

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER CDER/OPQ/OPMA/DPMA VI 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		DATE(S) OF INSPECTION 03/28, 03/31 – 04/04, 2025	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Claudio Cescato, Vice president, Head of Quality		FEI NUMBER 3012793444	
FIRM NAME Lonza AG	STREET ADDRESS Rottenstrasse 6		
CITY, STATE, ZIP CODE, COUNTRY Visp 3930 Switzerland	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: Observation 1 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed. Specifically, while reviewing the dynamic smoke study videos for the (b) (4) in Manufacturing Complex (b) (4) Module (b) (4) I (HL) observed the following deficiencies: a) While assembling the (b) (4) connection, your operator covered the sterile opening of the (b) (4) and both sterile ends of the (b) (4) tubing with (b) (4) b) Your operator blocked first air over the exposed indirect product-contact surface of the stopper chute and bowl during stopper addition operation. Your operator was also observed to block first air over the stoppers in the (b) (4) during removal of a jammed stopper.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Melissa D. Ray -S Thuy T. Nguyen -S Hyung-yul Lee -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Melissa Ray, PhD, Microbiologist Thuy Thanh Nguyen, DHSc., Branch Chief Hyung-yul Lee, PhD, Pharmaceutical Scientist	DATE ISSUED April 4, 2025