WARNING LETTER

Shoolin Pharma Chem LLP

MARCS-CMS 734100 — AUGUST 18, 2026

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Delivery Method:

VIA ELECTRONIC MAIL READ/DELIVERY RECEIPT REQUESTED

Reference #:

320-26-116

Product:

Drugs

Recipient:

Dr. Santosh R. Patel and Mr. Rajendra C. Patel

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Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

August 18, 2026

WARNING LETTER

Reference number: 320-26-116

To Dr. Santosh R. Patel and Mr. Rajendra C. Patel:

This warning letter advises you of significant violations observed during a U.S. Food and Drug Administration (FDA) inspection of your facility. Promptly address the violations described herein without delay, including ensuring that appropriate resources are allocated to fully address the violations and prevent their recurrence. This is not intended to be an all-inclusive list of the violations that exist at your facility. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations. Failure to adequately address violations may result in regulatory action without further notice.

FDA Inspection

Violations were observed and documented during an inspection of your drug manufacturing facility, Shoolin Pharma Chem LLP, FEI 3038200383, at Block/Survey No. 408, B/h. Ratnamani Tubes, Nr. Maruti Inox, Indrad, Dist. Mehsana, Gujarat, India, from April 13 to 17, 2026. This inspection was conducted under FDA's statutory authority and public health responsibilities to protect the public from unsafe, ineffective, and poor quality drugs.

Your drug products are adulterated under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(A), in that they have been prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health.

This warning letter also summarizes significant violations from Current Good Manufacturing Practice (CGMP) for active pharmaceutical ingredients (APIs).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your APIs are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your May 2, 2026, response to our Form FDA 483 in detail.

Violations of the Federal Food, Drug, and Cosmetic Act

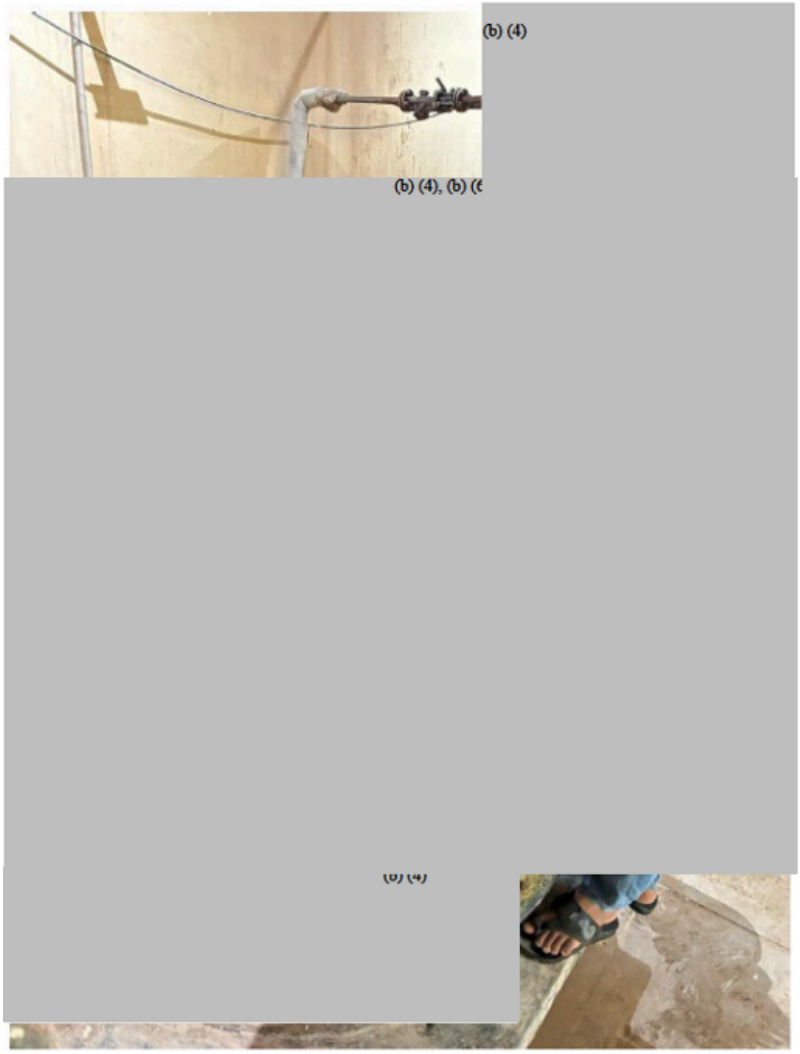
The following are violations identified during our inspection and review. As a reminder, this is not an all-inclusive list of violations at your facility.

