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 CDER-OC-OMQ-International483Response@fda.hhs.gov	11/12/2025-11/21/2025 FEI NUMBER 3007163376

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Si-Baik Kim, Manufacturing Colligation Division Head

FIRM NAME	STREET ADDRESS
Huons Co., Ltd.	100 Bio-Valley-Ro
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jecheon, Chungcheonbuk, 27159, Korea (The Republic of)	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

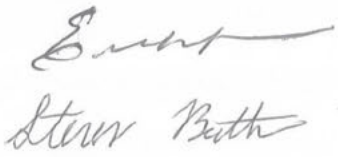
Laboratory records do not include complete data derived from all tests, examinations, and assay necessary to assure compliance with established specifications and standards. Specifically,

A. During review of the bioburden and endotoxin tests performed on 11/03/2025 for the (b) (4) Line (b) (4) media fill (b) (4) samples, we found the following.

a) The (b) (4) Tank" and (b) (4) Tank Transfer Line" samples endotoxin out of specification (OOS) results obtained on 11/03/2025 were not recorded and reported. They were later replaced with the within acceptance results from different samples by QC Microbiology Team Lead. The passing results were reported in the final certificate of analysis (COA).

b) The (b) (4) Tank (b) (4) and (b) (4) Tank Transfer Line (b) (4) positive bioburden test results obtained on 11/10/2025 were not recorded and reported. Specifically, the (b) (4) media plates that showed alert level colony forming units (CFU) at the completion of incubation on 11/10/2025 were discarded. No worksheet was generated to document the positive bioburden data. On 11/12/2025 when inquired by the FDA investigator, the QC Microbiology Team Lead changed camera time and date to take photos of the plates with microbial growth. She also instructed a team member to create worksheets by backdating test information.

B. The Incubator Usage Record logbook (INC-3127) was manipulated to remove two entries of bioburden samples collected for deviation investigation regarding (b) (4) during the vial

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sterilization in the Vial Line. The samples of concern were for Huons (b) (4) Injection (b) (4) Batch (b) (4) (domestic market). Specifically, on 10/31/2025 pages 60 to 62 of the logbook containing information of the deviation samples were removed by the QC Microbiology Team Lead. She replaced the torn out pages with blank forms and instructed a team member to backfill log information, excluding information for the deviation samples.

C. During the microbiology laboratory walkthrough on 11/12/2025, over thirty (30) different uncontrolled current good manufacturing practice (CGMP) blank document form types were identified as well as forms filled with original, raw data. Each blank form could be assessable to any personnel who had access to the microbiology laboratory without any additional controls and traceability. For example, one of the documents identified was a completed endotoxin gel clot test form (Analysis No. R251020004) for the following active pharmaceutical ingredient (API), (b) (4) Batch (b) (4) According to the laboratory personnel, the person identified an issue with the weight collected for the gel clot (power of 10), and the test was redone with a new, blank form two (2) days later. The original test form was not included with the test package for the raw material, there was no deviation or quality event initiated for the event, and no one reviewed the original form (no review signature). (b) (4) Batch (b) (4) was released for use, and the API batch was utilized for at least (b) (4) batches that were intended for the U.S. Market such as (b) (4) Vials (b) (4) and (b) (4) Ampoule (b) (4)

OBSERVATION 2

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up. Specifically,

From 01/2023 to date, a total of 39 complaints from the U.S. market were received regarding (b) (4) (b) (4) Injection USP being ineffective. No root cause was assigned for drug ineffectiveness. In 2022, out of the total (b) (4) batches manufactured and shipped to the U.S. market, (b) (4) batches received ineffective complaints (each batch can receive multiple complaints). Additionally in 2023, out of the total (b) (4) batches manufactured and shipped the U.S., (b) (4) batches received complaints. (b) (4) is administered (b) (4) Your firm's complaint investigations are inadequate in that to date no root cause(s) have been identified to assure product quality and patient safety.

