

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 3/17/2026-4/13/2026*
	FEI NUMBER 3016710931

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew C. Corbin, President & CFO

FIRM NAME Wells Pharma of Houston LLC	STREET ADDRESS 9265 Kirby Dr
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77054-2520	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 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's compounding technician was observed removing the bottle of sterile (b) (4) from the inside of the ISO 5 LAFH, to the outside within the ISO 7 Cleanroom to disinfect their sterile gloves and failing to re-disinfect the bottle of sterile (b) (4) prior to returning it to the ISO 5 LAFH. Your firm's procedure Aseptic Material Transfer from CHC Area into Classified Areas, HOU-OPS-017, Revision 5 fail to adequately define a method for the transfer of sterile (b) (4) bottles into and out of the ISO 5 LAFH.
- B. Your firm's compounding technicians were observed using hard to clean and disinfect pen within the ISO 7 Cleanroom to write within each production batch record that has the potential of being source of microorganism contamination transfer from the technician's sterile gloves into the ISO 5 LAFH.
- C. Your firm's dynamic ISO 5 LAFH smoke studies were found to be inadequate. Your firm's technician controlling the smoke wand failed to position the wand such that the smoke pattern provided adequate coverage to assess simulated aseptic production manipulations and interventions being performed by the aseptic processing technician impacting unidirectional laminar airflow within the ISO 5 LAFH.
- D. During review of your firm's ISO 5 LAFH dynamic smokes, your firm's technicians performing and recording the studies within your ISO 7 Cleanroom, failed to wear adequate gowning as required by the firm's written procedure. Recording technicians' facial hair and skin were

AMENDMENT 1

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exposed within proximity of the ISO 5 LAFH resulting in a potential of introducing microbiological contamination into the ISO 7 Cleanroom and ISO 5 LAFH.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm's quality unit failed to provide an adequate scientific rationale for changing your contract testing laboratory pH test method specification from (b) (4) and changed to a specification of (b) (4) with BUDs of 60 or 75 days. There have been approximately (b) (4) out of (b) (4) batches of CeFazolin lots compounded between September 2025 to April 2, 2026 been distributed. For example, your firm-initiated deviation, DEV-HOU-2025-068 dated 15-Sep-25 (Classification – (b) (4) documenting Out-of-Specification (OOS) investigation EMPM-HOU-2025-062 to assess the pH levels of Cefazolin 1g reconstituted in 10mL SWFI using a 10mL (b) (4) syringe, and Cefazolin 2g reconstituted in 20mL SWFI using a 30mL (b) (4) syringe. These three (3) batches included Lot #091125131102075 (BUD 11/14/2025), Lot #091125131102076 (BUD 11/14/2025), and Lot #091125132232081 (BUD 11/29/2025). Your firm's documented pH specification was (b) (4). All three different lots' pH results were reported as 6.1. Your firm's 2021 and 2024 stability reports document pH results of 6.1 after 30 days. Part of your firm's documented investigation and corrective actions, a retrospective study was performed resulting in a change in documented pH specification to (b) (4). Your firm's scientific rationale was found inadequate.

OBSERVATION 3

The written stability testing program is not followed.

Specifically, your firm's quality unit approved stability program for the finished drug, CeFazolin is inadequate. For example,

- A. Your firm's 4/12/2021 stability report for 3 different lots documented a pH specification of (b) (4)

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(b)(4) and CeFazolin assay specification of (b)(4) for CeFazolin 1 g in SWFI 10 mL, 10mL syringe, NDC 73702-131-10.

