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	4/16/2026-4/24/2026*
	FEI NUMBER 3004886113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Minseok Kim, Plant Manager

FIRM NAME	STREET ADDRESS
Hanlim Pharm Co., Ltd.	2-27 Yeongmun-ro
CITY, STATE, ZIP CODE, COUNTRY Yonginsi Ceoin-gu, Gyeonggi-do, 17040 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED OTC 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 are not established and followed.

Poor aseptic practices were observed during aseptic filling of sterile (b) (4) products. This is a repeat observation from the October 2018 FDA Warning Letter.

1. During the aseptic filling of (b) (4) batch (b) (4) on April 16, 2026, the following was observed:

a. On the (b) (4) filling line, the operator stands inside the Grade A area continuously for (b) (4) The operator repeatedly reached over open tubes with their arms, torso, and head while (b) (4) Additionally, the aseptic gown of one of the operators performing this activity had stains on the chest and arm.

b. When (b) (4) the operator used their hand directly over open tubes in the (b) (4)

c. The operator extends their hands and arms over the (b) (4) surface while (b) (4) (b) (4) This area is not subsequently disinfected. When the (b) (4) (b) (4), the open end of the tubes contact the same (b) (4) surface the operator had reached over.

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	Justin A Boyd, Investigator Hung H Do, Investigator X Justin A Boyd Investigator Signed By: 2000358686 Date Signed: 04-24-2026 15:19:39	4/24/2026

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2. During the set-up for the aseptic filling of (b) (4) batch (b) (4) on April 22, 2026, the following was observed:

a. The hands, arms, and head of the operator were used over the open sterile (b) (4) during installation of the (b) (4)

b. During installation of the (b) (4) valve, the operator reached their hand and forearm over the open (b) (4) valve (b) (4) These are direct product contact parts.

c. The operator used their hand above open tubes while (b) (4)

3. During the set-up and aseptic filling of US market (b) (4) batch (b) (4) on April 21, 2026:

a. The operator used their hand directly above the (b) (4) while (b) (4). After the (b) (4) were installed, the operator leaned their head over the open tubing that had not yet been connected to the (b) (4) The hand of the operator was used over the open (b) (4) when the open tubing was (b) (4) connected to the open (b) (4)

b. The (b) (4) are not sterilized. During set up of the line, the barrier (b) (4) is (b) (4), exposing the inner surfaces of the (b) (4) to Grade B. The (b) (4) are not wiped with disinfectant before (b) (4) (b) (4) These (b) (4) were observed to be used over sterile components and surfaces. For example:

i. (b) (4) were used to pass a wipe over the open and unconnected product tubing.

ii. During interventions to remove stuck (b) (4) at the (b) (4) bowl the (b) (4) reached over the

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(b) (4) in the bowl. An operator reached across the bowl with the (b) (4) to pass a forceps to a different operator.

iii. During interventions near the capper to remove fallen bottles, the (b) (4) was used over bottles with (b) (4) that had not yet been capped.

iv. During addition of the bottles, the (b) (4) was used over the open bottles in the (b) (4) Additionally, the operator allowed the bottle bag to touch the inside of the (b) (4)

4. During the aseptic filling of US market (b) (4) batch (b) (4) on April 16, 2026:

a. The (b) (4) reached over sterile components during addition, including bottles, (b) (4) caps.

b. The (b) (4) reached over open bottles on the conveyor that were not subsequently removed.

c. During an intervention to remove a jammed (b) (4), the operator used the (b) (4) over the (b) (4) bowl and exposed (b) (4)

OBSERVATION 2

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

1. Equipment surfaces that contact sterile components are not sterilized. They are left in place between batches to be disinfected. For example:

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a. On the (b) (4) line the following equipment surfaces are not sterilized:

i. The (b) (4), which has (b) (4) surfaces that contacts the open end of the tubes.

ii. The tube supply chute, which has (b) (4) surfaces that contact the open end of the tubes.

iii. The (b) (4), which physically contacts the open end of every open tube.

iv. The (b) (4) pipe, which (b) (4) each open tube.

b. On the (b) (4) filling lines (b) (4) the following equipment surfaces are not sterilized:

i. The (b) (4) hat contact the open bottles.

ii. The (b) (4) on the (b) (4) equipment that are (b) (4)

iii. The (b) (4) bowl, track, and (b) (4) equipment that contact the sterile (b) (4)

iv. The (b) (4), bowl, track, and (b) (4) equipment that contact the sterile caps.

