

DISTRICT ADDRESS AND PHONE NUMBER Zhihao Peter Qiu, Division Director, Division of Biotechnology Manufacturing WO Building 22, Rm 5112 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 796-6655 Email: OPFBLAinspection483Responses@fda.hhs.gov	DATE(S) OF INSPECTION 08/13/2021-08/24/2021
	FEI NUMBER 3010479596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
 Sam MacHour, Senior Vice President/Chief Quality Officer, Quality Center

FIRM NAME Samsung Biologics Co., Ltd.	STREET ADDRESS 300 Songdo bio-daero, Yeonsu-gu
CITY, STATE, ZIP CODE, COUNTRY Incheon, 21987, Republic of Korea	TYPE ESTABLISHMENT INSPECTED Drug Substance Manufacturer

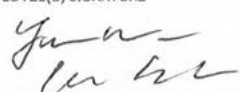
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to 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 (WE) OBSERVED

OBSERVATION 1

Acceptance criteria for cleaning validation are not always justified to prevent product cross-contamination. For example,

- a. GNR-02129, Total Organic Carbon (TOC) Limit Calculation Report for (b)(4) Product, Ver. 1.0, Approved 10/06/2020 only includes TOC limit calculations for cross-contamination of the existing products manufactured in the facility by (b)(4). There is no assessment for cross-contamination of (b)(4) by the other products. TOC limit calculation for (b)(4) in (b)(4) Total Organic Carbon (TOC) Calculation Report for (b)(4) Product, Ver. 1.0, Approved 09/12/2018 does not include an assessment of (b)(4) cross-contamination by residual (b)(4) either. Degradation studies have not been conducted for (b)(4). However, upstream production in Train (b)(4) for (b)(4) ended on 8/18/2021, with (b)(4) being the next product, starting on 08/25/2021. There is no assurance that residual levels of (b)(4) in the shared product contact process equipment are within the maximum carryover for (b)(4).
- b. Dirty Hold Time (DHT) for shared product-contact process equipment in Plan (b)(4) is (b)(4). However, SOP-VAL-00030, Swab and Rinse TOC Recovery Verification for Cleaning Sample, Ver. 5.0, 05/06/2021 only requires a \geq (b)(4) drying time for soiled coupons used in TOC recovery studies. The drying time is unrepresentative of the DHT.


SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Yun Wu, Staff Fellow Chen Sun, Biologist	DATE ISSUED 08/24/2021
--------------------------	--	---	---------------------------

DISTRICT ADDRESS AND PHONE NUMBER Zhihao Peter Qiu, Division Director, Division of Biotechnology Manufacturing WO Building 22, Rm 5112 10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 796-6655 Email: OPFBALinspection483Responses@fda.hhs.gov		DATE(S) OF INSPECTION 08/13/2021-08/24/2021
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Sam MacHour, Senior Vice President/Chief Quality Officer, Quality Center		FEI NUMBER 3010479596
FIRM NAME Samsung Biologics Co., Ltd.	STREET ADDRESS 300 Songdo bio-daero, Yeonsu-gu	
CITY, STATE, ZIP CODE, COUNTRY Incheon, 21987, Republic of Korea	TYPE ESTABLISHMENT INSPECTED Drug Substance Manufacturer	

OBSERVATION 2

Discrepancies are not always investigated to identify the root cause to implement adequate corrective actions. For example,

- a. DEV-007978, Action Level Excursion of Air Viable Sample Collected from (b) (4) in (b) (4) Bioreactor Hall Area (Grade D), was opened on 07/01/2021, for mold detection from (b) (4) locations in the bioreactor hall. The most likely root cause was identified but not confirmed to be preventative maintenance activities of the HVAC filters at the time of environmental monitoring sampling on 06/25/2021. Mold was recovered from the (b) (4) of the (b) (4) used for HVAC filter integrity test. However, additional investigation was not conducted to assess if the HVAC filters were contaminated by mold.
- b. On 08/18/2021, I observed bioburden testing for (b) (4) Cycle at the Plant (b) (4) QC Microbiology Lab. (b) (4) of the sample rinse was abnormally slow for the (b) (4) mL test volume. The testing was aborted and repeated with reduced sample volume (b) (4) mL as per MET-00370, (b) (4) Determination of Bioburden. However, the procedure only requires notification of QC Management. A deviation is not required to be initiated to investigate the root cause or track for recurrence.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Yun Wu, Staff Fellow Chen Sun, Biologist	DATE ISSUED 08/24/2021
-----------------------------------	--	---	---------------------------