1. Your record reported pH results that exceeded the documented specification at 30 days (pH 6.3/6.2/6.2), and CeFazolin assay documented results as low as 89.1% at 60 days. Your firm's contract testing laboratory reported, "Physical and chemical data for Cefazolin has demonstrated that Cefazolin in the present formula and packaging did not meet client specification through 75 days at refrigerated storage conditions". Your firm's quality unit failed to provide a document containing written actions taken to correct the deficiencies reported by your approved contract testing laboratory. Your firm's quality unit provided no additional stability report in support of the finished drug products meeting the written product specification.
 2. Your firm's 4/21/2021 Stability Report for the drugs, CeFazolin 1 gm in SWFI 10 mL, 10 mL syringe, NDC 73702-131-10; CeFazolin 2 gm in SWFI 10 mL, 10 mL syringe, NDC 73702-132-10; and CeFazolin 2 gm in SWFI 20 mL, 30 mL syringe, NDC 73702-132-23 fail to support assigned 60- and 75-day BUDs assigned to finished products. Your firm's stability report reported pH results that exceeded the documented specification at 30 days (pH 6.3/6.2/6.2) and CeFazolin assay documented results as low as 89.1% at 60 days.
- B. In 2024, your firm performed a stability study for 3 different lots of CeFazolin 1g added to 0.9% Sodium Chloride 100 mL (1000 mg/bag) bags.
1. Your firm's quality unit failed to provide an adequate scientific rationale for the written specification for pH of (b)(4) with a CeFazolin assay specification of (b)(4). The firm's quality unit approved specification for Cefazolin drug products filled in syringes document a pH of (b)(4). Reported pH results for Cefazolin bag filled products exceed this specification within 30 days (pH results of 6.1). No other stability reports for CeFazolin 1g added to 0.9% Sodium Chloride 100 mL (1000 mg/bag) bags were provided.
 2. Your firm's quality unit approved stability reports for the finished drug products, Cefazolin 1 gm added to 0.9% Sodium Chloride 100 mL Bag, 73702-131-02; Cefazolin 2 gm added to 0.9% Sodium Chloride 100 mL Bag, NDC 73702-132-02; and Cefazolin 3

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gm added to 0.9% Sodium Chloride 100mL Bag, NDC 73702-133-02 failed to support 60- and 75-day BUDs assigned. Reported pH results for Cefazolin bag filled products exceeded the syringe filled written pH specification within 30 days (pH results of 6.1).

OBSERVATION 4

Drug products failing to meet established specifications and quality control criteria are not rejected.

Specifically, during a review of your firm's compounded and distributed finished drug products, I found your firm's quality unit released and distributed, Lot # 091625104652129, Expiry 1/16/2026 for Dextrose 50% (500MG/ML) Repackaged 50ML ^{(b) (4)} Syringe Injectable 500MG/ML, which underwent contract laboratory testing, using an incorrect USP monograph pH test method. The pH results were found to be within specification using the incorrect test method. Due to a delay and inadequacy of an investigation by your firm's quality unit into the pH failure of the two (2) different batches, Lot # 091625104652129 was released and distributed. The quality unit's investigation was not expanded to include a review of other finished drug products to assess the potential of contract testing laboratory test method not being accurate until this inspection's discussions with management.

OBSERVATION 5

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

Specifically, during a walk-through of your firm's Labeling Production Area, I found an unsecured black storage filing cabinet containing issued printed CeFazolin labels for production use. Your firm's pharmacist and quality unit reported the key location for the unsecure unlocked cabinet was unknown at the time of the site walk-through. The area supervisor reported that the labels were removed from the cabinet at the end of the shift and returned to the label printing cage. A review of your written procedures, Labeling Procedure, HOU-OPS-019, Revision 1; and Label Control, HOU-OPS-020, Revision 1 found the discussed process for label removal at shift end was not written within your firm's procedures. The firm's quality unit was unable to provide documentation of printed labels being removed from the unsecured black cabinet and being returned to the returned to the label printing cage.

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This is a repeat observation.

OBSERVATION 6

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

Specifically,

- A. Your firm's quality unit initiated CAPA HOU-2025-012 failed to adequately investigate and define corrections to secure and control finished product labeling and prevent mix-up within your firm's product labeling production area. For example, an unsecured cabinet containing CeFazolin labels was found in the labeling production area. Your firm's quality unit initiated CAPA-HOU-2026-008 after being made aware on March 17, 2026 during the labeling productions area walk-through.
- B. 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 3/17/2026, during a walk-through of your firm in-process and finished drug refrigeration area, I found your firm's quality unit failed to collect, review, and approve (b) (4) Temperature and Relative Humidity logs on in-process refrigerator, Location EQ-HOU-CSC-180. The records documented unit storage data ranging from 11/2025 to 02/2026. The data was recorded on obsolete forms, Cleaning, Disinfection, and Operations of Refrigerators, Freezers, and Incubators, FRM-HOU-QA-046-02, Revision 3. Your firm's quality unit currently approved form is Cleaning, Disinfection, and Operations of Refrigerators, Freezers, and Incubators, FRM-HOU-QA-046-02, Revision 5.
- C. Your firm's Quality unit failed to ensure your firm's labeling procedures, Labeling Procedure, HOU-OPS-019, Revision 1; and Label Control, HOU-OPS-020, Revision 1 adequately define your firm's label control and storage within the Labeling Production Area prior to approval and release.

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***DATES OF INSPECTION**

3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/31/2026(Tue),
4/01/2026(Wed), 4/02/2026(Thu), 4/07/2026(Tue), 4/08/2026(Wed), 4/13/2026(Mon)

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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."