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	6/10/2024-6/14/2024
	FEI NUMBER 3022125340

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Arun Kumar Gupta, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Biocon Biosphere Limited	Ramky Pharma City, Jawaharlal Nehru Pharma City; Sez Unit
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam, Andhra Pradesh, 531021 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

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, your firm does not have approved protocol driven equipment performance qualification (PQ) studies with pre-approved acceptance criteria and which describes all aspects of the testing performed, and with a final summary report of the data generated and a determination of whether equipment qualification status was achieved. The process validation report titled "Process Performance Qualification Report of (b) (4) API" MVD-000146683, ver 3.0, was executed using equipment that was not fully qualified (IQ/OQ/PQ). The following are some examples of production equipment that lacks protocol-based equipment qualifications:

A. (b) (4) (Equipment ID # PB1(b) (4)-001), utilized in the (b) (4) stage of (b) (4) USP production.

B. (b) (4) Vessel (Equipment ID # PB1(b) (4)-009), utilized in the (b) (4) stage of (b) (4) USP production.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandy N Lepage, Investigator X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-14-2024 08:18:42	6/14/2024

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C. (b) (4) (PB2(b) (4)001), utilized in the (b) (4) stage of(b) (4) USP production.

D. (b) (4) (Equipment ID # PB3-(b) (4)001), utilized in the(b) (4) (b) (4) stage of(b) (4) USP production.

E. (b) (4) (Equipment ID # PB4(b) (4)001), utilized in the (b) (4)stage of(b) (4) USP production.

F. (b) (4) (Equipment ID # PB4-(b) (4)001), utilized in the (b) (4)stage of(b) (4) USP production.

OBSERVATION 2

In-process materials are not tested for identity, strength, quality and purity and approved or rejected by the quality control unit after storage for long periods.

Specifically,(b) (4) Intermediate has an established hold time of(b) (4) per the study titled "Hold Time Study of In-Process Samples of(b) (4) PDD/TR/BL.14.0653/19/004, ver 1.0, dated: 09/13/2019.(b) (4) Intermediate, lot #(b) (4) was released on 01/24/2023, and the batch was utilized to produce(b) (4) USP, lot #(b) (4) on 06/15/2023. The(b) (4) Intermediate batch exceeded its established hold time by(b) (4) days. The Quality Unit failed to investigate and perform a risk assessment of the potential impact of the

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utilization of the intermediate in the drug substance production, prior to the release of (b) (4) USP, lot # (b) (4)

OBSERVATION 3

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 microbial enumeration test method validation titled "Study Report to Perform the Method Suitability of (b) (4) Testing" BP/SMV/QA/STY/R/19/091-01, ver 001, does not include the strain *Aspergillus brasiliensis*, or equivalent, to access the suitability of your method and growth promotion capabilities of the media to detect the presence of molds. The test method titled "(b) (4) (b) (4) Microbiological Testing Procedure" MET-000079118, ver 1.0, is employed for routine (b) (4) testing, which is utilized for equipment cleaning and is a component utilized in the production of (b) (4) USP.

B) The test method titled "Raw Material Specification (b) (4) " QC/SPEC/RM/046, ver 006, for (b) (4) identification testing, which is a raw material component utilized in the production of (b) (4) USP, does not include gas chromatography analysis for the limit of (b) (4) The raw material used to produce the (b) (4) USP, lot ## (b) (4) and # (b) (4) was not analyzed for the limit of (b) (4) by the firm during

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raw material testing.

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