DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/19/2026-1/23/2026
	FEI NUMBER 3033881432

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. C. Srinivas Rao, Partner

FIRM NAME	STREET ADDRESS
Shimoga Chemicals	W57 A Shimoga Chemicals, Kupwad MIDC
CITY, STATE, ZIP CODE, COUNTRY Sangli, Maharashtra, 416436 India	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components and raw materials conform to appropriate standards of identity. Specifically,

A.Laboratory control procedures are not followed:

-During review of electronic data for (b) (4) USP API, we observed multiple unreported sample injections prior to or after the official reported sample injections for Related Substances and Assay by HPLC testing that were not documented in laboratory batch records. API batches involved included batch numbers (b) (4). Batches (b) (4) were approved by QA and shipped to the U.S. market.

-During the current inspection we requested your firm to perform calculations for all unreported Related Substances and Assay injections, where at least one batch, (b) (4) revealed an unreported injection with an OOS result. Specifically, on 12/20/2024, your analyst injected a blank and single injection for sample (b) (4), with calculations during the current inspection resulting in OOS for assay, with calculated result as (b) (4) % versus specification of (b) (4) %. The official reported result documented in your laboratory batch records for (b) (4) was performed on 12/22/2024, with reported result as (b) (4) %. This batch was shipped to the U.S. Market.

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-When we asked one of your analysts why they performed an unreported injection prior to the official injection, the analyst stated that the owner of the firm provided the sample and asked them to perform the test. Review of this analyst's training record revealed no laboratory training on performing any testing operations, including chromatography testing, no cGMP training, and no data integrity training.

-After discussion of these deficiencies with your QC Manager, he stated that "for export purpose we check for confirmation again and again."

-Furthermore, we observed that your firm appears to be performing arbitrary in-process sampling. Per your firm's QC Manager, your firm does not always perform in-process sampling, only when the firm's owner provides samples to test. We observed no laboratory batch records or calculations for in-process sampling, no assigned batch numbers in the sample set to in-process samples, and no mention of in-process sampling in batch records. In sample sets reviewed, there is no way of determining what batch numbers of (b) (4) USP API were tested from the electronic data. Your firm's QC Manager stated that they did not know what batches were tested.

-Consequently, QA and QC do not review electronic data, nor does your firm have a procedure for review of electronic data for the (b) (4) standalone HPLC and (b) (4) standalone GC equipment. Similarly, your firm does not have a procedure for sample set and sample naming conventions.

B.During our walkthrough of the QC laboratory on January 19, 2026, a discarded printout was found in a trash bin. After review, your QC Manager stated that the printout documented a Loss on Drying (LOD) test for (b) (4) raw material, AR. No. (b) (4) dated January 18, 2026. Per your QC Manager, the test was performed in duplicate by an analyst by accident. Review of the discarded printout revealed that the analyst performed the weighing of the first LOD bottle, then performed the weighing of the second LOD bottle. After completing the second bottle, the analyst

re-weighed the first bottle again, mistakenly believing the first bottle had not been weighed yet. The weight recorded for this re-weighing was (b) (4) g, while the reported initial test weight was (b) (4) g, indicating the same bottle was weighed twice. However, instead of initiating a laboratory incident as required by your procedures, your analyst discarded the second printout without documentation. During the inspection, your firm acknowledged the discrepancy; however, as of the closeout of the inspection, your firm failed to initiate a formal investigation. Furthermore, our review found zero incidents have been initiated within your QC unit over at least the last three years, despite routine analytical testing.

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically,

Your firm has failed to establish adequate process validation and production control procedures. Your process validation for (b) (4) USP API and key starting materials does not accurately reflect actual manufacturing, making production non-replicable.

A. Your firm's process validation does not clearly identify the batch records used, their execution sequence, or how records are (b) (4) during the manufacture of (b) (4) USP API and (b) (4) (b) (4), a key starting material. For example, each (b) (4) USP API batch produced following (b) (4) manufacture was (b) (4) a practice not addressed in the process validation documentation. In addition, production occurs through the (b) (4) (b) (4) execution of (b) (4) batch records—manufacture of (b) (4) (b) (4) however, this approach was not addressed in the process validation.

