DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	6/2/2025-6/6/2025
	FEI NUMBER 3024253503

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Mekonnen Abebe, CEO

FIRM NAME	STREET ADDRESS
Lux Therapeutics LLC dba Ponya Therapeutics LLC	13 Corporate Blvd. NE
CITY, STATE, ZIP CODE, COUNTRY Brookhaven, GA 30329-1906	TYPE ESTABLISHMENT INSPECTED Tissue Processor

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:

OBSERVATION 1

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, you have not validated the manufacturing process for your Umbilical Cord, Wharton's Jelly, Luxegen product. During manufacturing you (b) (4) Wharton's Jelly from the umbilical cord (b) (4) Since the start of operations on 12/21/2022, you have distributed (b) (4)

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, you have not established procedures for testing your Umbilical cord, Wharton's Jelly, Luxegen Product, for identity or strength of any components, or for the quality and purity. You manufacture Luxegen product using a ratio of (b) (4) (b) (4) Your Director of Quality Management stated that this (b) (4) was based on your competitor's products. However, you have not established final specifications to include the identity and strength of components.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mizanne E Lewis, Investigator Nerming V Briones, Investigator Jannet M Peroti, Investigator	X Mizanne E Lewis Investigator Signed By: MIZANNE E. LEWIS - S Date Signed: 06-06-2025 13:01:23	6/6/2025

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OBSERVATION 3

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

a. your firm failed to validate your cleaning process. Your standard operating procedures (SOP) titled: Facility Cleaning Work Instruction states that your cleanroom workstations should be (b) (4) The cleanroom should (b) (4) In addition, your SOP titled: Facilities Controls lists the cleaning agents to be used for (b) (4)

b. Your firm has not adequately established and followed written procedures for cleaning and maintenance of the ISO 5 and ISO 7 cleanrooms used to manufacture your umbilical cord, Wharton's Jelly, Luxegen Products since October 2023, and your amniotic membrane TheraMend products since August 2023. Your facility cleaning logs from September 2024 to June 2025 are inconsistently completed, and they are not reviewed by quality or management. Your facility cleaning logs do not allow for documentation of (b) (4) (b) (4)

OBSERVATION 4

Procedures to validate and approve processes that cannot be fully verified by inspection and tests were not established.

Specifically,

a. you have not validated your process for manufacture of your amniotic membrane TheraMend Patch Product. When processing TheraMend, after establishing a sterile field in the ISO 5 processing area, the membrane is (b) (4). (b) (4)

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(b) (4)

From (b) (4) you have manufactured (b) (4) lots and distributed (b) (4) lots of your TheraMend patch products.

b. Your (b) (4) sterilization process is not described in the manufacturing standard operating procedure for TheraMend, and your firm does not have a standard operating procedure that describes the (b) (4) Also, your (b) (4) sterilization validation does not address the (b) (4) The (b) (4)-sterilized patches are (b) (4) differently with (b) (4)

OBSERVATION 5

Procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps were not maintained, followed and revised.

Specifically,

a. you failed to follow your SOP titled: Manufacturing of Double-Sided Amniotic Membrane Allograft. During the observation of manufacturing of your amniotic membrane, TheraMend patch, it was observed that the humidity level of the (b) (4) was (b) (4) Your SOP states that (b) (4) The processing technician failed to ensure the humidity level of the (b) (4) is (b) (4) Since (b) (4) distributed lots of TheraMend batch records documented humidity levels of the (b) (4)

b. Lot# (b) (4) processed on (b) (4) in the ISO 5 processing

area instead of being placed in a (b) (4) which is not consistent with the Manufacturing of Double-Sided Amniotic Membrane Allograft SOP. This SOP does not have a process for (b) (4) the tissue (b) (4) and does not include a time frame or humidity percentage for tissue (b) (4) (b) (4)

c. Additionally, you failed to maintain the standard operating procedure titled: Equipment Controls to accurately reflect the firm's current operations. The SOP states that "preventative maintenance requirements for each piece of equipment are identified on Form 200.101.F01 - Equipment PM/CAL Requirements". However, Form 200.101.F01, Equipment PM/CAL Requirements, has not been used to record preventative maintenance performed for your (b) (4) (b) (4) tissue and processed release tissue for distribution. In (b) (4), your firm processed (b) (4) lots of TheraMend, and distributed (b) (4) lots.

OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, you assigned a (b) (4) expiration date from the date of manufacture to your umbilical cord, Wharton's Jelly, Luxegen products. However, you did not base this expiration date on stability testing of your Luxegen products. Since the start of manufacturing, you have distributed (b) (4) and (b) (4)

OBSERVATION 7

After completion of the donor-eligibility determination, HCT/Ps were not accompanied with the summary of the records used to make the donor-eligibility determination.

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Brookhaven, GA 30329-1906	Tissue Processor

Specifically, you do not include a summary of records used to make the donor-eligibility determination with your amniotic membrane TheraMend Patch product when sending it to your customer. The Instructions for Use and Product Information form that accompanies all your amniotic membrane TheraMend Patch products, does not contain the listing and interpretation of the results of all communicable disease tests performed for the specific distributed tissue.

X Nerming V Briones
Investigator
Signed By: Nerming Briones -S
Date Signed: 06-06-2025 13:01:52

X Jannet M Peroti
Investigator
Signed By: JANNET M. PEROTI -S
Date Signed: 06-06-2025 13:02:30

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Mizanne E Lewis, Investigator
Nerming V Briones, Investigator
Jannet M Peroti, Investigator

X Mizanne E Lewis
Investigator
Signed By: MIZANNE E. LEWIS -S
Date Signed: 06-06-2025 13:01:23

DATE ISSUED
6/6/2025

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."