2. For the smoke studies used to evaluate airflow in the aseptic filling area:

a. The following operations were not evaluated in the (b) (4) line: assembly of the (b) (4) and (b) (4) valve in the (b) (4) LAF and subsequent installation on the line; installation of the (b) (4) (b) (4); the (b) (4) aseptic connections to connect the (b) (4) to the (b) (4); removal of

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covers from sterile equipment at the (b) (4) LAF and transfer to the filling line; and use of the (b) (4) LAF.

b. The following were not evaluated in the (b) (4) line (b) (4) : aseptic connection of the product transfer line; connection of the product tubing to (b) (4) ; and removal of covers from sterile equipment at the (b) (4) LAF and transfer to the filling line.

c. The study shows the (b) (4) disrupt the airflow over sterile components on line (b) (4) during interventions. For example: removal of jammed (b) (4) ; passing of the forceps at the (b) (4) bowl (b) (4) ; removal of jammed cap (b) (4) ; addition of bottles (b) (4) ; addition of (b) (4) ; and addition of caps (b) (4) .

d. During (b) (4) interventions on (b) (4) the airflow exits outwards horizontally and does not show that it can reach the critical surfaces. For example: at the (b) (4) ; at the capping station (b) (4) ; at the (b) (4) ; and at the (b) (4) area (b) (4) There are (b) (4) the RABS above the barrier (b) (4)

e. There appeared to be turbulence at the (b) (4)

f. For the (b) (4) line, smoke is generated and propelled out of a pipe in a downward direction. This did not demonstrate whether appropriate airflow was achieved when demonstrating interventions.

g. In the (b) (4) aseptic filling area there are (b) (4) for the Grade A area directly below and overlapping the Grade B HEPA supply. The (b) (4) lines similarly have (b) (4) above the RABS (b) (4) . There has been no evaluation of the Grade B areas to ensure appropriate airflow can be achieved.

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h. (b) (4) is used to generate the smoke. There has been no demonstration of whether this can produce neutrally buoyant smoke and the smoke appeared to quickly dissipate, preventing thorough evaluation of the air flow.

3. The type, frequency, and time of routine interventions using the (b) (4) have not been recorded in the batch records. Because of this, there was a lack of reliable data to determine the quantity and duration of interventions to simulate during media fills.

When these interventions were recorded on aseptic filling line (b) (4) on April 23, 2026, for US market batch (b) (4) of (b) (4)

a. There were 36 interventions at (b) (4) where the (b) (4) are used to remove stuck bottles at the capping machine. During previous media fills, interventions at this location have occurred a maximum of 8 times.

b. There were 18 interventions at (b) (4) to remove stuck (b) (4) During previous media fills, interventions at this location have occurred a maximum of 8 times.

4. The tubing connecting the (b) (4) to the (b) (4) on the (b) (4) line has been designed in small sections that require (b) (4) aseptic connections.

OBSERVATION 3

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

The environmental monitoring locations have not been chosen based on operations occurring in the area and the risk to the product. This is a repeat observation from the 2018 FDA Warning Letter. For example:

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1. For the (b) (4) line:

a. There is no daily air or surface monitoring in the area where operators (b) (4). The operator stands in the Grade A area continuously and open tubes are exposed in the area.

b. There is a non-viable particle counter in the (b) (4) area, but it is located approximately (b) (4) (b) (4) off of the ground. This is above the level of all open tubes and operator activities and it is located behind a (b) (4) partition separating it from the open tubes and operator activities.

c. Inside the (b) (4) barrier, surface monitoring locations do not include surfaces that contact the open end of the tubes like the tube chute, (b) (4)

