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	1/21/2026-1/29/2026*
	FEI NUMBER 3003766921

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Helene Fehrm, VP Manufacturing Operations

FIRM NAME	STREET ADDRESS
Apotek Production & Laboratorier AB	Formvagen 5b
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Umea, Vasterbotten, 906 04 Sweden	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 I 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,

A. During review of your firm's airflow visualization (smoke) study, document ID VFU315T, entitled, "Rokstudie modifiering (b) (4) ", dated 2024/07/03, conducted on the filling line used to fill the (b) (4) (b) (4) drug, (b) (4) the following was observed:

1. Your, airflow visualization study is deficient as it was only conducted under static conditions. The study fails to evaluate but is not limited to the following:
   i. aseptic filling process under dynamic conditions
   ii. set-up activities
   iii. expected and unexpected operator interventions

2. The static study performed shows air turbulence in the Grade A filling area of filling machine (b) (4) at the level of the HEPA filter where the ceiling meets the surrounding (b) (4) barrier. The HEPA in the ceiling is surrounded by a (b) (4) that is approximately (b) (4) from the edge of the HEPA filter to the Grade A barrier. Turbulence was observed around this (b) (4) .
3. The study failed to show smoke that is uniformly supplied and distributed covering the entire airflow cascade from the HEPA filter to the working area.
4. There is no evidence to show that the smoke generated is neutrally buoyant. Smoke used for the airflow visualization study is generated by using handheld device which dispenses (b) (4)

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	Anastasia M Shields, Investigator	X Anastasia M Shields Investigator Signed By: ANASTASIA M. SHIELDS -S Date Signed: 01-29-2026 10:06:14	1/29/2026

5. The smoke discharged from the handheld device during the airflow visualization study failed to demonstrate unidirectional airflow. During the smoke study, the operator moved the device around the inside of the Grade A filling line, discharging the smoke upward in bursts resulting in its reversing direction and falling back onto the device and the operator making it difficult to evaluate the direction of the airflow.

B. Aseptic Process Simulation Studies (Media Fill), performed per procedure SOP-01412-17.0, are not designed in a manner that challenges the aseptic filling process. A media fill protocol has not been established to outline and challenge the worst-case conditions of the filling process, including maximum number of interventions that must occur and the minimum length of time each intervention needs to be challenged in order to validate your aseptic filling process.

OBSERVATION 2

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

Specifically,

Examples of poor aseptic behavior were observed during review of the aseptic process simulation study, media fill batch (b) (4) and batch (b) (4) on the ampoule line (b) (4) used to fill the (b) (4) drug (b) (4) (b) (4).

1. During line set up for both media fill batches an operator was observed setting up the (b) (4) using their gloved hands where their hands came in direct contact with the components used to hold the (b) (4) (b) (4) in place on the line and components that the (b) (4) They were observed physically manipulating multiple machine parts around the (b) (4) and touching the upper part of the (b) (4) with their hands when placing the (b) (4) onto the machine.

2. An operator was observed using their gloved hands to secure and arrange unfilled ampoules onto the (b) (4) (b) (4) (ampoule loading area) in the Grade A filling machine.

3. Operators were observed using their gloved hands to unwrap a (b) (4) ampoule (b) (4) during machine set up. Using their hands they placed the (b) (4) onto the machine. During aseptic filling, ampoules progress down the line onto the (b) (4) via the (b) (4). Each ampoule comes in contact with this (b) (4) as it progresses on to filling.

4. Operators were observed wearing direct vent goggles during set up of the aseptic filling line (b) (4) and during filling. The goggles have large holes on the top directly venting them to the external environment. During machine set up, operators wearing these goggles were observed leaning their upper torso and head down over the (b) (4) and over the surfaces of the line where aseptic filling takes place.

OBSERVATION 3

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

Specifically,

A. Your firm does not have a risk assessment to justify the environmental monitoring and personal monitoring locations and frequencies.

1. There is no surface monitoring on the Grade A aseptic filling line, (b) (4) used to fill the (b) (4) drug, (b) (4) While reviewing machine set up of the media fill dated September 15, 2025, and while observing machine set up on January 23, 2026, it was noted that area of the line that houses the (b) (4) requires multiple manual manipulations and adjustments during set up and operation which are performed with the operator's gloved hands. Environmental monitoring of these surfaces and associated (b) (4) has never been performed.

