

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240) 402-9160 orabioinspectionalcorrespondence@fda.hhs.gov		<small>DATE(S) OF INSPECTION</small> 8/5/2024-8/13/2024*	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Chiron G.T. Howell, Site Director		<small>FEI NUMBER</small> 3001417487	
<small>FIRM NAME</small> Protherics UK Limited	<small>STREET ADDRESS</small> Blaenwaun, Ffostrasol		
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Llandysul, Ceredigion, SA44 5JT United Kingdom	<small>TYPE ESTABLISHMENT INSPECTED</small> Biological Drug Substance Manufacturer		
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p> <p>OBSERVATION 1</p> <p>(b) (4)</p> <p>Your firm has not fully investigated or assessed the impact of finding various molds in a (b) (4) room in which manufacturing materials (used for manufacturing of (b) (4) and (b) (4)) and stability samples are held.</p> <p>From March 2023 to April 2024, five quality investigations were initiated to address molds in (b) (4) (b) (4) room (b) (4) of a (b) (4) and include: (b) (4) #70445; (b) (4) #73010; (b) (4) #73044; DEV-00267; and DEV-00331. These investigations were generated in accordance with procedure (b) (4) -SOP-(b) (4)-000015, Control of Quality Events and Corrective and Preventive Actions, Ver 21, 23 & 23, which allow for such actions as additional monitoring activities (e.g., (b) (4)) and requires the use of a root cause investigation (which would allow for the expansion of the scope of investigation). Although your firm initiated various corrective actions (CAPAs), the following was revealed during this inspection:</p> <p>a) Your firm did not initiate investigative environmental monitoring and sampling in manufacturing areas of building (b) (4) to detect for mold contamination beyond routine EM monitoring to address, for example, routes or pathways of supply items which were put at risk by being exposed to molds in (b) (4) room (b) (4). Note that supply items undergo a cleaning/disinfection regimen before going into controlled areas but given the potential for cross contamination and movement of mold spores, routine EM might not be sufficient to capture the extent of, for example, emerging mold risks.</p>			
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Gene D Arcy, Investigator - Team Biologics Peng Zhou, Investigator		<small>DATE ISSUED</small> 8/13/2024
<small>SEE REVERSE OF THIS PAGE</small>		<small>EMPLOYEE(S) SIGNATURE</small> Peng Zhou, Investigator Signed By: 2002104595 Date Signed: 06-13-2024 09:56:49 X	

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<p>b) A primary cause of the molds occurring in (b) (4) room (b) (4) was due to the (b) (4) in a (b) (4) of (b) (4) of two (b) (4) units (b) (4), due to a (b) (4) (Deviation 00267, April 2024). Investigation of other similar (b) (4) units which contain a (b) (4) was not done to assess for impacts of the (b) (4) which may need to be, for example, inspected and cleaned frequently or replaced by (b) (4) units that are designed with less risk. (b) (4) units with similar designs include:</p> <ul style="list-style-type: none"> i. (b) (4) unit (b) (4) (b) (4) in Building (b) (4) ii. Unit (b) (4) - Room (b) (4) in Building (b) (4) iii. Unit (b) (4) - Room (b) (4) in Building (b) (4) iv. Unit (b) (4) - Room (b) (4) in Building (b) (4) 			
<p>*DATES OF INSPECTION 8/05/2024(Mon), 8/06/2024(Tue), 8/07/2024(Wed), 8/08/2024(Thu), 8/09/2024(Fri), 8/12/2024(Mon), 8/13/2024(Tue)</p> <div style="margin-top: 20px;"> <small>Gene D Arcy Investigator - Team Biologics Signed By: 1300159983 Date Signed: 08-13-2024 09:57:40</small> <div style="display: flex; align-items: center;"> <div style="width: 20px; height: 20px; border: 1px solid black; margin-right: 5px;"></div> <div style="border-bottom: 1px solid black; width: 150px;"></div> </div> </div>			
SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Gene D Arcy, Investigator - Team Biologics Peng Zhou, Investigator <div style="text-align: right; margin-top: 20px;"> <small>Peng Zhou Investigator Signed By: 2002104595 Date Signed: 08-13-2024 09:56:49</small> <div style="display: flex; align-items: center;"> <div style="width: 20px; height: 20px; border: 1px solid black; margin-right: 5px;"></div> <div style="border-bottom: 1px solid black; width: 150px;"></div> </div> </div>	
		<small>DATE ISSUED</small> 8/13/2024	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."