WARNING LETTER

Chemspec Chemicals Private Limited

MARCS-CMS 718403 — DECEMBER 23, 2025

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Delivery Method:
Via Email
Reference #:
320-26-34
Product:
Drugs

Recipient:
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Issuing Office:
Center for Drug Evaluation and Research (CDER)
United States

Warning Letter 320-26-34

December 23, 2025

Dear Mr. Vora:

The United States Food and Drug Administration (FDA) inspected your drug manufacturing facility, Chemspec Chemicals Private Limited, FEI 3004947391, located at Plot 3-C, Taluka Panvel, Navi Mumbai, Maharashtra, from July 28, 2025, to August 1, 2025.

This warning letter summarizes significant deviations 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 August 21, 2025, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific deviations including, but not limited to, the following.

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

Your quality unit failed to ensure adequate document control over paper and electronic records. Your quality unit was not exercising its basic responsibilities for oversight and control of the adequacy and reliability of all CGMP data at your facility. In addition, your quality unit failed to ensure that employees involved in CGMP operations for APIs understand and adhere to data integrity principles. For example:

- Your quality unit failed to ensure that batch production records were prepared with complete information relating to the manufacture and control of each lot of API produced. You manufactured and released lots of APIs without creating or maintaining batch manufacturing records. Your quality unit failed to identify this deviation and did not investigate until our investigators cited it as a CGMP deficiency.
- You distributed multiple lots of the API **(b)(4)** without documenting review and release by the quality unit.
- Your quality unit kept two separate logbooks for the issuance of lot numbers which showed that two batch manufacturing records were issued for the same lot numbers. In addition, we observed two API batch records in use, in production, with neither an assigned control number nor any documentation that they had been issued by the quality unit.
- Your quality unit engaged in deficient data integrity practices. For example:
  o Your quality unit failed to control your process for replacing controlled documents. Your quality unit replaced original CGMP documents consisting of numerous pages of executed batch production records and a laboratory-testing record in which original pages were discarded or destroyed without a documented investigation. Your quality assurance manager stated that you do not maintain the original pages. We found blank forms used to replace controlled records in the production department with no indication that they had been issued by the quality unit.
  o Your quality unit allowed your production operators to retroactively complete CGMP information in batch production records for production steps performed by the previous **(b)(4)**. Your quality unit did not start an investigation until this data integrity failure was pointed out during our inspection. We observed your **(b)(4)** production personnel – who had not performed or witnessed the previous **(b)(4)** operations – in the production office non-contemporaneously documenting CGMP information, such as weights and measures of components, solvents, and temperatures, on API batch records for operations performed by the previous **(b)(4)**.

Your response dated August 21, 2025, acknowledges multiple deficiencies in your documentation practices, including inconsistencies in batch manufacturing record issuance, missing quality assurance review, uncontrolled forms, and inadequate documentation oversight. You acknowledge that your quality unit is responsible for preparing, reviewing, and approving master production and control records, and for ensuring their accuracy, distribution, and reconciliation.

You responded that you recovered approximately half of the original API batch manufacturing records. You stated that you will update your procedures to include a batch manufacturing record closure checklist and mandatory reconciliation of these records to ensure they are not lost. Additionally, you stated that you failed to document the release of lots because you do not have enough quality assurance personnel to review batch production records and release batches.

You stated that you misclassified replacement of CGMP documents as administrative corrections, and you did not have procedures requiring an investigation when you replaced these documents. You stated your procedures will be updated to require original document retention and documented deviation investigations for all replacements.

Your response is inadequate. You do not sufficiently address and reconcile all missing batch records. You do not provide results of any comprehensive retrospective evaluation, nor do you provide any testing data and release documentation.

You do not provide a plan or procedures to holistically improve your document lifecycle controls, issuance traceability, and quality unit release processes. You do not provide results from comprehensively investigating past incidents of non-contemporaneous documentation, nor have you reconciled existing batch manufacturing records for completeness and release by the quality unit.

