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	4/6/2026-4/14/2026*
	FEI NUMBER 3008808745

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shiramatsu Hirofumi, General Director

FIRM NAME	STREET ADDRESS
Rohto-Mentholatum (Vietnam) Co., Ltd.	No. 16 VSIP, Street No. 5, Vietnam Singapore Industrial Park
CITY, STATE, ZIP CODE, COUNTRY Ho Chi Minh, Thuan Giao Ward Vietnam	TYPE ESTABLISHMENT INSPECTED OTC 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 followed.

The procedure SOP-QA-024 describing aseptic behavior and how to perform interventions was not followed:

1. During the aseptic filling of US market (b) (4) batch (b) (4) the following was observed:

a. (b) (4) intervention at the bottle chute. The operator picked up stuck bottles with their hand and put them on a conveyor that reintroduces the open bottles back into the bottle supply. The intervention was not documented in the batch record.

b. (b) (4) intervention in the (b) (4) area to check the (b) (4) Exposed open bottles in the area where the operator was reaching were not rejected. The intervention was not documented in the batch record.

c. (b) (4) intervention near the (b) (4) The open, exposed bottles at the time of the intervention were not removed. The intervention was not documented in the batch record.

AMENDMENT 1

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d. (b) (4) intervention at the capping machine to adjust the height of the capping equipment. Exposed bottles in the area were not rejected. The intervention was not documented in the batch record.

e. A (b) (4) was used above the (b) (4) and open bottles during interventions to adjust (b) (4) and tubing. The open bottles were not rejected. These interventions were not recorded in the batch record.

f. A forceps from the Grade B area was passed into the Grade A area in the (b) (4) area of the line and used to remove a stuck bottle. During the intervention, the (b) (4) was repeatedly used above open bottles that were not removed. This intervention was not recorded in the batch record.

g. Operators were seen repeatedly using a (b) (4) to touch open bottles that were misaligned. These bottles were not removed. The interventions were not recorded in the batch record.

2. During the aseptic filling of US market (b) (4) batch (b) (4) the following was observed:

a. (b) (4) intervention to remove a fallen bottle between the (b) (4) station and the capping station. The exposed bottles in the area were not removed. The intervention was not recorded in the batch record.

b. An operator performed (b) (4) intervention where they reached over the chute with open bottles on it. The operator picked up a bottle, walked through the Grade B area, handed the bottle into the Grade A area near the (b) (4), and placed it onto the line before the (b) (4). The intervention was not recorded in the batch record.

c. Operators were seen repeatedly using a (b) (4) to touch open bottles that were misaligned.

AMENDMENT 1

These bottles were not removed. The interventions were not recorded in the batch record.

d. During addition of bottles, the operator did not spray the outer bag before beginning the process. The operator opened the outer bag and then allowed the inner bag of bottles to touch their body and arm as it was placed in the Grade A area. In some instances, the bag was not disinfected and in other cases the bag was not sufficiently disinfected after being placed in the Grade A area. There is a (b) (4) used to separate the area where the bags are added to Grade A and where the bags are opened. The operators did not (b) (4) the (b) (4) before opening the bottle bag as described in the procedure.

The second operator opened the bag, but did not work in a slow and controlled manner. The (b) (4) (b) (4) were used over the open bottles and the outer surface of the bag was allowed to touch open bottles in the (b) (4)

e. An operator used their (b) (4) hand directly on the Grade A side of the (b) (4) in the bottle supply area and on a (b) (4) These areas were not disinfected.

3. During the aseptic filling of US market (b) (4) batch (b) (4) the following was observed:

a. (b) (4) intervention at the capping machine to remove blocked caps. Exposed bottles in the area were not rejected. The intervention was not documented in the batch record.

b. An operator was using a personal cell phone while working in the clean room during aseptic filling operations.

4. At the end of a batch, partially used, open sterile component bags are removed from the Grade A area of the RABS. These partial bags are stored for up to (b) (4) and can be reintroduced to future batches

AMENDMENT 1

without assurance the components or bag surfaces that are reintroduced to the Grade A area remained sterile.