B. Your process validations do not reflect validated hold steps that occur routinely. For example, (b) (4) was stored in (b) (4) to (b) (4) drums without defined hold-time limits or supporting studies prior to use in the manufacture of (b) (4) USP API. For batch (b) (4) was stored beginning on (b) (4) at (b) (4) and held for approximately (b) (4) before use in batch (b) (4) on (b) (4) at (b) (4), and for approximately (b) (4) before use in batch (b) (4) on (b) (4) at (b) (4)

C. Equipment transfers between GMP and non-GMP areas are not validated. Equipment designated for GMP area use (including (b) (4) 003) was routinely moved to non-GMP areas for earlier production stages and returned, with no validation of impact on product quality, cleaning procedures, or verification of clean status.

D. Your firm has not performed revalidation for (b) (4) USP API and key starting materials, despite process validation reports for (b) (4) stating, "Revalidation has to be performed by (b) (4)." In addition, the process validation report for (b) (4) does not provide a timeframe for revalidation, stating "The next validation has been suggested to do (b) (4)."

OBSERVATION 3

Batch production and control records do not include complete information relating to the production and control of each batch. Specifically,

A. Your firm fails to maintain accurate and consistent cleaning logs and batch records, demonstrating significant data integrity deficiencies in the documentation of (b) (4) 001 cleaning and (b) (4) of (b) (4) USP API (b) (4) batches for (b) (4) Review of the following batch

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records and Equipment log of (b) (4) reveal discrepancies in cleaning times, as cleaning times recorded in the Equipment log of (b) (4) appear to occur simultaneously with the (b) (4) of the (b) (4) batches (b) (4) of (b) (4) USP API. Additionally, the duration for (b) (4) the (b) (4) batches (b) (4) 001 varied inconsistently between (b) (4) across batches without documented justification or hold time data.

(b) (4)

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Batches (b) (4) were shipped to the U.S. market.

B. Your firm failed to document raw material quantities used in the production of (b) (4) USP API. For example, in (b) (4) batches (b) (4) a total of (b) (4) of (b) (4) was used in each (b) (4) batch and was added (b) (4) times through each (b) (4) batch; however, the quantity of (b) (4) was not documented when it was added to (b) (4) 003 in step (b) (4) Per the firm's Production In Charge, (b) (4) of (b) (4) was added in step (b) (4). Additionally, your firm failed to document the procedure for producing (b) (4) in the production of key starting material, (b) (4) batch (b) (4), in Step (b) (4) which was used to (b) (4)

C. Your firm does not record the container usage and quantities throughout production. Multiple instances of inadequate container documentation were observed across batches. Although not documented in their respective batch records, (b) (4) was stored in (b) (4) drums after the (b) (4) production Step (b) (4) and (b) (4) USP API was stored in an unspecified number of drums after (b) (4) operations and subsequently placed in (b) (4) drums after (b) (4), per the firm's Production In Charge.

D. Equipment used during production operations was not consistently documented in the batch records. For example, in the (b) (4) batch (b) (4), the (b) (4) 001 was not identified in steps (b) (4) In (b) (4) USP API (b) (4) batch (b) (4), the (b) (4) (b) (4) 001 (b) (4) was not identified during step (b) (4) activities. In (b) (4) USP API (b) (4) batch (b) (4), the equipment numbers were no identified for (b) (4) (b) (4) 003 in step (b) (4) dditionally, the (b) (4) USP API (b) (4) batch records (b) (4) did not document that after product was

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(b) (4) (step (b) (4) it was (b) (4) taken out of the GMP area (b) (4) for (b) (4) (step (b) (4) and was then subsequently put into (b) (4) drums and (b) (4) (b) (4) to the GMP area through (b) (4) to a separate area for (b) (4) (step (b) (4) There was no batch record that documents the material transferred on 09/03/2025 from the (b) (4) (b) (4) 002 (step (b) (4) in (b) (4) USP API (b) (4) batches (b) (4) into (b) (4) drums to the (b) (4) 001 (step (b) (4) in (b) (4) USP API batch record for (b) (4)

E. Your firm's batch records did not define the sampling locations and methods, as well as whether QC sampling of (b) (4) USP API was performed before or after (b) (4) batches, as evidenced in (b) (4) USP API (b) (4) batches (b) (4). Per the firm's Production In Charge, QC samples were collected after (b) (4) the (b) (4) batches and were collected in arbitrary locations across (b) (4) drums, with operators routinely sampling only from the (b) (4)

F. Your firm does not have adequate packaging batch records. Per your firm's Production In Charge, the firm's customer for (b) (4) USP API may request different variations of packaging, including (b) (4) where product was packaged in (b) (4) bags, (b) (4) and labeled before shipment to customers. These packaging operations, including packaging configurations were not documented in product batch records.

