DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/7/2025-5/9/2025
	FEI NUMBER 3005075182

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sajja Eswaraiah, Head of New Product Development

FIRM NAME	STREET ADDRESS
MSN Laboratories Private Limited	Plot No 12, 258 275 - 280 Phase - Iv; Village; Sy No 119 - 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pashamylaram, Telangana, 502307 India	R&D Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The establishment of laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit.

Specifically,

The Quality Unit failed to adequately review all Chromatographic related discrepancies recorded by laboratory personnel during routine operations.

Your firm is currently using SOP AR-G-0054-006 "Procedure for Analysis and Good Laboratory Practices in AR&D", Section 8.6 "Invalidation of Chromatograms/Reports". This invalidation protocol does not provide for any scientifically sound investigation or review into these discrepancies identified by your Quality Unit as "Invalids".

Additionally, the use of the invalidation protocol does not provide any mechanism for tracking or categorization of said discrepancies for the purposes of trending and adequate review. Approximately, 1,200 said "Invalids" were recorded in the past 29 months without appropriate review provided by the Quality Unit.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Bryan L Mcguckin, Investigator	X Bryan L Mcguckin Investigator Signed By: Bryan L. Mcguckin -S Date Signed: 05-09-2025 07:43:04	5/9/2025

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Routine inspection of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

Your facility has established a preventative maintenance program. However, this preventative maintenance program lacks complete maintenance of electronic systems, systems which can generate software warnings and errors during analysis. Review of your electronic "error logs" indicates your Quality Unit and Laboratory staff are not reviewing said software generated error messages for all your systems. It's unknown to what extent, if any these generated errors might indicate system conditions that alter your data if left unaddressed.

Additionally, your IT Department is using "Microsoft Windows Remote Desktop Protocol" to facilitate remote repair of software related discrepancies via 3rd party vendors. I requested to review but was not provided, any protocol or SOP that ensures your IT Unit has addressed vulnerabilities to your data when using this application such as but not limited to 1) two factor authentication; 2) regular, documented software updates to ensure current security measures are in place; 3) unique passwords per session; 4) local firewall use and/or use of a VPN and 5) account lockout policies as needed.

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