DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	1/18/2024 - 1/26/2024
	FEI NUMBER 3017888878

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dai Y. Jinn

FIRM NAME	STREET ADDRESS
Specialty Process Labs LLC	1850 E. Riverview Dr.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Phoenix, AZ 85034-6703	API 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:

Observation 1
Validation of manufacturing processes of thyroid API is inadequate

Specifically,

A. Prior to moving to its current location in May 2022, your firm failed to adequately validate your thyroid, USP API manufacturing processes. Your firm only conducted (b) (4) validation for thyroid API FS (full strength) and USP (1X), but not for other processing steps such as (b) (4) and (b) (4) at the old facility; however, intermediates produced from that facility are used for blending into thyroid FS and then into finished thyroid API USP (1X) for commercial use. Your firm manufactured (b) (4) batches of thyroid API USP (1X) and (b) (4) batches of thyroid FS using intermediates produced from the old facility released for the US market in 2023.

B. Your firm failed to adequately validate your thyroid USP API manufacturing processes after moving to its current location. Your firm has performed process validation of (b) (4) blending and (b) (4), but not for early stages of manufacturing processes such as (b) (4) and (b) (4). For example, your firm destructed thyroid, Lot# (b) (4) on 4/13/2023 given that the product was too greasy due to high fat content. Your firm is intended to produce intermediates for further processing into finished thyroid API products in the future.

C. Process validation for (b) (4) and blending did not record critical control parameters. For example, your firm has defined blender speed at (b) (4) and (b) (4) speed at (b) (4) as critical control parameters; however, these critical control parameters were not recorded in the validation protocols for Validation of Thyroid API USP (1X) (b) (4) Protocol # 17-013 Approval Date: 3/7/2023 and Process Validation for (b) (4) and (b) (4), Protocol # 17-017, Approval Date: 11/28/2022.

D. Your firm has established a (b) (4) hold time for thyroid intermediates; however, your firm has not performed

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microbiological testing to validate the hold time. For example, the hold time study for thyroid intermediate Lot# (b) (4) lacks microbiological testing.

E. Your firm failed to validate and /or qualify your microbiology laboratory equipment used in the laboratory analysis of API products and raw material. For example:
- (b) (4) used to prepare media like (b) (4) Solution was not validated.
- The (b) (4) and (b) (4) #(b) (4) was not validated and there was no performance qualification performed.

Observation 2
Failure to investigate out-of-specifications of strength of liothyronine and levothyroxine during both accelerated and long-term stability studies of thyroid API.

Specifically,

Your firm has established an acceptance criteria for T3 (Liothyronine): (b) (4) mcg/gr and T4 (Levothyroxine): (b) (4) mcg/gr on the (b) (4) (b) (4) in thyroid API; however, Out-of-specification (OOS) was reported during both accelerated and long-term stability studies. For example,

A. OOS was reported on the (b) (4) long-term stability study of thyroid API on 9/28/2023 for the following:

- T3: 10.584 mcg/gr & T4: 43.591 mcr/gr, thyroid API, Lot # L13152-1XV in (b) (4) bottles
- T3: 10.494 mcg/gr & T4: 42.068 mcr/gr, thyroid API, Lot # B10383-1XV in (b) (4) bottles

B. OOS was reported on the (b) (4) accelerated stability study of thyroid API on 9/28/2023 for the following:

- T4: 33.571 mcg/gr, thyroid API, Lot # L13152-1XV in (b) (4)
- T3: 10.360 mcg/gr, thyroid API, Lot # L13152-1XV in (b) (4) bottles
- T3: 11.129 mcg/gr, thyroid API, Lot # B10383-1XV in (b) (4) bottles

Additionally, your firm reported LOD (Loss On Drying) OOS during the stability study. For example, LOD was

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7.4 against the limit of (b) (4)[(b) (4)] on the (b) (4) long-term stability study for thyroid, Lot # (b) (4)

However, there is no documented evidence showing your firm has performed any OOS investigation into stability failures.

Observation 3

Procedures for equipment cleaning validation failed to address microbiological contamination, detergent and/or solution residues and hard-to-clean points

Specifically,

A. Your firm conducted cleaning validation of the (b) (4), (b) (4) and (b) (4) equipment used for the manufacture of thyroid intermediate and finished API; however your cleaning validation is inadequate as it does not address microbial quality or residual cleaning agent, and instead solely rely on visual cleanliness. For example, your firm conducted Cleaning Validation of the (b) (4), Protocol # 17-011, Approval Date: 11/5/2022 that has defined an acceptance criteria as no visible product and detergent residues; however, there was no microbiological testing of swab samples from the equipment and residual testing of the detergent - (b) (4) used for equipment cleaning.

B. On 1/18/2024, during walk-through of the facility, apparent product residues and foam were observed at hard-to-clean points near the (b) (4) entry of the (b) (4) used for (b) (4) after the lid was opened while the (b) (4) was labeled "Ready to Use".

C. Your firm has not established the (b) (4) water production system at the API manufacturing facility, and (b) (4) water is currently used for cleaning all equipment followed by (b) (4) sanitizing. On 1/18/2024, during walk-through of the facility, it was observed unknown residues (more like (b) (4) water residues) remaining on interior surfaces of the (b) (4) after the equipment was cleaned.

