DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Main Place 1201 Main Street Ste 7200 Dallas, TX 75202 (214)253-5200	11/03-07/25, 11/10/2025, 11/12-14/2025
	FEI NUMBER 3011887629
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Pejman Jonathan Abrarpour, Chief Operating Officer	
FIRM NAME Empower Clinic Services, L.L.C. dba Empower Pharma	STREET ADDRESS 5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041	TYPE ESTABLISHMENT INSPECTED 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 are not established, written and followed.

Specifically,

A. Aseptic process simulations (APS) are not adequately designed or controlled to demonstrate that aseptic operations can consistently prevent microbiological contamination of sterile drug products. For example,
   1. Your aseptic process simulations do not encompass the full aseptic process, as formulation, (b) (4) and (b) (4) filling operations are performed and qualified separately rather than as a single integrated simulation reflective of routine production. For example, products such as Ascorbic Acid Preserved 200 mg/mL (30 mL) require a sequential series of events, to include formulation of the bulk, transfer to (b) (4) and transfer to (b) (4) /Filling. Rather, your current APS breaks these steps into separate activities and evaluates growth or turbidity only at the (b) (4) filling step, without simulating or assessing upstream aseptic manipulations. As a result, contamination risks associated with these routine upstream manipulations are not challenged.

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2. Your firm has not performed a risk assessment to determine which aseptic interventions present the highest contamination potential or to justify the type and frequency of interventions to be simulated during media fills. Operators perform only one of each non-routine intervention (ex: "Sterile component change (tubing or (b) (4) connection)", "Filler maintenance by Facility staff"), and routine interventions (ex: "(b) (4) ", "Fill Volume Check") are performed "as needed" to complete the batch, rather than per a pre-defined plan representing worst-case conditions.
3. Your firm's APS failed to reflect actual production sizes based on bulk size processed through (b) (4) , and (b) (4) duration. A review of the firm's Summary Report B-REP-STR-0013, titled "*Media Fill Process Family* (b) (4) *- Requalification Report 2025-1*", Revision 001, effective date 05/19/2025, and Protocol PROT -STR-0004, titled "*Media Fill Protocol- Requalification – Process Family* (b) (4) ", Revision 005, Effective Date 07/22/2025, reported a bulk size of (b) (4) processed through (b) (4) , which lasted (b) (4) . However, a review of firm's production records for the released batches showed the following:
   - Pyridoxine HCL (B6) 100MG/ML, (b) (4) vials (30 ML), Lot 615126, compounded on (b) (4) (BUD 08/06/2026), reported a (b) (4) bulk size of (b) (4) , and a (b) (4) Duration of (b) (4) .
   - Pyridoxine HCL (B6) 100MG/ML, (b) (4) vials (30 ML), Lot 611676, compounded on (b) (4) (BUD 11/01/2025), reported a (b) (4) bulk size of (b) (4) , and a (b) (4) Duration of (b) (4) .
   - LIPO-B (Methionine/ Choline Chloride/ Cyanocobalamin) 25/50/1MG/ML, (b) (4) vials (30 ML), Lot 614683, compounded on (b) (4) (12/24/2025), reported a (b) (4) bulk size of (b) (4) , and a (b) (4) Duration of (b) (4) .
   - LIPO-B (Methionine/ Choline Chloride/ Cyanocobalamin) 25/50/1MG/ML, (b) (4) vials (30 ML), Lot 614478, compounded on (b) (4) (12/09/2025), reported a (b) (4) bulk size of (b) (4) , and a (b) (4) Duration of (b) (4) .

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4. Your written media fill procedures do not require you to track and trend previous occurrences of routine and/or nonroutine interventions for future inclusion into your media fill program.
5. You lack a scientifically established qualification process for media fill unit inspections. There is no QC or microbiology oversight of the inspection process, and personnel are not trained or qualified using standardized defect (b) (4) or challenge (b) (4). As a result, you have not demonstrated that personnel can accurately and repeatedly detect failing units during media fill evaluation.

