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	9/11/2025-9/23/2025* FEI NUMBER 1972829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Steven Garhartt, Senior Director of 503B Outsourcing

FIRM NAME	STREET ADDRESS
Park Avenue Compounding	3662 Park Ave Ste 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63110-2512	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

A. Media fills completed by compounding operators are not representative of your firm's largest batch size.

1. Your firm's media fill "Process(b) (4) is designed with a batch size of(b) (4) units, while your firm's largest batch size produced and distributed from this facility is(b) (4) units. Your firm has not provided sufficient scientific justification for the discrepancy in units produced in the media fill "Process(b) (4)
2. Your firm's media fill "Process(b) (4) is designed with a batch size of(b) (4) units, while your firm's largest batch size produced and distributed from this facility is(b) (4) units. Your firm has not provided sufficient scientific justification for the discrepancy in units produced in the media fill "Process(b) (4)

B. Your firm's Media Fill records document the destruction of media fill units without adequate scientific justification. For example, but not limited to: With media fill "Process(b) (4) Lot# (b) (4) Qty(b) (4) units your firm documented manipulating and discarding 35 units. Your firm does not have clear and specific written procedures describing interventions in which media units may be removed prior to incubation. The table below outlines several batches for which your firm discarded media units:

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	June P Page, Manufacturing Compounding Quality Expert Sarah M Gauna, Manufacturing Compounding Quality Expert X June P Page Manufacturing Compounding Quality Expert Signed By: 2000405709 Date Signed: 09-23-2025 19:37:54	9/23/2025

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Date	Lot	Process	Batch Quantity	Actual Quantity	Units Destroyed
4/8/2024	(b) (4)	Process (b) (4) Media Fill	(b) (4)		5
4/15/2025		Process (b) (4) Media Fill			4
4/30/2025		Process (b) (4) Media Fill			25
5/6/2025		Process (b) (4) Media Fill			10
5/27/2025		Process (b) (4) Media Fill			5
8/5/2025		Process (b) (4) Media Fill			35
8/7/2025		Process (b) Media Fill			20

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OBSERVATION 2

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

Specifically, on 9/19/2025, during your firm's "Terminal Cleaning" of the ISO-7 classified buffer rooms, completed by your firm's contracted vendor, we observed the following deficiencies:

A. Cleaning technician used their gloved hands to adjust their sterile boot, exposing their skin to ISO 7 Buffer Room[(b)(4)] (Room 151).

B. Cleaning technician in Buffer Room[(b)(4)] (Room 151) was observed kneeling on the ISO 7 floor with their knees to clean the wheels of a (b) (4) cart, then continue cleaning without changing their sterile coverall and sterile boots.

C. Cleaning technician in Buffer Room[(b)(4)] (Room 149) was observed sitting on the ISO 7 floor to clean the bottom of the ISO 5 LAFH, then continue cleaning without changing their sterile coverall and sterile boots.

OBSERVATION 3

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

Specifically, your firm's June 2025 airflow evaluation (smoke studies) of the ISO-5 classified area where aseptic operations are performed shows unidirectional airflow is compromised and eddies/turbulence was observed under dynamic conditions. For example, but not limited to:

A. Timestamp: at approximately (b) (4)
   1. During critical manipulations in your aseptic operations, your aseptic operator was observed leaning against the workbench, which resulted in

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eddies/turbulent air hitting their chest and re-entering the ISO 5 air potentially compromising the ISO 5 air.

In addition, your firm does not perform personnel monitoring (PM) of each gowning sampling location (hood, chest, right forearm, left forearm) after each batch produced; instead these locations are rotated for each batch. For example, PM of the chest is taken every (b) (4) batch produced. However, your firm has not performed a risk assessment justifying this statistical criteria for the sampling and testing meet quality control criteria as a condition for their approval and release.

B. Your firm's risk assessment (included in VAL-24-001) is inadequate as there are no smoke studies evaluating the airflow when moving materials used in aseptic operations from an unclassified area to an ISO-7 classified area; there is no justification for the (b) (4) environmental monitoring frequency (viable surface and viable air sampling), when the (b) (4) is used (b) (4) ; there are no monitoring of pressure differentials ensuring air flows from higher to lower classification to prevent contamination.

Your firm utilizes this large (b) (4) , which connects non-classified Stockroom (room 132) to ISO 7 Stock Prep Room (room 147) for the movement of APIs and drug components.

In addition, this risk assessment was conducted prior to your firm performing routine aseptic operations and your risk assessment identifies this (b) (4) as your firm's highest risk.

