

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857		DATE(S) OF INSPECTION 11/14/2024-11/22/2024*	
		FEI NUMBER 3005652193	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Biju Mathew, Senior Vice President Quality			
FIRM NAME Steriscience Specialties Private Limited		STREET ADDRESS (b) (4) Division, Doresanipalya, 152/6 & 154/16, Bannerghatta Road	
CITY, STATE, ZIP CODE, COUNTRY Bengaluru, Karnataka, 560076 India		TYPE ESTABLISHMENT INSPECTED Sterile Drug 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 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process. Specifically, A. Airflow visualization (Smoke Studies) of Grade A laminar flow on Line (b) (4) do not adequately demonstrate airflow in the Grade A (b) (4) LAF where (b) (4) of the filling machine, via an aseptic connection, takes place. The airflow visualization study conducted on Line (b) (4) per protocol (b) (4) is limited to simulation of (b) (4) of the (b) (4) of the vial filling machine. The operator is then observed opening the canister and placing it (b) (4) via an aseptic connection. This intervention is in part performed using the (b) (4) and in part performed through (b) (4) intervention. This simulation does not represent this activity during commercial production. In commercial production, up to (b) (4) were observed (b) (4) of the vial filling machine on (b) (4). The operator was observed switching the canisters (b) (4) by removing an empty one and sliding the canisters around on the (b) (4) LAF to switch the empty one out with a full one.			
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		Anastasia M Shields Investigator Signed By: Anastasia M. Shields - Date Signed: 11-22-2024 05:45:59 X	

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B. Turbulence was observed in the airflow visualization study conducted on Line (b) (4) per protocol (b) (4), during the activity, "Fallen Vial on (b) (4) Conveyer", Serial No. (b) (4) Your Report (b) (4) failed to acknowledge this turbulence and scored this as #3, "Acceptable Airflow" "No Impact".			
OBSERVATION 2 Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Specifically, the software (b) (4) software, version (b) (4) installed on (b) (4) used for (b) (4) integrity testing of the (b) (4) and the (b) (4) Particle Counter (NVPC) (b) (4) Software, version (b) (4) used for environmental monitoring in the Grade A, B, C and D areas is not equipped and/or audit trail enabled.			
OBSERVATION 3 Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit. Specifically, your (b) (4) NVPC machines were accessible using a common user name "USER" and password until August 2024. Per SOP, PROC SSCOR SOP GQA 1196, "Change Management", a Change Control is to be initiated when changes are made which may have direct or indirect impact on quality and documentation of the product, system, material, process, equipment or procedures. Your firm failed to open a Change Control and conduct any associated risk assessments to existing data when individual user IDs and passwords were assigned to approved operators.			
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*DATES OF INSPECTION 11/14/2024(Thu), 11/15/2024(Fri), 11/18/2024(Mon), 11/19/2024(Tue), 11/20/2024(Wed), 11/21/2024(Thu), 11/22/2024(Fri)		
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