DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787)729-8500 Fax:(787)729-6809	5/11/2026-5/18/2026* FEI NUMBER 2623619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Yanira Santos, Head of Site Operations - Vega Baja

FIRM NAME	STREET ADDRESS
Viatris Pharmaceuticals LLC	Road 689, Km 1.9
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Vega Baja, PR 00693	Finished Dosage Form 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

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

Specifically,

a. Since the year 2024, approximately (b) (4) batches of drug products were released to the U.S. market without assurance that they had safety levels of Nitrosamine impurities (e.g., NDMA, NDEA, NMPA, NDIPA, NIPEA, NDBA, and NMBA). The following table depicts drug product and the approximately number of batches released to the U.S. market with this deficiency except for (b) (4) that was analyzed for NDMA.

Product name	Number of batches	Product name	Number of batches
(b) (4)			

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EMPLOYEE(S) SIGNATURE
Christian F Gomez Lugo, Investigator
Jose M Cayuela, Investigator - Dedicated Drug Cadre

X Jose M Cayuela
Investigator - Dedicated Drug Cadre
Signed By: 2000631739
Date Signed: 05-18-2026
14:54:04

DATE ISSUED
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(b) (4)

Total = (b) (4)

The inadequate Nitrosamine impurities control is a repetitive deficiency also cited during the last inspection.

OBSERVATION 2

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

The Quality Control Unit failed to perform adequate and scientifically sound out of specifications (OOSs) investigations and failed to follow the in-house written procedure for Analytical Laboratory Investigations (VB-LAB-028). For example,

a. On December 26, 2024, (b) (4) capsules, lot number (b) (4) stability sample for (b) (4) at (b) (4)°C and (b) (4)% RH (OOS 3700033) reported the presence of an unidentified peak with an area % of 0.7%. The specification is "not more than (b) (4)%". The OOS investigation did not find any root cause associated with the laboratory testing. The unidentified peak with the OOS value of 0.7% was considered an artificial peak of the sample preparation process based on (b) (4) new sample preparations that did not show the peak. The quality control unit failed to prepare and reanalyze the OOS product (b) (4) times as required by the SOP

to reach reliable conclusions. The degradation product OOS result of 0.7% was not reported; instead, it was reported as "None Detected" in the official stability record. This product was shipped to the U.S. market.

b. On May 31, 2024, (b) (4) Tablets, lot number (b) (4) stability sample for (b) (4) at (b) (4) °C and (b) (4) % RH (OOS 3515421) reported the presence of an unidentified peak with an area % of 0.2%. The specification is "not more than (b) (4)%". The OOS investigation did not find any root cause associated with the laboratory testing. The unidentified peak with the OOS value of 0.2% was considered an artificial peak for the sample preparation process based on (b) (4) new sample preparations that did not show the peak. The quality control unit failed to prepare and reanalyze the OOS product (b) (4) times as required by the SOP to reach reliable conclusions. The degradation product OOS result of 0.2% was not reported; instead, it was reported as "<LOQ" in the official stability record. This product was shipped to the U.S. market.

c. On March 31, 2025, (b) (4) Tablets, lot number (b) (4) stability sample for (b) (4) at (b) (4) °C and (b) (4)% RH (OOS 3789692) reported the presence of an unknown peak with an area % of 0.3%. The specification is "not more than (b) (4)%". The OOS investigation did not find any root cause associated with the laboratory testing. The unidentified peak with the OOS value of 0.3% was considered an artificial peak of the sample preparation process based on (b) (4) new sample preparations that did not show the peak. The quality control unit failed to prepare and reanalyze the OOS product (b) (4) times as required by the SOP to reach reliable conclusions. The unknown degradation product OOS result of 0.3% was not

reported; instead, it was reported as 0.1 in the official stability record. This product was shipped to the U.S. market.

d. On April 21, 2025, (b) (4) Tablets, lot number (b) (4) stability sample EXPIRY interval at (b) (4) °C and (b) (4) % RH (OOS 3807659) reported the presence of an unidentified peak with an area % of 3.0%. The specification is "not more than (b) (4) %". The OOS investigation did not find any root cause associated with the laboratory testing. The unidentified peak with the OOS value of 3.0 % was considered an artificial peak of the sample preparation process based on (b) (4) new sample preparations that did not show the peak. The quality control unit failed to prepare and reanalyze the OOS product (b) (4) times as required by the SOP to reach reliable conclusions. The degradation product OOS result of 3.0% was not reported; instead, it was reported as " < 0.10" in the official stability record. This product was shipped to the U.S. market.

e. On May 27, 2025, (b) (4) Capsules, lot number (b) (4) stability sample for (b) at (b) (4) °C and (b) (4) % RH (OOS 3843418) reported the presence of an unidentified peak with an area % of 0.3%. The specification is "not more than (b) (4) %". The OOS investigation did not find any root cause associated with the laboratory testing. The unidentified peak with the OOS value of 0.3% was considered an artificial peak for the sample preparation process based on (b) (4) new sample preparations that did not show the peak. The quality control unit failed to prepare and reanalyze the OOS product (b) (4) times as required by the SOP to reach reliable conclusions. The degradation product OOS result of 0.3% was not reported; instead, it was

reported as "None Detected" in the official stability record. This product was shipped to the U.S. market.