B. Your Environmental Monitoring (EM) program does not provide assurance that your ISO (b)(environment remains in a state of microbiological control during aseptic processing. For example,
   1. EM is not performed during aseptic operations conducted in any of your ISO (b) (4 classified areas, including but not limited to Rooms (b) (4) and (b) (4). Routine viable and non-viable monitoring is limited to (b) (4) static conditions and does not include active monitoring during dynamic manufacturing. Approximately (b) (4) sterile drug products manufactured under these conditions remain within expiry.
   2. On 11/06/2025, active viable air monitoring equipment used during aseptic filling of Ascorbic Acid Preserved 200 mg/mL (30 mL), Lot 615360, in your ISO (b) (4 laminar airflow hoods, was observed to be positioned more than 12 inches from the critical filling zone. This placement does not provide representative sampling of the area presenting the greatest risk to exposed sterile product.

C. Airflow visualization (smoke) studies performed for Room (b) (4) ((b) (4) / Filling) were not representative of routine dynamic operations and did not challenge the system under normal, or worst-case conditions. For example,
   - The studies were performed using a limited filling scenario where the operator filled and stoppered only one row of vials, while routine production involves (b) (4) rows being filled

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and stoppered throughout the filling of an entire tray of # vials, as observed during filling of Ascorbic Acid Preserved 200 mg/mL (30 mL), Lot 615360, in Room (b) (4), on 11/06/2025.

- The studies were limited to a single Laminar Airflow Hood (LAFH) operated by one operator and one assistant. While routine production involves concurrent use of (b) (4) LAFHs, each operated by (b) (4) and (b) (4), with additional equipment, such as the capping machine, operating simultaneously.

D. Personnel monitoring is not performed following aseptic connections or other critical manipulations during production, and your written procedures do not require personnel monitoring to be performed after these activities. For example, on 11/06/2025, during manufacture of Ascorbic Acid Preserved 200 mg/mL (30 mL), Lot 615360, operators performed aseptic connections under ISO (b) (4) without subsequent sampling of gloves or the connection site

This is a repeat observation.

OBSERVATION 2

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

A. Your visual inspection program lacks adequate controls and scientific justification to ensure consistent detection and evaluation of product defects, including, but not limited to, the following:

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1. Your firm failed to identify visible particulates detected during visual inspection to determine whether the material was intrinsic or extrinsic in origin. Extrinsic foreign matter such as hair, fibers, metal fragments, and other foreign particles had not been characterized or investigated to determine the source or potential impact on product quality. Defect types, including extrinsic and intrinsic particulates, were not tracked or trended until on or about 15 Oct 2025. Since that date, approximately (b) (4) batches have been tracked, with an average of 1.9 extrinsic and 30.9 intrinsic particulates per lot (average batch size (b) (4) units).

2. Procedure B-SOP-VIL-0003, *Visual Inspection of Injectables*, Revision 012, Effective Date 28-May-2025, outlines a process in which lots that exceed preset defect limits during the initial 100% inspection are (b) (4) AQL sampling is conducted (b) (4) . Nonconformances (NCs) are initiated only when a batch fails AQL for critical defects or when the total reject rate is exceeded during 100% inspection. Failures involving major or minor defect categories do not generate an NC, and the lot is instead subjected to additional 100% inspection without investigation or documented justification.

3. Defect classifications (critical, major, minor) are not scientifically supported. Risk is assigned without a documented assessment or justification. For example, glass particulates are categorized as major rather than critical defects. Your firm does not maintain a written process or record system for performing Health Hazard Evaluations (HHEs) or Health Hazard Assessments (HHAs) when product quality issues occur. Although your firm has previously conducted a product recall, firm management stated that no formal HHE or HHA process exists.

4. Your visual inspection qualification (b) (4) are not access controlled. (b) (4), along with the answer keys, are stored unsecured in the visual inspection room. (b) (4) are not issued,

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inventoried, or periodically verified by Quality, and only (b) (4) exists per product presentation. These (b) (4) are used to qualify all visual inspection quality inspectors on (b) (4) basis.

5. None of the defects included in your qualification (b) (4) are characterized or documented for size, visibility, or detectability. Many of the defects are grossly visible to the unaided eye, indicating that the (b) (4) are not designed to adequately challenge inspector acuity or to simulate routine production conditions.

6. You have not scientifically established the impact of inspection rates performed by your visual inspection operators. You do not document the length of time it takes your operators to qualify on your inspection (b) (4).

