DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

COPY

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Center for Drug Evaluation and Research OPQ/OPMA 10903 New Hampshire Ave. Silver Spring, MD 20993 Phone:301-796-2400; CDER (b) (4) @fda.hhs.gov; CDER-OC-OMQ-Domestic483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/24/2025-04/10/2025
	FEI NUMBER 3014028588

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Sachin S. Pandit, Senior Director

FIRM NAME	STREET ADDRESS
ULT 04/11/25 Aurolife ~~Aurolige~~ Pharma LLC	2929 Weck Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Durham, NC 27709 USA	Drug product manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

QUALITY SYSTEM

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

Specifically,

a. Your drug product stability sample testing and control program is deficient. Drug product stability samples, including those that are pending testing or have completed testing, were placed on (b) (4) located in QC Analytical LAB-(b) (4) Room # (b) (4) which were accessible to all QC and R&D personnel. According to your QC analyst, no procedural or system controls were implemented to ensure that only the right sample and the right amount of sample can be used to conduct the requisite stability testing. According to your OOS investigations, "error in sample selection is the likely cause of the initial out-of-specification (OOS) results" (OOS-AL2-24-0033,) and "the root cause for the failure is due to selection of wrong samples" (OOS-AL2-25-0001) were concluded as the root causes of the respective OOS events. However, the proposed CAPA (CAP-AL2-25-0001) was to include a control measure (verification of samples) by revising the SOP (SOP-AL2-QC-0007-005). Both OOS investigations were closed without verifying the effectiveness of the proposed CAPA.

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	Laurimer Kuilan-Torres	Laurimer Kuilan-Torres, Sr. Regulatory Specialist Yiwei Li, Supervisory Pharmaceutical Scientist	04/10/2025

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b. Your firm failed to follow the Stability Program for Finished Products SOP-AL1204.05 Studies Procedure and established Stability Studies Protocols for [redacted](b) (4) and [redacted](b) (4) Ointment [redacted](b) (4)% and [redacted](b) (4)%. The Stability Program for Finished Products procedure establishes that stability samples should be completed within [redacted](b) (4) of the sample receiving. However, it was documented in Deviation DEV-AL2-24-0058, that the stability samples were not tested within the requisite timeframe. In addition, in your documents provided in the submission for [redacted](b) (4) the dates of analysis provided are not accurate to the dates testing was completed. In occasions, the testing was completed six (6) months after the specify timepoint. Similarly, for [redacted](b) (4) Ointment, stability samples were not completed within the established procedure and protocol. In addition, in your documents provided in the submission for [redacted](b) (4) Ointment [redacted](b) (4) and [redacted](b) (4)% the dates of analysis provided are not accurate to the dates testing was completed. In occasions, the testing was completed six (6) months or over a year after the specify timepoint.

c. Your QC analysts have access to R&D projects in the Empower 3.0 chromatography data system (CDS).

d. The standard operating procedure (SOP) Change Control Procedure Document No. SOP-ABN-QA-0002 Version No. 009, establishes changes would be classify as minor, major and critical, depending on its impact to the identity, safety, strength, quality, purity and efficacy of the product or validation status of process, equipment, utility, facility or GMP compliance/procedures and systems or regulatory filings. However, the firm does not follow the established procedure, for example, changes that should be classify as major or critical are classified as minor. Change Control CC-AL2-23-0197 was initiated on 22-Dec-2023 for introduction of a [redacted](b) (4) to be installed in Room [redacted](b) (4) even when this change required introduction of [redacted](b) (4) to the room and may impact validated utilities, the change was classified as Minor. In another example, CC-AL2-21-0248 was initiated on 30-Nov-2021 for introduction of [redacted](b) (4) into the facility, however, the change which may impact the validation status of process, and impact other drug products was classified as minor.

