DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/17/2025-3/28/2025* FEI NUMBER 3016710931

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lisa G. Hawkins, Senior Vice President of Quality

FIRM NAME	STREET ADDRESS
Wells Pharma of Houston LLC	9265 Kirby Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77054-2520	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) On March 17, 2025, your aseptic pharmacy technicians were observed holding the filtered drug product filled in a sterile opened bag in a (b) (4) position that blocked first pass air in the (b) (4) ISO 5 Laminar Air Flow Hood (LAFH) during the preparation of the following batches:

- **i.** Fentanyl (2 mcg/ml) with 0.2% Ropivacaine HCL in 0.9% Sodium Chloride 100ml Bag, Lot: (b) (4), BUD: 07/15/2025; and,
- **ii.** Midazolam (1mg/ml) in 0.9% sodium chloride 50ml bag 1mg/ml, Lot: (b) (4), BUD: 07/15/2025.

Your aseptic pharmacy technicians were also observed removing drug product from the bag into a syringe used for the entire batching process in a (b) (4) orientation that blocked the critical areas from receiving first pass air flow from the (b) (4) ISO 5 LAFH. This practice was also observed on 03/18/2025 when aseptic pharmacy technicians were filling drug product intended to be sterile in syringes, i.e. Ketamine (10 MG/ML) in 0.9% Sodium Chloride 5ml in 10ml syringe, Lot: (b) (4), BUD: 07/16/2025. The syringe used to remove air was held in a manner that compromised first pass air.

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	Jazmine N Brown, Investigator X Jazmine N Brown Investigator Signed By: JAZMINE N. BROWN -S Date Signed: 03-28-2025 18:46:25	3/28/2025

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B) Your firm's operator media fill is deficient due to only aseptically filling (b) (4) container closure units consisting of (b) (4) bags, (b) (4) monoject syringes, and (b) (4) BD syringes, to fully qualify their sterile operators, under procedure SOP HOU-QA-051, *Aseptic Technique Operator Qualification*. For example, your firm's initial qualification includes performing aseptic filling of (b) (4) units in (b) (4) form and upon re-qualification only performing (b) (4) of the (b) (4) units (b) (4). However, your firm prepares different fill volumes using a larger batch size and processing time that is not represented in the aseptic technician's qualification or requalification the following:

1. 1ml to 50ml syringes are used on a maximum batch size of (b) (4) units filled by one operator, i.e. Ketamine 50mg (50mg/mL) repackaged 1ml in a 3ml Syringe, Lot: (b) (4), BUD: 06/12/2025, with a batch yield of (b) (4) units produced on 02/12/2025.

2. 50ml to 250ml bags are used on a maximum batch size of (b) (4) units filled by one operator, i.e. Fentanyl (10 mcg/mL) in 0.9% Sodium Chloride 100 mL filled bag, Lot: (b) (4), BUD: 05/02/2025, with a batch yield of (b) (4) units produced on 01/02/2025.

C) Additionally, your media fill program is deficient in that media fills do not include all equipment used in the preparation of filling drug products intended to be sterile. For instance, there is no media fill conducted for Ropivacaine 0.2% in 0.9% Sodium Chloride sterile drug product that allows (b) (4) or (b) (4) to be filled into a batch size of approximately (b) (4) (b) (4) pumps and there is no inclusion of the (b) (4) unit that is used during the preparation of the Cefazolin drug products intended to be sterile dispensed in syringes and bags.

D) Your aseptic process validation media fill fails to ensure that all simulated aseptic manufacturing operations are represented to include worst-case scenario (number of final container closure/

batch size/ volume/ time/ and interventions) in order to assess the potential for batch contamination. For the filling operation, your firm splits this batch size process into a maximum of (b) (4) ISO 5 LAFHs to accomplish the total number of units dispensed for a syringe or bag media fill, i.e. up to (b) (4) operators can perform a process validation for bag units in (b) (4) different hoods and up to (b) (4) operators can perform a process validation for syringe units in (b) (4) different hoods. This process does not simulate the actual drug production process that occurs when aseptically filling bags and syringes for drug product intended to be sterile in the ISO 5 LAFH using one operator.