G. Your firm does not adequately control batch record forms and their versions. All batch records for (b) (4) (b) (4) USP API and key starting materials utilize identical form numbers with two version numbers (b) (4) despite containing completely different content. Additionally, two separate forms both labeled as Version (b) (4) bear different effective dates (04/03/2024 and 05/03/2024).

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OBSERVATION 4

Procedures for the cleaning and maintenance of equipment and its release for use in the manufacture of intermediates and API are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembly of equipment as necessary to assure proper cleaning and maintenance. Specifically,

A. Your firm has not performed cleaning validation studies to address microbiological and residue contamination for processes where such contamination could be of concern during manufacture of (b) (4) Equipment used in the manufacture of (b) (4) USP API includes (b) (4) Cleaning procedures for equipment used to manufacture (b) (4) USP API for the U.S. market lack adequate detail and do not reflect actual practices. Your firm's cleaning procedures and batch records do not specify cleaning methods or techniques, materials used, contact times, acceptance criteria, or verification requirements. For example, while the cleaning SOPs for the (b) (4) indicate that (b) (4) water/solvent is used for cleaning, the firm stated that they use only (b) (4) water for all equipment cleaning, without differentiation by product, batch, or stage of manufacture. The firm confirmed that the specific type of solvent is not documented in any procedure and that operators determine which solvents to use based on memory. An undocumented exception to the use of (b) (4) water for cleaning was identified for equipment (b) (4) 1, which is cleaned with (b) (4) during processing. Per your firm's Production in Charge, during Step (b) (4) of production for batches (b) (4), as documented in (b) (4) Batch Production Record, Product: (b) (4), Stage: (b) (4) Version 03; Effective Date: 04.03.2024), (b) (4) is used for cleaning. This cleaning operation is not described in written procedures and is not documented in the batch records or cleaning logbooks. Your firm has not established clean hold time studies or defined time limits between cleaning and subsequent use of equipment. Equipment is cleaned only before the start of the next batch, with no differentiation

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between different products manufactured, including other API products such as (b) (4) (b) (4), and numerous intermediates for other markets.

During the inspection on January 19, 2026, we observed a (b) (4) that the firm identified as cleaned; however, black foreign matter was observed inside the (b) (4) and residual (b) (4) was observed in the (b) (4)

B. Your firm failed to establish adequate procedures for monitoring and controlling your water system, which consists solely of (b) (4) water used only for equipment cleaning. On January 19, 2026, the (b) (4) water sampling point was observed to be rusted and located outdoors in the sun in an area with standing water; a wet, soiled rag was present adjacent to the sampling point. In addition, your water handling procedure does not identify the type of water used in cleaning operations or specify the testing frequency for (b) (4) water, which is referred to as (b) (4) water. Although (b) (4) (b) (4) water is tested (b) (4), testing is limited to assessment of color, clarity, and hardness.

OBSERVATION 5

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use. Specifically,

A. Stability study reports provided during the inspection in support of (b) (4) USP API do not adequately support the stated (b) (4) shelf life/expiry date. During our review of your completed long-term 2015 stability study reports and recorded results, we observed that your firm did not have supporting raw test data, both electronic and physical laboratory batch records, for stated results for the long-term (b) (4) stability study. Furthermore, the current ongoing long-term

stability study has been performed up to (b) (4) with (b) (4) slated to be tested around (b) (4). Your firm has shipped approximately (b) (4) batches of (b) (4) to the U.S. market prior to completion of the stability study supporting the assigned expiry date. Additionally, your firm's stability management procedure requires that at least one commercial batch be placed on stability annually; however, your firm does not follow this adequately. Although it appears one batch was placed on stability for years 2021, 2022, and 2023, your firm only completed long-term stability testing to 6 months for these batches.

B. Per the firm, (b) (4) USP API product is packaged in (b) (4) bags, (b) (4) (b) (4) and labeled before shipment to customers. During our walkthrough on January 21, 2026, we observed (b) (4) API stability samples stored in (b) (4) bags with (b) (4) bags containing product inside the (b) (4) bags, which appeared different from the final container closure packaging used for commercial distribution. The packaging material for samples placed on stability has not been evaluated for equivalence to commercial packaging.