D. Your firm has developed a (b) (4) water system in your old facility; however, you have not validated the (b) (4) water system prior to be used for equipment cleaning.

E. The floor of the (b) (4) room had crevices that were difficult to clean, and unknown stains were observed

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on the floor. The room is used for blending intermediates and finished thyroid API.

Observation 4
There is lack of appropriate control to prevent unauthorized access to computers or related systems from modification, alteration or deletion or of electronic data

Specifically,

A. Your electronic batch record in its current version could not prevent it from modification of signatures and content. For example, during walk-through of the facility on 1/18/2024, it was observed that the electronic batch record for Thyroid API, Lot# 011524SF2 was unlocked and production operators could access and modify the batch record.

B. Records saved in (b) (4) could be deleted by users. For example, during walk-through of the facility on 1/18/2024, it was observed control records (e.g. thyroid batch record) saved in (b) (4) could be deleted by a production operator although your firm has configured control and permission to access to records depending on user privileges (e.g. production operators could only access manufacturing records).

C. The audit trail for (b) (4) used for (b) (4), Equipment ID QC007 has not been set up. On 1/23/2024, it was observed there were no system audit trail and sequence audit trial records for all sample sets saved in the software. (b) (4) is used for assay of thyroid intermediates and finished products at your facility.

D. During the tour of the microbiology on 01/22/2024, The analyst was able to change the stored analytical data for example:

• Thyroid FS (b) (4)(b) (4) (b) (4) lot # (b) (4), the analyst was able to change Staphylococcus count from originally not detected cfu/g to 10 cfu/g detected.

• Thyroid intermediate (b) (4) lot # (b) (4), the analyst was able to change Yeast and Mold count from not detected to 10 cfu/g detected.

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E. During the review of records on 01/24/2024 for the swabbing test of the manufacturing equipment, using (b) (4), to test cleaning effectiveness on this equipment, the technician was able to alter the stored data of the test, for example:

• Swab test results ((b) (4)) - (b)(4) performed on 1/16/2024 using (b) (4) ID# (b) (4). He was able to change the result for the scale reading recorded from 21 to 0.

Observation 5
The quality unit lacks the responsibility to review and approve all appropriate quality-related documents.

Specifically,

A. Your firm has not established a timeframe for closure of a CAPA and requirements for extension of a CAPA if needed according to SOP# 25-012, Deviations and CAPA Investigations, Revision #4, Effective Date: 6/15/2023. As such, multiple CAPAs initiated to correct deficiencies or non-conformances observed in 2021 have not been closed. For example, CAPA (#CAPA 2023-018) was initially opened 12/2/2021 due to laboratory data integrity issue identified and reassigned to this number on 10/12/2023; however, this CAPA has not been closed to date and there is no justification for that.

B. Your firm failed to timely complete the investigation with validating microbiological methods. CAPA # 2023-024 initiated on 10/13/2023 and CAPA # 2021-017 initiated on 12/2/2021 were not completed at time of inspection.

C. The specification for an impurity of thyroid API has not been established. Your firm has identified an impurity classified as a related compound to liothyronine and levothyroxine, as a (b) (4) on the chromatography results of finished thyroid API per CAPA 2023-023; however, the specification for this impurity has not been established to date, and there is no justification for that.

D. Your firm contracted with an outlier laboratory for microbial testing of finished thyroid API ; however, your firm has not audited the contract testing laboratory to date.

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Observation 6
Your firm failed to follow appropriate microbiological tests to determine conformance of specification, specifically

A. Your firm failed to validate non USP microbiological methods used for testing of intermediate IPA. Your firm does not have a validation study of the (b) (4) method in analyzing intermediate API used to produce final API. For example: Intermediate lot # (b) (4), and (b) (4) were used to produce final product lot # K12753-1X, Thyroid (1X) USP on 10/12/2023. This product was released to the market.

B. Your firm failed to growth promote all media made locally or purchased ready to use. There is no SOP for growth promotion of media used in the microbiology lab. For example:
1. Salmonella enrichment base solution lot # (b) (4), prepared on 6/27/2023 and used to analyze intermediate Thyroid FS (b) (4) (b) (4) lot # (b) (4).

2. (b) (4) plates lot # (b) (4) purchased ready to use, used for the analysis of Thyroid FS (b) (4) (b) (4) lot # (b) (4) on 6/28/ 2023.

C. During the microbiology laboratory tour of your firm on 01/22/2024, expired media was found stored in the microbiology lab refrigerator # QM001. (b) (4) broth from (b) (4) (b) (4) lot # (b) (4) exp. 2023-05-16 was found inside the refrigerator.

D. Your firm does not use your own SOPs to analyze products for Escherichia coli and Salmonella spp. At specialty process lab. SOP # 51-018 "Escherichia coli (E.coli) by USP method" and SOP # 51-019 "Salmonella spp. By USP method", both SOPs approved on 12/19/2022, are not used for Thyroid intermediate products analysis. Your firm instead still using unvalidated method (b) (4) Method) for those products analysis

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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."