DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	3/24/2026-3/31/2026*
	FEI NUMBER 3004813394

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Utpal J. Patel, CEO

FIRM NAME	STREET ADDRESS
Sunrise Pharmaceutical, Inc.	665 E Lincoln Ave
CITY, STATE, ZIP CODE, COUNTRY Rahway, NJ 07065-5711	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

Drug products are not stored under appropriate conditions of temperature so that their identity, strength, quality, and purity are not affected.

Specifically,
Your firm lacked data and scientific rationale for determining the routine temperature monitoring location in the warehouses of Building (b)(4) and Building (b)(4) which store finished drug products such as (b)(4) Tablets, (b)(4) Tablets, and (b)(4) Capsules, raw materials, and packaging materials. Building (b)(4) current warehouse layout has only been mapped during winter months (b)(4) with no summer temperature mapping performed. Building (b)(4) has only been mapped during summer months ((b)(4)), with no winter temperature mapping performed. Current temperature mapping studies do not account for seasonal variations when determining the worst-case location of the monitoring probe.

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*DATES OF INSPECTION

3/24/2026(Tue), 3/25/2026(Wed), 3/26/2026(Thu), 3/30/2026(Mon), 3/31/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alisha B Patel, Investigator	X Alisha B Patel Investigator Signed By: 2004159117 Date Signed: 03-31-2026 08:58:36	3/31/2026

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."