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CITY, STATE AND ZIP CODE Durham, NC 27709 USA	TYPE OF ESTABLISHMENT INSPECTED Drug product manufacturer

e. There are not procedures established for introduction of new drug products at the facility. The quality unit lacks a procedure to establish a process for introducing new products to the existing manufacturing lines which will need a risk assessment of the impact to existing validated processes and equipment.

f. Comprehensive reviews of raw manufacturing and analytical data including audit trails are not performed by the Quality Assurance (QA) unit for standalone and network equipment or systems for all production records and QC testing results prior to the final approval of manufacturing batch records (MBR). According to your QA reviewers, comprehensive batch record review by QA – prior to final approval of such record – is limited to paper review of the manufacturing record and verification of QC study reports including ELN. You do not review and verify critical raw data including equipment process parameters and/or audit trails to ensure completeness and accuracy of the critical process parameters and test results. In addition, you do not conduct periodic QA review of the quality system including QC analytical data to ensure ongoing compliance and product quality.

g. Temperature, humidity, and pressure differential in drug product manufacturing areas (Grade D) are not continuously monitored. According to your manufacturing manager and QA personnel, the above environmental controls are monitored and recorded only (b) (4) The current monitoring system do not provide assurance that any excursions from the normal operating ranges during manufacturing operations would be monitored, corrected, and documented.

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Durham, NC 27709 USA	Drug product manufacturer

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, the following deviations were reviewed and found deficient:

a. Investigation Report for Device Malfunction for [redacted] Solution USP, [redacted] Complaint Number A-PC2024-001 opened on 01/11/2024 is deficient. The investigation was initiated after complaint was received due to [redacted] malfunction. During your investigation report, you didn't identify a root cause associated to manufacturing process. However, your investigation failed to mention that previously, investigations INV-NC-018-015, INV-NCAL-018-001, INV-NCAL19-004 and DEV-19-013, were initiated for malfunction of the [redacted] during the submission batches manufactured in 2018. It was identified a potential root cause as the [redacted] of [redacted] to the bottles prior to filling may disrupt the [redacted] and inability of the [redacted] to function, however, after changes to the process were implemented, your firm received over a hundred (100) of complaints for [redacted] malfunction. Which indicates your investigation was deficient and corrective and preventive actions were not adequate to prevent recurrence of this issue.

b. During the review of Out of Specification (OOS) Investigation OOS-AL2-23-0008, we noted the following deficiencies: in-process test for [redacted] Solution USP, [redacted] (Lot [redacted] testing for assay of in-process sample [redacted] was out of specification. The % Assay of [redacted] USP, [redacted] in [redacted] was found to be [redacted] mg [redacted] %). The result for the [redacted] of Solution USP, [redacted] was [redacted] mg [redacted] %). The reportable [redacted] for the [redacted] is [redacted] mg [redacted] %). The in-process acceptance criteria is each [redacted] should contain not less than [redacted] mg and not more than [redacted] mg [redacted] % to [redacted] % of labeled amount). Re-testing the original sample confirmed the out of specification. Your firm identified the root cause as a sampling issue; however, the same sampling approach was used for the validation batches manufactured in April 2023 and not out of specifications were reported. In addition, your firm did not propose a corrective and preventive action nor efficacy checks to prevent future recurrences. This batch of [redacted] Solution USP, [redacted] was released and distributed to the market.

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c. During the review of Out of Specification (OOS) Investigation OOS-AL2-22-0005, we noted the following deficiencies: testing for content of (b) (4) and (b) (4) test on (b) (4) mg (b) (4) (Lot: (b) (4) release reported an out of specification. On December 21, 2022, the content of (b) (4) observed in the samples was an average of (b) (4) % (specification (b) (4) %). Your firm could not identify a laboratory error and therefore decided to repeat the test in a new sample over (b) (4) after the OOS. As the results for the new sample were acceptable, the investigation was closed. Your firm did not initiate a Phase 2 investigation as required by the Handling and Investigation of Out of Specification Results in Quality Control Laboratory Document No. SOP-AL1203.10 effective on 14Nov2022. Similarly, during the review of OOS Investigation Report INV-NCAL-22-020, initiated in 03Nov2022, the OOS for (b) (4) mg (b) (4) (Lot: (b) (4) was reported. The most probable root cause for this investigation was an analyst error during standard preparation, however, there was no indication that the standards prepared were not complying with your testing method acceptance criteria for percentage (%) of recovery. Your firm invalidated the initial OOS results and continue repeating the test with new samples on 29DEC2022 with acceptable results. Your investigation approach for these out of specifications cannot be considered thorough, as other root causes were not evaluated. In addition, your investigations do not extend to other batches, even when the same lot of (b) (4) is used for different (b) (4) strengths.

d. Investigation Reports for deviation investigation for Staphylococcus epidermidis found in microbial limit test of (b) (4) USP (DEV-AL2-23-0009) and the associated CAPA (CAP-AL2-23-0009) are deficient. The deviation was opened on 03/24/2023 due to observation microbial colony growth during the microbial limit testing of the drug product. A CAPA was performed to investigate and pinpoint the potential source of contamination. Bacillus spp. and Paenibacillus amylolyticus were recovered from swabs of the area floor in the manufacturing area. No follow up actions were taken and there were no data confirming that the (b) (4) (b) (4) did not support microbial growth. Subject CAPA was completed and approved by QA on 12/06/2023. These examples are not all inclusive but demonstrate that your investigations not always are conducted in a thoroughly manner and not all the potential root causes are evaluated.