7. Personnel who administer the visual inspection qualification tests are also qualified using the same (b) (4) and perform routine visual inspection activities.

B. The performance qualification for (b) (4) Sterilizer (Asset Tag: (b) (4)) was found inadequate. The firm's actual loads for the stoppers, caps, and scissors exceed their defined maximum qualified load. These components are in-process for use currently and were used in the compounding of the following drug products that were released to the US market as described in the following table:

Component	Quantity Validated in (b) (4) PQ	Quantity (b) (4)	(b) (4) Run Date	Drug Product made using the component	Drug Product Lot#	# Drug Product Units Made	BUD Date
Stoppers	(b) (4)			Ascorbic Acid Preservative Free (30 ML) 500MG/ML Injectable (IV)	615348	(b) (4)	05/16/2026
					615350	(b) (4)	05/16/2026

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	(b) (4)			Zinc Sulfate (30 ML) 10 MG/ML Zinc Injectable (IV)	614172	(b) (4) 06/22/2026
Caps				Semaglutide / Cyanocobalamin (2.5 ML) 5/0.5 MG/ML Injectable (SQ)	614140	04/30/2026
				LIPO-B (Methionine/Choline Chloride/Cyanocobalamin) (30 ML) 25/50/1 MG/ML Injectable (IM)	614683	12/24/2025
Scissors (used to cut tubing and open vial bag inside ISO (b))				Pyridoxine HCL (30 ML) 100 MG/ML In Injectable (IM, IV)	615223	06/08/2026
				Testosterone Cypionate IN GSO (30 ML) 200 MG/ML Injectable (IM, SQ)	615154	04/23/2026
				Vitamin B Complex (B1/B2/B3/B5/B6) (30 ML) 100/2/100/2/2 MG/ML Injectable (IM, SQ, IV)	614991	06/23/2026
				Zinc Sulfate (30 ML) 10 MG/ML ZINC Injectable (IV)	614172	06/22/2026
				Ascorbic Acid Preservative Free (30 ML) 500 MG/ML (IV)	615348	05/16/2026
				Testosterone Cypionate in GSO (30 ML) 200 MG/ML Injectable (IM, SQ)	615352	04/23/2026

This is a repeat observation.

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OBSERVATION 3

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 specification whether or not the batch has been already distributed.

Specifically,

A. Your firm implemented a change under CHR-0000005416 to reduce the retention timeframe for aseptic operation records based on reported "poor practices" and untimely investigation activities by quality personnel, however, no nonconformance, or CAPA had been generated to document, evaluate, or substantiate these behaviors within the quality system. As a result, a quality impacting change was made without supporting documentation, data, or risk assessment.

B. From 08/29/2024 to present, approximately 337 of approximately 963 nonconformance reports (NCs) (which include nonconformances, deviations, and OOSs) remained open, several of which were associated with, but not limited to, batch rejections, EM recoveries, and AQL failures related to extrinsic particles and glass defects. Firm management stated that investigations are delayed due to current onboarding of new investigation writers and are being prioritized "by risk," yet no documented risk assessment, justification, or criteria used for prioritization could be provided. In addition, no risk assessment or gap analysis has been performed to determine potential product impact. Examples include, but are not limited to:

1. NC-002613 was initiated on 07/02/2025, after the contract testing laboratory ((b) (4)) reported preliminary failing results for the USP Container Closure Integrity Test ((b) (4)) on Carnitine (L) 500 mg/mL Injectable (30 mL), stability lot 613292, at the (b) (4) month time point. The NC record identifies the event as an OOS, but no documented investigation, product-impact assessment, or corrective and preventive action has been initiated or completed, and no evaluation of other lots or container-closure components has been performed. All sterile drug products manufactured by your firm use this same

container-closure system, yet no assessment has been conducted to determine whether other batches may be affected.

2. NC-002511 was initiated on 06/16/2025 in response to an OOS result of 1 CFU mold recovered from an active viable air sample collected in the ISO (b) (4) formulation area during routine environmental monitoring. The event was assigned a low priority, and no documentation was provided to show that the organism was identified or that an investigation or corrective actions were performed.

While you provided in-process documentation such as laboratory reports or preliminary assessments for some events, these materials have not been finalized or approved within your formal quality system.

