DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	1/5/2026-1/14/2026* FEI NUMBER 3010680515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kyle Y. Flanigan, CEO

FIRM NAME	STREET ADDRESS
US Specialty Formulations LLC	1401 S Albert St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18103-4141	Outsourcing 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 WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

(A) Your firm has not established scientifically sound and appropriate specifications for finished drug product identity, pH, assay, and impurity specifications to verify the labeled strength of 0.17 g/mL for Sarracenia Purpurea 0.17 g/mL for Injection, nor has it conducted the required testing prior to release. From June 1, 2024, to January 5, 2026, (b) (4) lots of Sarracenia Purpurea 0.17 g/mL for Injection were released and distributed to the U.S. market without assay and impurities testing, totaling approximately (b) (4) vials, and two finished products lots (Lot # 02RS1502A and # 02RS1507A) were not tested for pH. pH testing was not performed for the lots produced prior to 2025.

(B) Your quality unit failed to ensure that potency and impurity testing of your in-house manufactured Sarracenia Purpurea Bulk Distillate were performed as part of product release specifications prior to filling of Sarracenia Purpurea 0.17 g/mL for Injection. From June 1, 2024, to January 5, 2026, (b) (4) released lots of Sarracenia Purpurea Bulk Distillate were used in the filling of (b) (4) lots of Sarracenia Purpurea 0.17 g/mL for Injection, totaling approximately (b) (4) vials.

(C) Your quality unit failed to ensure that sufficient data support the (b) (4) retest date for the in-house manufactured Sarracenia Purpurea Bulk Distillate used in the filling of Sarracenia Purpurea 0.17 g/mL for Injection. For example, Sarracenia Purpurea Bulk Distillate (Lot # Lot # (b) (4)) was produced on September 5, 2025, and assigned a (b) (4) retest date September 5, 2026. This bulk lot was used in the filling of finished drug product Sarracenia Purpurea 0.17 g/mL for Injection (Lot # 02RT1503A; Exp. 10/31/2026) on October 14, 2025 to October 15, 2025.

(D) Your Quality Unit failed to ensure that identity testing is performed on each lot of benzyl alcohol used in Sarracenia Purpurea Bulk Distillate production, which is subsequently filled into Sarracenia Purpurea 0.17 g/mL for Injection. An assay method is utilized for testing the benzyl alcohol ingredient, which is not an

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	Mindy M Chou, Investigator Lu Chen, Investigator	X Mindy M Chou Investigator Signed By: 2000648922 Date Signed: 01-14-2026 11:27:37	1/14/2026

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identity test and has not been validated for its intended use, to establish the suitability of the component.

(E) Following discovery of an incorrect expiration date on vial labels by the QC Lab Technician, approximately (b) (4) vials were relabeled for Sarracenia Purpurea 0.17 g/mL for Injection (Lot # 02RT1501A; Exp. 2/28/2026). However, there is no QA approval for the relabeling activity, no documented relabeling procedure, no reconciliation of removed labels, and no reconciliation of new labels printed and applied with the correct expiration date.

This represents a repeat observation from previous inspections, indicating that USSF has not implemented adequate corrective actions to address fundamental quality control deficiencies.

OBSERVATION 2

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically,

(A) You have not established stability-indicating test methods to determine the stability of Sarracenia Purpurea 0.17 g/mL for Injection, and the current analytical methods lack the capability to identify potential degradants and impurities in the finished drug product.

(B) You have not demonstrated that your in-house benzyl alcohol test method QC-0060, *Assay of Benzyl Alcohol*, for testing incoming material is equal to or better than the USP compendial method. Benzyl alcohol is the preservative in Sarracenia Purpurea 0.17 g/mL for Injection.

(C) Method validation has not been performed for QC-0060, *Assay of Benzyl Alcohol*. This method is utilized for benzyl alcohol raw material release testing as well as release and stability testing of Sarracenia Purpurea Bulk Distillate and Sarracenia Purpurea 0.17 g/mL for Injection.

