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	4/27/2023-5/5/2023*
	FEI NUMBER 3006767695

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jayaraman Kannappan, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Apicore Pharmaceuticals Private Ltd	Block No 252-253, Village-Dhobikuva, Opposite Jain Irrigation
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Vadodara, Gujarat, 391440 India	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 I 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. Your firm manufactures (b) (4) batches of sterile (b) (4) USP, API. Your firm calculated that one batch of (b) (4) USP API can be filled into (b) (4) - (b) (4) drug product vials. Media fill study # MF/CPMD/22/04/01, conducted in May 2021 and simulating the manufacture of sterile (b) (4) API, failed due to recovering (b) (4) CFU for the (b) (4) simulation, and (b) (4) CFU for the (b) (4) simulation (DV/22/046). Spore forming bacteria such as *Basileus subtilis*, *Basileus pumilus*, *Bacillus oceanisediminis*, and *Basileus megaterium,* were isolated from the recovered CFUs. Instead of performing re-validation via three consecutive media fills, your firm performed only one repeat media fill.

B. Your firm uses disinfectants to disinfect your facility and equipment, including surfaces that come into contact with the sterile APIs manufactured by your firm. Review of your disinfectant efficacy study (Protocol #s ACP-22-015-00) showed that the study was performed by pipetting (b) (4) uL of the test culture on the coupon and allowing it to dry, followed by pipetting about (b) (4) uL of the disinfectant over the dried culture. This method of disinfecting is different than your routine disinfecting procedure (APV-SOP-MFG253) wherein the disinfectant is spread using a

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Bijoy Panicker, Investigator	X Bijoy Panicker Investigator Signed By 2001996716 Date Signed 05-05-2023 05 29 35	5/5/2023

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mop or wiped using a lint free cloth.

OBSERVATION 2

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

Specifically,

Analytical balance QCE # 684 with a weight range of 20 mg to 200 g is used in your firm's QC chemistry laboratory to weigh test samples. Your firm's (b) (4) verification of this balance includes only 50 mg to 200 g weight range, and does not include the lower weight range of 20 mg to 50 mg.

***DATES OF INSPECTION**

4/27/2023(Thu), 4/28/2023(Fri), 5/01/2023(Mon), 5/02/2023(Tue), 5/03/2023(Wed), 5/04/2023(Thu), 5/05/2023(Fri)

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