DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Headquarters - White Oak CDER/OTS/OSIS/DNDSI 10903 New Hampshire Avenue Silver Spring, MD 20993; (301) 796-3865 Industry Information: www.fda.gov/oc/industry	8/25/2025 to 8/29/2025
	FEI NUMBER 3005865090

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Walid Elbast, Site Manager

FIRM NAME	STREET ADDRESS
SGS France Life Sciences	90 Avenue des Hauts de la Chaume BP 28
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
86281 Saint Benoit, Cedex, France	Bioanalytical facility

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) (WE) OBSERVED:

The following observations pertaining to method validation and study sample activities for (b)(4) (b)(4)):

1. The chiral analytical method described in reports (b)(4) did not demonstrate sufficient specificity to measure low concentrations of (b)(4) in the presence of high concentrations of (b)(4) (b)(4) in human plasma and neat solution. Specifically, a peak greater than 20% of the mean of LLOQ samples was consistently detected at the retention time of (b)(4) when only (b)(4) was added to matrix. Despite multiple attempts to find the source of interference, the issue was not resolved, and the analytical method was used to measure individual concentrations of (b)(4) in subject samples from studies evaluating (b)(4)

2. Not all tested analytical sequences were conveyed in method validation report # (b)(4) and bioanalytical report # (b)(4) ((b)(4)) for (b)(4) . Specifically:

2a. Method validation Run #9 analyzed on December 15, 2022, was rejected after completion due to erratic internal standard signals. The LC-MS/MS instrument was cleaned, and the run was reinjected and accepted on December 16, 2022. However, the method validation report does not mention the initial rejection, reasons for rejection, or reinjection of run #9.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Xingfang Li -S Digitally signed by Xingfang Li -S Date: 2025.08.29 08:50:51 -04'00' RUBEN C. AYALA -S Digitally signed by RUBEN C. AYALA -S Date: 2025.08.29 14:44:02 +02'00'	Ruben C. Ayala, PharmD, Lead Pharmacokineticist Xingfang Li, MD, RAC, Pharmacologist	08/29/2025

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2b. Run #3 containing subject samples from study (b)(4) 1 was analyzed on July 30, 2024. The run failed acceptance criteria due to a reconstitution error observed in three (3) calibration standards. The study report does not disclose the initial run rejection and reasons for rejection.

2c. Run #24 containing subject samples from study (b)(4) was analyzed on August 26, 2024. The run failed acceptance criteria due to carryover observed in a blank sample. The study report does not disclose the initial run rejection and reasons for rejection.

3. Not all method validation experiments were documented contemporaneously, and it was difficult to verify adherence to analytical plan. Specifically, sample preparation steps were routinely typed, printed, and pasted in source records post-experiment and with limited secondary verification. For example, in run #2 which evaluated matrix effect, typed notes stated that internal standard was added to run samples. However, corresponding results showed no internal standard signal in those samples. A subsequent note from the study director stated that a sample processing error had occurred; a statement which further casts doubt on the veracity of sample preparation steps typed non-contemporaneously by the technician.

4. Not all established SOPs were followed during method validation # (b)(4) for (b)(4) . Specifically, the technician who processed run #1 evaluating long term frozen stability of analytes (b)(4) rejected the run based on pre-established acceptance criteria because excessive analyte signal was observed in a blank sample. However, the study director overturned the decision to reject run #1 based on scientific perspective. Because the study director's decision was not based on pre-established acceptance criteria, a deviation from plan should have been documented in accordance with SOP-002946 version 3 titled "Methodology SOP," but none was documented in source records.

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	Xingfang Li -S Digitally signed by Xingfang Li -S Date: 2025.08.29 08:51:42 -04'00' RUBEN C. AYALA -S Digitally signed by RUBEN C. AYALA -S Date: 2025.08.29 14:46:08 +02'00'	Ruben C. Ayala, PharmD, Lead Pharmacokineticist Xingfang Li, MD, RAC, Pharmacologist	08/29/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."