

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032
Rockville, MD 20857

DATE(S) OF INSPECTION

6/30/2019-7/11/2019*

FBI NUMBER

3002808385

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Itamar Karsenti, Vice President, Head of Operations

FIRM NAME

Taro Pharmaceutical Industries, Ltd.

STREET ADDRESS

14, Ha-Kitor, Bay

CITY, STATE, ZIP CODE, COUNTRY

Haifa, 2624761 Israel

TYPE ESTABLISHMENT INSPECTED

Non-sterile Finished Drug and Active
Pharmaceutical 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:

Quality System

OBSERVATION 1

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product.

Specifically,

You initiated Deviation, DR19/0121, on February 14, 2019 for (b) (4) mg/(b) (4) ml (b) (4) z RX (b) (4) oz bottles (packaging bottles). Brown spots were observed on these bottles on 02/13/2019, during the filling process for (b) (4) mg/(b) (4) ml (b) (4) z RX (Batch (b) (4)). However, you did not perform a risk assessment or any testing on the bottles used for Batch (b) (4). Approximately 50% (b) (4) of units) were released and distributed to the market prior to the discovery of the brown spots. The same lot of bottles was used during the filling of (b) (4) mg/(b) (4) ml (b) (4) z RX, Batch (b) (4) which was released, distributed and not included within Deviation DR19/0121.

***DATES OF INSPECTION**

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Yvesna C Blaise, Investigator
Walden H Lee, Chemist/Biologist

DATE ISSUED

7/11/2019

Yvesna C Blaise
Investigator
Signed By: 2001788948
Date Signed: 07-11-2019 04:27:07

X

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Pharmaceutical Manufacturer

6/30/2019(Sun), 7/01/2019(Mon), 7/02/2019(Tue), 7/03/2019(Wed), 7/04/2019(Thu), 7/08/2019(Mon),
7/09/2019(Tue), 7/10/2019(Wed), 7/11/2019(Thu) * *7/07/19 (Sun)*
4B-7/11/19

Walden H Lee
Chemist/Biologist
Signed By: 1300071161
Date Signed: 07-11-2019 04:28:14

X

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