Insanitary Conditions

Your firm manufactures APIs for domestic and foreign markets, including erectile disfunction (sildenafil citrate and tadalafil), anticonvulsant and **(b)(4)** agents, using nondedicated production equipment. Your APIs were imported into the United States and utilized by compounding pharmacies to produce medications for US citizens. Your drug products are adulterated under section 501(a)(2)(A) of the FD&C Act because they were prepared, packed, and held under insanitary conditions.[1] Your production operations, including **(b)(4)** loading, and **(b)(4)**, are conducted in a facility that lacks adequate sanitary conditions. Specifically, our investigator observed evidence of layered unidentified residues, improperly gowned employees in the production area, and corroded equipment surfaces near open processing lines and API packaging. Further, our investigator observed the following:

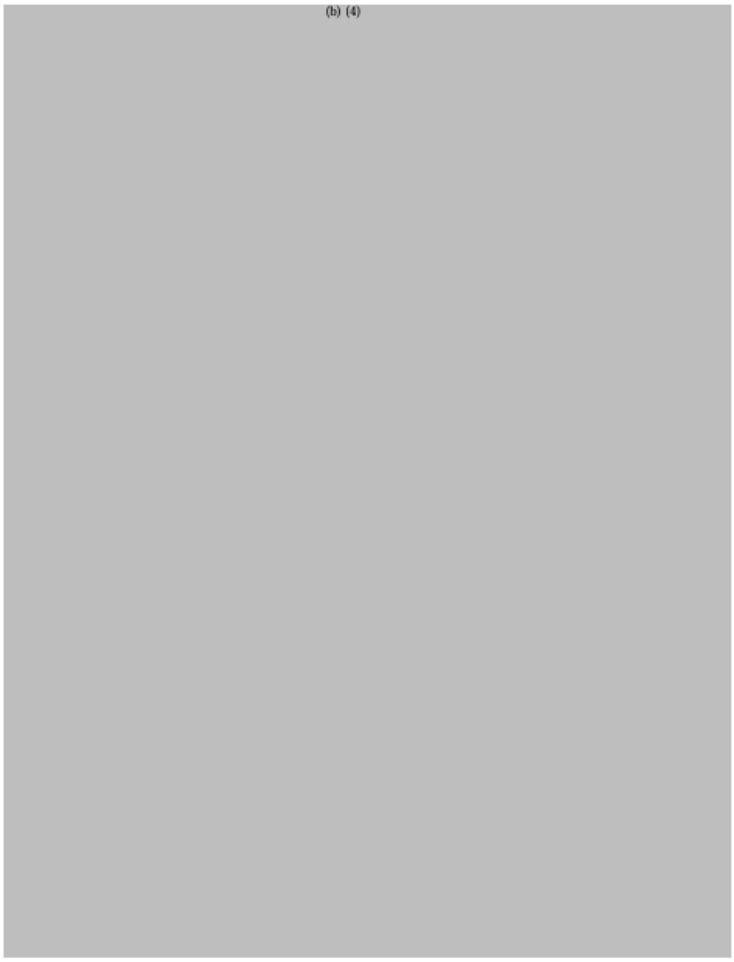
- **(b)(4)** lines (top of photo) showing evidence of leakage; **(b)(4)** residues on the production area walls, floors, and manufacturing equipment; and product transfer lines stored in a manner that risks contamination with filth and other chemical residues

- An employee was observed wearing open-toed sandals in the production area directly in front of open equipment, with **(b)(4)** chemical residues and corrosion documented on the product transfer line and the exterior and interior of the **(b)(4)** during open production operations