2. For (b) (4) batch associated environmental monitoring on the (b) (4) line (b) (4) (b) (4)

a. There is no viable air monitoring in the area where open bottles are added to (b) (4), near the (b) (4) (b) (4), on the conveyor to the (b) (4) area, or at the (b) (4) area. Open bottles are continually present in this area.

b. There is no viable air monitoring in the area where the (b) (4) caps are added to (b) (4) and are present in the bowls.

c. There is no viable air monitoring or surface monitoring in the area where the (b) (4) caps are placed onto the bottles.

d. The non-viable particle counter closest to the (b) (4) on (b) (4) is located approximately (b) (4)

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above the level of the open bottles.

OBSERVATION 4

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

1. A sporicidal is not periodically used to disinfect all surfaces in the aseptic filling areas used to fill US market products. For example, no sporicidal is used on the following surfaces:

a. (b) (4) ceiling, (b) (4) panels inside the aseptic filling RABS.

b. Cleanroom (b) (4) adjacent to critical areas where bottles, (b) (4) caps are exposed during aseptic filling operations

2. The disinfectant efficacy reports for (b) (4) sporicidal did not evaluate (b) (4) surfaces. (b) (4) is used on the (b) (4) that contacts open, sterile tubes on the (b) (4) line, and for the (b) (4) between the (b) (4) on aseptic filling lines (b) (4)

3. During the cleaning of the (b) (4) line after (b) (4) batch (b) (4) on April 16, 2026, the operators did not work in a systematic manner from high to low and from more critical areas outward. This resulted in operators reaching over already disinfected surfaces. The operators did not perform line clearance, including removal of the (b) (4) or excess (b) (4) tubes, before starting the disinfection of the (b) (4). After disinfecting the (b) (4), the operators reached over them to disinfect surfaces near the (b) (4) equipment. The HEPA vents on the top of the ceiling were wiped after disinfecting the surfaces below.

4. Surfaces with excess (b) (4) are wiped with sporicidal disinfectant wipes at the end of the batch.

There is no assurance this removes previous product and ensures appropriate disinfection. Removable pieces with visible (b) (4), like the (b) (4) are not removed for thorough cleaning.

OBSERVATION 5

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

Timely and appropriate maintenance actions are not taken in the aseptic filling rooms. For example:

1. Ceiling panels in the Grade B area of the (b) (4) aseptic filling line appeared to have bubbling on their surfaces. This was identified in a work request dated March 23, 2026, but no further corrective or preventive actions have been implemented.

2. The (b) (4) in the (b) (4) aseptic filling line had a broken (b) (4) sector and dividers in the (b) (4) This surface contacts open bottles. The broken piece had been covered with (b) (4) tape on March 11, 2026.

3. There was a (b) (4) wire installed on (b) (4) to prevent bottles from falling. It touches the rim of open bottles. There were no associated maintenance records describing its installation.

4. There was tape on a cable in the tube loading area of the (b) (4) line, close to where open tubes are loaded. There was no associated maintenance record.

5. On (b) (4) sensors inside the RABS had a peeling (b) (4) covering.

6. On (b) (4) there was tape on (b) (4) near the (b) (4)

7. On (b) (4) there was tape on the conveyor near the capped bottle exit.

8. Loose screws were observed on the base of the (b) (4) machine near the (b) (4) on March 16, 2026, and below the HMI on April 21, 2026.

9. The (b) (4) HMI panel had tape holding cables in place and had peeling surfaces.

OBSERVATION 6

Results of stability testing are not used in determining expiration dates.

1. There is no assurance the (b) (4) (b) (4) for the US market can meet the specification for the (b) (4) expiration date. The product was reintroduced in (b) (4) after not manufacturing it since (b) (4). When it was reintroduced, the supplier of the (b) (4) was changed, the production line was changed, and preparation tanks size and (b) (4) were changed.

