DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DPMA Attn: Christopher Downey, Ph.D., Division Director 10903 New Hampshire Avenue; White Oak Building 51/Room 2269 Silver Spring, MD 20993-0002 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	01/23/2025-01/30/2025
	FEI NUMBER 3002806285

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Benjamin Schroeder, Site Director

FIRM NAME	STREET ADDRESS
Allergan Pharmaceuticals Ireland Unlimited	Castlebar Road
CITY, STATE, ZIP CODE, COUNTRY Westport Co. Mayo F28 AW83, Ireland	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

1. Your examination and testing of samples did not assure that the drug product and in-process material conformed to specifications. Specifically,
   You did not adequately define visual inspection rejection limits for the total number of critical, major, and minor defects. Only limits for individual defect types were established. Your written procedures for 100% visual inspection allow up to (b) (4) % for each of the (b) (4) critical defects and up to (b) (4) % for each of the (b) (4) major defects. No limit was established for any of the (b) (4) minor defects.

2. The establishment of laboratory test procedures are inadequate. Specifically,
   a. At the time of this inspection, you have not established written procedures to perform endotoxin testing for the in process and filled (b) (4) drug product cartridges.
   b. There is no established written testing to support the claim that endotoxin samples must be tested within (b) (4) after being collected.
   c. Your endotoxin samples are not currently tracked in the logbook.

3. Cleaning validation has not been conducted for indirect product contact parts used in the filling (b) (4) For example, the manual cleaning processes for the (b) (4) tweezers and gaskets that are used in the filling (b) (4) which come into indirect contact with sterile components before filling have not been validated. There is no documented evidence to demonstrate that the current cleaning procedures effectively remove contaminant. There is no periodic revalidation or verification to ensure that the cleaning procedures remain effective over time.

4. Aseptic processing areas are inadequate regarding the system for monitoring environmental conditions. Specifically, your environmental monitoring plates are incubated in incubator R-521 at (b) (4) °C for (b) (4) (b) (4) then moved to incubator R-519 at (b) (4) °C for (b) (4) After the (b) (4) incubation, environmental monitoring plates are removed from incubation and either read immediately or placed in a 2-8°C refrigerator pending reading. Your written procedures QPP02-01-002-WPT2, Environmental

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Jie He -S Thuy T. Nguyen -S Digitally signed by Jie He -S Date: 2025.01.30 09:00:36 -05'00' Kejun Cheng -S Digitally signed by Kejun Cheng -S Date: 2025.01.30 09:03:51 -05'00'	Jie He, Senior Regulatory Specialist Thuy Nguyen, Branch Chief Kejun Cheng, Senior Chemist	January 30, 2025

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Monitoring of Classified Areas (version 2, effective September 20, 2023), failed to establish the limit day/time for reading your environmental plates in the refrigeration post incubation.

5. Deficiencies in shipping validation. Specifically: There is no specified SOP established for the packaging of QC and stability samples for shipping to the external testing facility.

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	Jie He -S Digitally signed by Jie He -S Date: 2025.01.30 09:01:11 -05'00' Thuy T. Nguyen -S Digitally signed by Thuy T. Nguyen -S Date: 2025.01.30 09:02:36 -05'00' Kejun Cheng -S Digitally signed by Kejun Cheng -S Date: 2025.01.30 09:04:32 -05'00'	Jie He, Senior Regulatory Specialist Thuy Nguyen, Branch Chief Kejun Cheng, Senior Chemist	January 30, 2025