OBSERVATION 4

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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,

A. Your firm's deviations are inconsistent or inaccurate regarding, reviews, risk assessment, root cause, immediate actions, historical reviews, and corrective and preventative actions (CAPA). For example, but not limited to:

1. QAL-25-018: (referenced in QAL-25-022 as a similar event) documents incorrect amounts of API injected into the "source bag" during the compounding of lot 20250303-71F6CA, Phenylephrine HCl 1000 mcg in 10 ml of NS Syringe. This error was potentially due to your aseptic operator using the incorrect syringe size when preparing your "source bags", not a repeater pump concern. (b) (4) units were sent for testing and (b) (4) resulted in 0% potency. The risk assessment for this deviation was categorized as "medium". This lot was destroyed.
    i. CAPA-25-005 (referenced in QAL-25-018) address the incorrect syringe size and stated multiple corrective actions will be implemented in your master batch record for Phenylephrine, but references your master batch record for Oxytocin. In addition, during our review of your firm's batch records, all corrective actions were not implemented. Your current Master Batch Record (MBR) for Phenylephrine HCl 1000 mcg in 10 ml of NS Syringe does not include clear instructions or is omitted, for example, but not limited to:

- Technicians must immediately stop compounding and notify a Pharmacist or QA upon identifying any issues.
- (b) (4) compounders will be responsible for removing (b) (4) ml NS from source bag.
- Vial to bag ratio adjustment: (b) (4) ml syringe will be used per vial of phenylephrine

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- Only (b)(4) ml syringe should still be used, and (b)(4) ml syringes will be completely removed from the drawing process. However, (b)(4) ml syringes are still scanned as a material item picked for each batch.

2. Deviation, QAL-25-022: Documents a discrepancy in your firm's repeater pump count when reaching its set calibration point at (b)(4)-units during the production of lot 20250317-5A4CE3, Potassium Chloride 40 mEq in 0.9% NaCl, BUD 09/13/2025. (b)(4) units were sent for testing and (b)(4) resulted in 0% potency. The risk assessment for this deviation was categorized as "high". This lot was reviewed and approved for distribution by a personnel with QA Manager access.
   i. CAPA-25-006 (referenced in QAL-25-022) address a calibration discrepancy identified with the repeater pump during processing of batch #20250317-5A4CE3 and stated three (3) batch record corrective actions are to be implemented for Potassium Chloride, but references your master batch record for Oxytocin. In addition, during our review of your firm's batch records, all corrective actions were not implemented. For example, but not limited to:
      - Mandatory compounding breaks

B. Your firm has completed at least 8 deviation since 02/07/2025 in which particulate matter was associated with finished drug products that were distributed. CAPA-25-003, was initiated on 02/27/2025 to address at least seven (7) of these deviations. This CAPA states "between 01/13/2025 and 03/31/2025, during compounding and 100% visual inspections, pharmacists identified black/dark particulate matter in a single bag or syringe across multiple compounded lots. In each instance a second 100% visual inspection was performed by a different pharmacists, which found no additional particulates. In all cases, AQL assessments conducted by quality personnel confirmed the initial defects but found no additional issues or concerns across the lots". However, during our review of your firm's batch records associated with these lots, we noted the following discrepancies:

Batch Record	Drug Name	1st Visual Inspection	2nd Visual Inspection

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		(defects found)	(defects found)
20250115	Fentanyl citrate 2500 mcg/50 mL	4 minor	1 critical 1 minor
20250131	Succinylcholine chloride 100mg/5mL (20mg/1mL)	1 critical 2 major 1 minor	1 major 1 minor
20250210	Fentanyl citrate 2500 mcg/50 mL	1 critical	0
20250122	Fentanyl citrate 2500 mcg/50 mL	1 critical	0

In addition, this same CAPA states (b) (4) are to be replaced every (b) (4) vials. However, this is step is not outlined in any of your master batch records.

Your aseptic operators continue to create deviations for particulate matter observed during visual inspections, which are linked to the same corrective action (CAPA-25-003) and your Quality Unit continue to release these batches for distribution.

OBSERVATION 5

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release.

Specifically,

A. Your firm lacks scientific justification for visual inspection re-inspection procedures:

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1. No documented rationale exists for performing additional 100% re-inspections following initial visual inspection failures. For example, but not limited to, the following batches underwent 100% re-inspection multiple times without justification:

   i. Potassium Chloride 40mEq in 0.9% sodium chloride 270 mL Lot# 20250806-3BE96A BUD 02/02/2026

   ii. Potassium Chloride 40mEq in 0.9% sodium chloride 270mL Lot#20250722-8F0F44 BUD 01/18/2025

   iii. Oxytocin 30 units in 0.9% sodium chloride 500mL Lot #20250708-85D2BE BUD: 09/06/2025

2. AQL (Acceptable Quality Level) re-inspections can be repeated up to [b] times.

B. Your firm does not have written processes for multiple inspectors splitting a 100% visual inspection. Additionally, your firm has not conducted a risk assessment to evaluate the impact of this practice on inspection consistency and reliability, nor provided justification for this process. For example, but not limited to:

Batch: Fentanyl Citrate 2mcg/mL /Ropivacaine 0.2% in NS 150 mL, Lot# 20250429-8FE10A, Qty: (b) (4) BUD 10/26/2025	
(QTY: (b) (4)	
Visual Inspector #1	Visual Inspector #2
(b) (4)	[b]

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Batch: Fentanyl Citrate 2mcg/mL /Ropivacaine 0.2% in NS 150 mL, Lot# 20250507-01D93C, Qty: (b) (4) BUD 11/04/2025	
(QTY: (b) (4)	
Visual Inspector #1	Visual Inspector #2
(b) (4)	(b) (4)
Batch: Phenylephrine Syringes 1000mcg/ 10 mL, Lot# 20250411-0D5546, Qty: (b) (4), BUD 10/08/2025	
(QTY: (b) (4)	
Visual Inspector #1	Visual Inspector #2
(b) (4)	(b) (
Batch Phenylephrine Syringes 1000mcg/ 10 mL, Lot# 20250612-6481F2, Qty: (b) (4), BUD 12/09/2025	
(QTY: (b) (4))	
Visual Inspector #1	Visual Inspector #2
(b) (4)	(b) (4)

C. Your firm has not established and implemented a comprehensive defect library system. For example, but not limited to:

1. No documented defect library exists containing representative examples of acceptable and unacceptable product defects.

