DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Headquarters - White Oak CDER/OTS/OSIS/DNDSI 10903 New Hampshire Avenue Silver Spring, MD 20993; Tel #: (301) 796-3326 Industry Information: www.fda.gov/oc/industry	February 16 to 20, 2026
	FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Jenny Laws, Quality Director, Perrigo New York.

FIRM NAME	STREET ADDRESS
Perrigo Company, PLC.	515 Eastern Avenue.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Allegan, MI 49010.	Biopharmaceutical Analytical Facility

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 (I) (WE) OBSERVED:

The following objectionable condition pertaining to study titled "(b) (4) manufactured by (b) (4)"

Observation #1

Not all test product slopes were correctly conveyed in study report # (b) (4). Specifically, the slope of 11th replicate (T11) of in vitro release testing conducted with test product (b) (4), Lot # (b) (4), was erroneously transcribed and conveyed as (b) (4) instead of (b) (4) in Table 2 and Table 3. Consequently, this transcription error resulted in the incorrect calculation and conveying of T/R ratios: 1.5150, 1.6349, 1.6357, 1.0350, 1.1147, 1.0457, 1.1754, 1.1730, 1.1161, 1.1404, 1.0000, 1.1255, 1.0851, 1.0451, 1.0177, 1.1146, 1.0453, and 1.0493. The correct T/R ratios should be 1.4766, 1.5936, 1.5943, 1.0088, 1.0865, 1.0192, 1.1457, 1.1434, 1.0878, 1.1116, 0.9747, 1.0971, 1.0577, 1.0186, 0.9919, 1.0864, 1.0188, and 1.0228.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	GAJENDIRAN MAHADEVAN -S Digitally signed by GAJENDIRAN MAHADEVAN -S Date: 2026.02.20 15:21:00 -05'00'	Gajendiran Mahadevan, Ph.D., Pharmacologist.	02/20/2026

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 judgement, 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."