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	5/18/2026-5/22/2026
	FEI NUMBER 3012763653

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ram Kishan Kallur, President

FIRM NAME	STREET ADDRESS
I 3 PHARMACEUTICALS, LLC	200 Park Ave
CITY, STATE, ZIP CODE, COUNTRY Warminster, PA 18974-4876	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 WE OBSERVED:

OBSERVATION 1

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically, on 05/18/2026, during a walkthrough of packaging line Room MR-45, lint free wipes were observed taped to the Unscrambler and Air Cleaner, Equipment #PR077. Firm management explained that the lint-free wipes were used to slow down the output from the Unscrambler and Air Cleaner to prevent empty bottles from being squeezed against bottles downstream on the filling line.

This lint-free wipe setup constitutes an unqualified equipment modification, and no documentation was found to indicate that this configuration was evaluated under any equipment qualification protocol. The duration for which this setup has been in place is unknown. Additionally, no change control record, deviation report, or quality unit authorization was found to document its addition to Equipment #PR077.

Furthermore, no written procedure was found governing the cleaning, inspection, maintenance, or performance verification of Equipment #PR077 as modified with the lint-free wipes. According to your records, the last production use of Equipment ID# PR077 was for packaging of (b) (4) Tablets (b) (4), Lot#(b) (4), released on 4/10/26, Expiry: (b) (4)

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	John D Mcintosh, Investigator Emily A Walters, Investigator	X John D Mcintosh Investigator Signed By: 2004159344 Date Signed: 05-22-2026 12:02:36	5/22/2026

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a) Specifically, cleaning verification swabs for microbiological testing were collected on 7/25/2023 from the (b) (4) Tablet Press (equipment #PR011) prior to the manufacture of (b) (4) Tablets, USP (b) (4) Lot (b) (4) Results exceeding your established alert limit were reported on 8/14/2023, but no Quality Investigation Report (QIR) was opened to investigate the results until 5/8/2024, approximately nine months after sampling. (b) (4) Tablets, USP (b) (4) lot (b) (4) were released on 12/20/2023, without a documented review and investigation of the out-of-range microbiological test results. Your batch release procedure, "QA016-04 Batch Record Review, Batch Release and Rejection," effective 7/31/2023, requires that in-process checks meet acceptance criteria, that unusual observations and/or investigations are noted in the batch record, and that deviations/quality incidents are addressed prior to the disposition of the batch. Distribution records show that (b) (4) Tablets, USP (b) (4) Lot (b) (4) were released for distribution on 12/20/2023 without fulfillment of these requirements.

b) Your procedure, "OP070-01 Cleaning Verification/Validation Program," effective 11/2/2023, establishes acceptable limits for equipment bioburden, and the individual Cleaning Validation Protocols require that a QIR is opened to investigate results outside of acceptable limits; however, no procedures have been established describing requirements for investigating results outside of established limits, retesting procedures, or batch and equipment hold requirements.

X Emily A Walters
Investigator
Signed By: EMILY A. WALTERS -S
Date Signed: 05-22-2026 12:03:52

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."