5. During aseptic filling for US market (b) (4) batches (b) (4) operators were observed with inappropriate gowning:

a. Aseptic area operators would remove their goggles and put them on their forehead, exposing the skin around their eyes.

b. Aseptic area operators were observed with gloves that were not pulled up to their forearms, leaving exposed skin on their wrists.

c. Aseptic area operators were observed unzipping their aseptic gowns.

6. During the (b) (4) cleaning of the aseptic filling room on (b) (4), operators did not wear goggles. One operator unzipped their gown and removed and used a personal cell phone during the ongoing cleaning activities.

7. The goggles operators wear during aseptic operations have direct, wide vent open holes along the top. These operators were observed with their heads inside the Grade A area during (b) (4) interventions.

OBSERVATION 2

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

1. Environmental monitoring and personnel monitoring data is not reliable. In-Process Quality Assurance (IPQA) personnel submit unexposed samples to the laboratory and represent them as the

required samples from the aseptic filling area in the records. For example:

a. Review of US market (b) (4) batches aseptically filled since February of 2026 found that (b) (4) of (b) (4) batches (b) (4) had no surface monitoring conducted for th (b) (4) sampling points reviewed, which included Grade A sample points (b) (4) and Grade B sample points (b) (4)

For the other (b) (4) batches reviewed, only partial sampling was performed:

(b) (4)

All missing samples were documented to have been collected and had (b) (4) CFUs reported.

b. An IPQA sampler confirmed production personnel leave the aseptic filling room before getting the required personnel monitoring samples. The IPQA sampler fills out the records and submits unexposed plates to the laboratory when this happens.

c. Review of active air monitoring for batch (b) (4) found samples were not taken at the locations and times indicated in the records.

AMENDMENT 1

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3. Environmental monitoring samples were counted by one analyst, verified by a second analyst, and reported to have (b) (4) CFUs of growth on the records. When the samples were verified during the inspection, the plates had visible growth. For example:

a. Grade A personnel monitoring sampling for operator (b) (6) at the (b) (4) sampling location on (b) (4) (b) (4) at (b) (4) The plate had (b) (4) CFU, exceeding the limit.

b. Settle plate point (b) (4) in aseptic filling line (b) (4) a Grade B sample, collected (b) (4) on (b) (4) (b) (4) The plate had (b) (4) CFU.

c. An active air sample from point (b) (4) in the (b) (4) area of aseptic filling line (b) (4) collected (b) (4) (b) (4) on (b) (4) The plate h d (b) (4) CFU.

d. A settle plate from point (b) (4) in the QC laboratory, Grade B sample, collected on (b) (4) The plate had (b) (4) CFU.

3. Since 2019 the microbiology laboratory has reported (b) (4) CFUs on all environmental monitoring (active air, settle plates, surface monitoring) and personnel mon oring from both Grade A and Grade B samples, with the exception of samples collected between November 4-21, 2025, when there was an investigation into rainwater leaking into aseptic filling line (b) (4)

Following discussions during the inspection about failing to take samples and inaccurate counting, the following results were observed:

For plates read from (b) (4), there were (b) (4) Grade A failures and an additional (b) (4) Grade B samples that showed microbial growth.

AMENDMENT 1

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Samples collected from aseptic filling line (b) (4) on (b) (4), were still under incubation on (b) (4) (b) (4) Review of a subset of these samples still being incubated identified there were at least (b) (4) Grade A excursions, (b) (4) Grade B alert level result, and (b) (4) other Grade B samples that showed growth.

OBSERVATION 3

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

1. The cleaning records are not reliable. Records were made for cleaning of the Grade A surfaces inside the (b) (4) RABS of aseptic filling line (b) (4) but the cleaning was not performed on (b) (4) (b) (4)

In each instance multiple production personnel signed the record indicating they had performed cleaning and an IPQA person signed for verification, but the activities were not performed.

