DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 Phone: (301)796-3334 Fax:(301)847-8738 Email: CDERPAIprogram@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/21/2026-04/21/2026 FEI NUMBER 3012158090

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Romit Jani M.S., Senior Director of Formulation Development

FIRM NAME	STREET ADDRESS
Solaris Pharma Corporation	49 Napoleon Court
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873	Control Testing Laboratory

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:
Where referenced, (b) (4) **, refers to** (b) (4) .

OBSERVATION 1

Your firm lacks adequate quality control capabilities to support commercial drug manufacturing operations for (b)(4) .

Specifically:
1. The quality control laboratory remains under construction and is not functional. This laboratory is proposed for analytical release testing and stability testing of commercial batches.

2. Essential quality control instruments, including HPLC systems, a pH meter, and analytical balances, have not arrived at the facility. These analytical instruments are necessary for quality control testing but have not arrived at the facility and, as such, have not undergone installation qualification (IQ), operational qualification (OQ), or performance qualification (PQ).

3. Although a method transfer protocol for in-house methods that will be used for analytical release testing and stability testing of commercial batches has been drafted, these methods have not been reviewed and approved by the quality assurance unit. Method transfer activities have not been performed, preventing the establishment of validated analytical methods necessary for commercial manufacturing operations.

4. Procedures applicable to the quality control unit are still undergoing updates to include requirements applicable to the control unit. These draft procedures have not been reviewed and approved by the quality assurance unit.

*DATES OF INSPECTION

4/21/2026 (Tues)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Adetutu M Gidado, Investigator X Adetutu Gidado -S Digitally signed by Adetutu Gidado -S Date: 2026.04.21 13:22:29 -04'00' Adetutu M Gidado Investigator	04/21/2026

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."