C. NC-001943 was initiated on 04/16/2025, in response to a metal fragment found embedded in a stopper during filling of Ascorbic Acid Preserved 500 mg/mL (Lot 612166), BUD 11/25/2025. The stopper was identified as the apparent source of contamination, however no analytical confirmation, supplier investigation, or supplier complaint was initiated, and production resumed using stoppers from the same component lot. The investigation did not assess the potential impact on other batches and no corrective or preventive actions were implemented. This NC was initiated approximately five months after occurrence, and (b) (4) additional batches were made using stoppers from the affected lot.

D. NC-002773 was initiated on 09/10/2025, in response to an extrinsic particle observed during AQL inspection of Glutathione Preservative-Free 200 mg/mL (Lot 615148) BUD 09/03/2026. The lot had previously passed 100% visual inspection. Your firm conducted a 200% reinspection of (b) (4) vials followed by an AQL Type (b) (4) re-inspection, which passed. The investigation attributed the cause to operator oversight, however, the extrinsic particle was not identified or characterized, and the investigation did not evaluate the adequacy of your visual inspection process. The lot was released with the conclusion of no impact to product quality or patient

safety.

E. NC-002814 was initiated on 09/23/2025, after Magnesium Chloride 300 mg/mL Injection, 30 mL (Lot 614920), BUD 08/26/2026, failed secondary and tertiary visual-inspection stages due to excessive "check" and "bump-check" defects (total reject rates 15–18 %, limits (b) (4) %). A tightened AQL inspection later met acceptance criteria, and the lot was released. The investigation attributed the failures to defective glass vial lot (b) (4) but continued to use this lot in (b) (4) additional batches after this event occurred. No assessment was performed to evaluate the potential impact to upstream/downstream batches manufactured with this glass component lot.

F. NC-002483 was initiated on 06/06/2025, in response to an environmental monitoring (EM) out-of-specification (OOS) result during (b) (4) of Testosterone Cypionate 200 mg/mL (Lot 614479). A TNTC CFU recovery of *Paenibacillus* sp. was detected on the right glove of your Sterile Manufacturing Operator. Your investigation stated that video review showed repeated contact with non-sterile surfaces and insufficient sanitization with (b) (4) . According to your investigation, this operator had at least five personnel monitoring excursions within the past 12 months. The lot was released without additional in process or product testing, without assessing the source or potential impact of the contamination, and no CAPA was generated in response to this event.

G. NC-001629 was initiated on 09/19/2024 in response to one action-level excursion for a sterile manufacturing operator during the (b) (4) operation for Vitamin B Complex, lot number 610814. The recovery (1 CFU) appeared on sample ID (b) (4) ((b) (4) fingertips) when exiting ISO (b) (4) hood (b) (4) located in Room (b) (4). The action limit for personnel monitoring fingertip samples in an ISO- (b) (4) space is (b) (4) No adequate investigation was conducted to evaluate the potential root causes behind the OOS excursion. The investigation stated that this has been observed in past occasions and that *"it's possible that an item touched by the operator (prior to plating) was not thoroughly wiped with* (b) (4) *or that some items/materials may have been touched*

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by gloved hands which were not using freshly donned gloves, or gloves that had not been first disinfected by (b) (4) *or gloved hands that touched multiple ISO* (b) (4) *items just prior to entry into the BSC".* The root cause was identified as cleanroom behaviors. The lot was released without an assessment of the source of the contamination or an evaluation of the historical excursions reported for the operator within the past 12 months. Additionally, no corrective or preventive actions were implemented.

This is a repeat observation.

OBSERVATION 4

Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions

Specifically,

Per the firm's procedure B-SOP-STR-0004, titled "*Cleaning and Disinfection of the Cleanroom*", Revision 017, effective date 10/05/2025, Section 6.7.4, following HD injectable formulation in Room (b) (4), the room (b) (4) and clean HD substances prior to resuming the subsequent operations as stated below:

- *"If injectable formulation lots consisting of different actives are scheduled to be formulated consecutively (ex: Testosterone Cypionate and Estradiol Cypionate),* (b) (4) *cleaning shall be completed prior to the formulation of different active sterile injectable lots.*