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2. No established procedure exists for identifying, evaluating, and incorporating new defect types into the defect library.

D. Your firm does not adequately control and document lighting conditions for visual inspections. For example, but not limited to:

1. Lux light intensity measurements are not documented for lights used during visual inspection operations.

2. Prior to 03/19/2025, lux light intensity was not measured for visual inspections completed on distributed drug products.

As a result, approximately (b) (4) units of drug products produced by your firm were released and distributed between 11/20/2024 and 09/11/2025 without verification and documentation of the lux light intensity used for visual inspection.

OBSERVATION 6

Drug product production and control records, are not reviewed by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, a review of your firm's batch records found your firm released purportedly sterile drug products before reviewing the completed deviations or complaints associated with each batch. For example, but not limited to:

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A. Forty-three (43) days after this batch was approved for release, your firm's Quality Unit received the vendor's final investigation report for PCC-25-058, identifying the particulate matter by FTIR analysis, was found to be polyamide and cellulose, wood fiber. The investigation also stated the "particles were on the inside of the bags and would have been in contact with the solution."

However, the batch record for Fentanyl Citrate 2mcg/mL/Ropivacaine 0.2% in NS 150mL, Lot 20250507-01D93C, BUD 11/04/2025, was approved for release without a thorough review of the following documents associated with this batch record, resulting in the release of (b) (4) units.

For example, multiple discrepancies related to particulate matter were found associated with this batch:

1. On 05/12/2025, the batch record, which was approved for release, documents visual inspection failed AQL for one (1) unit identified with a critical defect. However, multiple AQL failures were noted:

i. Product complaint, PCC-25-058:

(1) First AQL fail: One (1) unit containing foreign particulate matter

(2) Second AQL fail: Seven (7) additional units contained foreign particulates

AMENDMENT 1

2. Deviation, QAL-25-037:

i. AQL fail: Eight (8) units were found to contain visible foreign particulate matter

ii. Batch is to remain on QA hold pending the outcome of the vendor investigation for PCC-25-058.

B. Deviation, QAL-25-002, was initiated on 01/21/2025, documenting your firm's Inventory personnel removed finished drug products from quarantine to be released, resulting in the distribution of (b) (4) units of the incorrect lot of Potassium Chloride 40mEq in 0.9% NaCl, prior to receiving release testing results.

OBSERVATION 7

Equipment surfaces that contact components, in-process materials and drug products are reactive, additive or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

Specifically, your firm did not provide scientific justification or evaluate the material of construction for the (b) (4) totes used to transport drug products and drug components used in sterile operations from an unclassified area to higher areas of classification (ISO-7).

The (b) (4) totes that contain drug product and components come into direct contact with your firm's cleaning agents. However, your firm did not evaluate the degradation of the (b) (4) material when repeated exposure of your firm's cleaning agents occur over time to ensure (b) (4) particles are not

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emitted.

OBSERVATION 8

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. Your firm utilizes a shared network that is accessible to all employees (operations, production, and quality) to access your firm's Quality Control Documents. For example, but not limited to:

1. Environmental and Personnel Monitoring, Deviations, Complaints, Change Controls, Validation Protocols. Your non-quality personnel has unrestricted to access make changes to the following:

i. Uncontrolled excel spreadsheet used to track and trend your firm's environmental monitoring for classified areas.

ii. Modify, delete, add data to complaint files.

B. Your computerized software used for batch record release includes quality events associated with each batch record release (complaints, deviations, recalls, non-conformances). However, your firm does not have any written procedures for electronic reviews and has not performed any electronic audit trails to track the creation, modification, or deletion of such data to date.

C. Your firm's control documents, such as environmental and personnel

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monitoring result forms, visual inspection result forms are accessible for unlimited printing, without any means of reconciliation (i.e. no date/time-stamp) by non-QC personnel.

In addition, your firm's managment stated your employee has reprinted at least one form instead of adhering to Good Documentation Practices.

***DATES OF INSPECTION**

9/11/2025(Thu), 9/12/2025(Fri), 9/15/2025(Mon), 9/16/2025(Tue), 9/17/2025(Wed), 9/18/2025(Thu), 9/19/2025(Fri), 9/22/2025(Mon), 9/23/2025(Tue)

X Sarah M Gauna
Manufacturing Compounding Quality Expert
Signed By: 2004033743
Date Signed: 09-23-2025 19:38:47

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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."