Process validation batches were manufactured in (b) (4). The (b) (4) levels dropped between the bulk solution (approximately (b) (4) %) at the preparation step to the filled bottles (approximately (b) %), for all three batches. This was not further investigated before the process validation was approved.

The batches were released and shipped to the US market before stability data had been acquired for these changes. At the three-month stability time point, all three process validation batches failed the specifications for (b) (4) %) in the accelerated condition: (b) (4) %), (b) (4) %), and (b) (4) %). The long-term data showed similar drops to near the specification limit: (b) (4) (initial: (b) (4) %, 3-month: (b) (4) %), (b) (4) (initial: (b) (4) %, 3-month: (b) (4) %), and (b) (4) (initial (b) (4) %, 3-month: (b) (4) %). There was no manufacturing investigation

opened to investigate the root cause or thoroughly evaluate whether the product would meet the (b) (4) (b) (4) expiration date.

Commercial batches after the process validation batches have been released and shipped to the US market with lower release (b) (4) levels compared to the process validation batches: (b) (4) %), (b) (4) %), and (b) (4) %). No evaluation was performed to evaluate whether these batches would continue to meet specification if they had a similar drop in (b) (4) as observed in the stability data for the process validation batches.

2. (b) (4) was reintroduced in (b) (4), after not manufacturing it since (b) (4). It was reintroduced with a new (b) (4) API supplier, a larger batch size, and filled on a new filling line. The new process validation batches were approved by the quality unit to start shipping before obtaining any stability data after the changes. It was given a (b) (4) expiration date. Subsequently, the three accelerated stability batches failed the (b) (4) related (b) (4) specification of not more than (b) (4) % with results of (b) (4) % (b) (4) % (b) (4) % (b) (4) at the six-month testing point in (b) (4). There was no thorough investigation of whether the product released would be able to meet its expiration date.

OBSERVATION 7

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.

The following discrepancies were noted during the review of visual inspection procedures:

1. Rejects from the (b) (4) 100% visual inspection are not further evaluated to categorize the type of defect or investigate the potential source (intrinsic, extrinsic, inherent).

2. No acceptance criteria based on total defects relative to batch size has been established. An action limit of (b) (4) rejects was established March 30, 2026, regardless of batch size. Prior to this date, there was no limit established.

OBSERVATION 8

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

Procedures for reviewing electronic data and audit trails do not ensure a thorough review of data. This a repeat observation from the 2022 FDA inspection. For example:

1. Analysts had access to too numerous to count project folders in the Empower software where data could be created. Data and audit trail review only reviews the electronic data reported by the analyst for the batch that has been created in one specified folder. There is no assurance data is not created in other locations available to the analyst. Further, analysts had access to three projects folders that had no audit trail enabled.

2. Procedure QC-164 "Work Instructions for Data Integrity Oversight" requires (b) (4) (b) (4) to review electronic data and audit trails. Only equipment and data associated with that specific batch will be reviewed. There is no justification for this frequency or assurance that all critical data is being reviewed.

3. General procedures have been created for electronic data and audit trail review to be applied to all software. Specific instructions for how to review the different software have not been established.

4. The Empower system audit trail is not periodically reviewed.

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OBSERVATION 9
Established test procedures are not documented at the time of performance.

Environmental and personnel monitoring records are not made contemporaneously. There are no written records with the sampling personnel in the aseptic filling areas. Records are made at a later time after the samples are returned to the incubation room.

OBSERVATION 10
The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

A tablet containing (b) (4) is manufactured at this facility. No cross-contamination prevention plan for (b) (4) has been established.

Incoming (b) (4) API is opened for sampling upon arrival. The raw material sampling room (b) (4) lacks a separate or defined clean booth area for sampling (b) (4) Other raw materials used for US market (b) (4) like (b) (4) are opened and sampled in the same room.

OBSERVATION 11
Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Analytical methods for organic leachables used in leachable testing are not validated. The methods SM18-HPLC-UV (UV-active compounds) and SM18-GC-MS (volatile and semi-volatile compounds) used to evaluate (b) (4) were not transferred from R&D to the quality unit for method validation.

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