DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Viviana Ramirez Telephone: 202-309-7886 Industry Information: www.fda.gov/oc/industry	March 27, 2026 March 30, 2026 to April 02, 2026
	FEI NUMBER 3008919998

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Sarina Cheng, QA Compliance Department Deputy Manager

FIRM NAME	STREET ADDRESS
Adimmune Corporation	No. 3 Sec. 1, Tanxing Rd., Tanzi District
CITY, STATE AND ZIP CODE Taichung City, 42743 , Taiwan	TYPE OF ESTABLISHMENT INSPECTED Pre-Approval Inspection

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1) Your firm failed to follow written procedures designed to prevent mix-up of drug products, specifically:

During the inspection of the product (b) (4) conducted on March 27, 2026, it was observed, in (b) (4) Building (b) (4), final fill and finish (b) (4) of drug products displaying (b) (4) labels were stored in the (b) (4) area instead of the designated (b) (4) area as required by established procedures [SOP (b) (4) 010 Procedure of (b) (4) Management].

2) Your firm failed to establish the reliability of supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. Specifically, (b) (4) and (b) (4) utilized for drug product overlay have not been conducted to validate supplier analyses.

3) Your firm failed to establish, follow and document preventive maintenance procedures, specifically,

a. There is no documentation to support the replacement of (b) (4) utilized at the (b) (4) supply source for drug product overlay after (b) (4) uses according to Standard Operating Procedure (SOP) (b) (4) 140: BLD (b) (4) Filling & Packaging Line (b) (4) The Standard of Integrity Test in BLD (b) (4) Filling & Packaging Plant Line (b) (4), effective 04/23/24.

b. Procedures have not been established as part of the (b) (4) preventative maintenance protocol to ensure the (b) (4) system is maintained in a good state of repair. (b) (4) accumulation was found (b) (4) (b) (4) of the facility (b) (4) system (b) (4). Additionally, deterioration of the (b) (4) on (b) (4) was observed.

4) Written operating procedures are not followed or are inadequate, specifically,

a. On March 30, 2026, during observation of the Formulation process, we observed staff not regularly sanitizing their gloves as per procedure. Specifically, we observed the (b) (4) main manufacturing staff working (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Hoda Thai Viviana Ramirez	Viviana Ramirez, Consumer Safety Officer Hoda Thai, Consumer Safety Officer	04/02/2026

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laminar flow hood (b) (4) the hood without sanitizing. Section 7.3.3 of SOP (b) (4) S067 Good Aseptic Operation Practice states: "Sterile gloves should be (b) (4) sanitized or changed (b) (4) (b) (4) aseptic operation."

b. SOP (b) (4) S067 Good Aseptic Operation Practice does not clearly define the frequency of glove sanitization for manufacturing staff i.e. (b) (4) a laminar flow hood.

c. During observation of the Formulation process on March 30, 2026, manufacturing staff was seen placing a (b) (4) on the laminar flow hood labeling it as (b) (4) processing. No cleaning of the laminar flow (b) (4) was observed (b) (4). Section 7.6.1 Per SOP (b) (4) 285 states: Cleaning of the (b) (4) (b) (4) each (b) (4), the (b) (4) must be wiped and disinfected with a (b) (4) containing (b) (4) ."

d. On March 31, 2026, during observation of the Filling operation on Line (b) (4) a deviation from established aseptic practices was noted when manufacturing personnel performed troubleshooting activities. Specifically, gowned operators were observed making direct contact with the (b) (4) using (b) (4) and allowing their (b) (4) (b) (4) to contact the (b) (4) surface while wearing cleanroom personal protective equipment (PPE).

This practice is not consistent with the facility's SOP (b) (4) 067, Section 7.2 Item 2, which states: " (b) (4) (b) (4) gowning (b) (4) ."

e. Additionally, during observation of the Filling process on March 31, 2026, aseptic processing personnel / maintenance staff were observed repeatedly contacting the (b) (4) with their (b) (4) after those same (b) (4) had contacted the (b) (4) surface.

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