DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/11/2026-5/19/2026*
	FEI NUMBER 3008425092

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeong-Ho Ryu, Plant Director

FIRM NAME	STREET ADDRESS
Samchundang Pharm Co., Ltd.	Hyangnam Pharmaceutical Industries Complex, 71 Jeyakgongdan2-Gil; Hyangnam-Eup
CITY, STATE, ZIP CODE, COUNTRY Hwaseong, Gyeonggi, 18622 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

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,

Your facility utilizes Filing Line (b) (4) or commercial manufacturing of (b) (4) products, including the following U.S. products: (b) (4)

A. Your airflow visualization (smoke) study for Filling Line (b) (4) (PQR-08-061, Revision 001), performed after the installation of (b) (4) is inadequate. The study did not evaluate line setup or all interventions representative of actual manufacturing operations. Interventions not evaluated included: trouble at the (b) (4) station, trouble at the bottle (b) (4) filling station, and aseptic connections. Notably, during aseptic filling of (b) (4) batch (b) (4) on Filling Line (b) (4) on May 12, 2026, the intervention "Trouble at the (b) (4) station" occurred 35 times.

   Additionally, review of smoke study videos that support PQR-08-061, Revision 001, revealed turbulent and non-unidirectional airflow in the Grade A areas, including above the (b) (4) The video angles also did not allow for adequate airflow visualization in the work area or at the HEPA filter face.

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	Khoa Nathan V Tran, Investigator Damaris Y Hernandez, Investigator	X Khoa Nathan V Tran Investigator Signed By: 2003026741 Date Signed: 05-19-2026 12:51:12	5/19/2026

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B. Your airflow visualization (smoke) study for Filling Line (b) (PQR-08-061, Revision 000), performed prior to the installation of (b) (4), during which (b) (4) interventions were performed, is inadequate. The study did not evaluate line setup or all interventions representative of actual manufacturing operations. Interventions not evaluated included: trouble at the (b) (4) station, trouble at the bottle (b) (4) filling station, and aseptic connections.

Additionally, review of smoke study videos that support PQR-08-061, Revision 000, revealed turbulent airflow in the Grade A areas, including above the (b) (4) The video angles also did not allow for adequate airflow visualization in the work area or at the HEPA filter face.

In smoke study video 60-2012-0025, your firm attributed turbulence to a 45 mm gap in the HEPA filter cover; however, this gap and six other HEPA filter gaps (up to 140 mm) in the Grade A areas were not evaluated during smoke studies. Smoke study PQR-08-061, Revision 001, performed after (b) (4) installation, showed turbulent air in the same areas.

C. The aseptic process simulations performed on Filling Line (b) (4) are deficient in that:

1. The complexity and duration of interventions that occur with each run (routine and non-routine, events including line stoppages, and equipment adjustments are not sufficiently representative of your commercial aseptic manufacturing. On May 12, 2026, we observed commercial filling activities on your (b) (4) Filling Line (b) and witnessed multiple stoppages with interventions that lasted from (b) (4) upwards to over (b) (4) However, the interventions performed during the simulations are performed significantly under (b) (4)

2. The number of units filled during the process simulation (b) (4) units) is not proportionate to the number of units filled during commercial manufacturing in which the largest quantity was (b) (4) units for (b) (4) (Batch #(b) (4) that was shipped to the US.

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3. The filling duration of the process simulation is not representative of normal commercial manufacturing. Your firm fills approximately (b) (4) units within (b) (4) during commercial manufacturing, while your simulation fills (b) (4) units within (b) (4) with (b) (4) only filling approximately (b) (4) units. Additionally, during the simulation, the filling is not performed continuously as in commercial manufacturing. There are pauses after the specified interventions are completed to prepare for the next set of interventions.

OBSERVATION 2

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

Specifically,

A. Your firm has no written procedure detailing how operators are to perform (b) (4) interventions on Filling Line (b) (4) During aseptic filling of (b) (4) batch (b) (4) on May 12, 2026, different operators were observed pe rming the same intervention, "Trouble at the (b) (4) station," in different manners over the sterile (b) (4) bowl. Some operators were observed blocking first air to the sterile (b) (4) while performing the intervention.

B. Your firm has no written procedure detailing how operators are to perform (b) (4) interventions on Filling Line (b) (4)

C. Poor aseptic practices were observed in smoke study videos supporting study PQR-08-061, Revision 000, which captured operations on Filling Line (b) prior to the installation of (b) (4) during which (b) (4) (b) (4) interventions were performed. Your f (4) m does not video record aseptic filling operations; therefore, smoke study videos were used to assess aseptic behavior during commercial production using (b) (4) interventions. Only qualified operators in proper aseptic behavior participate in smoke studies. The following was observed:

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1. An operator was observed bringing forceps out of the Grade A barrier system into the Grade B area and then back into the Grade A area to perform the intervention over sterile open bottles.

2. An operator unnecessarily (b) (4) of the barrier (b) (4) to insert and remove a settle plate through the (b) (4) of the barrier (b) (4), introducing unnecessary airflow disruption to the Grade A area above the (b) (4) Your confirmed this was normal practice during commercial production using (b) (4) interventions.

D. Your firm has no written procedure defining what action is required when (b) (4) pass over sterile (b) (4) container and closure components.

E. Your procedure for assembly of Filling Line (b) (4) SOP MS-203) is inadequate. The procedure does not specify the work area in which assembly is t be performed. During setup for (b) (4) batch (b) (4) on May 13, 2026, operators were observed working above the (b) (4), an area where smoke study videos revealed turbulent and non-unidirectional airflow. Additionally, connection tubing was observed hanging beneath the barrier (b) (4) during assembly and contacting a knee-height table located in the Grade A (b) (4) LAF. The connection tubing connects the (b) (4) tank to the (b) (4) (b) (4) Your firm confirmed that the hanging tubing is normal practice and that the knee-height table is not sterilized. The sterilization wrap on some tubing ends was observed to have detached, leaving the tubing end exposed.

