

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER New England District Office 109 Holton St. Winchester, MA 01890 781-587-7500 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/18/2024-03/22/2024* FEI NUMBER 3008656542
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Rajashekar Reddy Gopu, Deputy General Manager	
FIRM NAME MSN Laboratories Private Limited, Unit-II	STREET ADDRESS Sy. No. 50, 53, 53/A, 54, 54/A, Kardanur, Patancheru
CITY, STATE AND ZIP CODE Sangareddy, Telangana, 502300, India	TYPE OF ESTABLISHMENT INSPECTED Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Your firm failed to properly maintain buildings and facilities used in the manufacture of API in a clean condition.

Specifically, during a walkthrough of your facility on March 18, 2024, I observed what appeared to be water staining and unknown (b) (4) residue on ceiling tiles located above retain samples, as well as on the baseboard behind the retains, in your API Reserve Sample Storage Room. Examples of retain samples stored in the API Reserve Sample Storage Room on March 18, 2024 include: (b) (4) lot (b) (4) and (b) (4) lot (b) (4)

(b) (4) lot (b) (4) On March 18, 2024, I also observed what appeared to be water staining on ceiling tiles above retain samples in your KSM and Intermediate Reserve Sample Storage Room, which your firm uses to store retain samples from lots of key starting raw material and from lots of intermediates during API production.

*DATES OF INSPECTION

03/18/2024(Mon), 03/19/2024(Tue), 03/20/2024(Wed), 03/21/2024(Thu), 03/22/2024(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Daniel L. Zheng -S Digitally signed by Daniel L. Zheng -S Date: 2024.03.22 00:16:03 -04'00'	EMPLOYEE(S) NAME AND TITLE (Print or Type) Daniel L. Zheng, Investigator	DATE ISSUED 03/22/2024
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