- The production area (**(b)(4)** room) was found to have **(b)(4)** residue and stains covering the walls, floor, and equipment, in areas where in-process material is handled and stored

- The equipment within this production area (**(b)(4)**) was observed to have **(b)(4)** layers of residue covering its inner walls, floor, and **(b)(4)** used to **(b)(4)** multiple APIs



In response to this letter, provide:

- A comprehensive plan to remediate the facility, given the pervasive nature of the insanitary conditions
- Detailed procedures that demonstrate your firm can maintain buildings and equipment in a clean and sanitary state
- Photographic evidence of the completed remediation showing the entire facility is now in an acceptable state of repair and maintenance.

CGMP Violations

1. Failure to clean, store, and sanitize equipment and utensils to prevent contamination or carry-over of a material that would alter the quality of the API beyond the official or other established specifications.

Your firm manufactures sildenafil citrate and tadalafil APIs for the U.S. market. Our investigators observed layers of unidentified residue and apparent rust on and around product contact surfaces of various nondedicated manufacturing equipment used in the production of your APIs.

You lack adequate procedures for the cleaning and maintenance of your manufacturing equipment. Additionally, your employees stated that written cleaning and equipment maintenance procedures have not been established, and cleaning verification using swab or rinse sample testing has not been performed.

In your response, you acknowledge the absence of formal cleaning and maintenance procedures. You commit to developing standard operating procedures (SOPs), validating a cleaning process, establishing a preventive maintenance program for all equipment, and repairing or replacing all affected equipment.

Your response is inadequate because it fails to comprehensively address cleaning and maintenance deficiencies or to outline a system for preventing recurrence. For example, you have not provided evidence of a risk assessment for worst-case product residues to be evaluated as part of a cleaning study; you have not evaluated hold times to determine if microbial bioburden is adequately controlled between cleaning operations; and you have not provided a detailed cleaning process for review.

In response to this letter, provide:

- A comprehensive, independent retrospective assessment of your cleaning effectiveness to evaluate the scope of cross-contamination hazards. Include the identity of residues, other manufacturing equipment that may have been improperly cleaned, and an assessment whether cross-contaminated products may have been released for distribution. The assessment should identify any inadequacies of cleaning procedures and practices and should encompass each piece of manufacturing equipment used to manufacture more than one product.
- A corrective action and preventive action (CAPA) plan, based on the retrospective assessment of your cleaning program, that includes appropriate remediations to your cleaning processes and practices, and timelines for completion. Include the following as part of the assessment and CAPA plan:
  o A detailed summary of vulnerabilities in your process for lifecycle management of equipment cleaning
  o A list of improvements, with an explanation how each will enhance cleaning effectiveness
  o Improved ongoing verification of proper cleaning execution for all products and equipment
  o Any other needed remediations.
- Appropriate improvements to your cleaning validation program, with special emphasis on incorporating conditions identified as worst case in your drug manufacturing operation. This should include but not be limited to identification and evaluation of all worst-case:
  o Drugs with higher toxicities
  o Drugs with higher drug potencies
  o Drugs of lower solubility in their cleaning solvents
  o Drugs with characteristics that make their manufacturing equipment difficult to clean
  o Swabbing locations for areas that are most difficult to clean
  o Maximum hold times before cleaning
- A description of the steps that must be taken in your change management system before introduction of new manufacturing equipment or a new product.
- A summary of updated SOPs that ensure an appropriate program is in place for verification and validation of cleaning procedures for products, processes, and equipment.

2. Failure to have laboratory control records that include complete data derived from all laboratory tests conducted to ensure your API complies with established specifications and standards.

Your firm conducts testing of raw materials, intermediates, and APIs, either in-house or through a contract laboratory; however, your firm failed to ensure that laboratory testing records were complete. For example, when our investigator requested supporting documentation, including equipment printouts, laboratory notebooks, worksheets, and analytical data, your firm was unable to provide any evidence that the testing reported on your certificates of analyses had actually been performed.

