

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		DATE(S) OF INSPECTION 2/19/2026-2/24/2026* FEI NUMBER 3029497444
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Carla A. Maxime, Director Manufacturing Quality and Regulatory		
FIRM NAME Pharmalogic Salt Lake City, LLC	STREET ADDRESS 383 W Vine St Ste 100	
CITY, STATE, ZIP CODE, COUNTRY Salt Lake City, UT 84123-4745	TYPE ESTABLISHMENT INSPECTED Positron Emission Tomography (PET) Drug Manufacturer	
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: QUALITY SYSTEM		
OBSERVATION 1 You did not take appropriate action to correct any identified problems to prevent recurrence of a nonconforming product or other quality problem. Specifically, During review of the quality system related incidents, we observed the following: A. There were at least five occurrences of QC analytical chromatography testing involving operator error resulting in no blank injected during finished product testing of (b)(4) Injection in a period of approximately four months from 05/29/2025 – 10/01/2025. For each occurrence, the testing was re-performed with blank and met specification. For each occurrence, awareness training was conducted. The action taken was inadequate in preventing recurrence. In one example, a repeat incident was logged for the same operator on two consecutive days. B. There were at least three occurrences of QC analytical chromatography testing involving operator error resulting in sample injected without product or no product injected during drug product testing of (b)(4) and (b)(4) Injections in a period of approximately 9 months from 02/25/2025 – 11/16/2025. For two of the incidents, the testing was re-performed and met		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joey V Quitania, Investigator Lillian S Wu, Investigator Matthew R Clabeaux, Investigator	DATE ISSUED 2/24/2026 Joey V Quitania Investigator Signed By: Joey V. Quitania -S Date Signed: 02/24/2026 13:37:23 X

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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6th & Kipling St. (P.O. Box 25087)
Denver, CO 80225-0087
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DATE(S) OF INSPECTION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Carla A. Maxime, Director Manufacturing Quality and Regulatory

FIRM NAME

Pharmalogic Salt Lake City, LLC

STREET ADDRESS

383 W Vine St Ste 100

CITY, STATE, ZIP CODE, COUNTRY

Salt Lake City, UT 84123-4745

TYPE ESTABLISHMENT INSPECTED

Positron Emission Tomography (PET) Drug
Manufacturer

specification; for the third, the data was rejected and testing was re-performed at a later date. Awareness training was conducted. The action taken appears to be inadequate in preventing recurrence.

***DATES OF INSPECTION**

2/19/2026(Thu), 2/20/2026(Fri), 2/23/2026(Mon), 2/24/2026(Tue)

X Lillian S Wu
Investigator
Signed By: 2003443287
Date Signed: 02-24-2026 13:38:04

X Matthew R Clabeaux
Investigator
Signed By: Matthew R. Clabeaux -S
Date Signed: 02-24-2026 13:38:49

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Joey V Quitania, Investigator
Lillian S Wu, Investigator
Matthew R Clabeaux, Investigator

X Joey V Quitania
Investigator
Signed By: Joey V. Quitania -S
Date Signed: 02-24-2026
13:37:23

DATE ISSUED

2/24/2026

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."