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Durham, NC 27709 USA	Drug product manufacturer

OBSERVATION 3

A (b) (4) Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically,

Your firm failed to submit a Field Alert Report (FAR) to the agency within three (3) working days. Your firm failed to follow standard operating procedure (SOP) APL-GP-GEN-0039 Field Alert Reporting Version 1.0.0.0, which establishes that an event investigation that indicates potential/confirmed failure of one or more batches of the drug product that is distributed in market is a condition for filing FAR from manufacturing site. Your firm received a complaint for the distributed drug product (b) (4) solution USP (b) (4) Lot Number (b) (4) on 01/11/2024 due to (b) (4) malfunction where the patient could not extract drug product from the bottle due to (b) (4) malfunction, however, not FAR was submitted. In addition, your firm received similar complaints for distributed drug product (b) (4) Solution USP (b) (4) Lot Number (b) (4) between February 7, 2024, and March 27, 2024. Until March 27, 2024 your firm had received six (6) complaints due to (b) (4) malfunction (b) (4) malfunction and initial FAR was submitted to the agency on March 28, 2024. Your firm submitted a FAR after seventy-seven (77) days has passed since your firm became aware of the product quality defect.

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FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 4

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

a. Compounding Room (b) (4) of the (b) (4) manufacturing area, where compounding unit operation for commercial production of (b) (4) is performed, houses (b) (4) pieces of equipment – (b) (4) (b) (4) Until December 2024, this (b) (4) equipment collectively shared the same equipment ID number ME-EQP-18, as evidenced by: (b) (4)

Concurrently with the commercial production of (b) (4) (b) (4) drug products were performed in the Compounding Room (b) (4) This was evidenced by logbook entries in Log Book #: (b) (4) (b) (4)

Multiple manufacturing equipment were shared during the manufacturing production of the above products including (b) (4) (b) (4)

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According to Equipment Cleaning Verification Protocol for Manufacturing Equipment (SOP-AL2-PR-0007, which governs (b) (4) manufacturing equipment cleaning) and Cleaning Validation Protocol for (b) (4) the effectiveness of the equipment cleaning is demonstrated by 1) visual inspection of the equipment, and 2) analytical testing with an acceptance limit of not more than (b) (4) ppm of the residual drug substance content. There were no scientific justification or data to demonstrate that potential safety risks of carryover contamination of the previous drug products are adequately mitigated. The protocols did not consider or justify, with data, the hardest to clean areas. Equipment specific (b) (4) programs were not evaluated or validated as part of the validation or verification protocols. No dirty and clean hold time limits were defined and validated. There was also no evidence that the analytical method for (b) (4) residue detection was validated under the actual condition of use.

b. According to Aurolife (b) (4) Preventive Maintenance (PM) Checklist (Form FE-1201-F02.00), (b) (4) (b) (4) (Equipment ID #: MF-EQP-18) preventive maintenance was performed on the equipment on July 31, 2024. The same information was not recorded in the Cleaning and Usage Log Book (Log Book #: (b) (4) from 02Jan2024 to 31Dec2024). No cleaning action was recorded in the Log Book following the preventive maintenance. During this period, (b) (4) was manufactured using the same equipment:

(b) (4)

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OBSERVATION 5

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and are free of infestation by insects and other vermin.

Specifically,

a. Filth, spider web, and insects are found on (b) (4) pallets used to stack and store boxes containing packaging/ (b) (4) such as (b) (4) in the warehouse.
SOP for Pest and Rodent Control (SOP-HS 1203.00) describes that the Pest and Rodent Control are outsourced to outside contractors. The SOP did not describe how your firm would evaluate the effectiveness of the pest control services to ensure that the manufacturing process, testing, and storage areas are free from infestation of vermin. Upon request, your firm provided (b) (4) pest and rodent finding reports generated by the outside contractor. However, there is no documented evidence that such reports were reviewed by your quality unit and that the effectiveness of the pest control program was evaluated, maintained, and trended on a regularly basis.

b. According to the SOP for Cleaning of All Manufacturing Rooms and Clearance (SOP-MF 1202.02), (b) (4) water (b) (4) is used to clean the floor of the manufacturing rooms including those in Grade D area. Effectiveness of the cleaning/sanitization using such cleaning agents was not established.

