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	2/10/2020-2/21/2020*
	FEI NUMBER 3011248248

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kiran Kumar, Vice President and Site Head

FIRM NAME	STREET ADDRESS
Biocon Sdn Bhd	No. 1., Jalan Biooteknologi 1, Kawasan Perindustrian Silc
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Iskandar Puteri, Johor, 79200 Malaysia	Biotech

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

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, batch records reviewed and approved by quality department included Environmental Monitoring (EM) Interventions into the grade A unit which recorded unexplained durations for those interventions. Unexplained discrepancies in the batch records were not investigated to determine whether (QCM) employees followed written procedures during interventions into the Grade A space during filling. For Example:

- (b) (4) filling batch record (b) (4) shows on 10 January 2020 from (b) (4) Environmental Monitoring was performed in (b) (4) Grade A interventions to collect/dispense 7 EM plates and subsequent personnel monitoring was recorded as completed at (b) (4) (b) (4) after initiation of the intervention.
- Undocumented interventions into the Grade A unit, related to collection and distribution of EM plates was observed in the batch records and Personnel Monitoring Details as far back as February 2019.
- (b) (4) illing batch records from 2018 and 2019 documented Environmental ventions as short as (b) (4) respectively.

No investigation was initiated during quality review to determine if these interventions negatively impacted product quality. Filling room Environmental Monitoring locations include 7 inside of the grade A unit and 14 outside of the grade A unit in the immediate vicinity. For comparison on 17 February 2020, EM sampling was observed to require (b) (4) for grade A and (b) (4) of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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intervention time was required to complete the immediate vicinity EM monitoring before the grade A unit was fully closed.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically, Performance requalification approved by quality on 10 February 2020, for the airflow visualization of the grade A filling unit does not appropriately correspond to filling processes or document all critical aspects of unidirectional airflow. For Example:

- Protocol, BM/PDP/RQ/P/067-01, lists acceptance criteria in sections 10.3 and 10.4 to exclude lower quality air from outside or after contacting the operator. Interventions for periodic component replenishment were marked as "Satisfactory"; however, the video files for visualizations under dynamic conditions did not demonstrate the acceptance criteria were met during periodic component replenishment of (b) (4) stoppers.
- Air flow visualization videos provided did not correspond with periodic component replenishment intervention times observed in (b) (4) batch records.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

- Equipment Qualification SOP BM/QA/SOP/057, states that operational qualification includes "…verification that all aspects of an equipment which can affect product quality, operate as intended

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throughout all anticipated ranges…". Your firm's quality department was unable to provide an operational qualification for the integrity tester used for intervention (b) (4) which are part of your firm's grade A filling unit.

- Your firm opened CAPA - BM / CAPA / QA – 19 – 088 to investigate out of trend results from a product quality review conducted for the period of April 2018 to March 2019. Your firm's quality department closed this CAPA in November 2019 without completing the derivative investigations, corrective actions and effectiveness checks.

***DATES OF INSPECTION**

2/10/2020(Mon), 2/11/2020(Tue), 2/12/2020(Wed), 2/13/2020(Thu), 2/14/2020(Fri), 2/17/2020(Mon), 2/18/2020(Tue), 2/19/2020(Wed), 2/20/2020(Thu), 2/21/2020(Fri)

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