

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Building 51 Silver Spring, MD 20993 301-796-3150 Fax: (301) 594-1204		DATE(S) OF INSPECTION 12/5/2025-12/11/2025*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kalakuntla Srinivas Rao, Executive Vice President		FEI NUMBER 3035592613	
FIRM NAME MSN Laboratories Private Limited	STREET ADDRESS Unit-05, Sy. Nos. (Parts of) 7,8,13 and 189 Chinna Chilkamarri, Chilkamarri (Chelka) Village		
CITY, STATE, ZIP CODE, COUNTRY Farooqnagar Mandal, Rangareddy , Telangana, 509216 India	TYPE ESTABLISHMENT INSPECTED Sterile Manufacturer		
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 WE OBSERVED: OBSERVATION 1 Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use. Specifically, You failed to perform a protocol-driven Performance Qualification (PQ) study for multiple equipment used during the production of (b) (4) (b) (4) According to your <i>Equipment/System Impact Assessment Report</i> (Document Number: IAR/5DEPS068/001-00 approved on 09/12/2023, IAR/5DEPS033-00 approved on 05/15/2023, IAR/5DEPS034-00 approved on 05/15/2023), the equipment are considered "Direct Impact" due to the reasons listed: A. (b) (4) Equipment (ID No: (b) (4)) is an equipment that provides product identification information, which includes a lot number and expiration date. B. (b) (4) Integrity Tester (ID No: (b) (4)) and (b) (4) Integrity Tester (ID No: (b) (4)) are equipment that impact the products safety, integrity, strength, purity, and quality and would impact the quality of the product if there is a malfunction to the equipment.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Brandy N Lepage, Investigator Jessica S Estriplet, Investigator		DATE ISSUED 12/11/2025 Brandy N Lepage Investigator Signed By: BRANDY N. LEPAGE Date Signed: 12-11-2025 10:36:04 X

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OBSERVATION 2 Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis. Specifically, Testing was not conducted for impurities, (b) (4) in the (b) (4) (Lot# (b) (4)) raw material prior to the production of the (b) (4) (b) (4) mg/mL) exhibit/process validation batches: (b) (4)		
OBSERVATION 3 The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, A) The Quality Unit failed to approve appropriate finished and stability drug product specifications for (b) (4) mg/mL). According to the procedure titled "Quality		
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Assurance Responsibilities” SOP AQA-060, section 5.2.1.12, the responsibilities of QA include “approving or rejecting all test procedures and specifications on the identity, strength, quality, and purity of the drug products.” The finished product release and stability specifications for pH in (b) (4) (b) (4) mg/mL) is (b) (4) and does not reflect the USP monograph pH requirement of (b) (4) for drug products with the component (b) (4) B) The Quality Unit reviewed and released the following batches that simultaneously serve as the exhibit and process validation batches for (b) (4) mg/mL) that are delineated in the process validation reports titled “(b) (4) (b) (4) mg/mL) (b) (4) mL)” dated: 07/26/2024 and “(b) (4) mg/mL) (b) (4) mL)” dated: 01/01/2025. The following exhibit and process validation batches did not have final release pH specifications within the required USP monograph range: (b) (4)			
OBSERVATION 4			
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In-process materials are not tested for quality and approved or rejected by the quality control unit during the production process. Specifically, The placement of Line (b) (4) active air samplers (Equipment IDs: (b) (4) (b) (4) and passive open settle plates, in Class B spaces, are not supported by scientific rationale. The document 5MB/MD/009-00, titled "Risk Rationale for Selection of Viable Monitoring Locations Line (b) (4) Aseptic Processing Area (b) (4) Block" instructs that the viable active air samplers and passive, open settle plates to be placed in the stream of first pass air, receiving the cleanest air in the room, and does not represent the most significant risk locations that should be monitored. The following environmental monitoring locations have samplers/plates situated in the direct stream of HEPA supplied air: <table border="1" style="width:100%; margin-top: 20px; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Location Name</th> <th style="width: 45%;">Location Description</th> <th style="width: 30%;">Type of Environmental Monitoring</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="height: 150px; background-color: #cccccc; text-align: center; vertical-align: middle;">(b) (4)</td> </tr> </tbody> </table>			Location Name	Location Description	Type of Environmental Monitoring	(b) (4)		
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(b) (4)								
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(b) (4)			
OBSERVATION 5 Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically, A) The sampling plan to visually inspect (b) (4) mg/mL), which is contained in a (b) (4) bottle that does not allow for 100% visual inspection, is done via a (b) (4) testing method in which (b) (4) for visual inspection as per test procedure (b) (4) (b) (4) This sample size of (b) (4) is not representative of the batch, nor adequate to ensure that batches do not contain units with visible particulates. The batch sizes are: B) There are no alert and action limits established for the viable and non-viable environmental monitoring (i.e., air, surface, and personnel) for the Grade A-Grade D classified areas that are utilized to produce, fill, and package the drug products, (b) (4)			
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(b) (4)			
C) The procedure that describes the environmental monitoring of viable microorganisms collected from the Grade A and Grade B production and filling areas of Unit (b) (4) Line (b) (4) is "Viable Monitoring Procedure for Aseptic Processing Area (APA) (b) (4) Block Line (b) (4)" SOP 5MB-004. The (b) (4) drug products, (b) (4) are produced and filled on Line (b) (4). The viable environmental monitoring procedure titled does not delineate the following: 1) The timing during (b) (4) that dynamic active air sampling is required (e.g., setup, filling, etc.). Section (b) (4) of the procedure indicates for the active air sampling to transpire during "(b) (4) (b) (4)." ." 2) There is no maximum exposure limit for passive air monitoring media plates. Section (b) (4) of the procedure indicates for the environmental monitoring personnel to "expose (b) (4) settle plates for a minimum of (b) (4) at defined locations."			
*DATES OF INSPECTION 12/05/2025(Fri), 12/08/2025(Mon), 12/09/2025(Tue), 12/10/2025(Wed), 12/11/2025(Thu)			
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