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- *If injectable formulation lots consisting of the same active are scheduled to be formulated consecutively (ex: Testosterone Cypionate and Testosterone Enanthate),* (b) (4) *cleaning shall be completed"*

Upon review of the cleaning records for Room (b) (4) (HD Fill-Finish Room (b) (4)), the following was observed:

1. On (b) (4), Testosterone Cypionate IN GSO (5 ML), Lot 614031, was formulated in Room (b) (4), followed by the formulation of Nandrolone Decanoate IN GSO (5 ML), Lot 613969. A (b) (4) cleaning was not performed between the two formulations as required by the firm's cleaning procedure. Both lots were released to the US market.
2. On (b) (4), Nandrolone Decanoate IN GSO (5 ML), Lot 614442, was formulated in Room (b) (4), followed by the formulation of Testosterone Cypionate IN GSO (5 ML), Lot 614485, on (b) (4). No documentation was found for the (b) (4) cleaning (or any cleaning record) between the two batches. Both lots were released to the US market.
3. On (b) (4), Testosterone Cypionate IN GSO (5 ML), Lot 614485, was formulated in Room (b) (4), followed by the formulation of Testosterone Cypionate IN GSO (5 ML), Lot 614479, on (b) (4). No documentation was found for the (b) (4) cleaning (or any cleaning record) between the two batches. Both lots were released to the US market.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

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The firm's written procedure, B-SOP-STR-0002, titled " *Sterile Hazardous Drug Area Requirements*," Revision 002, effective date 03/28/2025, is not always followed. As specified in Section 6.1, "*Engineering controls are required to protect the preparation from cross contamination and microbial contamination during all phases of the compounding process*". The procedure specifies three categories of engineering controls for hazardous (HD) containment: C-PEC (Containment Primary Engineering Control), C-SEC (Containment Secondary Engineering Control which is the room in which the C-PEC is placed), and supplemental controls (which are adjunct controls to offer additional levels of protection, such as closed-system drug-transfer devices (CSTD) should be used when appropriate). However, during the walkthrough in the manufacturing areas on 11/03/2025, the followings were observed:

1. Non-sterile Hazardous (HD) drug mixing and formulation is performed using Mixer (EQ ID: (b) (4)) that is located outside the Containment Primary Engineering Control (C-PEC) in Room (b) (4) (HD Fill-Finish Room (b) (4)).
2. The remaining phases of the compounding of HD drug products occur in rooms that host (b) (4) and filling operations for both HD and non-HD drug products, including Sterile (b) (4) in Room (b) (4) , and Sterile (b) (4) and Filling in Room (b) (4) . Both Rooms (b) (4) and (b) (4) operate under positive pressure and are not equipped with external exhaust vents through which air is exhausted directly to the outside of the building without recirculation.
3. Per section 6.2 of the firm's procedure B-SOP-STR-0002: "*HD drug products shall only be brought out of the Formulation Room in sealed containers such as IV bags"*. However, Bulk HD drug products formulated in Room (b) (4) (HD Fill-Finish Room (b) (4)), are transferred from Room (b) (4) to (b) (4) Room (b) (4) for (b) (4) in (b) (4) (bulk vessel) that is only covered from the top with (b) (4) and placed on a (b) (4) . Additionally, according to the batch record instructions, the (b) (4) cover of the (b) (4) must (b) (4) is transferred from the HD Room (b) (4) to the non-HD (b) (4) Room (b) (4) for (b) (4) .
4. Per the firm's procedure B-SOP-STR-0003, titled "Aseptic Gowning and Gloving", Revision 006, effective date 08/13/2025, for HD sterile compounding manipulations during mixing and

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Main Place 1201 Main Street Ste 7200 Dallas, TX 75202 (214)253-5200	11/03-07/25, 11/10/2025, 11/12-14/2025 FEI NUMBER 3011887629
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Pejman Jonathan Abrarpour, Chief Operating Officer	
FIRM NAME Empower Clinic Services, L.L.C. dba Empower Pharma	STREET ADDRESS 5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77041	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

initial (b) (4) activities, manufacturing operators must don a (b) (4) respirator and a (b) (4) gown. However, a (b) (4) respirator and a (b) (4) gown are only worn during Formulation (Room (b) (4)) but not during (b) (4) (Room (b) (4)).

