U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via email
Return Receipt Requested

February 5, 2025

Mr. Ashish Dagade
Chief Operating Officer
Chemspec Chemicals Private Limited
Plot No 3-C, MIDC Taloja, Taluka Panvel, District Raigad
Navi Mumbai, Maharashtra 410208, India

Dear Mr. Dagade:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Chemspec Chemicals Private Limited, FEI 3004947391, at Plot No 3-C, MIDC Taloja, Taluka Panvel, District Raigad, Navi Mumbai, Maharashtra, from August 19 to 21, 2024.

This letter summarizes 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 September 10, 2024 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 APIs manufactured at your facility are in compliance with CGMP.

Your quality unit (QU) failed to ensure adequate document control over CGMP paper and electronic records (e.g., manufacturing records, equipment qualification records, laboratory instrumentation records, release testing data, and stability data) for (b) (4) API lots distributed to the U.S. market.

On December 28, 2023, your firm experienced a fire that destroyed (b) (4) of (b) (4) manufacturing buildings. Buildings affected included locations where your firm stored CGMP paper documentation. Electronic records and electronic system back-up files were maintained in the same location and destroyed by the fire.

Finished APIs were stored in a facility more than 1.5 km away and were not directly impacted by the fire. Your firm utilized third-party laboratories to conduct testing prior to distributing these lots between January and June 2024. While you did conduct limited testing, the methods used did not appear to be appropriately verified or validated and you did not address other gaps in CGMP data created by the destruction of your records, such as ensuring appropriate stability data.

Your firm's investigation for the fire (DV/QA/001/23) did not adequately address the failure to maintain documentation and records for the lots that were dispatched to the U.S. market after the fire. Of note, your firm experienced a fire in April 2013 at this establishment. Your investigation also fails to implement adequate storage procedures for CGMP records, (e.g., electronic back-up and recovery system, off-site storage of back-up), particularly as your firm has experienced multiple fires at this facility.

We note that your firm conducted a market withdrawal of the (b) (4) lots that were sent to your U.S. distributor.

Your response is inadequate. It did not include a detailed corrective action and preventive action (CAPA) plan that comprehensively remediates your firm's documentation practices to ensure you retain attributable, legible, complete, original, accurate, contemporaneous records throughout your operation (e.g., off-site back-up and recovery system in the event of a disaster such as a fire).

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/media/71518/download.

Drug Production Suspended

We acknowledge your site is under construction and you are unable to produce APIs at this facility for the U.S. market. In response to this letter, clarify whether you intend to resume manufacturing drugs for the U.S. market at this facility in the future.

If you plan to resume any manufacturing operations regulated under the FD&C Act, we request you notify this office before resuming your drug manufacturing operations. You are responsible for resolving all deficiencies and systemic flaws to ensure your firm is capable of ongoing CGMP compliance. In your notification to the Agency, provide a summary of your remediations to demonstrate that you have appropriately completed all CAPAs.

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.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, we request you respond to this office in writing within 30 working days. 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: Carrie Hughes.

Sincerely,

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