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OBSERVATION 6

Routine calibration of automatic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

The balance with Equipment Id. MF-BS-11 (Serial No. (b) (4) used for in-process controls in the (b) (4) manufacturing area Room (b) (4) is not calibrated within the range of use. For example, the weight balance is use for the in-process controls of (b) (4) all strengths. The (b) (4) calibration of balance is conducted using standard weights between the range of (b) (4) however, the in-process controls for (b) (4) to determine (b) (4) weight ranges from (b) (4) (b) (4) Inaccurate weight of in process samples can lead to acceptance of (b) (4) with a variance greater than the established for the (b) (4) weight and discrepancies in drug content.

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LABORATORY CONTROL SYSTEM

OBSERVATION 7

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release. Specifically,

a. During the review of Out of Specification (OOS) Investigation OOS-AL2-24-0003, we noted the following deficiencies: testing for (b) (4) in (b) (4) Solution (Lot (b) (4) an out of specification was reported with results of (b) (4) % (Acceptance criteria (b) (4) % to (b) (4) %). Your investigation could not identify a root cause in the laboratory, and therefore, continue to repeat the test with other bottles as the original sample could not be located. The new tested samples complied with the acceptance criteria and therefore the lot was released for distribution.

b. During the review of Out of Specification (OOS) Investigation OOS-AL2-23-0007, initiated on 06Jun2023 after (b) (4) test was out of specifications for 6-month stability time point 25°C/60%RH (b) (4) (b) (4) mg (b) (4) Lot (b) (4) batch). The Content of (b) (4) (%Label Claim) in sample (sample ID (b) (4) was found to be (b) (4) %. The result for the (b) (4) (sample ID (b) (4) of (b) (4) mg (b) (4) Lot: for 6 Month stability timepoint, 25°C/60% was (b) (4) %. The reportable (b) (4) for the (b) (4) was (b) (4) %. Which is below the acceptance criteria of NLT (b) (4) %. Your firm could not identify a root cause for the OOS in the laboratory or in the documentation associated to the analysis, therefore, repeating the testing with a new sample was authorized since the original sample solution was expired. During the review of raw data that supported this analysis and investigation the following I noted the OOS investigation was initiated on 29Jun2023, over three (3) weeks of the sample analysis therefore the original sample was not available. In addition, during the review of the raw data I observed that other results reported as passing for (b) (4) mg (b) (4) 6-month 40°C/75RH % Lot: (b) (4) but individual results were (b) (4) % and (b) (4) %, however, because (b) (4) was over (b) (4) % (b) (4) %) it was accepted.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Laurimer Kuilan-Torres, Sr. Regulatory Specialist Yiwei Li, Supervisory Pharmaceutical Scientist	04/10/2025

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Center for Drug Evaluation and Research OPQ/OPMA 10903 New Hampshire Ave. Silver Spring, MD 20993 Phone:301-796-2400; CDER [redacted]@fda.hhs.gov; CDER-OC-OMQ-Domestic483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/24/2025-04/10/2025 FEI NUMBER 3014028588

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Sachin S. Pandit, Senior Director

FIRM NAME	STREET ADDRESS
Auroligе Pharma LLC	2929 Weck Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Durham, NC 27709 USA	Drug product manufacturer

In addition, your firm analyzed other samples for [redacted] mg [redacted] 6-month 25°C/60RH % Lot: [redacted] in the same analytical run but because [redacted] was NLT [redacted] %, result was accepted. Your testing procedure does not indicate that this practice is acceptable.

c. During the review of analytical raw data [redacted] mg [redacted] Lot [redacted] assay determination I observed an unidentified peak eluting at around [redacted] of the chromatographic run. Your firm could not provide scientific evidence of what the unknown peak is as it was not observed during the establishing of standard testing procedure. Similarly, the peak was observed in other chromatographic runs for assay in stability samples. In addition, your firm confirmed that there is no procedure for investigating unknown peaks.

