

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032
Rockville, MD 20857

DATE(S) OF INSPECTION

04/07/2026-04/10/2026

FEI NUMBER

3003342394

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Hans Fredrik Aasell, VP Sweden Operations

FIRM NAME

AstraZeneca AB

STREET ADDRESS

Gartunavagen

CITY, STATE, ZIP CODE, COUNTRY

Sodertalje, 151 85 Sweden

TYPE ESTABLISHMENT INSPECTED

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:

QUALITY

OBSERVATION 1

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

Your firm's investigations of deviations are not always adequate.

- a. Quality Event QE-239020 was initiated 16NOV2025 following the identification of foreign particles in (b) (4) batches of (b) (4) tablets. Analytical characterization identified the particles as containing (b) (4). Your investigation proposed the potential source as excipient/API (b) (4) material). The following batches were affected:

Strength	Batch	Expiration Date	Quantity of (b) (4) tablets found with foreign	Quantity of (b) (4) Tablets Inspected	Quantity of Tablets manufactured
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(b) (4)

SEE REVERSE
OF THIS PAGE

Rowena S. Nguyen - Investigator
Allison A. Aldridge, PhD - Consumer Safety Officer

Rowena S. Nguyen - S
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Digitally signed by Rowena S. Nguyen - S
Date: 2026.04.10 09:04:05 -0700
Allison Aldridge - S
Digitally signed by Allison Aldridge - S
Date: 2026.04.10 09:07:19 -0700

04/10/2026

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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12420 Parklawn Drive, Room 2032 Rockville, MD 20857		04/07/2026-04/10/2026	
		FEI NUMBER 3003342394	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Hans Fredrik Aasell, VP Sweden Operations			
FIRM NAME AstraZeneca AB		STREET ADDRESS Gartunavagen	
CITY, STATE, ZIP CODE, COUNTRY Sodertalje, 151 85 Sweden		TYPE ESTABLISHMENT INSPECTED Drug Manufacturer	

Despite the inability to conclusively identify the source of the (b) (4) material, your investigation was closed. No additional investigation was conducted to definitively determine the origin of the (b) (4) material to prevent recurrence.

- b. Quality Event QE-226480 was initiated 11SEP2025 during the manufacture (b) (4) mg tablets, Batch (b) (4) QTY: (b) (4) tablets, EXP: (b) (4) when four instances of (b) (4) were observed in (b) (4) 2, where tablets (b) (4) and exhibited a (b) (4). An abnormal (b) (4) was first detected during subplot (b) (4). Subsequent sublots (b) (4) showed (b) (4) with (b) (4) variation and (b) (4) surfaces. Tablets with inadequate (b) (4) from these sublots were discarded (b) (4).

Affected sublots were identified through in-process observation and appearance inspection and were subsequently discarded. The root cause was determined to be equipment performance, as the (b) (4) in the (b) (4) was not (b) (4). The correction included cleaning the (b) (4) for each sub lot during the batch. Despite the (b) (4) four times, no corrective and preventive action (CAPA) was initiated, and the issue was deemed minor.

OBSERVATION 2

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

Your firm's CAPA system is not always adequate to ensure deviations have appropriate measures implemented to prevent recurrence. During the manufacturing of (b) (4) mg tablets, Batch (b) (4), QTY: (b) (4) tablets, EXP: (b) (4), manufactured from (b) (4) through (b) (4), in-process appearance testing revealed four tablets containing foreign particulate matter. This was from the inspection of (b) (4) tablets.

Laboratory analysis identified the contaminant as (b) (4). Quality Event QE-239020 was initiated 16NOV2025, and your investigation attributed the defect to a worn tablet press. However, the preventative maintenance program was not updated to address the equipment wear condition that caused this deviation.

SEE REVERSE OF THIS PAGE	Rowena S. Nguyen - Investigator	Rowena S. Nguyen - S	04/10/2026
	Allison A. Aldridge, PhD - Consumer Safety Officer	Allison Aldridge - S	