You do not perform a comprehensive retrospective review of the replaced CGMP document pages. You do not provide any indication of the relevance of the original pages that were not maintained. You do not provide adequate revised procedures to ensure that original data will be recorded contemporaneously and indelibly.

Complete and accurate batch production and control records must be contemporaneously documented to ensure that manufacturing processes are consistently followed and are reproducible. Additionally, incomplete manufacturing records deprive you of the ability to adequately investigate deviations.

Reliability of data is fundamentally compromised when there is a failure to contemporaneously record and/or maintain complete and accurate records of testing conditions and results. Furthermore, the lack of reliable data compromises the ability of your quality unit to exercise its function of ensuring compliance to applicable standards.

In response to this letter, provide:

- A comprehensive assessment and remediation plan to ensure your quality unit is given the authority and resources to effectively function. The assessment should also include, but not be limited to:
  o A determination of whether procedures used by your firm are robust and appropriate
  o Provisions for quality unit oversight throughout your operations to evaluate adherence to appropriate practices
  o A complete and final review of each batch and its related information before the quality unit disposition decision
  o Oversight and approval of investigations and discharging of all other quality unit duties to ensure identity, strength, quality, and purity of all products
- A complete assessment of documentation systems used throughout your manufacturing and laboratory operations to determine where documentation practices are insufficient. Include a detailed corrective action and preventive action (CAPA) plan that comprehensively remediates your firm's documentation practices to ensure you retain attributable, legible, contemporaneous, original, accurate, and complete records throughout your operation.

Data Integrity Remediation

Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture. See FDA's guidance document *Data Integrity and Compliance With Drug CGMP* for guidance on establishing and following CGMP compliant data integrity practices at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-integrity-and-compliance-drug-cgmp-questions-and-answers.

We strongly recommend that you retain a qualified consultant to assist in your remediation. In response to this letter, provide:

- A comprehensive investigation into the extent of the inaccuracies in data records and reporting including results of the data review for APIs or advanced intermediates distributed to the United States or intended for drug products subsequently distributed to the United States. Include a detailed description of the scope and root causes of your data integrity lapses.
- A current risk assessment of the potential effects of the observed failures on the quality of your drugs. Your assessment should include analyses of the risks to patients caused by the release of drugs affected by a lapse of data integrity and analyses of the risks posed by ongoing operations.
- A management strategy for your firm that includes the details of your global corrective action and preventive action plan. The detailed corrective action plan should describe how you intend to ensure the reliability and completeness of all data generated by your firm including analytical data, manufacturing records, and all data submitted to FDA.

Repeat Observations at Facility

In a previous untitled letter dated February 5, 2025, FDA cited similar CGMP deviations. You proposed specific remediation for these deviations in your response. Repeated failures demonstrate that executive management oversight and control over the manufacture of APIs are inadequate.

Additional CGMP Guidance for APIs

FDA considers the expectations outlined in ICH Q7 when determining whether APIs 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 APIs at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q7-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients-guidance-industry.

Conclusion

The deviations cited in this letter are not intended to be an all-inclusive list of deviations that exist at your facility. You are responsible for investigating and determining the causes of any deviations and for preventing their recurrence or the occurrence of other deviations.

Failure to address any deviations may also result in the FDA refusing admission of articles manufactured at Chemspec Chemicals Private Limited, FEI 3004947391, located at Plot 3 - C, Taluka Panvel, Navi Mumbai, Maharashtra, 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).

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days1. Specify what you have done to address any deviations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3004947391 and ATTN: Brian Nicholson.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

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1 Under program enhancements for the Generic Drug User Fee Amendments (GDUFA) reauthorization for fiscal years (FYs) 2023-2027, also known as the GDUFA III Commitment Letter, your facility may be eligible for a Post-Warning Letter Meeting to obtain preliminary feedback from FDA on the adequacy and completeness of your corrective action plans.