The "(b) (4) section shows smoke travel up towards the ceiling and then enter into the ISO-5 perimeter area (5:52-6:10 minutes). The perimeter area is where the syringe plunger (b) (4) and other fill line component(b) (4) bags are opened during line setup.

IV. For the (b) (4) Avastin filling line (b) (4) airflow video dated 23JUL2020 and 26JAN2024, your firm did not adequately evaluate the airflow within the filling line enclosure at close proximity ((b) (4)) to the HEPA filters to show airflow is uniform and non-turbulent near the ceiling throughout the entire ISO-5 enclosure. The frame shown at approximately 5:58 into the video dated 26JAN2024, shows non-unidirectional airflow at the HEPA filter interface above the syringe loading station.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Inadequate investigations were noted during the 2024 FDA inspection.

A. Since September 2024, you firm has documented 14 sterility positive investigations for products tested in your microbiology laboratory. Four sterility positive investigations were for product made at your Canton, MA, facility, while 10 investigations were for product made at the Wichita, KS, facility. Your firm has opened multiple action items and corrective and preventative actions to address the sterility positive events and identified multiple potential root causes to include deficiencies with the sterility testing (b) (4) systems and inadequate material disinfection during production activities as documented in action items AI-2025-0268,

AI-2025-0270, and CAPA-2024-0181. Your opened CAPA-2025-0139 in July 2025 due to the ongoing sterility failures and your firm continues to sterility test drugs intended to be sterile. No definitive root cause(s) have been identified. Your firm has failed to critically and holistically evaluate your aseptic production processes and sterility testing program to ensure they are in a state of control.

B. Since April 2024, your firm has received four adverse events for the Avastin Injection (1.25 mg per 0.05 mL) drug product. Adverse events include infections and endophthalmitis. Your firm failed to holistically and critically evaluate your Avastin drug product repackaging process to ensure that aseptic operations were in a state of control (see Observation 1B-E above for deficiencies observed with the Avastin aseptic filling process).

C. Your firm does not properly document and evaluate atypical events during aseptic filling operations. During the aseptic fill of Avastin Injection (1.25 mg/0.05 mL) lot (b) (4) (BUD: 12/12/2025) on 7/15/2025, the operators dropped a component from the syringe tray loading mechanism (component in ISO-5 area) on the floor as seen at approximately11:49 am in the associated video. The operators retrieved the component; wiped the component with a (b) (4) (b) (4) saturated wipes and placed the component back into the ISO-5 environment. No documentation of the above atypical event was noted in the batch record or in the unplanned incidents system.

D. Your firm opened issue review ISSUE-2025-0024 in June 2025 to evaluate aseptic process improvements for fill room (b) (4) and Oxytocin production in response to multiple ISO-5 environmental monitoring excursions. The assessment was due 07/24/2025. As of 8/7/2025, the assessment remains open without a documented extension request. In addition to fill room (b) (4), your firm also has initiated another issue assessment for syringe production, ISSUE-2025-0025 due to multiple ISO-5 environmental monitoring excursions. Since January 2025, your firm has documented 188 ISO-5 microbial recoveries (personnel, passive viable air, viable air), 41 being spore forming microorganisms, in the various aseptic areas where you produce drugs intended to

be sterile. No holistic assessment has been conducted of all aseptic operations at your facility despite the numerous ISO-5 microbial excursions.

OBSERVATION 3

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically,

Your firm does not maintain production areas and associated equipment adequately. The following were noted during the inspection on 7/29/2025 and 7/30/2025:

- Unknown black discoloration within the ISO-5 area of the fill hood for Fill Line (b) (4)
- What appeared to be rust on a cart holding scale calibration weights used for compounding (ISO-8).
- What appeared to be rust on fasteners/bolts within ISO-7 material passthroughs in rooms 323 and 340.
- Dark greenish fuzzy spots were observed on the light fixtures and status tag of cold room (b) (4) (b) (4), which is utilized to store retain samples and finished product before distribution. Units from Vancomycin HCl in sodium chloride injection IV bags from lot (b) (4) (Expiry 11/17/2025) were observed in the room.

OBSERVATION 4

The number of qualified personnel is inadequate to perform the manufacture of each drug product.

Specifically,

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CITY, STATE, ZIP CODE, COUNTRY Wichita, KS 67226-2636	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Your firm does not have adequate resources to conduct environmental monitoring (EM) excursion investigations in a timely manner. As of 7/29/2025, your firm has over 64 open EM excursions investigations. Your firm has documented in associated deviation investigation extension requests the inability to complete the investigations due to inadequate time and prioritizing investigations for priority batches. Open EM investigations include excursions in critical ISO-5 filling areas such as deviation DEV-2025-1523, which was opened on 6/18/2025 for recovery of filamentous fungi (*Penicillium citrinum*, 1 CFU) from a passive viable air sample in the ISO-5 hood during production of Vancomycin IV bag lot (b) (4) (BUD: 12/7/2025).

OBSERVATION 5

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

Specifically,

Your firm lacks adequate ISO-7 storage space for staged production materials. You utilize aseptic fill room (b) (4) for storage and staging of production material (IV bags, syringes, (b) (4) water bags) when the room is not being utilized for Avastin Injection (1.25 mg/0.05 mL). On 7/15/2025, your firm stored (b) (4) carts of various production items in fill room (b) (4) as shown on video. Ten of the (b) (4) carts were pushed within the ISO-5 boundary of the fill room. Your operator cleaned the floor and walked and rolled the carts over the floor while the floor was still visibly wet, which is prohibited per procedure FSS-SOP-0227 "Site Cleaning, Sanitization and Disinfection Policy". You firm subsequently utilized the fill room to produce Avastin Injection lot (b) (4) (BUD: 12/12/2025).

OBSERVATION 6

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

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Specifically,

Procedure FSS-SOP-0369 "Use, Operation, and Cleaning of the (b) (4) Syringe Filling Machine" is inadequate as it lacks detailed cleaning instructions prior to equipment use to include instructions on cleaning the critical ISO-5 areas first, followed by the remainder of the equipment. The cleaning of the (b) (4) equipment observed on video for 7/15/2025, showed operators place multiple (b) (4) wipes on the base/deck of the equipment. The operators subsequently utilized the wipes to clean various areas within the ISO-5 to include the critical fill area. The equipment was then utilized to fill Avastin Injection lot (b) (4) (BUD: 12/12/2025).

***DATES OF INSPECTION**

7/29/2025(Tue), 7/30/2025(Wed), 7/31/2025(Thu), 8/01/2025(Fri), 8/04/2025(Mon), 8/05/2025(Tue), 8/06/2025(Wed), 8/07/2025(Thu), 8/08/2025(Fri)

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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."