DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Christopher Downey, Ph.D., Director of Division of Biotechnology Manufacturing US Food & Drug Administration, Office of Pharmaceutical Quality-OPMA-DBM 10903 New Hampshire Avenue, Bldg. 22, Silver Spring, Maryland 20993 OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www fda.gov/oc/industry	01/11-13, 16/2023
	FEI NUMBER 3004575449

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Paul E. Ruther, Vice President of Drug Product Manufacturing (Paul.Ruther@US.AjiBio-Pharma.com)

FIRM NAME	STREET ADDRESS
Ajinomoto Althea, Inc. DBA Ajinomoto Bio-Pharma Services	6175 Lusk Blvd. (11040 Roselle Street)
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Diego, CA 92121	Manufacturer

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

OBSERVATION 1: Quality oversight of validation activities is inadequate. Specifically,

a. The Building (b) (4) Filling Line (b) capping and (b) (4) machine was validated using only one batch run and not three for the study, VAL-1764, rev. 1.0, effective date 09/23/2021, Final Report for the Container Closure Integrity Testing (CCIT) for the (b) (4) DP (b) mL Container Closure Configuration.
b. The Quality Control Microbiology Laboratory's cGMP material ambient (20-25 degrees Celsius) storage room, Rm. 902, is not qualified for 20-25 degrees Celsius.

OBSERVATION 2: Facility and Equipment maintenance are deficient in their ability to support cGMP production activities. Specifically,

a. SOP-1021, rev. 5.0, effective date 05/31/2021, Cleaning and Sanitization for Building (b) Line (b) Area, directs cleaning to be a (b) (4) contact time using disinfectants for the facility cleaning procedures. This contact time is not validated by the efficacy studies, VAL-1209, rev. 3.0, effective date 07/14/2022, Disinfectant Coupon Efficacy Study, or 8-SR-363, rev. 1.0, issue date 01/28/2015, Disinfectant Coupon Efficacy Study. Additionally, SOP-1021 does not direct the capture of the exposure time for the cleaning records.
b. During the Production Suite tour on 01/12/2023, it was noted that the Pre-wash Room, Rm. 1015, has a sink with a (b) (4) -trap. There is no microbial control maintenance or sanitization procedure practiced or described in SOP-1021, rev. 5.0, effective date 05/31/2021, Cleaning and Sanitization for Building (b) Line (b) Area, for sinks with a (b) (4) -trap in manufacturing areas.
c. During the facilities area tour on 01/11/2023, it was noted that the (b) (4) sensor for the (b) (4) used in the production of (b) (4) with equipment ID 2027-006 SN3116-12 was due for maintenance on 12/16/20. The (b) (4) produced by this system is used to manufacture (b) (4) for the production and filling of (b) (4) (b) (4) drug product.

Observation 3: The responsibilities and procedures applicable to the quality control unit are not fully followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Michael R. Shanks -S Digitally signed by Michael R. Shanks -S Date: 2023 01 16 16:35 57 05'00' Christopher R. Czajka -S Digitally signed by Christopher R. Czajka -S Date: 2023.01.16 13:41:18 -08'00' Yi Wang -S Digitally signed by Yi Wang -S Date: 2023.01.16 16:45:28 -05'00'	Michael R. Shanks, Senior Biologist Christopher R. Czajka, Consumer Safety Officer Yi Wang, Ph.D. Staff Fellow	01/16/2023

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CITY, STATE AND ZIP CODE San Diego, CA 92121	TYPE OF ESTABLISHMENT INSPECTED Manufacturer

Specifically,

During the QC lab tour on 01/11/2023, it was noted that pages 18-25 of your laboratory notebook 903, which contain entries documenting the preparation of laboratory reagents between 11/09/21 and 12/19/22, were all reviewed on 01/03/23. Your SOP-0337, rev. 20.0, effective date 12/15/2022, Use of Log Books in cGMP Areas, states in section 7.4.1: "Area/equipment owners or designees will review paper-based logbooks at a minimum of (b) (4) to monitor compliance to documentation requirements."

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Michael R. Shanks -S Digitally signed by Michael R Shanks -S Date: 2023 01 16 16 48:34 05'00' Christopher R. Czajka -S Digitally signed by Christopher R. Czajka -S Date: 2023.01.16 13:40:15 -08'00' Yi Wang -S Digitally signed by Yi Wang -S Date: 2023 01 16 16:46:06 05'00'	Michael R. Shanks, Senior Biologist Christopher R. Czajka, Consumer Safety Officer Yi Wang, Ph.D. Staff Fellow	01/16/2023