

Hetero Labs Limited

October 17, 2025

Credit Update

The US Food and Drug Administration (USFDA) conducted an inspection of Hetero Labs Limited's (HLL) Active Pharmaceutical Ingredient (API) manufacturing facility (Unit IX) at Nakkapalli, Anakapalli district, Andhra Pradesh between September 19 and 26, 2025. Following the inspection, the regulator issued Form 483 containing six observations. At this stage, observations suggest possible concerns around data and product integrity, and procedural inconsistency. As per media reports, following are the six observations.

Sr. No.	Observations
1	Quality control unit procedures not fully followed
2	Unregistered testing laboratory located outside official facility
3	Finished APIs for the US released to offsite API warehouse without documentation
4	Raw materials and quantities do not support actual API yield produced
5	Quality control unit failed to adequately control documents
6	Failure to document out of specification results obtained from unregistered facility

According to the company, it is planning to submit a comprehensive response to the USFDA within the stipulated timeline of 15 days. This unit is the one of the largest API manufacturing within HLL and is primarily manufacturing Antiretroviral (ARV) products. Production from this unit remains unaffected for now. A portion of the output from Unit IX is also supplied to the US market. As informed by the management, some of the production from this facility can be shifted to other USFDA-approved sites, if required.

CARE Ratings Limited (CareEdge Ratings) is actively engaging with the company to obtain further clarity and will continue to closely monitor developments arising from the USFDA inspection and assess its impact on the company's operations and overall credit profile.

Please refer to the following link for the latest press release that captures key rating drivers and rating sensitivities of HLL:

Entity Name	Link to Press Release
Hetero Labs Limited	Click here

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