OBSERVATION 6

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

Your firm failed to establish validated hold-times for sterilized bulk drug products to mitigate the risk of contamination of finished drug products.

For example,

The variability in the number of days the drug product is held between the first (b) (4) and the second (b) (4) and filling steps of the production process is described in the following table:

Drug product	Lot#	Formulation End Date	A (b) (4) Date	B (b) (4) & Filling Date	Time between End of activity A and beginning of activity B
Testosterone Cypionate 200MG/ML (5ML)	614993	(b) (4)			6 days
Testosterone Cypionate 200MG/ML (30ML)	615154				2.5 days

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Drug product	Lot#	Formulation End Date	A (b) (4) Date	B (b) (4) & Filling Date	Time between End of activity A and beginning of activity B
Semaglutide / Cyanocobalamin 5/0.5MG/ML (2.5 ML)	614140	(b) (4)			1.5 day
	613985				3 days, 11 hours
	613992				11 hours
	614220				2 days, 5 hours
Pyridoxine HCL (B6) 100MG/ML (30 ML)	615223				5.5 days
	615126				8 days, 15 hours
	611676				3 days, 18 hours
LIPO-B (Methionine/ Choline Chloride/ Cyanocobalamin) 25/50/1MG/ML (30 ML)	614683				4 days, 9 hours
	614478				21 hours

Drug products filled in IV bags after the first (b) (4) are stored on the shelves in the ISO (b)(Room.

OBSERVATION 7

HEPA filters are not sealed around the perimeter.

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Specifically,

The HEPA filters in the ISO (b) (4) Formulation Room (Room (b) (4)) and ISO (b) (4) and Filling Room (Room (b) (4)), where sterile compounding occur, were not properly sealed. The perimeter of the HEPA filter did not fully overlap with the ceiling. The filters were not adequately sealed and had gaps. A jagged and uneven grating was also observed along the seams of one HEPA filter in Room (b) (4). For example, the work order (No. 42980) indicates that maintenance work (re-caulk) was performed along the seams of HEPA filters in Room (b) (4) on 07/05/2024. The last two requalification records for the HEPA filters (conducted in July 2025 and December 2024) documented passing results for all HEPA filters in Room (b) (4), even though grating around the HEPA filter was noted during the inspection walkthrough on 11/03/2025. During the inspection, we observed the following production activities:

- Formulation of Ascorbic Acid Preserved 200 MG/ML (30 ML) Injectable Vials, Lot 615360, was performed in Room (b) (4) on 11/05/2025.
- Room (b) (4) contains (b) (4) ISO (b) (4) Laminar Air Flow Hoods used in the second (b) (4) and the aseptic filling of Ascorbic Acid Preserved 200 MG/ML (30 ML) Injectable Vials, Lot 615360, on 11/06/2025.

OBSERVATION 8

Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. Your firm also failed to validate and establish the reliability of your component supplier's test analyses at appropriate intervals.

Specifically,

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One Main Place 1201 Main Street Ste 7200 Dallas, TX 75202 (214)253-5200	11/03-07/25, 11/10/2025, 11/12-14/2025 FEI NUMBER 3011887629
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
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A. You failed to conduct an identity test on each shipment of each lot of components used in the production of your drug products, including the Sterile Water for Injection (WFI) used in the formulation of your drug products.

B. Certificates of Analysis from the suppliers of the Ready-to-Use sterile single-use critical materials for drug product formulation, (b) (4) and filling bag are accepted without verifying test results for sterility initially and periodically.

C. Your firm does not audit any of your ready to use sterile single use critical material suppliers.

OBSERVATION 9

The written stability program for drug products does not include reliable, meaningful and specific test methods.

Specifically,

A. The methods used during stability testing have not been demonstrated to be stability indicating. Although limited stress studies were performed by your contract laboratories, they did not include sufficient evaluation of degradation products or impurities. In addition, you do not review the method validation data to confirm that these methods are stability indicating before approving and using them for stability testing. As a result, you do not ensure that the stability methods can detect and quantify all potential impurities and degradation products that may form over time.

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B. Your written stability program for sterile drug products does not ensure that at least one batch of each drug product manufactured is included in the ongoing stability program each year. Several currently marketed products are not represented in any active stability studies, and no justification has been documented for their exclusion.

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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."