(D) Prior to December 29, 2025, your firm used the (b) (4) sample from the benzyl alcohol ingredient supplier as the in-house reference standard and did not qualify this secondary standard against the USP reference standard. Benzyl alcohol assay is part of the finished product release testing of Sarracenia Purpurea 0.17 g/mL for Injection.

(E) The method validation of QC-0102, *Assay of* (b) (4) , was conducted with accuracy assessment inferred from acceptable linearity and precision results rather than through direct

accuracy evaluation.

(F) Product-specific method validation has not been performed for bacterial endotoxin testing of Sarracenia Purpurea 0.17 g/mL Injection to validate the use of a (b) (4) and the (b) (4) sampling technique involving (b) (4) vials as outlined in QC-0035.F2, *Bacterial Endotoxin Assay Report for Sarracenia Purpurea*, when analyzed using the (b) (4) system.

(G) Growth promotion testing for (b) (4) plates (plate volume × diam.: (b) (4)) used in batch environmental monitoring is conducted by the firm's third-party laboratory. The testing methodology involves using (b) (4) microorganism. Your Quality Unit did not confirm that appropriate validation comparing single-organism plates versus (b) (4) was completed by your third party lab.

OBSERVATION 3

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

(A) You do not have adequate stability data from a scientifically sound stability program to support the labeled 12-month product expiry date for Sarracenia Purpurea 0.17 g/mL for Injection. In addition, the finished product expiration date is calculated from the filling date rather than the bulk manufacturing date, and the stability program design does not account for the age of the bulk material at the time of filling. Sarracenia Purpurea Bulk Distillate Lot # (b) (4) (manufactured (b) (4) ; retest date (b) (4)) was used to fill two lots of Sarracenia Purpurea 0.17 g/mL for Injection with different expiration dates: Lot #02RT1501A filled on February 21, 2025 (Exp. 02/28/2026) and Lot #02RT1502A filled on May 16, 2025 (Exp. 5/31/2026).

(B) The long-term stability study for Sarracenia Purpurea 0.17 g/mL for Injection is conducted at the label storage condition of 15°C to 30°C. The stability sample vials are stored in a (b) (4) storage cabinet that lacks temperature and humidity control and therefore are not stored under controlled conditions.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

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(A) On January 5, 2026, we observed QC Lab Technician (b) (6), (b) (7)(C) performing AQL testing of Sarracenia Purpurea 0.17 g/mL for Injection after the Production Team had completed 100% visual inspection of unlabeled vials. According to Section 4.3.1.1 of QC-0003, *Visual Inspection Program*, AQL inspection is performed after the vials are labeled. We observed QC Lab Technician (b) (6), (b) (7) (C) visually inspecting the labeled vials for defects including particulate. We also observed the QC Lab Technician performing visual fill volume verification without using referenced vials to adequately assess fill volume and the firm does not have a procedure describing how to perform fill volume verification check.

(B) There is no written procedures describing the assembly of the visual inspection test set used to qualify visual inspectors. The vial inspection test set was assembled in 2022 and consists of (b) (4) vials, with approximately 65% defective units, including (b) (4) vials with (b) (4) on the flip-off cap. No written records exist to document the test set assembly process, and the test set has not undergone qualification to demonstrate its suitability for personnel training purposes. According to your Executive Director of Quality, only (b) (4) vials from the complete test set are utilized for visual inspection qualification purposes. No standardized written procedure exists governing the selection criteria for vials used in personnel qualification. Additionally, the initial inspector qualification is conducted with (b) (4) of the (b) (4) vials from the test set, whereas during routine 100% visual inspection during production, inspectors can examine up to (b) (4) vials in a (b) (4) session before a break is required

(C) The firm requires visual inspectors to undergo (b) (4) eye examinations; however, the examination record consists only of an eye exam prescription with no written comments. No verification exists that inspectors achieve 20/20 vision with correction or meet other visual acuity standards.