OBSERVATION 3

Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds insects, and other vermin.

Specifically,

Your firm failed to maintain buildings free of insect infestation. From November 2025 through April 2026, your firm documented multiple pest control incidents in manufacturing and packaging areas of Building (b) (4) including the presence of live insects in active manufacturing and inspection rooms where drug product was present or in-process, creating conditions under which drug products being manufactured, packaged, or held in these areas could have been exposed to insect infestation.

- On March 13, 2026, a live insect (ant) was observed on the inspection table in Inspection Room (b) (4) during the active inspection of (b) (4) Tablets, Lot (b) (4) . The portion of product present on the inspection table at the time of the incident was exposed to the insect and was discarded as waste (3.2 kg). Additional drums of the same lot (Drums (b) (4)) were present in the room at the time of the incident. This event was documented under PR ID 4084969.

- On March 17, 2026, live insects (Asian Subterranean Termites) were identified in Granulation Washroom (b) (4) (Manufacturing (b) (4) Floor) and Packaging Line (b) (4), Room (b) (4), during active manufacturing and packaging operations. At the time of the incident, multiple drug product lots were in-process across granulation, encapsulation, compression, coating, and packaging areas,

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including but not limited to:

- Granulation Area: Lots (b) (4)
- Chemical Weighing Area: Lots (b) (4)
- Encapsulation Area: Lots (b) (4)
- Compression Area: Lots (b) (4)
- Packaging Lines: Lots (b) (4)

As a result of this incident, the packaged portion of Lot (b) (4) ((b) (4) Tablets, (b) (4)) present on Packaging Line (b) (4) at the time of the incident was discarded as waste due to potential pest exposure. All manufacturing and packaging operations were halted for evaluation. This event was documented under PR ID 4082953.

- From March 31 through April 17, 2026, nine additional pest control events involving live Asian Subterranean Termites were identified across multiple areas of Buildings (b) (4), including Mechanical Rooms (b) (4) and (b) (4), (b) (4) Warehouse Room (b) (4), Material (b) (4), Packaging Lines (b) (4) (Rooms (b) (4)), Granulation Room (b) (4), and primary Gowning Area Room (b) (4) Manufacturing and packaging operations were halted on multiple occasions for evaluation. These events were documented under PR ID 4099810.

OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

A review of site-provided tracking data revealed a systemic pattern of Incident Investigations, Customer Complaint Investigations, and Corrective and Preventive Actions (CAPAs) being allowed to exceed

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christian F Gomez Lugo, Investigator Jose M Cayuela, Investigator - Dedicated Drug Cadre	X Jose M Cayuela Investigator - Dedicated Drug Cadre Signed By: 2000631739 Date Signed: 05-18-2026 14:54:04	5/18/2026

established due dates without timely extension requests, in violation of your firm's own written procedures.

- Incident Investigations: A review of 240 investigation records opened between April 2024 and March 2026 showed that of the 219 records requiring extensions, only 37% had extension requests submitted on time. Your firm's SOP-002757594, Incident Investigation (Version 7.0, effective December 24, 2025), requires that extension requests be submitted and approved by Quality Assurance prior to exceeding the established due date.

- Customer Complaint Investigations: A review of 141 complaint records opened between May 2024 and April 2026 showed that of the 104 records requiring extensions, only 33% had extension requests submitted on time. Your firm's SOP-002773463, Product Customer Complaints (Version 4.0, effective February 19, 2025), Section 6.5.7, explicitly requires that extensions be documented and approved prior to passing the date due.

- Corrective and Preventive Actions (CAPAs): A review of 169 CAPA records opened between May 2024 and May 2026 showed that only 36 records (21.30%) were completed or extended on time. The remaining 133 records (78.70%) exceeded their established due dates without a timely extension request. Your firm's SOP-002512192, Action Tracking System — Corrective Actions and Preventive Actions (Version 13.0, effective June 9, 2025), Section 6.1.6, requires that a due date extension be requested if a CAPA will not be closed by the due date.

Your firm indicated that records are sometimes intentionally allowed to exceed their due dates in order to submit a single, more informed extension request. This practice is not consistent with your firm's established written procedures and does not constitute a recognized exception under any of the cited SOPs.

***DATES OF INSPECTION**
5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/18/2026(Mon)

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X Christian F Gomez Lugo
Investigator
Signed By: CHRISTIAN F. GOMEZ LUGO -S
Date Signed: 05-18-2026 14:54:38

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EMPLOYEE(S) SIGNATURE
Christian F Gomez Lugo, Investigator
Jose M Cayuela, Investigator - Dedicated Drug Cadre

X Jose M Cayuela
Investigator - Dedicated Drug Cadre
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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."