DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	3/17/2026-3/20/2026
	FEI NUMBER 1418028

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen E. Rundlett , General Manager

FIRM NAME	STREET ADDRESS
SGS North America Inc.	616 Heathrow Dr
CITY, STATE, ZIP CODE, COUNTRY Lincolnshire, IL 60069-4205	TYPE ESTABLISHMENT INSPECTED Contract Lab

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

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm does not perform minimum verification testing to qualify the reference standards you use for testing of various drug products and raw materials for release, or for stability testing. Instead, according to SOP-000898, Reference Standards, Version 4, your firm relies on a review of the Certificate of Analysis of incoming lots to assess the quality of the reference standard. Examples are as follows:

A. Your firm used (b) (4) Reference Standard (Lot (b) (4) supplied by (b) (4) received 04Jun2025) to conduct method transfer activities without performing verification testing to confirm the identity, quality, and suitability of the reference standard lot prior to use. According to your SOP SOP-000898 - Reference Standards, V4, section 5 your firm relies on the COA to verity the purity and identification of reference standards. Examples include, but are not limited to:

- SGS-MT-09-25-29R, *Method Transfer Report for the Determination of* (b) (4) *Concentration in* (b) (4) *by* (b) (4) *and Assay for* (b) (4) *in* (b) (4) (b) (4) (November 03, 2025): Reference Standard Lot (b) (4) was used throughout the method transfer study (Section 4.2, page 7; Section 6.3.1.1, page 43) without documented

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Gabriel Bermudez-Picart, Investigator
Michele L Glendenning, Investigator

X Michele L Glendenning Investigator Signed By: Michele L. Glendenning -S Date Signed: 03-20-2026 12:52:59

DATE ISSUED
3/20/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	3/17/2026-3/20/2026
	FEI NUMBER 1418028

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Stephen E. Rundlett , General Manager	
FIRM NAME SGS North America Inc.	STREET ADDRESS 616 Heathrow Dr
CITY, STATE, ZIP CODE, COUNTRY Lincolnshire, IL 60069-4205	TYPE ESTABLISHMENT INSPECTED Contract Lab

evidence of verification testing upon receipt or prior to uses.

- SGS-MT-09-25-20R, *Method Transfer Report for Identification of* (b) (4) (b) (4) *by* (b) (4) (b) (4) (b) (4) (b) (4) (November 03, 2025): The same Reference Standard Lot (b) (4) was used as the positive control throughout all (b) (4) independent assay sessions (Section 6.3.3, pages 44-45; Table 6, page 47) without documented verification testing.

B. According to SGS protocol SGS-SS-09-24-001, *Release Testing for* (b) (4) (b) (4) *for* (b) (4) (January 08, 2026, through February 10, 2026): (b) (4) Reference Standard (Lot (b) (4)) was used throughout multiple analytical methods for release testing of Batch (b) (4) (Assignment (b) (4) /Sample (b) (4) without documented evidence of verification testing upon receipt or prior to use. The reference standard was utilized in the following methods:

- ☐ HPLC Assay (Method 09D05-563)
- ☐ Dissolution Testing (Method 09D05-467)

The Certificate of Analysis (pages 43-48, dated 09-Feb-2026, corrected version 3 dated 10-Mar-2026) reports results for (b) (4) Assay (98.6%), (b) (4) Impurities and Degradation Products, and Stage (b) (4) Dissolution testing, all of which relied on the reference standard for quantitation and system suitability.

C. According to Lab Assignment ID:(b) (4) (SGS Protocol SGS-SS-09-22-04P, *Release Testing for* (b) (4)) *for* (b) (4) (December 04, 2025, through December 17, 2025) your firm used USP (b) (4) reference standard (RS) ((Lot (b) (4)) to perform release testing for (b) (4) for (b) (4) (b) (4) dose (b) (4) lot (b) (4) (Assignment (b) (4) /Sample (b) (4) Released on (b) (4) the Certificate of Analysis (pages 49-56, dated 19-Dec-2025) reports results for (b) (4) Assay (102.9%), (b) (4) Impurities and Degradation Products, Uniformity of Content, and Stage (b) Dissolution testing.Tests using this sample

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Gabriel Bermudez-Picart, Investigator Michele L Glendenning, Investigator	X Michele L Glendenning Investigator Signed By: Michele L. Glendenning -S Date Signed: 03-20-2026 12:52:59	3/20/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	3/17/2026-3/20/2026
	FEI NUMBER 1418028

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Stephen E. Rundlett , General Manager

FIRM NAME	STREET ADDRESS
SGS North America Inc.	616 Heathrow Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lincolnshire, IL 60069-4205	Contract Lab

and reference standard include:

- ☐ Identification, Impurities, and Uniformity of Content (Method 09D05-428)
- ☐ HPLC Assay (Method 09D05-564)
- ☐ Dissolution Testing (Method 09D05-345)

These tests were performed using a reference standard that had not undergone minimal verification testing to qualify the RS upon receipt and prior to use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Gabriel Bermudez-Picart, Investigator Michele L Glendenning, Investigator X Michele L Glendenning Investigator Signed By: Michele L. Glendenning -S Date Signed: 03-20-2026 12:52:59	3/20/2026

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 judgment, 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."