

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10 Waterview Blvd., 3rd Fl Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 CDER-OC-OMQ-Domestic483Response@fda.hhs.gov		<small>DATE(S) OF INSPECTION</small> 04/14/2026-04/20/2026* <small>FEI NUMBER</small> 3030238141
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Mr. Dhaval A. Shah, President		
<small>FIRM NAME</small> Paxeuticals LLC	<small>STREET ADDRESS</small> 333 New Rd, Suite 3	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Parsippany, NJ 07054-4212	<small>TYPE ESTABLISHMENT INSPECTED</small> Contract Packager	
<p>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.</p> <p><i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i></p>		
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p> <p>OBSERVATION 1</p> <p>Your firm failed to establish adequate 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,</p> <p>A. You have not performed product specific Filling Validation Studies for (b) (4) (b) (4) and (b) (4) (b) (4) drug products at your firm.</p> <p>B. You have not completed equipment cleaning validation studies to validate equipment cleaning SOP #10, <i>Cleaning and Sanitization Procedure Packaging Room and Equipment</i>, effective date 02/01/2024 which is used for the cleaning of shared equipment used in the packaging of the drug products (b) (4) (b) (4) and (b) (4) (b) (4) as well as several (b) (4) products.</p> <p>OBSERVATION 2</p> <p>Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.</p> <p>Specifically, your firm failed to complete protocol driven Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) studies for the following packaging machines</p>		
SEE REVERSE OF THIS PAGE	Yvins Dezan, Investigator Yvins Dezan -S <small>Digitally signed by Yvins Dezan -S Date: 2026.04.20 13:11:15 -04'00'</small>	
<small>DATE ISSUED</small> 04/20/2026		
<small>FORM FDA 483 (09/08)</small>		
<small>PREVIOUS EDITION OBSOLETE</small> INSPECTIONAL OBSERVATION		
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Parsippany, NJ 07054-4212

TYPE ESTABLISHMENT INSPECTED

Contract Packager

used to package the commercial drug products (b) (4)

(b) (4) and (b) (4)

- Checkweigher Model #(b) (4)
- Labeler Model #(b) (4)
- Neckband applicator Model #(b) (4)

You did not perform a protocol driven PQ study with product for the (b) (4) fillers on (b) (4) Machine Model #(b) (4) utilized to package (b) (4) and (b) (4) drug products.

In addition, you have never calibrated nor verified proper operation prior to use, the balances utilized for (b) (4) filling and weighing operations of (b) (4) and (b) (4) drug products. According to your President (DAS), these (b) (4) balances were utilized during packing operations of (b) (4) and (b) (4)

You have packaged and shipped to your clients the following finished drug products using the equipment listed above:

Customer Lot #	Expiry Date	Product Name	Packaging Date	Ship Date
(b) (4)				01/31/25
				08/27/25

OBSERVATION 3

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

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Specifically, your firm failed to obtain stability study data, from the drug product owner, to support the (b) (4) expiry date they requested your firm to label the following drug products below with:

: (b) (4)

OBSERVATION 4

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

On 04/16/2026, I observed presence of unknown "Reddish and Whitish" residue inside the product loaders/elevators and inside the product filling (b) (4) (b) (4) on the (b) (4) Machine Model (b) (4). You did not document when the equipment was last used, the products packaged, lot number, and cleaning records performed for the equipment. The (b) (4) Machine Model (b) (4) is utilized for packaging capsules and (b) (4) and (b) (4) drug products at your firm.

OBSERVATION 5

The batch production and control records are deficient in that they do not include a statement of the actual yield and percentage of theoretical yield. Specifically,

Your Packaging Batch Records for (b) (4) and (b) (4) drug products do not include a statement of the actual yield and percentage of theoretical yield for packaging, the identity of individual major equipment used, the identification of the persons performing, and checking each significant step in the operation for each batch of drug product packaged (not all-inclusive).

OBSERVATION 6

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

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Specifically, your firm failed to complete a summer warehouse temperature mapping study in the warehouse where you store finished (b) (4) which has a labeled storage condition of (b) (4) 0 C.

***DATES OF INSPECTION**

04/14/2026 (Tue), 04/15/2026 (Wed), 04/16/2026 (Thu), 04/17/2026 (Fri), 04/20/2026 (Mon).

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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."