DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	06/04/2026 – 06/10/2026*
	FEI NUMBER 3014286622

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
YongWoo Park, President	
FIRM NAME SK Biotek Co., Ltd. (Sejong Plant)	**STREET ADDRESS** 80, Myeonghaksandan-Ro
CITY, STATE, ZIP CODE, COUNTRY Yeondong-Myeon, Sejong-si, 30068, Republic of South Korea	**TYPE ESTABLISHMENT INSPECTED** API 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 I OBSERVED:

OBSERVATION 1

Your firm's established specifications for the microbial enumeration testing of API (b) (4) (b) (4) permit intermittent (skip-lot) or reduced testing frequency. However, the firm has not provided adequate scientific justification to support this reduced testing program at your production facility.

Specifically,

The established specifications for the microbial enumeration testing of API (b) (4) state that if (b) (4) batches all meet the acceptance criteria, the applicable test shall be conducted (b) (4) and that the test must be conducted (b) (4) However, no documented risk assessment, historical data analysis, or validation study was provided during the inspection to support the conclusion that reduced testing provides equivalent assurance of microbiological quality for the API batches produced at your facility.

Since April 2025, approximately (b) (4) batches of the API (b) (4) have been approved for release to the U.S. market.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Lisa R. Hilliard -S Digitally signed by Lisa R. Hilliard -S Date: 2026.06.10 15:56:49 +09'00'	Lisa R. Hilliard, Investigator	06/10/2026

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OBSERVATION 2

Your firm has established hold time studies to support the maximum allowable storage duration or hold times for raw materials, intermediates, and finished APIs held between manufacturing steps and stages. However, the hold times are not documented and verified in the batch record or other production documents.

Specifically,

Your firm's manufacturing process for the production of the APIs (b) (4) (b) (4) includes (b) (4) major process stages for each finished API. It is unclear in the API production batch records whether hold steps are required and documented during the process stages. No written procedures or risk assessments were provided during the inspection to justify the lack of hold time documentation and verification to ensure that materials, intermediates, and finished APIs are held at various stages during production and prior to final API packaging without adversely affecting quality attributes, such as purity, microbial limits, and moisture content.

Since November 2024, approximately (b) (4) batches of the (b) (4) (b) (4) have been approved for release to the U.S. market.

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*DATES OF INSPECTION
06/04/2026 (Thu), 06/05/2026 (Fri), 06/08/2026 (Mon), 06/09/2026 (Tue), 06/10/2026 (Wed)

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	Lisa R. Hilliard -S Digitally signed by Lisa R. Hilliard -S Date: 2026.06.10 15:57:16 +09'00'	Lisa R. Hilliard, Investigator	06/10/2026