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	5/5/2026-5/13/2026* FEI NUMBER 3009964119

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nilesh M. Patel, Compliance & Regulatory Officer

FIRM NAME	STREET ADDRESS
InvaTech Pharma Solutions, LLC	40c Cotters Ln Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
East Brunswick, NJ 08816-2037	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

Representative samples are not taken of each shipment of each lot of components for testing or examination.

Specifically,
Testing of high-risk components such as (b) (4) USP, (b) (4) USP, and (b) (4) USP for (b) (4) and (b) (4) is not conducted on each container of each shipment of each lot received. Per SOP 05, Rev. 02, "SAMPLING, APPROVAL AND STORAGE OF COMPONENTS, DRUG PRODUCT CONTAINERS AND CLOSURES", Section 8.5, the firm takes (b) (4) to determine the number of containers to be sampled for (b) (4) testing. Your firm currently manufactures (b) (4) products that contain high-risk components, including (b) (4) Solution USP (b) (4) and (b) (4) Solution (b) (4)

OBSERVATION 2

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written and followed.

Specifically,
Your firm failed to ensure (b) (4) is free of (b) (4) prior to use in the manufacture of non-sterile drug products. The firm's SOP for (b) (4) monitoring, SOP 92, Rev. 02, "PROCEDURE FOR SAMPLING, TESTING, USAGE AND MAINTENANCE OF (b) (4) (b) (4) SYSTEM", does not include (b) (4) as a required test parameter for routine (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Suchan Kim, Investigator Alisha B Patel, Investigator	X Suchan Kim Investigator Signed By: 2004038747 Date Signed: 05-13-2026 14:52:57	5/13/2026

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(b) (4) monitoring. Your firm manufactures (b) (4) non-sterile products that use (b) (4) as a component in manufacturing including but not limited to (b) (4) Tablets and (b) (4) Solution USP (b) (4) .

OBSERVATION 3

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

Specifically,

On 05/05/2026, during the facility walkthrough, the structural wall inside of the (b) (4) (Equipment ID: EC-061367 in (b) (4) Room #(b) (4)), used to package prescription drug products, was observed to be taped with cardboard. Since 01/03/2026, commercially distributed prescription drug products, including, but not limited to, the following lots were packaged on the (b) (4) :

a) (b) (4) Solution USP (b) (4) (Product Code: (b) (4)), Lot# (b) (4) (Date of packaging (b) (4)) Batch Size (b) (4) .
b) (b) (4) Solution) USP (b) (4) (Product Code: (b) (4)), Lot# (b) (4) (Date of packaging (b) (4)) Batch Size (b) (4)
c) (b) (4) Solutions (b) (4) (Product Code: (b) (4)), Lot# (b) (4) (Date of Packaging (b) (4)) Batch Size (b) (4)

OBSERVATION 4

Laboratory records do not include complete records of any testing and standardization of laboratory reference standards and standard solutions.

Specifically,

Your firm uses (b) (4) secondary standard in analytical method validation, system suitability testing, and stability testing of drug product; however, the secondary standard have not been qualified

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against official compendial standards to ensure their identity, strength, quality and purity.

OBSERVATION 5

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically,
Your firm has not conducted annual visual inspections of retain samples since approximately February 2023. Additionally, your firm does not have a written procedure or documented checklist describing the requirements for annual visual examination of retain samples, including what attributes are to be assessed.

OBSERVATION 6

There was a failure to handle and store components at all times in a manner to prevent contamination.

Specifically,
Your firm failed to physically separate quarantined and approved materials. Review of the warehouse/storage area revealed that quarantined and approved components were stored together without physical separation or clearly designated storage locations. Labeled storage racks were not utilized, and materials were not stored in designated locations on the shelves. Additionally, rejected materials were observed stored outside of the designated reject cage.

***DATES OF INSPECTION**

5/05/2026(Tue), 5/06/2026(Wed), 5/08/2026(Fri), 5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed)

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5/13/2026

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."