

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032
Rockville, MD 20857

DATE(S) OF INSPECTION
3/28/2023-3/28/2023*

FEI NUMBER
3002930340

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ewald Amherd, Head Quality, Visp

FIRM NAME

Lonza AG

STREET ADDRESS

Lonzastrasse 2

CITY, STATE AND ZIP CODE

Visp, Valais, 3930, Switzerland

TYPE OF ESTABLISHMENT INSPECTED

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 (S) (WE) OBSERVED:

PRODUCTION SYTEM

OBSERVATION 1

A) Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards. Specifically,

You firm failed to report exact values for TAMC (Total Aerobic Microbial Count) action limit results as indicated in Lonza Test Method, Total Aerobic Microbial Count in (b) (4) Water, Doc. No.: CHVI-15464, Version: 11.0, Effective Date: 13-DEC-2022. For example, during the review of (b) (4) Water Trend Test Results from 2019-2022 (b) (4) I found the following action limit excursions only reported and trended as > (b) (4) CFU/ml but no exact counts are available, recorded or documented.

1. EAR-2579, 30-Jul-2019, (b) (4) WP TAMC > (b) (4) CFU/ml
2. EAR-2581, 29-Jul-2019, (b) (4) WP TAMC > (b) (4) CFU/ml
3. EAR-2585, 31-Jul-2019, (b) (4) WP TAMC > (b) (4) CFU/ml
4. EAR-2688, 14-Oct-2019, (b) (4) WP TAMC > (b) (4) CFU/ml
5. EAR-3296, 28-Aug-2020, (b) (4) WP TAMC > (b) (4) CFU/ml
6. EAR-3707, 28-Jan-2021, (b) (4) WP TAMC > (b) (4) CFU/ml
7. EAR-4108, 23-Apr-2021, (b) (4) WP TAMC > (b) (4) CFU/ml
8. EAR-4119, 26-Apr-2021, (b) (4) WP TAMC > (b) (4) CFU/ml
9. EAR-4219, 25-May-2021, (b) (4) WP TAMC > (b) (4) CFU/ml
10. EAR-7147, 14-Oct-2022, (b) (4) WP TAMC > (b) (4) CFU/ml
11. EAR-7345, 06-Dec-2022, (b) (4) WP TAMC > (b) (4) CFU/ml

B) Your firm failed to report appropriate Environmental Monitoring action limit results as prescribed in Lonza

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	 Vaishali Patel	Santos Camara, Investigator Vaishali Patel, Investigator	03/28/2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Ewald Amherd, Head Quality, Visp

FIRM NAME Lonza AG	STREET ADDRESS Lonzastrasse 2
CITY, STATE AND ZIP CODE Visp, Valais, 3930, Switzerland	TYPE OF ESTABLISHMENT INSPECTED Drug Substance Manufacturer

SOP, Doc. No.: CHVI-5509, Version: 1.0, Effective Date: 23-NOV-2022. For example, during the review of Environmental Monitoring Trend Test Results from 2019-2022 (b) (4) I found the following action limit excursions only reported and trended as > (b) (4) CFU but no exact counts are available, recorded or documented.

- 1. EAR-2756, 28-Nov-2019, (b) (4) (Personnel (b) (4)) > (b) (4) CFU
- 2. EAR-3130, 16-Jun-2020, (b) (4) Washing room (b) (4) > (b) (4) CFU
- 3. EAR-3630, 06-Jan-2021, (b) (4) Fermentation (b) (4) > (b) (4) CFU
- 4. EAR-4289, 16-Jun-2021, (b) (4) Fermentation (b) (4) > (b) (4) CFU
- 5. EAR-4510, 04-Aug-2021, (b) (4) Fermentation (b) (4) > (b) (4) CFU
- 6. EAR-4839, 15-Sep-2021, (b) (4) Fermentation (b) (4) > (b) (4) CFU
- 7. EAR-7368, 07-Dec-2022, (b) (4) Fermentation (b) (4) > (b) (4) CFU

Building (b) (4) (Bio Pharmaceutical Manufacturing) is used for the manufacturing of drug substance (b) (4) and (b) (4) for manufacturing drug substance (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Vaishali Patel	EMPLOYEE(S) NAME AND TITLE (Print or Type) Santos Camara, Investigator Vaishali Patel, Investigator	DATE ISSUED 03/28/2023
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