DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg 71, Rm 5054 Silver Springs, MD 20993-0002 (240)402-9160	01/22/2026-01/30/2026
	FEI NUMBER 3020223359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Umesh Shaligram, Executive Director, Manufacturing and R&D

FIRM NAME	STREET ADDRESS
Serum Institute of India Private Ltd.	S. No. 203-205, 212, 223, 268-270(H) & 104-110, 113-114, 168-170 (M)
CITY, STATE, ZIP CODE, COUNTRY Hadapsar, Pune, Maharashtra, 411 028, India	TYPE ESTABLISHMENT INSPECTED Vaccine 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:

DRUG SUBSTANCE

OBSERVATION 1

Out of Specification Investigation for the Drug Substance is not thoroughly investigated.

(A) Specifically, you initiated an Out-of-Specification (OOS) investigation (b) (4) for SARS-CoV-2rS Drug (b) (4) Batch No. (b) (4) on February 20, 2025, after obtaining a (b) (4) (b) (4) and (b) (4) investigations identified no laboratory or manufacturing errors, respectively, and a (b) (4) on March 18, 2025, confirmed the OOS at (b) (4) The investigation timeline and results are summarized below:

Investigation Step	Result/Finding	Specification/Expected
(b) (4)		

The OOS result was invalidated by attributing it to degradation of the (b) (4) despite inconsistent (b) (4) testing where only (b) (4) data aligned with historical trends. The investigation concluded the reference standard had declined in performance and invalidated the OOS, even though (b) (4)

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	(b) (6), (b) (7)(C) (b) (6), (b) (7)(C) Investigato	01/30/2026

yielded a result (b) (4) Drug (b) (4) batch (b) (4) was released for processing into finished product batch (b) (4), which was subsequently released to the U.S. market (released: January 27, 2026)

DRUG PRODUCT

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

(B) Your Out-of-Specification SOP 1003-0006-008 Section 6.5.21 explicitly prohibits (b) (4) original OOS results with (b) (4) results during investigations, as this obscures variability. Despite this requirement, you (b) (4) (b) (4) data for SARS-CoV-2rS drug product lots when some individual results are OOS and others are within specification to justify invalidating the OOS results, as demonstrated in the following investigations:

OOS No.	Batch	Individual Results	Specification	Average Result	Investigation Conclusion*
(b) (4)					No laboratory error is detected; (b) (4) OOS stands invalid if (b) (4)
					No obvious analytical error was identified; (b) (4) considered for final reporting; shall stand invalid, without any further investigation
					No obvious analytical error was identified

*as reported in the respective investigation reports

(C) Action level excursions of non-viable particulates (NVPC) in the Grade (b) (4) used for filling of SARS-CoV-2rS drug product are not always investigated for the potential of ingress into drug product units, and exposed (b) (4) during

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these excursions are not (b) (4) from the filling line. During filling operations on January 28, 2026, torn (b) (4) was observed in close proximity to open (b) (4) units undergoing filling. The table below summarizes NVPC action level excursions encountered during the filling of (b) (4) manufactured in 2025 that were not investigated.

Batch	Number of Excursions
(b) (4)	18
	9
	2
	8
	9
	14

OBSERVATION 2

Written production and process control procedures are not documented at the time of performance.

Specifically,

(A) Pertaining to active air testing used to evaluate the environmental conditions of Grade (b) (4) areas supporting drug product manufacture, the following deficiencies were identified in the concurrence between electronic records (i.e., instrument history) and official documentation.

From February 8, 2025, to October 10, 2025, approximately (b) (4) active air samples cannot be accounted for based on instrument history. Additionally, there is a lack of correspondence between sample nomenclatures and sampling sites, preventing confirmation that intended samples were procured. Multiple instances were identified where samples retained identical identifiers:

Date	Instrument	Total Samples Taken	Samples with Identical Identifier
January 8, 2026	(b) (4)		

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(b) (6), (b) (7)(C) Investigator

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January 8, 2026	(b) (4)
September 29, 2025	

Your firm does not reconcile the disposition of aborted sample plates and cannot determine whether aborted samples led to overexposure of subsequent samples. While your firm hypothesized that samples may have been overexposed and subject to desiccation, no study has been conducted to evaluate these implications. All quality control documentation is silent regarding aborted sampling events.

Incomplete active air samples were used for reporting, yet the "Environmental Monitoring Record" does not indicate when incomplete sample volumes or aborted testing occurred. For example, on February 6, 2025, sampling for point (b) (4) was procured at an incomplete volume, but the record provides no indication of this deficiency.

(B) Your production records demonstrate a lack of attributability between manufacturing activities and batch documentation. (b) (4) that Production personnel document, and the same Production personnel who complete the documentation also (b) (4) For instance, on January 27, 2026, this occurred with the (b) (4) This and other similar patterns of inadequate attributability and lack of independent verification extends to 2025 drug product lots for the U.S. market, including lots (b) (4) (b) (4) and (b) (4).

(C) On January 28, 2026, within the (b) (4) laboratory, the "Sterilization Start Time" of format (b) (4) was not completed despite ongoing sterilization activities. Your firm's Deputy General Manager explained a procedural handling of documentation whereby the sterilization start time is not contemporaneously documented. Subsequently, a backdated sterilization start time was entered.

(D) On January 30, 2026, in the (b) (4) laboratory, an analyst was observed rapidly completing documentation on format (b) (4) for a (b) (4) used to test the purity of Drug (b) (4) by (b) (4). When questioned, the analyst stated they were retrospectively documenting the (b) (4) activity while the (b) (4) was actively undergoing the (b) (4) process.

DRUG SUBSTANCE

OBSERVATION 3

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Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination of Drug (b) (4) Lots.

Specifically, the product contact surfaces of (b) (4) and systems used in SARS-CoV-2rS Drug (b) (4) manufacturing are not adequately maintained.

(A) On January 29, 2026, the (b) (4) system (b) (4) displayed (b) (4)

These conditions were subsequently identified as (b) (4) system. The equipment had been documented as cleaned on January 28, 2026.

(B) Additionally, the resin in (b) (4) system (b) (4) (b) (4) yet the (b) (4) was classified as clean and recorded as being on its (b) (4) use of a (b) (4) lifetime allowance.

***DATES OF INSPECTION**

1/22/2026(Thu), 1/23/2026(Fri), 1/24/2026(Sat), 1/27/2026(Tue), 1/28/2026(Wed), 1/29/2026(Thu), and 1/30/2026(Fri).

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