DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	02/16/2026-02/20/2026
	FEI NUMBER 3010999645

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dan Williams, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Orean Personal Care Ltd	Unit E1, Stubs Beck Lane, West 26 Ind. Estate
CITY, STATE, ZIP CODE, COUNTRY Cleckheaton, West Yorkshire, BD19 4TT, United Kington	TYPE ESTABLISHMENT INSPECTED OTC Drug Product 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

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, you manufacture Over the Counter (OTC) drug products for the US market on non-dedicated manufacturing equipment. You designed a cleaning matrix that identified most difficult product to clean, (b) (4) FDA product Code No. (b) (4) also called (b) (4) You did not validate the respective cleaning procedures such that,

A. You clean your manufacturing vessels (b) (4) according to the cleaning procedure/check list, WIM020 OTC Cleaning and Sanitizing Vessel Check Sheet. You recorded the data for cleaning validation in, Cleaning Validation Report for Cleaning Process WIM020 On Manufacturing Vessel Issued on 9/11/2025. The report contains cleaning data after manufacturing a single batch of (b) (4) in (b) (4) Your Quality Head (b) (6) stated that the batch number for drug product, (b) (4) was not available.

B. You clean your tube filling line (Line (b) (4) according to a cleaning procedure/check list, WIPROD008 OTC Cleaning and Sanitising Tuber Check Sheet. You recorded the data for cleaning validation in, Cleaning Validation Report for Cleaning Process WIPROD008 on Tube

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	RAJIV R. SRIVASTAVA -S Digitally signed by RAJIV R. SRIVASTAVA -S Date: 2026.02.20 15:13:37 Z	Rajiv R Srivastava, CSO	02/20/2026
	DOROTHY P. KRAMER -S Digitally signed by DOROTHY P. KRAMER -S Date: 2026.02.20 15:26:16 Z	Dorothy P Kramer, CSO	

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Fillers Issued on 9/9/2025. The report contains cleaning data after manufacturing a single batch of (b) (4) in Line (b) (4) Your Quality Head (b) (6) stated that the batch number for drug product, (b) (4) was not available.

C. You clean your (b) (4) filling line (Line (b) (4) according to a cleaning procedure/check list, WIPROD007 OTC Cleaning and Sanitising Line Check Sheet. You recorded the data for cleaning validation in, Cleaning Validation Report for Cleaning Process WIPROD007 on (b) (4) Filling Line, Issued on 9/11/2025. The report contains cleaning data after manufacturing a single batch of (b) (4) in Line (b) (4) Your Quality Head (b) (6) stated that the batch number for drug product, (b) (4) was not available.

None of your cleaning validation protocols and/or reports have the equipment design to identity the swabbing locations. You Quality Head (b) (6) confirmed that the transfer pipes and hoses used in the manufacturing were not product dedicated and were not part of the cleaning validation.

On 2/17/2026, during walkthrough of your manufacturing area, I saw pipes and hoses hanging on the walls without any (clean/to-be-cleaned/dirty) status. Your Quality Head (b) (6) stated that the hoses and pipes were in clean status. I checked inside of one of the hoses with a paper towel. The surface of the paper towel that rubbed the inside of the hose became soiled with (b) (4) material. Your Quality Head (b) (6) stated that these pipes will be cleaned one more time when they are picked up for the manufacturing and all the manufacturing equipment are verified for sanitization through a Sanitization Equipment Check List FDA F023.

You currently manufacture (b) (4) drug products for the US market and (b) (4) for the UK. You did not have any scientific justification why (b) (4) US product, (b) (4) is the most difficult material to clean in comparison to many of your (b) (4) In addition, the non-dedicated hose and pipes also present opportunity for cross contamination of the US products with that of the actives present in many of the (b) (4) You use (b) (4) different (b) (4) across your multiple products that are manufactured in your facility. You have no data to confirm how easy or difficult to clean these (b) (4)

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	RAJIV R. SRIVASTAVA -S Digitally signed by RAJIV R. SRIVASTAVA -S Date: 2026.02.20 15:14:18 Z	Rajiv R Srivastava, CSO	02/20/2026
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OBSERVATION 2

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

Specifically,

A. You released the batches of finished products before completing all the test to ensure the OTC drug products meet all the specification. Your procedure, WIPROD027 OTC Products Sampling and Processes Version 12 (Issued on 11/28/2024) require a review of all the test to ensure the product meets specification for the prior to releasing the batch. Your Quality Head (b) (6) stated that the firm released the batches under quarantine as per the quality agreement with the customer. You shared a generic quality agreement with the respective customer that was created on September 2024 and signed but not dated. The QA is also open ended without an expiry/re-certification timeline.

B. You did not initiate deviations for delayed stability studies. Specifically, you initiated Long Term stability studies for the process validation batches after >3 months from the date of manufacturing. Your Quality Head (b) (6) stated that the firm did not have a deviation procedure and shared a form, OTC Deviation Form FDAF012 Version 1 that the firm uses to record deviations.