(D) Your firm has not completed process validation for the filling operation of Sarracenia Purpurea 0.17 g/mL Injection to demonstrate that fill volume accuracy and precision are consistent across batches. Additionally, no production yield specification has been established to ensure batch-to-batch consistency. Your firm has not defined filling operation loss limits and excludes spilled Sarracenia Purpurea Bulk Distillate from yield calculations. Your firm also has not performed container closure integrity validation.

(E) The following discrepancies were observed in the (b) (4) and (b) (4) performance qualification (PQ) for (b) (4) (Equipment #(b) (4)) and (b) (4) (Equipment #:(b) (4)) used in the (b) (4) sterilization of Sarracenia purpurea 0.17 g/mL Injection:

(i) The (b) (4) PQs were conducted with (b) (4) vials and did not include worst-case partial (b) (4) study. Validation has not been performed for the smallest (b) (4) size used in (b) (4) sterilization of Sarracenia purpurea 0.17 g/mL Injection. You do not have validated data to

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demonstrate that the (b) (4) is the worst-case (b) (4).

(ii) There is no documented rationale for not monitoring the (b) (4) during (b) (4) performance qualification to confirm drain behavior has not changed.

(iii) A three-run performance qualification (PQ) of (b) (4) conducted in 2024 identified minimum accumulated lethality values at locations (b) (4) and (b) (4) (Run (b) (4)), (b) (4) (Run (b) (4)), and (b) (4) and (b) (4) (Run (b) (4)). The (b) (4) run 2025 PQ identified location (b) (4) as exhibiting the minimum accumulated lethality. Although all acceptance criteria were met, no variability assessment was performed.

(iv) (b) (4) and (b) (4) studies have not been completed for (b) (4) and (b) (4).

This represents a repeat observation from previous inspections.

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

(A) The balance (Equipment ID: (b) (4); Equipment # (b) (4)) calibration was performed at a single calibration point ((b) (4)) and did not cover the operating range. The balance is used to perform pump calibration during setup of Sarracenia Purpurea 0.17 g/mL for Injection production, where the target weight is (b) (4) (equivalent to (b) (4) target fill volume).

(B) The (b) (4) (Equipment Name: Autocapper (b) (4); Equipment # (b) (4); Serial # (b) (4)) used to crimp seal the Sarracenia Purpurea 0.17 g/mL for Injection vials has not been qualified and there is no maintenance program for the capper.

(C) The (b) (4) printer and (b) (4) software used in batch label printing of Sarracenia Purpurea 0.17 g/mL for Injection has not been qualified.

OBSERVATION 6

Certificates of testing of containers and closures are accepted in lieu of testing without establishing the reliability of the supplier's test results through appropriate validation of the test results at appropriate intervals.

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Specifically, your firm accepts supplier certificates of analysis for (b) (4) vial stoppers without adequately demonstrating the reliability of the supplier's testing. Although the firm has procedures for vendor qualification, it has not performed periodic verification of supplier results through testing or audits, does not maintain a quality agreement with the stopper supplier, and has not conducted confirmatory testing to demonstrate ongoing confidence in the supplier's analytical data. As a result, the firm has not adequately established the reliability of supplier test results for these container-closure components prior to use.

OBSERVATION 7

Drug products are not stored under appropriate conditions of temperature so that their identity, strength, quality, and purity are not affected.

Specifically, Sarracenia Purpurea Bulk Distillate bags used in the production of Sarracenia Purpurea 0.17 g/mL for Injection are stored in (b) (4) with no temperature monitoring of the area.

***DATES OF INSPECTION**

1/05/2026(Mon), 1/06/2026(Tue), 1/07/2026(Wed), 1/08/2026(Thu), 1/09/2026(Fri), 1/12/2026(Mon), 1/13/2026(Tue), 1/14/2026(Wed)

X Lu Chen
Investigator
Signed By: 2003284605
Date Signed: 01-14-2026 11:28:07

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	Mindy M Chou, Investigator Lu Chen, Investigator	X Mindy M Chou Investigator Signed By: 2000648922 Date Signed: 01-14-2026 11:27:37	1/14/2026

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."