OBSERVATION 8

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

a. Your firm failed to establish a scientifically sound method to test related substances in [redacted] Drug Substance. The method transfer of the Related Substance by HPLC method for [redacted] was completed and effective on 03Aug2023, however, testing for [redacted] Drug Substance batches (Batch No. [redacted] No. [redacted] used in the submission of [redacted] was released by Quality Assurance in July 2022 and September 2022 for usage in submission batches manufactured on August 2022 and November 2022. Your testing of drug substances was conducted with a method that has not been implemented.
b. In addition, as documented in Method Transfer of related Substances by HPLC method from [redacted] for [redacted] protocol TFR01-198RP-21.00, the percentage of difference (%error) between the results for [redacted] from your firm and the certificate of analysis from the vendor was [redacted] % (Acceptance Criteria NMT [redacted] %), nevertheless, the method was implemented by adjusting the acceptance criteria without a scientific sound justification.

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Center for Drug Evaluation and Research OPQ/OPMA 10903 New Hampshire Ave. Silver Spring, MD 20993 Phone:301-796-2400; CDER (b) (4) @fda.hhs.gov; CDER-OC-OMQ-Domestic483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/24/2025-04/10/2025 FEI NUMBER 3014028588

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Sachin S. Pandit, Senior Director

FIRM NAME	STREET ADDRESS
LLT 09/10/25 Aurolige ~~Aurolige~~ Pharma LLC	2929 Weck Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Durham, NC 27709 USA	Drug product manufacturer

OBSERVATION 9

In-process samples are not representative. Specifically,

Batch manufacturing record for (b) (4) Solution USP (b) (4) (Batch No. (b) (4) requires that (b) (4) samples are collected for in-process testing (b) (4) by the manufacturing associates and (b) (4) (b) (4) samples are collected (b) (4) by quality assurances. (b) (4) (b) (4) dated 22SEP2022, requires that (b) (4) samples are collected for in-process testing (b) (4) by the manufacturing associates and (b) (4) samples are collected (b) (4) by quality assurances. There is no assurance that the sampling approach is a statistically representative of each product and each lot and has a precise representation of the quality attributes purposed to have.

OBSERVATION 10

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

According to the Operation Instruction of (b) (4) Machine (4.6.2018), (b) (4) in which "the machine must be stored or operated (mandatory)" included room quality requirements for the (b) (4) room "in which the front part of machine is positioned". The requirements included (b) (4) (b) (4) However, a review of your (b) (4) Log Book for (b) (4) (b) (4) Manufacturing Log Books revealed that the above (b) (4) controls including (b) (4) were not controlled to always meet the (b) (4) machine requirements in Room (b) (4)

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DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Center for Drug Evaluation and Research OPQ/OPMA 10903 New Hampshire Ave. Silver Spring, MD 20993 Phone:301-796-2400; CDER (b) (4) @fda.hhs.gov; CDER-OC-OMQ-Domestic483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/24/2025-04/10/2025 FEI NUMBER 3014028588

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Sachin S. Pandit, Senior Director

FIRM NAME	STREET ADDRESS
Aurolige LLT 04/10/25 Aurolige Pharma LLC	2929 Weck Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Durham, NC 27709 USA	Drug product manufacturer

According to the same logbooks (b) (4) during the period of August 2022 to January 2023 and on the days when the (b) (4) operations were performed for (b) (4) (b) (4) mg (b) (4) exhibit batches manufacturing (b) (4) were outside of the above (b) (4) control ranges. A review of exhibit batch (b) (4) mg assay testing OOS investigations (OOS number OOS-AL2-22-0002) revealed that you experienced aberration in the manufacturing process which caused variability in weight (b) (4) of the product (b) (4)

OBSERVATION 11

Procedures for corrective and preventive action have not been adequately established.

Specifically,

Investigation Report for Device Malfunction for (b) (4) Solution USP, (b) (4) Complaint Number A-PC2024-001 opened on 01/11/2024 is deficient. The investigation was initiated after complaint was received due to (b) (4) malfunction. During your investigation report, you didn't identify a root cause associated to manufacturing process. However, your investigation failed to mention that previously, investigations INV-NC-018-015, INV-NCAL-018-001, INV-NCAL19-004 and DEV-19-013, were initiated for malfunction of the (b) (4) during the submission batches manufactured in 2018. It was identified a potential root cause as the (b) (4) of (b) (4) to the bottles prior to filling may disrupt the (b) (4) however, after changes to the process were implemented, your firm has received over a hundred (100) of complaints for (b) (4) malfunction. The corrective and preventive actions implemented were inadequate in that the condition for the malfunction of the (b) (4) was not corrected before the batches were released for distribution.

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