C. You did not follow your FDA Change Control Procedure, FDASOP001 Version 1 such that you did not initiate change control prior to revising the batch manufacturing records. Specifically, during the process validation, you made several modifications into the first process validation batches to bring the batch in specification. You then updated the manufacturing instructions for the (b) (4) subsequent batches and completed the process validation. You did not initiate change controls to evaluate the impact of changes on the overall drug product quality. As of 2/20/2026, you have not initiated any change control for your manufacturing site.

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	DOROTHY P. KRAMER -S Digitally signed by DOROTHY P. KRAMER -S Date: 2026.02.20 15:27:37 Z	Dorothy P Kramer, CSO	

D. You did not conduct accelerated stability study for the OTC drug products that you manufacture for the US market. You shared data for accelerated study that did not have batch numbers. Your Quality Head (b) (6) stated that these data were generated from the lab batches and not from the commercial batch.

E. Your procedure, Annual Product Quality Review for OTC Product WIT021 Version 5.0 (Issued on 9/10/2024) does not have provision for trending key quality attributes as a way to monitor the manufacturing process. In 2024, you manufactured (b) (4) batches of (b) (4) You did not include/trend the manufacturing data and test results in respective Annual Product Quality Review for OTC Form QAF003 Version 1.0 (Effective date 4/1/2025). You also did not conduct annual quality review for your (b) (4) that is used as raw material for OTC drug products.

F. You do not have quality agreements with the suppliers of API (b) (4) The release test and stability study of your drug products is carried out at a third-party lab (b) (4) You do not have quality agreement with this (b) (4) lab.

G. There are not written procedures that guide the production of (b) (4) or the cleaning/maintenance of the (b) (4) system used for the production of OTC drug products and the cleaning of equipment used to produce OTC drug products.

H. You did not follow your procedure, Control of Quality Documents Version 1 dated 11/27/2024 to ensure all the documents and data related to the US OTC drug products are secured and the most current version are in use. During walkthroughs and document review, several deficiencies were observed, e.g.

   a. In your production lab, loose sheets of the pH calibration test data (for 2024 and 2025, 2026) were stored. The data were not reviewed by the quality assurance. Your Quality Head (b) (6) was not sure why old data were not bounded and archived.

b. The Cleaning Validation Protocols and Reports were not reviewed and signed by quality assurance.

c. The Process Validation Protocol and Reports were not reviewed and signed by quality assurance.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, test procedures designed to assure that components of drug product, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Your firm failed to monitor the (b) (4) system to ensure that it consistently produces (b) (4) that, at a minimum, meets the USP monograph for (b) (4) at the point of use. Furthermore, your firm uses the (b) (4) for equipment cleaning and as a raw material in OTC drug products exported to the US, including but not limited to the bulk batches manufactured (and tested in the production lab) for the US market between 1/28/2026 and 2/16/2026, which are summarized below in **Table 1**.

On multiple occasions during 2025, your (b) (4) exceeded your upper limit of (b) (4) yet no investigation or deviation was implemented to determine the cause of the out of specification (b) (4) In addition, the (b) (4) was consistently outside the parameters of your pre-determined range over the course of 2025. In 2025, a risk assessment was conducted to raise the (b) (4) range to (b) (4) with no scientific rational as to why the upper limit was raised to (b) (4)

The test methods for microbial and chemical testing are not validated. Some of the batches manufactured for the US market include but are not limited to: (b) (4) (b) (4)

B. The (b) (4) system was not qualified when installed in 2022 and complete preventative maintenance records are not kept of the (b) (4) maintenance done on the (b) (4) system, including the cleaning and sanitization of the system. You do not have a written procedure that guides the sampling, sanitizing, cleaning and maintenance of the (b) (4) system.

C. On 2/16/2026, an expired standard of pH 7.0 buffer (Lot # (b) (4) was found in your production lab. The label on the bottle read, the Recommended use by date 1/28/2026. You calibrate your pH meter in the production lab with pH 4.0 and pH 7.0 standards. There was no other pH 7.0 standard in the lab. On 2/19/2026, your Quality Head (b) (6) stated that on 2/16/2026, the firm placed a new pH 7.0 standard (Lot # (b) (4) Recommended use by date 9/17/2027) in the production lab.

The bulk batches manufactured (and tested in the production lab) for the US market between 1/28/2026 and 2/16/2026 are summarized in **Table 1**.

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Table 1. Bulk batches manufactured for the US market between 1/28/2026 - 2/16/2026

Date	Product Name	Product Code	Batch No.	Batch Size
	(b) (4)			(b) (4)

OBSERVATION 4

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, you currently manufacture (b) (4) OTC drug products for the US market. You have not validated the respective manufacturing processes such that,

A. You designed the process validation protocol, PVal014 for (b) (4) from (b) (4) batches at (b) (4) batch size. According to your Process Validation Report, the first batch failed. You added a (b) (4) batch at (b) (4) to complete the process validation. You have manufactured commercial batches that range in

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batch size, (b) (4). Your Production Head (b) (6) stated that the process validation batch sizes were designed to utilize the minimum and maximum working volume of the (b) (4) (b) (4) capacity). Mr. (b) (6) also stated that the commercial batches sizes are executed as per the customer order.