2. While observing machine set up and filling of filling line (b) (4) on January 23, 2026, the operators were observed leaning their head and torso over the (b) (4) and surrounding area of the machine.

Personnel monitoring of the operators during routine production does not include any point that is representative of the head or torso.

3. A settle plate that is placed in the Grade A area is located in an area beneath a (b) (4) on a table that sits lower than the level of the filling line. The (b) (4) is attached to the filling line and is suspended approximately (b) (4) over the top of the settle plate. This limits the exposure of the settle plate to the surrounding environment and to operator interventions and activity that occur during filling. This settle plate is the passive air monitoring point closest to the (b) (4)

B. Your firm failed to demonstrate the effectiveness of disinfectants and sporicidal agents used in classified, Grade A and Grade B, manufacturing areas. Your firm uses (b) (4) (b) (4) to disinfect Grade A and Grade B areas, including the aseptic filling line and surrounding room where (b) (4) is aseptically filled. However, no disinfectant efficacy studies have been performed to validate the effectiveness of these agents against the relevant microorganisms in your manufacturing environment.

OBSERVATION 4

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing and processing.

Specifically,

Batch records do not contain documentation of all interventions performed in the Grade Aor the length of time taken to perform each intervention. Routine interventions not recorded include but are not limited to the following:

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a. Cleaning of (b) (4)

b. Adjustment of (b) (4) at (b) (4)

c. Removal of Broken (b) (4) and Cleaning

d. Adjustment of (b) (4)

e. Loading of Ampoule (b) (4) and positioning of ampoules on the (b) (4) (ampoule loading area).

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and suitably located to facilitate operations for its intended use.

Specifically,

1. The (b) (4) is located above the end of the filling line (b) (4) at the ceiling level. HEPA filtered air is drawn up and directly off the line when a (b) (4) on the end is removed for the duration of machine set up. (b) (4) are located on each side of the line and extend down from the top of the line to approximately (b) (4) above the table holding the filling line. The aseptic filling line is not equipped with RABS technology or (b) (4) and is not fully enclosed on all sides. The front and back are partially covered with a (b) (4) that extends from the top of the line downward. The front (b) (4) stops approximately (b) (4) before the table that holds the filling line and the line is open from the end of this (b) (4) down to the table.

2. The (b) (4) (ampoule loading area) extends out of the Grade A into the surrounding Grade B room. (b) (4) sterilized ampoules are loaded onto the (b) (4) protruding out of the Grade A prior

to progressing down the loading area to the filling line.

OBSERVATION 6

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, your firm's (b) (4) Equipment ID (b) (4) does not save testing data generated from a (b) (4) nor is it attached to any type of system that will print or save the generated raw data. The current process relies on a single analyst to manually transcribe results from the equipment display into the laboratory record without independent verification or electronic capture of raw data. Two person verification is not required. This (b) (4) is used to conduct assay and impurity testing on the (b) (4) drug (b) (4)

OBSERVATION 7

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.

Specifically, your firm has omitted the (b) (4) °C incubation step during incubation of the plates used to conduct environmental monitoring of all classified areas and operators. No method suitability study was performed or able to be provided that demonstrates that eliminating this incubation temperature does not have a negative impact on recovery of mold and yeast in the EM samples being tested.

OBSERVATION 8

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.

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Specifically, qualification of the (b) (4) visual inspection machine, SY1002, and operators performing the (b) (4) visual and (b) (4) AQL inspections have not been completed using (b) (4) mL (b) (4) ampoules which are intended to be used as (b) (4) packaging of the (b) (4) drug (b) (4)

OBSERVATION 9

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, there is no requirement for stratification or distinct timepoints throughout the filling process at which BET samples are to be collected. A single vial is randomly collected from each batch of (b) (4) and is used for Bacterial Endotoxin Testing (BET) per SOP 1525, "Kontrollomfattning Steril Produktion". There are approximately (b) (4) ampoules filled in one commercial scale batch of (b) (4)

*DATES OF INSPECTION

1/21/2026(Wed), 1/22/2026(Thu), 1/23/2026(Fri), 1/26/2026(Mon), 1/27/2026(Tue), 1/28/2026(Wed), 1/29/2026(Thu)

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