2. Grade A areas inside the (b) (4) RABS are not cleaned or fully disinfected between batches.

a. The (b) (4) chutes, conveyor, (b) (4) used during interventions are not cleaned or disinfected during (b) (4) changeover. Open bottles are exposed in this area and contact these surfaces. Cleaning by wiping with (b) (4) followed by (b) (4) (b) (4) is only required by procedure to be performed (b) (4) . (b) (4) there were (b) (4) production interventions and (b) (4) activities during line clearance in this area, with no requirement to clean or disinfect the area before aseptically filling the next batch.

b. Other areas of the filling line receive (b) (4), but are not cleaned (b) (4) (b) (4) This includes sterile component contact surfaces like the (b) (4) bowls, tracks, and (b) (4) (b) (4) This equipment is left in place between batches and only requires wiping

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with (b) (4) There is no assurance the (b) (4) can remain effective on surfaces that are not routinely cleaned and ensure these component contact surfaces are sterile.

c. The (b) (4) used to perform interventions in the filling machine and bottle supply area do not receive physical cleaning (b) (4) . They are only required to be wiped (b) (4) (b) (4) They receive (b) (4) but the (b) (4) are not (b) (4) to ensure the (b) (4) can effectively disinfect the entire (b) (4)

3. During the (b) (4) cleaning on (b) (4) , cleaning of the Grade A surfaces did not follow procedures. Personnel performing the cleaning did not wipe all areas, did not use a unidirectional wiping technique, did not periodically replace their wipes, and used wipes in the Grade B area and then later used the same wipe in the Grade A area.

4. The (b) (4) qualification studies for the (b) (4) RABS in aseptic filling room (b) (4) (initial qualification Reference No (b) (4) STERILEEFFICACY (b) (4) conducted in (b) (4) ; requalification Reference No. (b) (4) RABS.ReV01 conducted in (b) (4) did not demonstrate that biological indicator (BI) placements represent the most challenging locations for (b) (4) penetration. The following deficiencies were identified:

a. No risk assessment was provided demonstrating that the BI locations used during (b) (4) decontamination represent worst-case conditions.

b. Failure to evaluate the shadow effect where equipment parts (e.g., (b) (4)) inside the (b) (4) RABS Grade A blocks the flow of the (b) (4) preventing proper decontamination of surfaces behind or underneath them.

c. Photographs of BI placements do not clearly depict the specific locations inside the (b) (4) RABS.

AMENDMENT 1

d. BI placement on the (b) (4) was at the (b) (4) The (b) (4) area is not evaluated and the (b) (4) are not (b) (4) to prevent (b) (4)

5. Prior to October 2025, (b) (4) was used to decontaminate the Grades A and B areas in aseptic filling room (b) (4) The (b) (4) qualification study (Reference No. (b) (4) failed to evaluate whether the process left (b) (4) residues on component contact surfaces like (b) (4), chutes, bowls, and tracks that contact sterile bottles and (b) (4) or the (b) (4) used to perform interventions. This decontamination process was used prior to aseptic filling for US market (b) (4) batches: (b) (4) (b) (4)

OBSERVATION 4

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

1. The following was observed during the airflow smoke studies for aseptic filling line (b) (4)

a. The position of the (b) (4) above the (b) (4) bowl obstructs the air flow to the (b) (4) located in the (b) (4) bowl. For example, video #013 and #028.

b. During (b) (4) interventions the smoke was observed exiting upwards and failing to reach the equipment surfaces and sterile components. For example, video #50 at the (b) (4) and video #53 at the (b) (4) bowl. There are air intakes built into the filling line above where the (b) (4) interventions can occur.

AMENDMENT 1

c. There appeared to be turbulence at the (b) (4) – video #008 and at the (b) (4) – video #054.

d. After addition of bottles, the operators push multiple empty bags into the space below the conveyor. Smoke studies have not evaluated how this impacts the airflow, which would usually exit through the area and could become blocked by the empty bags.

e. The HEPA filters in the Grade B area ceiling are near to air intakes on the top of the RABS that supply the Grade A RABS. No evaluation has been performed to ensure appropriate airflow from the Grade B HEPAs.

f. Smoke used during the studies was generated using (b) (4) There was no evaluation of whether this produced neutrally buoyant smoke.