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OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy or 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. The firm's OOS investigation OS-LC23-006 was inadequate. OS-LC23-006 was initiated following an OOS result for unknown substance in (b) (4) Injection (b) (4) Batch (b) (4) finished product. The OOS for Batch (b)(4) found unknown purity of (b) (4) % (Acceptance is (b) (4) % or less). The firm's Phase I investigation assigned dirty glassware being the root cause. However, no scientific evidence was provided to confirm contaminated glassware was the cause for the OOS data. A new sample was tested using a "clean" glassware, the result was within acceptance, and the batch was released to the U.S. in 05/17/2023. Batch (b)(4) was manufactured in 04/05/2023 with an expiration date of (b) (4)

B. The firm's OOS investigation OOS OS-LC23-010 was initiated following (b) (4) impurity in (b) (4) Injection (b) (4) ml USP (b) (4) Batch (b) (4) The OOS for the above batch was (b) (4) ppm (acceptance is (b) (4) or less). The firm's Phase I investigation assigned insufficient (b) (4) time being the root cause. However, the firm's conclusion was based on a previous OOS investigation occurred in 10/12/2022. The firm has no scientific evidence to show insufficient (b) (4) was the cause tor the current OOS result. A new sample was tested and the batch was released to the U.S. market in 10/18/2023. Batch (b) (4) was manufactured in 08/31/2023 with an expiration date of (b) (4)

C. Your Quality Control (QC) team failed to thoroughly document laboratory investigations such as, but not limited to Column Failure and Device Malfunction. Additionally, there is no documentation available to demonstrate that your Quality Assurance (QA) team reviewed and evaluated the laboratory investigations at the form utilized to document the investigation, at the batch release review and release stage, and the annual product quality review.

OBSERVATION 4

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. Specifically,

During the inspection, we watched videos of airflow visualization studies (smoke studies) performed for the Ampoule Line (b)(4) dated 08/03/2025 and for the Vial Filling Line dated 05/08/2025. The above filling lines manufacture injectable products for the U.S. market. The lack of adequate smoke coverage, turbulent airflow, or poor aseptic practice were observed. Examples including but were not limited to:

A. The static smoke studies were not performed under true static conditions. Specifically, you captured and evaluated the airflow between filling machine movement and called it static conditions. You failed to provide a comprehensive baseline study of your cleanroom design and cleanroom airflow before personnel and operations were introduced.

B. Per Ampoule Line (b)(4) interventions performed:

a) Video TEC-25051-FIL-1001-A01/B01 (Setting of filling machine) showed turbulent airflow inside the Grade B zone within the (b)(4) RABS enclosure. You failed to demonstrate that there was no ingress of the Grade B air into the Grade A filling line.

b) Video TEC-25051-FIL-1001-A02/B02 (Breakage of ampoule during filling) showed an operator's head and upper body extended inside of the Grade A area while performing intervention. This video also showed an updraft of airflow adjacent to the (b)(4) RABS (b) (4) area in the Grade B room. You failed to demonstrate that the updraft airflow did not result in the ingress of the Grade B air into the Grade A filling line.

c) Video TEC-25051-FIL-1001-A04/B04 (Resetting change part) showed an operator's head and upper body inside the Grade A area while performing this intervention.

d) Video TEC-25051-FIL-1001-A07/B07 (Resetting of (b) (4) showed an operator's head and upper body inside the Grade A area while performing intervention "Remove rack for material" and intervention "Re-setting of (b) (4)

C. Per Vial Filling Line intervention performed:

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a) Video TEC-25051-FIL-1002-A02/B02 (Replacement of (b) (4) showed the operator brought a replacement (b) (4) from the Grade B room to inside of the Grade A filling area. The replacement (b) (4) was neither contained in a (b) (4) bag nor sanitized before moving into the Grade A filling line.

b) Video TEC-25051-FIL-1002-A03/B03 (Resetting on (b) (4) of (b) (4) stopper) showed an operator's head, arm, and shoulder inside the Grade A area while performing intervention.