E) Your smoke studies, performed on November 25, 2024, were deficient in visualizing a unidirectional airflow pattern while performing dynamic movements that are normally performed during aseptic operations in the ISO 5 LAFHs. Your firm's validation specialist deemed all smoke studies performed as acceptable and ruled that the airflow was unidirectional in nature and uniform in flow patterns.

F) Your operators were observed utilizing sterile goggles that are not designed to prevent microbial contamination. The sterile goggles have holes on the top and bottom allowing for potential particulates from the operator's skin to have egress when working in the (b) (4) ISO 5 LAFH. On 3/17/2025, operators were observed leaning into the ISO 5 LAFH while actively producing sterile drug product in ISO 5 LAFH #61, Midazolam (1mg/ml) in 0.9% sodium chloride 50ml bag 1mg/ml, Lot: (b) (4), BUD: 07/15/2025.

OBSERVATION 2

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Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A) Your firm's ISO 5 LAFH environmental monitoring specifications are inadequate for viable surface samples (alert (b) (4) CFU and action (b) (4) CFU) as governed by your firm's procedure SOP HOU-QC-014, Environmental Monitoring for ISO 5, ISO 7, and ISO 8 Classified Environments, effective date: 09Feb24.

B) Your firm's non-viable particle (NVP) count monitoring is inadequate as it is not representative of the entire batch instead you conduct NVP at the (b) (4) of a production run therefore missing critical data from the (b) (4) of the batch process. There is no assurance that one required non-viable particulate sample is representative of the entire (b) (4) of continuous manufacturing process for sterile drug processing.

C) Your firm's procedure SOP HOU-QC-014 is silent on instructing when to perform the active viable sample during aseptic processing of a batch. According to your quality control Environmental Monitoring technician, all active viable samples are performed at the (b) (4) of a batch process. There is no assurance that one required active viable sample is representative of the entire (b) (4) of continuous manufacturing process for the production of sterile drug products.

D) Your firm's aseptic pharmacy technician was observed only tapping their fingertips onto the (b) (4) environmental monitoring plate at the end of the production process of Ephedrine Sulfate, Lot: (b) (4) on 03/27/2025. Your firm fails to ensure aseptic pharmacy technicians (b) (4) their fingertips while (b) (4) onto the (b) (4) plate, as outlined in procedure, SOP HOU-QC-004, *Handling, Storage, Use and Shipping of Microbiological Media,* effective date: 09Aug21.

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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 specifications whether or not the batch has been already distributed.

Specifically,

A) Your firm failed to investigate and follow up on an adverse event, PC-HOU-2024-008, initiated for a patient complaint. Your firm failed to follow your adverse event procedures, SOP HOU-QA-041, *Pharmacovigilance Procedure for Adverse Events*, effective date 12Nov21, to ensure patient complaints are appropriately investigated, followed up on, and reported in a timely manner.

B) Your firm failed to adequately incubate environmental monitoring plates for (b) (4) batches of drug products. Deviation, DEV-HOU-2025-002, was initiated due to the failure of incubating environmental monitoring plates for the appropriate time and temperature per SOP HOU-QC-014, *Environmental Monitoring for ISO 5, ISO 7, and ISO 8 Classified Environments*, effective date: 09Feb24. The environmental monitoring plates were not removed from the initial incubation environment at (b) (4) after (b) (4) of incubation in order to perform a plate reading. The plates were transferred into the (b) (4) incubator (b) (4) after the minimum required hours inside of the initial environment. Your firm then allowed the plates to incubate for an additional (b) (4) inside the second incubation environment (b) (4). Your firm's quality stated that no growth was observed after completing the entire incubation cycle when a reading was performed on 06Jan25 to facilitate the release of the products. For example, sample testing conducted on (b) (4) drug product lots intended to be sterile between December 17, 2024, through December 31, 2025 were inadequately incubated. Gowning requalification samples taken for aseptic pharmacy technicians on December 05, 2024, were also not appropriately incubated. Your firm determined that the root cause due to being short staffed and all associated batches were approved for release into commercial distribution since no growth were observed on the plates on 06Jan2025.

