DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	5/4/2026-5/8/2026
	FEI NUMBER 2517175

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel C. Kloss, Associate Vice President & Site Head

FIRM NAME	STREET ADDRESS
PPL Healthcare LLC	650 Cathill Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sellersville, PA 18960-1512	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:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm failed to establish specifications for (b) (4) (b) (4), such as (b) (4), for incoming (b) (4) API used in the manufacture of (b) (4) Capsules USP (b) (4), and (b) (4)

For example, Per Deviation PR 304366 (created 08/22/2025), your firm used (b) (4) API lots (lots (b) (4)), containing (b) (4) at levels ranging from 1.325 ppm to 227.3 ppm, in the manufacture of (b) (4) Capsules USP 1 (b) (4), and (b) (4) (lots (b) (4)), without detection. Initial out-of-specification results were identified in 11 of (b) (4) annual stability lots tested across all (b) (4) marketed strengths ((b) (4), and (b) (4) with initial stability test results as high as 271.6 ppm. Your firm has manufactured and distributed approximately (b) (4) batches of (b) (4) Capsules USP between 09/01/2020 through 03/29/2025, without the prior (b) (4) (b) (4) specification for the API.

OBSERVATION 2

Equipment and utensils are not sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	David A Oluwo, Investigator Daniel T Lee, Investigator X David A Oluwo Investigator Signed By: 2001987776 Date Signed: 05-08-2026 16:52:15	5/8/2026

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Specifically, the (b) (4) and (b) (4) which are used to clean equipment used in the manufacturing of drug products, such as (b) (4) Capsules USP, were not sanitized for a period exceeding (b) (4) months, as documented in PR 248605. Both dedicated (b) (4) (b) (4) supporting (b) (4) and (b) (4) supporting (b) (4)) failed the required (b) (4) (b) (4) test in 07/2023. Prior to the failures, the last fully completed sanitizations for (b) (4) and (b) (4) occurred on 01/06/2023. The (b) (4) were not installed until 07/24/2024. Sanitization for the (b) (4) systems was not performed until 07/29/2024. Per PR 248605, microbial contamination in (b) (4) was identified and determined to be directly attributable to the system remaining un-sanitized for up to (b) (4) .

Furthermore, on 09/05/2024 and 09/06/2024, routine microbial testing of the (b) (4) (b) (4) detected action-level microbial counts across (b) (4) sample sites simultaneously as documented in PR 264541. The root causes were identified as facility (b) (4) being dumped into the (b) (4) (b) (4) for an extended period of time and unconfirmed age of the (b) (4) , despite action-level microbial counts being detected across (b) (4) sample sites simultaneously.

OBSERVATION 3

The written stability testing program is not followed.

Specifically, your firm fails to follow SOP-4380, *Sellersville Stability Program*, in that stability samples are not consistently tested and reviewed within their respective testing windows and stability samples are not always stored at appropriate environmental conditions.

For example,

a) Your firm failed to complete stability testing and data review for multiple products and lot numbers within the (b) (4) testing window for non-accelerated samples, as documented in PR 222822. The scope of this failure encompassed lots across multiple drug products, including but not limited to

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(b) (4) Capsules USP, (b) (4) lot (b) (4) and (b) (4) Capsules USP, (b) (4) lot (b) (4), among others. Your firm attributed the failures to ineffective knowledge transfer between management, lack of attention to the stability testing program, and gaps in the process of tracking stability sample scheduling for testing and releases.

b) Your firm failed to perform stability testing for (b) (4) Capsules USP (b) (4), Lot (b) (4), at the (b) (4) timepoint under controlled room temperature storage conditions (b) (4)) within (b) (4) from the date of sample withdrawal, as documented in PR 263660. The sample was pulled from the stability chamber on 07/05/2024, establishing a due date of 08/19/2024; however, testing was not initiated until 09/03/2024.

c) Per PR 284527, on 01/21/2025 stability samples were exposed to out of the specified storage range (b) (4)) for approximately (b) (4) during an equipment failure in Environmental Room ENR (b) (4)), when the condenser malfunctioned due to motor failure. The stability samples stored in ENR (b) (4) were exposed to out-of-specification temperature conditions for the full duration of the excursion because no qualified backup chamber for (b) (4) conditions was available to receive transferred samples.

X Daniel T Lee
Investigator
Signed By: 2000991740
Date Signed: 05-08-2026 16:54:56

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."