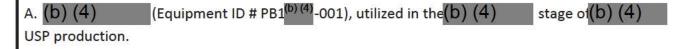
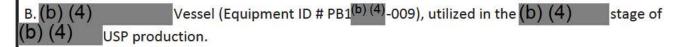
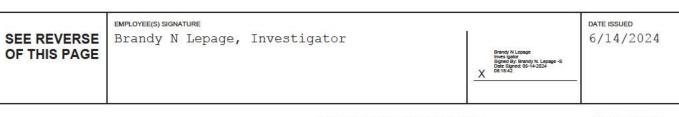
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 6/10/2024-6/14/2024 FEI NUMBER 3022125340				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED					
Arun Kumar Gupta, Chief Operating Office	T STREET ADDRESS				
Biocon Biosphere Limited	Ramky Pharma City, Jawaharlal Nehru Pharma City; Sez Unit				
CITY.STATE.ZIP CODE.COUNTRY Visakhapatnam, Andhra Pradesh, 531021	TYPE ESTABLISHMENT INSPECTED Manufacturer				
India					
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 the table above the identity attention of the stable of	r production and process controls designed to assure				

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:







FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 4 PAGES

		G ADMINISTRATI	ON		
DISTRICT ADDRESS AND PHON			DATE(S) OF INSPECTION 6/10/2024-6/14/2024		
Rockville, M			FEI NUMBER 3022125340		
			3022123340		
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED		<u>.</u>		
	upta, Chief Operating Officer				
Biocon Biosph	nere Limited	Ramky Pharma City, Jawaharlal Nehru Pharma City; Sez Unit			
City, STATE, ZIP CODE, COUN Visakhapatnar India	n, Andhra Pradesh, 531021	TYPE ESTABLISHMENT INSPECTED Manufacturer			
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.					
250	ON 2 crials are not tested for identity, street rol unit after storage for long period		y and purity and approv	ed or rejected by	
ver 1.0, dated: (01/24/2023, an The(b) (4)	ne Study of In-Process Samples of (b) (4) Intermediat (b) (4) eded its est	ve, lot #(b) (4) wa USP, lot #(b) (4) ablished hold time by ^{(b}	4.0653/19/004, as released on on 06/15/2023.	
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Brandy N Lepage, Investigat	or	Brandy N Lepage Investigator Stigned By: Brandy N, Lepage Discount of the Control X 08:18-42	DATE ISSUED 6/14/2024	
FORM FDA 483 (09/08)	PREVIOUS EDITION ORSOLETE INS	SPECTIONAL C	DBSERVATIONS	PAGE 2 of 4 PAGES	

INSPECTIONAL OBSERVATIONS

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

	DEPARTMENT OF HEAL FOOD AND DRU	TH AND HUMA G ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032			DATE(S) OF INSPECTION 6/10/2024-6/14/2024		
Rockville, MI		1	FEI NUMBER 3022125340		
			3022123340		
NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED				
	upta, Chief Operating Officer				
Biocon Biosph	nere Limited	Ramky Pharma City, Jawaharlal Nehru			
CITY, STATE, ZIP CODE, COUNT		Pharma City; Sez Unit			
ACTA TO A SECRETARIO DE COMPANSO DE LO	n, Andhra Pradesh, 531021	TYPE ESTABLISHMENT INSPECTED Manufacturer			
India		Immaradearer			
utilization of the USP, lot #(b) (4	e intermediate in the drug substand 1)	ce productio	n, prior to the relea	ase of(b) (4)	
OBSERVATIO	ON 3			7	
	rols do not include the establishme		(T)		
1 To	gned to assure that drug products co	onform to ap	propriate standards	of identity, strength,	
quality and puri	ty.				
Specifically,					
A) The microbia	l enumeration test method validat	ion titled "St	udy Report to Perf	orm the Method	
Suitability of (b) (4) Testing" BP/SMV/QA	A/STY/R/19/	091-01, ver 001, do	es not include the	
strain Aspergillu	is brasiliensis, or equivalent, to acc	ess the suita	bility of your meth	od and growth	
promotion capa	bilities of the media to detect the	presence of	molds. The test me	thod titled "(b) (4)	
(b) (4) Microbio	logical Testing Procedure" MET-00	0079118, ve	r 1.0, is employed	for routine (b) (4)	
testing, w	hich is utilized for equipment clear	ning and is a	component utilize	d in the production of	
(b) (4) USP	(b) (4) USP.				
B) The test met	nod titled "Raw Material Specificat	ion(b) (4)	" QC/SPEC/RM/046	5, 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 materia	al used to produce the(b) (4)	USP, lot ##	b) (4)	and	
$\sharp(b)$ (4) was not analyzed for the limit of (b) (4) by the firm during					
l					
	EMPLOYEE(S) SIGNATURE			DATE ISSUED	
SEE REVERSE	Brandy N Lepage, Investigat	or	Brandy N Lepage	6/14/2024	
OF THIS PAGE			lines igained By: Brandy Date Signed By: Brandy Date Signed: 06-1-	IN. Lepage -8 4-2024	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL O	RSFRVATIONS	PAGE 3 of 4 PAGES	
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) SEE REVERSE OF THIS PAGE Brandy N Lepage, Investigator DATE ISSUED 6/14/2024					

	DEPAR	TMENT OF HEAL'			ES	
DISTRICT ADDRESS AND PHON				DATE(S) OF INS		
Rockville, M	wn Drive, Room 203 D 20857	2		6/10/2 FEI NUMBER	024-6/14/2024	
ROCKVIIIE, III	D 20037			302212	5340	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			l.		
Arun Kumar G	upta, Chief Operat	ing Officer				
FIRM NAME			STREET ADDRESS			
Biocon Biosph	here Limited				ty, Jawaharlal	Nehru
CITY, STATE, ZIP CODE, COUN		3	Pharma City; Sez Unit			
AND THE PROPERTY OF THE PROPER	m, Andhra Pradesh,	531021	Manufact			
India	m, Andria Fradesh,	551021	Panulact	urer		
India						
raw material te	sting.					
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	EMPLOYEE(S) SIGNATURE				÷	DATE ISSUED
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OF THIS PAGE					Brandy N Lepage Inves igator	Calcarati inscient
					Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-14-2024 O8:18:42	
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INS	PECTIONAL O	OBSERVATI	ONS	PAGE 4 of 4 PAGES