DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/Division of Biotechnology Manufacturing Attn: Christopher Downey, Ph.D., Division Director 10903 New Hampshire Ave.; White Oak Bldg. 51 Room 2269, Silver Spring, MD 20993 E-mail: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	5/6/2024-5/14/2024
	FEI NUMBER 3011255424

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Wallace Torres, Vice President Manufacturing and ASM Site Head

FIRM NAME	STREET ADDRESS
AMGEN Singapore Manufacturing Pte. Ltd.	1 Tuas View Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Singapore 637026	Drug Substance 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) (WE) OBSERVED:

1. Your firm did not conduct a disinfectant efficacy study (DES) based on environmental isolates and materials used specific to your site. According to RPT-526033 (version 6.0): Technical Assessment on the Efficacy of Disinfectant Used in ASM and (b) (4) you used studies performed at Amgen Thousand Oaks (ATO) and (b) (4) (b) (4) Specifically,

a. You included only four materials of construction (floor, wall, equipment, and window) in the ATO disinfectant qualification study. The DES does not adequately support the sanitization procedures for the antimicrobial and sporicidal effectiveness of the disinfectants and sporicidal agents for all representative manufacturing surfaces in the facility. For example, materials used for (b) (4) chairs, packaging of (b) (4) equipment, etc. were not included in the study.
b. The environmental isolates tested in the ATO and (b) (4) disinfectant qualification study were the isolates recovered from ATO and (b) (4) The study did not include the in-house isolates from ASM.

2. Procedures designed to prevent microbiological contamination of drug substances are not adequately established. Specifically,

a. On May 8, 2024, we (TTN, LZ, and SK) observed plate reading for environmental plates. Your SME stated that bioburden plates can be read anytime after the minimum incubation period. You do not have an established maximum time period for plate reading. Your SOP-418520 (version 17), Reading and Approving Micro Plates has no time limits for plate reading after the minimum incubation period.

b. On May 8, 2024, we (TTN, LZ, and SK) observed your operators disinfecting the exterior surfaces of packages of (b) (4) materials in the material transfer (b) (4) to the non-classified and classified manufacturing areas. Operators were observed using dry cloths and spraying with disinfectant(s) prior to wiping the exterior surfaces of the packages. We observed the operators were inconsistently spraying disinfectant(s) and wiping the packaging materials. There is no assurance that the dry cloths were saturated or that the wiping covered all the surfaces with

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Thuy T. Nguyen -S Liqun Zhao -S Sudipan Karmakar -S Milos Dokmanovic -S	Thuy Nguyen, Branch Chief Liqun Zhao, Pharmaceutical Scientist Sudipan Karmakar, Chemist Milos Dokmanovic, Senior Biologist	05/14/2024

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disinfectant (s). Your written procedures SOP-423923, ASM (b)(4) Personnel, Material and Equipment Movement failed to include instructions for operators to perform the spraying and wiping down of materials prior to transfer to manufacturing areas.

APPEARS THIS WAY ON ORIGINAL

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Thuy T. Nguyen -S Digitally signed by Thuy T. Nguyen -S Date: 2024.05.14 00:02:18 -04'00' Liqun Zhao -S Digitally signed by Liqun Zhao -S Date: 2024.05.14 00:01:23 -04'00' Sudipan Karmakar -S Digitally signed by Sudipan Karmakar -S Date: 2024.05.14 00:05:06 -04'00' Milos Dokmanovic -S Digitally signed by Milos Dokmanovic -S Date: 2024.05.14 00:06:42 -04'00'	Thuy Nguyen, Branch Chief Liqun Zhao, Pharmaceutical Scientist Sudipan Karmakar, Chemist Milos Dokmanovic, Senior Biologist	05/14/2024