

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> 8/15/2024-8/23/2024* <small>FEI NUMBER</small> 3000323524	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Peter White, PhD, Managing & Technical Director			
<small>FIRM NAME</small> Nova Laboratories Ltd		<small>STREET ADDRESS</small> Gloucester Cresent	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Wigston, Leicestershire, LE18 4YL United Kingdom		<small>TYPE ESTABLISHMENT INSPECTED</small> Biologics - (b) (4) , Pharmaceuticals, Medical Devices	
<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>Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.</p> <p>Specifically,</p> <p>Regarding the cleaning of manufacturing equipment or glassware used in the production of a sterile (b) (4) and a (b) (4) used for a (b) (4) the production of (b) (4) drug product (b) (4) (b) (4) in (b) (4) , includes, but is not limited to, (b) (4) , the SOP titled, <i>Preparation of Equipment, Including Pressure Vessels, Mixing Vessels, Glassware, Tools And Seals For Use In Manufacturing</i>, SOP1367, Ver. 15, states that for post cleaning, “(b) (4)” The cleaning of each piece of equipment or glassware is documented on (b) (4) In addition, no study could be provided that substantiates the (b) (4) until drying.</p>			
<p>OBSERVATION 2</p> <p>DRUG SUBSTANCE</p>			
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Gene D Arcy, Investigator - Team Biologics Peng Zhou, Investigator - Team Biologics		<small>DATE ISSUED</small> 8/23/2024 <small>Gene D Arcy Investigator - Team Biologics Signed By: 1300159963 Date Signed: 08-23-2024 06:40:07</small> X

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<p>Your firm does not appear to have qualified airflow effectiveness of (b) (4) to address normal operating conditions, including addressing the apparent risk of (b) (4)</p> <p>A. Your firm's performance qualification protocol report, (b) (4) (b) (4), addresses the qualification of airflow dynamics with use of an (b) (4) study which is captured on (b) (4). One commercial product manufactured in (b) (4) (b) (4) is a sterile (b) (4). Associated with the qualification is a (b) (4) showing the application of an (b) (4) and the following objectionable conditions were observed in the (b) (4):</p> <ul style="list-style-type: none"> i. No operators (b) (4) were observed engaging in (b) (4) operations. ii. The overall unidirectional air flow of the (b) (4) /fog cannot be discerned. iii. Verification of the function of (b) (4) ports was done using (b) (4) (b) (4), but the instrument was (b) (4) and not in a fashion which would provide confidence that the ports would function as intended. <p>B. In addition, the above airflow visualization (b) (4) shows the use of (b) (4) (b) (4). The risk of using such (b) (4) has not been addressed via qualification regarding your firm's not disassembling the (b) (4) and cleaning them, and the risk of, for example, accumulation and presence of particles due to potential degradation because of repeated exposure to (b) (4) or routine surface cleaning.</p> <p>C. Your firm's approach to smoke (b) (4) studies and the use of (b) (4) (b) (4), was reported to be the same for other (b) (4) (b) (4), such as for (b) (4) (b) (4).</p>			
SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Gene D Arcy, Investigator - Team Biologics Peng Zhou, Investigator - Team Biologics <div style="text-align: right; margin-top: 10px;"> <small>Gene D Arcy Investigator - Team Biologics Signed By: 1300159963 Date Signed: 08-23-2024 06:40:07</small> X </div>	
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Silver Spring, MD 20993-0002	FEI NUMBER
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Peter White, PhD, Managing & Technical Director

FIRM NAME	STREET ADDRESS
Nova Laboratories Ltd	Gloucester Cresnet

CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wigston, Leicestershire, LE18 4YL United Kingdom	Biologics - Viral Vectors, Pharmaceuticals, Medical Devices

8/15/2024(Thu), 8/16/2024(Fri), 8/19/2024(Mon), 8/20/2024(Tue), 8/21/2024(Wed), 8/22/2024(Thu),
8/23/2024(Fri)

x

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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."