2. Media fill studies (b) (4) do not adequately challenge the aseptic processing operations because they fail to replicate actual commercial manufacturing conditions for (b) (4). The media fill protocol divides the simulated (b) (4) process into (b) (4) stages with personnel absent from the aseptic area for more than (b) (4) between stages. However, batch records for (b) (4) commercial lots (b) (4) demonstrate that personnel remain present in the aseptic processing area continuously throughout actual (b) (4) production runs.

OBSERVATION 5

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

Deviations were opened for US market batches that exceeded the (b) (4)% reject limit during visual inspection. The investigations did not attempt to characterize the articles to determine their sources and

whether they were intrinsic, extrinsic, or inherent to the product. The batches were not reevaluated through additional visual inspection or tightened AQL evaluation as part of the investigation. They were shipped to the US market even though the investigations remain open with no root cause or preventive actions.

Deviation Report No. 25024/DR-E was initiated on July 4, 2025, for lot (b) (4) Product ID: (b) (4) Expiry Date: (b) (4) Visual inspectors rejected (b) (4) bottles: (b) (4) bottles contained dust, (b) (4) bottles contained fiber, and (b) bottles were categorized as "other." (b) (4) bottles from this lot were shipped to the US on (b) (4)

Deviation Report No. 26011/DR-E was initiated on February 10, 2026, for lot (b) (4) (b) (4) Product ID: (b) (4) Expiry Date: (b) (4) Your visual inspectors rejected (b) (4) bottles: (b) (4) bottles contained dust, (b) (4) bottles contained fiber, and (b) bottle was categorized as "other". (b) (4) bottles from this lot were shipped to the US on (b) (4)

OBSERVATION 6

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. A limit of (b) (4) % total rejects has been applied to all US market (b) (4) products without adequate justification for the establishment of this limit.

2. There is a lack of limits for individual categories of defects during the visual inspection process (dust, fiber, other).

AMENDMENT 1

3. SOP-PR-007/018 details the qualification of foreign matter visual inspectors which requires the supervisor "(b) (4) defect samples which contain some representative foreign matters (such as dust, fiber) both black and white and some defects such as metal, glass, insect, etc.". The challenge kit lacks detail, such as the size and source of the foreign matter, to ensure the visual inspectors are appropriately challenged.

OBSERVATION 7

Aseptic processing areas are deficient in that ceilings are not smooth and/or hard surfaces that are easily cleanable.

The ceiling in the Grade B area surrounding aseptic filling line (b) (4) is constructed of (b) (4) panels covered with (b) (4) paint. On April 13, 2026, there was visible peeling of the (b) (4) paint, exposing the underlying (b) (4)

This room was subject to a water leak during heavy rain on November 5, 2025. Rainwater entered the facility and leaked through the (b) (4) panels into aseptic filling room (b) (4) Environmental monitoring conducted during investigation of this leak recovered mold species. After this event, the water damaged (b) (4) panels were not replaced. Damaged areas were painted over.

Filling line (b) (4) is no longer used for filling US market products, however it shares a common entrance and exit as well as common access to equipment and component storage areas with US market filling line (b) (4)

OBSERVATION 8

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

1. The risk assessment 25EMQRM01 concluded surface monitoring would not be performed for equipment surfaces that contact inner surfaces of (b) (4) packaging materials. Surfaces that contact

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product and sterile packaging components like (b) (4) (b) (4), bottle chutes, (b) (4) bowl, (b) (4) machine, cap bowl, and the capping machine are not included in the post batch surface monitoring.

2. (b) (4) are used to perform Grade A interventions (b) (4) They are only sampled (b) (4)

3. Tools used on the filling line like the (b) (4), forceps, and wrenches are not included in the post batch sampling.

4. There is no air monitoring (settle plate, active air) during aseptic filling activities of the Grade A areas where bottle bags are opened, added to (b) (4), and where open bottles are continually exposed in the (b) (4)

***DATES OF INSPECTION**
4/06/2026(Mon), 4/07/2026(Tue), 4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue)

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AMENDMENT 1

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