c) Video TEC-25051-FIL-1002-A04/B04 (Insertion of (b) (4) stopper) showed addition of (b) (4) stoppers. In this video, we observed the operator placed the bag containing sterile stoppers directly over the stopper bowl blocking the clean first air. We also observed the outside surface of the bag touching the sterile stoppers inside the bowl. The firm confirmed the stoppers are single bagged. There was no video showing how the bags were transferred to the (b) (4) LAF (b) (4)

d) Video TEC-25051-FIL-1002-A05/B05 (Operator is moved under the conveyor belt) showed an operator crawling underneath the conveyor line inside the Grade A filling area. The firm stated this activity was conducted during machine setup. This operator was to transfer a (b) (4) to the other side of the filling line where a (b) (4) was located. This video did not show the operator carrying a (b) (4) unit. Thus, the airflow cannot be adequately reviewed.

e) Video TEC-25051-FIL-1002-A06/B06 (Re-setting (b) (4) showed an updraft of airflow to the left side of the conveyor line carrying stoppered vials in the Grade A area. There was no evaluation of the non-laminar airflow. This video also showed a wrench was brought inside the Grade A area without being sanitized.

f) Video TEC-25051-FIL-1002-A07/B07 (Fallen vials on (b) (4) showed operator's hand and arm directly over sterile open vials on the (b) (4) Impacted vials were not rejected.

g) Video TEC-25051-FIL-1002-A08/B08 (Fallen vials on conveyor) showed operator's hand and arm directly over sterile open vials on the conveyor after leaving the (b) (4) Impacted vials were not rejected.

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D. Aseptic process simulation (APS) or media fill for the U.S. Ampoule Line (b)(4) did not simulate the worst case commercial manufacturing conditions. Specifically, commercial filling intervention types, frequency, and duration were not tracked for adequate simulation studies during APS. Your firm lacked sterility assurance for your drug products if APS was not appropriately performed.

E. During the walkthrough of the Ampoule Filling Line (b)(4) on 11/19/2025, I observed the HEPA grill for FIL-1004-HO2 appeared to be bent within the Grade A filling area. According to your firm management, the HEPA Grill appears to be bent approximately 2cm, and there is no documentation available to establish how long the grill was bent. No smoke study was completed for Ampoule Filling Line (b)(4) (Grade A area), and there was no risk assessment completed by your Quality Unit to scientifically justify the lack of a smoke study. Additionally, a piece of (b) (4) was identified within the Ampoule Filling Line (b)(4) (Grade A area) on 11/19/2025. According to firm management, an employee was interviewed and explained that the (b) (4) was applied to one of the bolts within the Grade A area to secure it; however, there was no documentation available to confirm. There is no written procedure to require documentation of the (b) (4) being (b) (4) for the Ampoule Filling Line (b)(4) (Grade A) for both static and operating conditions (interventions) for Terminal Sterilization (TS).

OBSERVATION 5

Batch production and control records do not include complete information relating to the production and control of each batch. Electronic records are used, but they do not meet audit trail requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records. Specifically,

Your Audit Trail Review procedure and practice is inadequate. The checklist currently utilized for (b) (4) audit trail reviews do not specifically require the identification and tracking of events logged within the audit trail such as, but not limited to abortion of injections. The audit trail log printout attached to each final product release record is incomplete where only the beginning of the laboratory testing is printed. There are no audit trail log printouts dedicated to stability testing. Additionally, the written procedure for audit trail reviews prior to July 2023 only require random equipment and time length of audit trail logs reviewed. There are a number of batches intended for the U.S. Market and within expiry where the audit trail review was not conducted to verify the reported laboratory data aligns with the audit log record.

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OBSERVATION 6

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

Your firm lacked adequate justification for washing and sterilizing (b) (4) gloves only (b) (4) To sanitize gloves before each batch, (b) (4) is used. Also, (b) (4) is used as needed and (b) (4) (a sporicide) is used (b) (4) However, there is no written procedure on how to clean (b)(4) gloves. You also have no study to monitor cleaning effectiveness. At the end of each batch production, only the (b) (4) glove is sampled per viable EM procedure. No fingers are monitored. You lacked justification for not monitoring gloves that are used during production and not sampling glove fingers.

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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."