Notably, a particle count excursion at Filling Station (b) (4) was documented during equipment setup for (b) (4) (b) (4) Batch (b) (4) on June 17, 2025 (DOS202506006), where the particle count reached (b) (4) ea/m³, exceeding the limit of (b) (4) ea/m³. The root cause was attributed to the operator inadvertently generating particles during assembly and setup of filling components.

OBSERVATION 3

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Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, the design of Filling Line (b) (4) is inadequate to maintain first air contact with sterile containers during filling operations. For example:

A. The (b) (4) is equipped with a cover that blocks first air from contacting sterile open bottles inside the (b) (4) Review of smoke study Video 60-2013-0076 confirmed that the (b) (4) cover blocks first air to sterile open bottles.

B. The (b) (4) loading port is a (b) (4) chute that blocks first air from contacting sterile bottles as the bottles are dispensed into the (b) (4) During aseptic filling of (b) (4) batch (b) (4) on May 12, 2026, sterile bottles were observed backing up and piling on top of each other in the loading port, requiring operators to open and close the loading port valve to facilitate bottle movement. Additionally, there is no smoke study evaluating airflow when bottles are backed up into the loading port.

C. The (b) (4) which (b) (4) onto the conveyor track leading to the (b) (4) is angled in a manner that blocks first air as sterile bottles exit the (b) (4)

OBSERVATION 4

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically, your complaint investigation process is inadequate. Retain samples are not tested for sterility when microbial contamination is identified in complaint samples. Instead, retain samples are only visually inspected, and sterility testing is not performed unless foreign matter is visually observed. For example, you received six complaints for foreign substances, each confirmed by external laboratory analysis to contain microorganisms, across multiple (b) (4) drug product batches. In each case, sterility testing of the retain sample was not

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performed:

- PR 28677: *Cladosporium sp*. identified in (b) (4) Batch (b) (4)
- PR 102663: *Penicillium sp*. identified in (b) (4) Batch (b) (4)
- PR 264883: *Penicillium sp.* identified in (b) (4) Batch (b) (4)
- PR 206711: *Cladosporium sp*. identified in (b) (4) Batch (b) (4)
- PR 342363: *Cyphellophora sp*. identified in (b) (4) Batch (b) (4)
- PR 350141: *Alternaria sp*. identified in (b) (4) Batch (b) (4)

Additionally, environmental monitoring reviews conducted as part of these investigations were limited to EM data captured in the complaint batch's manufacturing record. No broader facility-wide EM review was performed to determine whether the identified isolates were present elsewhere in the facility.

OBSERVATION 5

Equipment and utensils are not sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. You do not sterilize the (b) (4) on Filling Line (b) (4) between batches. The (b) (4) (b) (4) on Filling Line (b) (4) make direct contact with sterile bottles. The sterile bottles pass through this equipment before progressi(4) to the (b) (4)

B. You do not sterilize (b) (4) on Filling Line (b) (4) between batches. During aseptic filling of (b) (4) batch (b) (4) on May 12, 2026, operators were o(4) erved blocking first air while performing interventions with (b) (4) over the bowl containing sterile (b) (4)

OBSERVATION 6

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Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, your visual inspector qualification program (PQP-12-157), is inadequate. The qualification uses challenge particles consisting of (b) (4) foreign matter; however, the size of these particles is not characterized or measured. There is no supporting document justifying the size of the particles currently used in the qualification. Additionally, the challenge particles are prepared at the time of each qualification and requalification. Since the size of the generated challenge particles is not measured, there is no assurance that all operators are evaluated equally or that operators are qualified to detect particles down to a specific size.

OBSERVATION 7

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

Specifically, your environmental monitoring program for Filling Line (b) (4) lacks adequate justification for sampling location selection. For example:

A. The (b) (4) bowl compartment of Filling Line (b) (4) is not monitored for non-viable particles, active air, or settle plates. There were frequent intervention observed in this compartment during aseptic filling of (b) (4) Batch (b) (4) on May 12, 2026, with a cumulative intervention duration of approximately (b) (4) (b) (4) The total filling time for this batch was approximately (b) (4) Your EM justification document (QS-801-A1) does not provide rationale for the exclusion of these sampling points in the (b) (4) bowl compartment.

B. The conveyor track compartment located immediately upstream of the (b) (4) on Filling Lin (b) (4) is not monitored for non-viable particles. Your airflow visualization (smoke) study (PQR-08-061, Re(4) sion 001) videos showed turbulent and non-unidirectional airflow within this compartment. Your EM

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justification document (QS-801-A1) does not provide rationale for the exclusion of this sampling point in the conveyor track compartment.

OBSERVATION 8

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your investigation for deviation DOS202506006 is inadequate. During equipment setup for (b) (4) (b) (4) Batch (b) (4) on June 17, 2025, a particle count excursion at Filling Station (b) (4) reached (b) (4) ea/m³, exceeding the limit of (b) (4) ea/m³. The investigation identified the root cause as the operator inadvertently generating particles during assembly and setup of filling components. However, the investigation does not identify the specific operator behavior or action that caused the excursion. The investigation also did not include any CAPA addressing the aseptic behavior that caused the excursion, nor did it include reevaluation or retraining of the operator responsible for the excursion.

*DATES OF INSPECTION

5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/18/2026(Mon), 5/19/2026(Tue)

X Damaris Y Hernandez
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