

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Denver District Office 6th Ave & Kipling St, Building 20 Denver, CO 80225-0087 Phone: 303-236-3000 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 11/08-19/2021*
	FEI NUMBER 3017888878

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Thomas K. Langdon, Chief Quality Officer

FIRM NAME Specialty Process Labs, LLC	STREET ADDRESS 1030 E. Lone Cactus Dr.
CITY, STATE AND ZIP CODE Phoenix, AZ 85024	TYPE OF ESTABLISHMENT INSPECTED 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 (I) (WE) OBSERVED:

**Facilities and Equipment System**

**OBSERVATION 1:**

Failure to exercise sufficient controls over computerized systems to prevent unauthorized access or changes to data.

Specifically,

**A. Quality Control (QC) Laboratory:**

1. Raw data used for assay and ID testing regarding all validation lots of finished thyroid API was altered from its original state.
2. The electronic spreadsheet used to perform HPLC assay calculations was never validated.
3. There are no restricted privileges for QC personnel using the (b) (4) HPLC software.
4. No established auditing program for computer generated laboratory data.

**B. Operations:**

1. Lack of controls for access to the (b) (4) where manufacturing, packaging, complaints, and other quality documents are stored for thyroid API. For example, on 11/17/21, I observed top level management, quality personnel, and production personnel having full control to create, modify, and delete files on the (b) (4).

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Christopher M. Jenner -5 <small>Digitally signed by Christopher M. Jenner -5 Date: 2021.11.19 15:05:17 -07'00'</small>	EMPLOYEE(S) NAME AND TITLE (Print or Type)  Christopher M. Jenner, Investigator	DATE ISSUED  11/19/2021
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**OBSERVATION 2:**

Failure to appropriately qualify critical equipment.

Specifically,

A. You approved the performance qualification for the (b) (4), ID: (b) (4), without adequate data to support your justification. Only (b) (4) runs were performed and each did not pass your predetermined acceptance criteria. The (b) (4) is used to blend all finished API.

B. The API storage area used to store materials, intermediates, finished API, reserve samples, and real time stability samples has never been temperature mapped. The API storage area is approximately 24 ft. x 24 ft. x 11 ft (L x W x H) and there is only one temperature monitoring device.

**OBSERVATION 3:**

Failure to validate and monitor the (b) (4) to ensure (b) (4) is of appropriate quality.

Specifically, your firm has never tested the (b) (4) from the (b) (4) or the (b) (4) (b) (4). The (b) (4) is used for cleaning in manufacturing. The (b) (4) is used for cleaning, standard preparation, and sample preparation in the analytical laboratory. No routine maintenance is performed on either of these (b) (4).

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Production System

**OBSERVATION 4:**

Failure to establish written procedures to monitor the progress and control the performance of processing steps that may cause variability in the quality characteristics of your intermediates.

Specifically, the firm has not fully validated the manufacturing process for the thyroid API.

**OBSERVATION 5:**

Failure to ensure that intermediate batches meet specifications prior to blending with other batches.

Specifically, intermediate API lot (b) (4) was never retested before being used to subsequently produce finished thyroid API lot B20361-FS. The finished API batch, lot B20361-FS, was released and distributed. You stated intermediate API batches should be retested (b) (4) from the initial analytical test date to ensure product quality and purity is maintained.

Laboratory System

**OBSERVATION 6:**

Failure to establish an impurity profile for identified and unidentified impurities.

Specifically, there are unknown peaks on the chromatography results for your finished thyroid API. This was observed on your HPLC data and on your UPLC data for your validation lots.

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**OBSERVATION 7:**

Failure to validate and verify the suitability of microbiological methods.

Specifically, your firm has never validated the microbiological method used to test finished thyroid API to ensure it is equivalent or better than USP test methods. In addition, no suitability was performed for your API drug product.

Quality System

**OBSERVATION 8:**

Failure of your quality unit to ensure that effective systems are used for maintaining and calibrating critical equipment.

Specifically,

Freezer ID: (b) (4) – This freezer is used to store raw frozen thyroid glands and has been in use for approximately four years. Per your Director of Quality, the operating range for this freezer is (b) (4). The monitoring records indicate a minimum of -12.2°F to a maximum of 91.2°F from 11/01/20 to 11/16/21. No qualification, maintenance, or calibration records were available for this freezer.

Freezer ID: (b) (4) – This freezer is used to raw store frozen thyroid glands and has been in use for approximately four years. Per your Director of Quality, the operating range for this freezer is (b) (4). The monitoring records indicate a minimum of -12.0°F to a maximum of 80.0°F from 11/01/20 to 11/16/21. No qualification, maintenance, or calibration records were available for this freezer.

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Refrigerator ID: SPL Refrigerator – This refrigerator is used to thaw raw grinded thyroid glands for up to (b) (4) and has been in use for approximately four years. Per your Director of Quality, the operating range for this refrigerator is (b) (4). The monitoring records indicate a minimum of 34.4°F to a maximum of 77.3°F from 11/01/20 to 11/16/21. No qualification, maintenance, or calibration records were available for this refrigerator.

Your Director of Quality stated there was always a monitoring device in Freezer (b)(1), Freezer (b)(4) and the SPL Refrigerator; however, all devices were not working properly prior to him starting the temperature monitoring program around 10/08/21 for the freezers and around 09/28/21 for the refrigerator.

**OBSERVATION 9:**

Failure to reserve samples in the same packaging system that represents the finished API.

Specifically, on 07/29/21 and 10/29/21, there were no reserve samples collected for finished thyroid API lot B20361-FS that was repackaged in to 64 oz wide mouth (b) (4) bottles.

**OBSERVATION 10:**

Failure to ensure that necessary calibrations are performed and recorded.

Specifically, all (b) (4) luminometer devices, with IDs SPL-1 095553, SPL-2 096299, and SPL-3 095930, were not being calibrated per the manufacturer’s instructions. Your firm uses these devices to test cleaning effectiveness on equipment prior to all manufacturing operations.

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**OBSERVATION 11:**

Failure to evaluate contract laboratories to ensure the specific operations occurring at the contract sites are CGMP compliant.

Specifically, the firm has never documented any evaluation of third-party laboratories used for finished thyroid API testing. Third-party laboratory testing includes fat analysis, inorganic iodides, and residual solvents.

\*Dates of Inspection: 11/08-10/21, 11/12/21, 11/15-17/21, and 11/19/21

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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."