DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	9/21/2023-9/29/2023*
	FEI NUMBER 3003065803

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Annalisa Barile, VP and General Manager Monza

FIRM NAME	STREET ADDRESS
Patheon Italia S.p.A.	Viale Gian Battista Stucchi 110
CITY, STATE, ZIP CODE, COUNTRY Monza, Monza E della Brianza, 20900 Italy	TYPE ESTABLISHMENT INSPECTED Biological 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

Procedures describing the warehousing of drug products are not followed.

Specifically, your written procedure SOP-29727 version (b) (4) gives instructions to use the (b) (4) " to track storage and movements of materials including those held for dispensing to manufacturing areas and finished product (b) (4) storage.

On 22 SEP 2023, we observed inventory of the dispensing location identified as (b) (4) where (b) (4) inventory did not match the indication in the (b) (4). For example: (b) (4) different (b) (4) of (b) (4) were indicated in (b) (4) but only (b) (4) of these items were (b) (4) located in the dispensing area.

On 28 SEP 2023, we observed (b) (4) retrieved from (b) (4) location (b) (4) while the (b) (4) showed (b) (4) of product in storage. This batch of finished product (b) (4) was manufactured as (b) (4) batch (b) (4) in 2021.

***DATES OF INSPECTION**

9/21/2023(Thu), 9/22/2023(Fri), 9/25/2023(Mon), 9/26/2023(Tue), 9/27/2023(Wed), 9/28/2023(Thu), 9/29/2023(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Scott T Ballard, Investigator Alan L Truong, Investigator	X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 09-29-2023 07:06:38	9/29/2023

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X Alan L Truong
Investigator
Signed By: 2002619229
Date Signed: 09-29-2023 07:07:41

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Scott T Ballard, Investigator
Alan L Truong, Investigator

X Scott T Ballard
Investigator
Signed By: Scott T. Ballard -S
Date Signed: 09-29-2023
07:06:38

DATE ISSUED
9/29/2023

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."