DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Building 51 Silver Spring, MD 20993 301-796-3150 Fax:(301)594-1204	6/2/2025-6/6/2025
	FEI NUMBER 3002807001

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Masafumi Dohi, Executive Director & General Manager

FIRM NAME	STREET ADDRESS
Astellas Pharma Inc.	Sakae-Machi 30, Toide
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Takaoka, Toyama, 939-1118 Japan	Sterile Drug Product 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

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.

Specifically,

A) Your firm's visual inspection of the [redacted] (b) (4) injection [redacted] (b) (4) mg/vial and [redacted] (b) (4) mg/vial is inadequate. After visually inspecting the [redacted] (b) (4) of the [redacted] (b) (4) in the vials, your firm fails to perform [redacted] (b) (4) supplemental visual inspection of [redacted] (b) (4) vials for visible particles.

B) Your firm's challenge test vials used for the qualification of the visual inspectors is inadequate, as it does not include particles that could potentially originate from the manufacturing environment such as, [redacted] (b) (4) etc.

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Bijoy Panicker, Investigator X Bijoy Panicker Investigator Signed By: 2001996716 Date Signed: 06-06-2025 03:38:33	6/6/2025

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Your firm uses disinfectants to disinfect your facility and equipment, including surfaces that come into contact with sterile (b) (4) drug products. Review of your disinfectant efficacy study (Protocol # 22H1-015) showed that it is deficient in that:

A) Your firm inoculated (b) (4) to (b) (4) CFU of microorganisms on the challenge surfaces, which is insufficient to demonstrate at least a (b) (4) log reduction for bacterial spores and (b) (4) log reduction for vegetative bacteria.

B) Part of this study was performed by pipetting the test culture on the (b) (4) and allowing it to dry, followed by spraying the disinfectant, (b) (4) over the dried culture. This method of disinfecting is different than your routine cleaning and disinfecting procedure (SOP # 88974-304/32) wherein the disinfectant is spread using a mop.

C) USP vegetative bacterial challenge organisms such as, E. coli, S. aureus, and P. aeruginosa were not included in your study.

D) Not all the surfaces present in your aseptic area were evaluated in your study. For example, (b) (4) (part of (b) (4) windows) and (b) (4) (used as equipment wraps) were not included in the study.

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