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	9/18/2023-9/22/2023
	FEI NUMBER 3016688535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Guillermo Paraja Arrechea, Site Director, Site Director

FIRM NAME	STREET ADDRESS
Rovi Pharma Industrial Services S.A.	Paseo De Europa 50
CITY, STATE, ZIP CODE, COUNTRY San Sebastian De Los Reyes, Madrid, 28703 Spain	TYPE ESTABLISHMENT INSPECTED sterile 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

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,

A. Your quality unit opened CAPA SC-160/23 to document and correct the amount of time allowed to read environmental monitoring plates that have completed incubation. Procedure PNTSR035, which provides instruction for plate incubation and reading, did not include a timeframe for reading/interpreting plates that have completed incubation. According to the associated documentation, during the approximately 1-month timeframe (February - March 2023) plate results were not read and recorded after incubation, but had a lapsed timeframe for as much as 21 days for some plates. Although CAPA SC-160/23 includes actions to amend the written procedure with a required recording timeframe, associated deviations (including S0102/23-DV) and CAPAs do not include an analysis of all plate results affected or impact on results obtained.

B. On 04/22/23, an aberrant result was obtained for the [redacted] analysis of [redacted] sample point [redacted]. Associated Investigation report IR-20011/1 includes the cumulative review of several aberrant results obtained on 04/22/23. According to IR-20011/1, the first sample to obtain an aberrant result was from [redacted] sample point [redacted] this sample was run [redacted] consecutive times due to not meeting %RSD suitability requirements for a given run; the procedure for [redacted] only permits [redacted] attempts (total) when suitability %RSD is not met and the event was not elevated to an investigation or equivalent. Investigation report IR-

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer Lalama, Investigator Dorothy P Kramer, Investigator	X Jennifer Lalama Investigator Signed By: Jennifer Lalama -S Date Signed: 09-22-2023 04:58:39	9/22/2023

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20011/1 concluded that contamination from the dirtiest samples at the beginning of the run affected subsequent samples; IR-20011/1 did not establish which test results were invalidated, which samples were eligible for a repeat test, and when the system was adequate to produce reproducible results.

OBSERVATION 2

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically, the logbook for the receipt and removal of materials from room (b) (4) (*Introduccion de Materiales a Zona Clasificada D 1a Planta* (SR049F01)) requires a (b) (4) hold time for materials that have been freshly sanitized with (b) (4) before being moved to the Classified D zone. The (b) (4) logbook shows that during the period from June 16-July 19, 2023 at least four items were removed after only a (b) (4) hold time. Additionally, many items were left for an extended period of time in (b) (4) before being removed. According to procedure PNTSR049/2.0 Introduccion y Salida de Materiales en Zona Clasificada D, there are no instructions to define the extended length of time a material may be held in (b) (4) after sanitization or when the material must be re-sanitized.

X Dorothy P Kramer
Investigator
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Date Signed: 09-22-2023 04:59:18

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	Jennifer Lalama, Investigator Dorothy P Kramer, Investigator X Jennifer Lalama Investigator Signed By: Jennifer Lalama -S Date Signed: 09-22-2023 04:58:39	9/22/2023