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OBSERVATION 4

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

Specifically,

A) Your firm's visual inspection process governed by SOP HOU-QC-006, *Finished Sterile Product Visual Inspection*, effective date 03Jul24, is deficient in that:

1. Your firm's procedure does not require Quality Assurance approval prior to initiating a second 100% visual inspection after an Acceptable Quality Limit (AQL) has been performed from the initial 100% failed visual inspection and fails to include a (b) (4) AQL after the second 100% visual inspection, if performed.

2. Your firm's visual inspection process fails to categorize defects as critical, major, or minor with acceptance and rejection rates within the categories when visually inspecting bags, syringes, and vial units.

3. Your firm's visual inspection process is deficient in that it does not require identification of particulates found during the visual inspection process in order to implement adequate corrective and preventative actions in your manufacturing process.

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B) Your firm's visual inspection training program governed by SOP HOU-QA-006, *Visual Inspection Qualification Program*, effective date 23Mar21, is deficient:

1. Failure to identify units during the initial 100% visual inspection process does not trigger a retraining of your visual inspection technicians after additional defects were found during the (b) (4) or during AQL visual inspection process to ensure the maintenance of your firm's ability to detect defects in your sterile drug product.

2. Your firm's visual inspection program lacks the requirement of a qualified visual inspection sample defect kit for syringes, bags, vials used for solid API, and the (b) (4) pumps for liquid solutions. Additionally, your firm does not have documented training to challenge vials or (b) (4) pumps used to hold drug product intended to be sterile. Additionally, the (b) (4) pumps are not removed from the (b) (4) container shells during 100% visual inspection.

C) Your firm's quality unit lacks the responsibility to exercise control over documents that are either pending changes or in-process, obsolete procedures, or forms, pending investigations, and other quality records, in a manner that would ensure that they stay in a state of control. On 03/19/2025, your firm had uncontrolled quality documents hidden inside the sleeve of the (b) (4) logbook inside your microbiology lab. Additionally, on 03/25/2025, your firm was unable to find an investigation, HOU-2025-INV-010, initiated this year to produce during the inspection.

OBSERVATION 5

Strict control is not exercised over labeling issued for use in drug product labeling operations.

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Specifically,

Product labels for drug product waiting to be labeled or visually inspected are left in the labeling area with the batch records and issued labels over a span of several days until it is moved onto the next part of the process. Your firm allows the labels and the batch records to remain in plain sight, on top of the drug product bins, or unlocked cabinets. Additionally, on March 24, 2025, the door to the labeling room was not locked. Labeling technicians left the labeling room for the day and exited the room. The labeling room houses all of the spools of labels which were unlocked, allowing access by anyone, until the employees come and access the labeling room the next day. Furthermore, your firm initiated 4 deviations that involved inadvertently misplacing, losing, or having printing errors on product labels. Your firm has failed to implement corrective and preventative actions that will ensure there is sufficient label control.

OBSERVATION 6

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

Specifically, your firm's Disinfectant Efficacy Study Protocol for Wells Pharma of Houston, performed and provided by a third-party vendor, is silent on describing the following to ensure dwell times are adequately established:

i. (b) (4) types used in study was not descriptive to ensure all components used in daily production was included. The (b) (4) failed to further identify the composition of material for supply bins, door type (b) (4) and (b) (4) and the plastic and metal components of the lights. Bins and covers composed of (b) (4) are utilized during batch production is not included in this study. (b) (4) that is along the ISO 5 LAFHs are also not included in this study.

ii. The application of the cleaning agents were not applied in the same manner as that used during the normal cleaning process.

iii. Ensuring that spore forming organisms are mitigated using a longer dwell time when performing sporicidal cleaning for aseptic drug manufacturing.

OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

A) Your firm failed to perform protocol driven equipment qualification studies for the (b) (4) , used for sterilizing goggles worn in the clean room. Sterilizing cycles are not qualified for personal protection equipment, goggles worn in the cleanroom. Additionally, your firm failed to place the biological indicators in one of the (b) (4) being sterilized when setting up an (b) (4) run as instructed by your firm's procedure, SOP HOU EQ-021, *Use, Care, and Maintenance of the* (b) (4) , effective date 27Aug21.

B) During the walkthrough performed on 03/17/2025, cracked plexiglass siding with an appearance of a yellowish brown and black discoloration was observed around the metal brackets used to hold the (b) (4) bar in place on (b) (4) plexiglass panels affecting (b) (4) ISO 5 LAFHs. Your firm's Pharmacist In Charge was not aware of the cracked plexiglass paneling and could not identify the discoloration under the bracket.

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C) Your firm uses (b) (4) totes to transfer materials used in production from non-classified environments into the ISO 7 cleanroom suite, which are further staged in the ISO 7 cleanroom and adjacent to the ISO 5 LAFHs. These totes appear to have ridged bottoms and handles that are difficult to clean. Your firm does not ensure that there are totes that only remain inside the ISO 7 cleanroom suite to minimize the introduction of microbial contamination.

D) Your firm's environmental monitoring procedures are silent on performing sampling of the difficult to clean areas in order to monitor contamination brought into the cleanroom. These areas of concern can harbor microorganisms that could contaminate drug product purported to be sterile.

OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the following information is not found on your drug product labels:

a) The statement "This is a compounded drug";

Examples of your drug product labels that do not contain this information, include but are not limited to:

- Fentanyl 1000 mcg/100 mL (10 mcg per mL) Injectable Solution in 0.9% Sodium Chloride

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- Phenylephrine 1000 mcg/10 mL (100 mcg/ mL) Injectable Solution in 0.9% Sodium Chloride
- Ketamine 50 mg/ 5 mL (10 mg per mL) Injectable Solution in 0.9% Sodium Chloride
- Naloxone 2 mg/2 mL (1 mg per mL) Oral Solution in 2 mL Syringe

OBSERVATION 9

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the following products were compounded and not identified on your report dated June 10, 2024, and December 16, 2024.

June 2024 Product Report:

·Norepinephrine 8 mg added to 250 mL 0.9% Sodium Chloride (Injection for Intravenous Use Only)

·Vancomycin 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g, 2 g, or 2.5 g added to 250 mL of 0.9% Sodium Chloride (Injection For Intravenous Use Only)

December 2024 Product Report:

·Fentanyl 500 mcg (2 mcg/mL) and Ropivacaine HCl 250 mg (0.1%) added to 250 mL 0.9% Sodium Chloride Injection (For Epidural Use Only)

·Fentanyl 50 mcg/mL (2,500 mcg Total Dose) 50mL IV Bag (Injection for Intravenous Use Only)

·Ketamine 50 mg per 5 mL (10mg/mL) Syringe

·Norepinephrine 8 mg added to 250 mL 0.9% Sodium Chloride (Injection for Intravenous Use Only)

·Phenylephrine HCl 1 mg per 10 mL (100 mcg/mL) Syringe

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·Succinylcholine Cl 100 mg per 5 mL (20 mg/mL) Syringe
·Vancomycin 750 mg, 1 g, 1.25 g, 1.5 g, 1.75 g, 2 g, or 2.5 g added to 250 mL of 0.9% Sodium Chloride (Injection For Intravenous Use Only)

***DATES OF INSPECTION**

3/17/2025(Mon), 3/18/2025(Tue), 3/19/2025(Wed), 3/20/2025(Thu), 3/21/2025(Fri), 3/24/2025(Mon), 3/25/2025(Tue), 3/27/2025(Thu), 3/28/2025(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."