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed. Specifically,

A. Complaint CM(b) (4) 002/25 was received via email on January 16, 2025, from a customer regarding an out-of-specification (OOS) result for an unspecified impurity in the Related Substances by HPLC test during analysis of (b) (4) intermediate, batch number (b) (4) (b) (4) Your firm's investigation, documented in CM(b) (4) /002/25 dated January 16, 2025, determined that your firm did not use the specified column required by the customer, despite the Method of Analysis (MOA) requiring use of that column or equivalent. The CAPA included your firm

committing to purchase a new column per the customer specification. By committing to purchase the specified column, your firm's investigation implicitly validated the customer's OOS result, indicating that use of the specified column could have resulted in an OOS result at your facility. However, your firm's investigation was inadequate. No documentation was provided demonstrating that the new column was ordered or received. Your firm did not perform additional testing of retain samples from batch (b) (4) or other distributed batches using the specified column to determine whether previously released material met specifications. Your firm did not evaluate whether other batches of (b) (4) intermediate tested with the non-specified column should have been OOS and whether distributed material was compliant.

B. Your firm does not perform investigations within your Quality system per procedures for OOS, OOT, deviations, and laboratory incidents. Since April 2023, your firm has manufactured and distributed approximately (b) (4) batches, including (b) (4) API batches (which include (b) (4) USP API) and (b) (4) intermediate batches. Despite this production volume, your firm has had zero OOS and OOT investigations since at least April 2024 across all batches manufactured for all markets. However, during the inspection, we identified multiple deficiencies that should have triggered investigations, demonstrating that your firm is not adequately identifying or documenting discrepancies. Similarly, our review found zero laboratory incidents initiated within your QC unit over at least the last three years and zero complaints since April 2025.

OBSERVATION 7

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

Your firm has not established or documented method verification studies for the USP compendial assay and residual solvent test methods used for (b) (4) USP API. The methods lack

demonstrated acceptable performance for accuracy, precision, and specificity. During the inspection, we observed data integrity deficiencies related to testing of this product, including trial injections and unreported testing of final finished API batches that were shipped to the U.S. market. Without verified methods, your firm cannot ensure that test results are reliable and that only compliant batches are released for distribution.

OBSERVATION 8

Buildings used in the holding of active pharmaceutical ingredient do not have the suitable construction to facilitate cleaning, maintenance, and proper operations. Specifically,

During our walkthrough of the production area on January 19, 2026, we observed multiple deficiencies with (b) (4) equipment and surrounding areas where (b) (4) API is manufactured. Equipment and piping located on and above (b) (4) where product material is (b) (4) showed visible rust. (b) (4) identified as clean or in operation had missing or removed bolts scattered around or placed on top of the (b) (4) . A (b) (4) and hose assembly used to transfer product from the (b) (4) (b) (4) to the (b) (4) was held together with tape and metal wiring. Plastic tarps positioned below the (b) (4) to catch material during (b) (4) operations were visibly soiled. These conditions demonstrate inadequate equipment maintenance and cleaning practices that present a risk of contamination to the API.

OBSERVATION 9

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

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A. Your firm failed to follow its vendor qualification procedure. Vendor qualification questionnaires were available for only (b) (4) raw materials, (b) (4), and your firm did not document a rationale for limiting vendor qualification to these materials.

B. Your firm failed to establish quality agreements with your broker and distributor who facilitate and directly export your product to foreign markets. During the inspection, your firm could not readily provide accurate information about which (b) (4) batches were shipped to the U.S. market. Your Production In Charge initially stated that batches (b) (4) (b) (4) were shipped to the U.S. through both the broker and distributor. After approximately four business days of back-and-forth email communication with the distributor, your firm determined that the distributor had not actually shipped any product to the U.S. Only after our investigation directed your firm to review broker records from 2024, was your firm able to identify the actual batches shipped to the U.S. market. This review revealed that only batches (b) (4) (b) (4) were shipped to the U.S., and all shipments occurred exclusively through the broker and were for (b) (4) only.

OBSERVATION 10

Failure to ensure training is regularly conducted by qualified individuals and covers, at a minimum, the particular operations that each employee performs and CGMP as they relate to the employee's functions. Specifically,

Your firm failed to ensure that personnel involved in drug manufacture operations were adequately trained. Per your firm's QA Executive, induction and (b) (4) training were not consistently performed, as outlined in your training procedure. For example, operators performing (b) (4) operations for (b) (4) USP API batches (b) (4) lacked documented training for the

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activities performed. No training records were available for the operator who (b) (4) batch (b) (4) Only induction training records from 2016 were available for the operator who (b) (4) batch (b) (4) ; training records for equipment did not include the (b) (4) (b) (4) , despite the operator signing batch record (b) (4) for (b) (4) operations using this equipment.

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