Additionally, in instances when a contract laboratory performed the testing, your firm reported the results on certificates of analyses printed on company letterhead, without identifying the entity that performed the original analysis.

In your response, you acknowledge your failure to maintain adequate records, and you commit to establishing controlled documentation systems and audit-trail review procedures. You also commit to investigating the missing raw data, reconstructing data where available to support previously released batches, and training employees in good documentation practices.

Your response is inadequate because it fails to provide evidence of implemented corrective actions. Moreover, you do not consider a retrospective review and risk assessment to evaluate the potential impact of the inadequate documentation on the validity of your reported results.

In response to this letter, provide:

- A comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate

the effectiveness of your laboratory system.

- A comprehensive assessment of documentation systems used throughout your manufacturing and laboratory operations to determine where documentation practices are insufficient. Include a detailed CAPA plan that comprehensively remediates your firm's documentation practices to ensure that you retain attributable, legible, complete, original, accurate, contemporaneous records throughout your operation.
- A management strategy for your firm that includes the details of your global CAPA plan to implement attributable, legible, complete, original, accurate, contemporaneous records throughout your operation. The detailed corrective action plan should describe how you intend to ensure the reliability and completeness of all data, including microbiological and analytical data, manufacturing records, and all data submitted to FDA.

3. Failure to design a documented, ongoing stability testing program to monitor the stability characteristics of API and to use the results to confirm appropriate storage conditions and retest or expiry dates.

Your firm's stability program is inadequate. For example, you were unable to provide the laboratory control records used to support your labeled **(b)(4)** expiry dates for tadalafil and sildenafil citrate APIs, respectively. Additionally, your sample storage chambers were observed to be powered off, and out-of-specification for temperature and/or humidity when powered on. Further, you were unable to locate stability samples of tadalafil, which were scheduled for future time-point testing.

In your response, you acknowledge the deficiencies of your stability program and propose corrective actions that include revising SOPs, investigating missing samples and affected time points, and performing an impact assessment for ongoing studies.

Your response is inadequate because it does not address why the chambers were powered off, and it does not provide sufficient detail or evidence of corrective actions to bring your operations into compliance with CGMP.

Without an adequate stability program, you cannot ensure that your APIs meet established specifications and all predetermined quality criteria throughout the APIs' assigned shelf-life.

In response to this letter, provide a comprehensive, independent assessment and CAPA plan to ensure the adequacy of your stability program. Your remediated program should include but not be limited to:

- Stability-indicating methods
- Stability studies for each drug product in its marketed container-closure system before distribution is permitted
- An ongoing program in which representative batches of each product are added each year to the program to determine whether the shelf-life claim remains valid
- Detailed definition of the specific attributes to be tested at each station (timepoint), as part of a program that encompasses each quality attribute that may change over the product shelf-life
- All procedures that describe these and other elements of your remediated stability program

4. Failure of your quality unit to exercise its responsibility to ensure the API manufactured at your facility are in compliance with CGMP.

Your quality unit (QU) failed to exercise its basic responsibilities for oversight of API production and testing operations. For example, your QU failed to:

- Evaluate the risk of process-related impurities on non-dedicated manufacturing equipment (i.e., microbial contamination, API cross-contamination, **(b)(4)** impurities)
- Establish written procedures for the cleaning and maintenance of facilities and equipment
- Qualify contract laboratories prior to use for CGMP testing
- Validate manufacturing operations prior to commercial distribution
- Calibrate and maintain equipment as appropriate for its intended use in API production operations

- Test materials for conformance with in-house or compendial specifications prior to use in manufacturing APIs
- Perform product reviews at least annually

In your response, you acknowledge inadequate QU oversight and the absence of a validation lifecycle approach to manufacturing. You commit to establishing an independent QU with the authority to address the deficiencies found during FDA's inspection.

Your response is inadequate because you did not provide a detailed remediation plan or procedures to address the identified deficiencies, nor did you provide any evidence of implemented corrections. Additionally, you have not evaluated the impact of these deficiencies on previously released batches or committed to withhold further distribution until appropriate CAPAs have been implemented and verified.

Significant findings in this letter demonstrate that your firm does not operate an effective quality system in accordance with CGMP. In addition to the lack of effective management oversight of your production operations, we found your QU is not enabled to exercise proper authority and/or has insufficiently implemented its responsibilities. Executive management should immediately and comprehensively assess your company's global manufacturing operations to ensure that your systems, processes, and products conform to FDA requirements.

In response to this letter, provide a comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to:

- A determination of whether procedures used by your firm are robust and appropriate
- Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices
- A complete and final review of each batch and its related information before the QU disposition decision
- Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all products

Drug Recall

On July 27, 2026, FDA held a teleconference with you, recommending that you recall all your APIs currently in distribution within the U.S. market. On August 4, 2026, you initiated a voluntary recall of all your APIs currently distributed within the U.S. market. The recall was posted to the FDA's Enforcement Report website at https://www.accessdata.fda.gov/scripts/ires/?Event=99547.

Additional API CGMP Guidance

FDA considers the expectations outlined in ICH Q7 when determining whether API are manufactured in conformance with CGMP. See FDA's guidance document Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients for guidance regarding CGMP for the manufacture of API at https://www.fda.gov/media/71518/download.

Cross Contamination Assessment

Contamination is generally nonuniformly distributed. Data obtained from retrospectively testing a small proportion of a batch (e.g., retain samples) is limited in its ability to retrospectively assess the extent of contamination in other portions of a batch. The lowest or highest results obtained from testing a small sample size is unlikely to reveal the true range of minimum and maximum contamination level that exists in a batch exposed to the contamination hazards identified at your firm. Consequently, substantial residual uncertainty remains regarding the actual range of variability of contamination levels in batches produced by your firm.

Because of the limitations of retrospective testing in gaining a representative understanding of the entire lot, testing retain samples alone is insufficient to determine the scope of the contamination issues and mitigate the associated risks. Further evaluation and scientific rationale is needed in your firm's risk assessment to reflect the nature of cross-contamination events and determine the degree of cross-contamination risk that may be posed to portions of marketed batches.

Data Integrity Remediation

Your quality system does not adequately ensure the integrity of data to support the safety, effectiveness, and quality of the APIs you manufacture. See FDA's guidance document *Data Integrity and Compliance With Drug CGMP: Questions and Answers* for guidance on establishing and following CGMP compliant data integrity practices at https://www.fda.gov/media/119267/download.

CGMP Consultant

Based upon the nature of the violations we identified at your firm, you should engage a consultant qualified to evaluate your operations and to assist your firm in meeting CGMP requirements. The qualified consultant should also perform a comprehensive six-system audit of your entire operation for CGMP compliance and evaluate the completion and efficacy of your CAPA before you pursue resolution of your firm's compliance status with FDA.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Conclusion

You are responsible for investigating and determining the root causes of any violations and implementing corrective and preventative measures to ensure future and sustained compliance so that these violations and any others do not occur.

FDA placed all drugs and drug products offered for import into the United States from your firm on Import Alert 66-40 on August 11, 2026.

FDA may withhold approval of new applications or supplements listing your firm as a manufacturer until any violations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to any violations.

Failure to address any violations may also result in the FDA continuing to refuse admission of articles manufactured at Shoolin Pharma Chem LLP, Block/Survey No. 408, B/h. Ratnamani Tubes, Nr. Maruti Inox, Indrad, Dist. Mehsana, Gujarat, India, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Articles under this authority that appear to be adulterated may be detained or refused admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

Send your written response to CDER-OC-OMQ-Communications@fda.hhs.gov within fifteen (15) business days of receipt of this letter. Identify your written response with FEI 3038200383 and ATTN: Christopher Leach in the subject line of the email.

If you have information that you believe demonstrates that your products are not in violation of the FD&C Act and FDA regulations, include that information for our consideration.

FDA posts warning letters to www.FDA.gov.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Cc: Benjamin L. England, Registered U.S. Agent
FDA Imports
(b)(4)

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1 CDER is including photographs of your facility in this warning letter to document the gross insanitary conditions violations.