B. You designed the process validation protocol, PVal017 for (b) (4) (b) (4) from (b) (4) batches at (b) (4) batch size. You have manufactured (b) (4) commercial batch at (b) (4) batch size. Your Production Head (b) (6) stated that the process validation batch sizes were designed to utilize the minimum and maximum working volume of the (b) (4) capacity). Mr. (b) (6) also stated that the commercial batches sizes are executed as per the customer order.

C. You designed the process validation protocol, PVal015 for (b) (4) (b) (4) from (b) (4) batches at (4) (b) batch size. According to you Process Validation Report, the first batch failed. You added a (b) (4) batch at (b) (4) to complete the process validation. You have manufactured commercial batches that ranges in batch size, (b) (4). Your Production Head (b) (6) stated that the process validation batch sizes were designed to utilize the minimum and maximum working volume of the (b) (4) (b) (4) capacity). Mr. (b) (6) also stated that the commercial batch sizes are executed as per the customer order.

The finished product, (b) (4) ml Batch No's (b) (4) (b) (4) (b) (4) (b) (4) manufactured from the (b) (4) bulk batches failed at time t = 0 for the long-term (25 ± 5 °C/60 ± 5% RH) stability study that is carried out at a third party. The (b) (4) batches failed for pH (b) (4) against Specification (b) (4). In addition, Batch No. (b) (4) also failed for viscosity (b) (4) cps against Specification (b) (4) cps). You have shipped a total of (b) (4) units from these implicated batches to the US market. You did not investigate the OOS results as

of 2/20/2026.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy and 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,

A. On 12/26/2025, your vendor (b) (4) who carries out stability study has recorded OOS result for (b) (4) mL. The OOS result was recorded for Batch No. (b) (4) (Mfg. date 7/7/2025 Expiry date (b) (4) for pH (b) (4) against the Specification (b) (4) the initiation (t = 0) of long-term (25 ± 5 °C/60 ± 5% RH) stability study.

The OOS result was confirmed via Re-Measurement Testing. No Laboratory Assignable Root Cause was found. Your vendor (b) (4) communicated to you to initiate Phase II full scale manufacturing investigation. As of 2/20/2026, you did not take any action and did not share any investigation report.

You have shipped (b) (4) units of the above implicated batch to the US market.

B. On 12/26/2025, your vendor (b) (4) who carries out stability study recorded OOS result for (b) (4) mL. The OOS result was recorded for Batch No. (b) (4) (Mfg. date 8/15/2025 Expiry date (b) (4) for pH (b) (4) against the Specification (b) (4) at the initiation (t = 0) of long-term (25 ± 5 °C/60 ± 5% RH) stability study.

The OOS result was confirmed via Re-Measurement Testing. No Laboratory Assignable Root Cause for found. Your vendor (b) (4) communicated to you to initiate Phase II full scale

manufacturing investigation. As of 2/20/2026, you did not take any action and did not share any investigation report.

You have shipped (b) (4) units of the above implicated batch to the US market.

C. On 1/12/2026, your vendor (b) (4) who carries out stability study recorded OOS result for (b) (4) mL. The OOS result was recorded for Batch No. (b) (4) (Mfg. date 8/22/2025 Expiry date (b) (4) for pH (b) (4) against the Specification (b) (4) and Viscosity (b) (4) cps against Specification (b) (4) cps) at the initiation (t = 0) of long-term (25 ± 5 °C/60 ± 5% RH) stability study.

The OOS result was confirmed via Re-Measurement Testing. No Laboratory Assignable Root Cause for found. Your vendor (b) (4) communicated to you to initiate Phase II full scale manufacturing investigation. As of 2/20/2026, you did not take any action and did not share any investigation report.

You have shipped (b) (4) units of the above implicated batch to the US market.

Your Regulatory Head (b) (6) and Quality Head (b) (6) stated that there were minor differences in the pH and Viscosity. These non-conformances are not likely to cause harm to the patients/users. Your procedure, FDA Out of Specification FDASOP002 Version 1 (Issued date 6/10/2025) requires investigation to close within (b) (4) or an extension is approved by QA. On 2/20/2026, your Quality Head (b) (6) confirmed there was no report or extension available to share/review.

OBSERVATION 5

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, on 2/16/2025, a notebook was found in your production lab where you test the bulk batches for pH, viscosity, and specific gravity. I saw handwritten data in some of the notebook pages. One of the pages contained data for pH, viscosity, and specific gravity for the (b) (4) (sample). Your production personal (b) (6) owner of the notebook) stated he did not write the data. Your Quality Head (b) (6) stated that the firm manufactures numerous products, and it was not possible to attribute the data to a specific batch. Through a review of the submitted data for the bulk batches, it was determined that the data belonged to a US product, (b) (4) Product Code (b) (4) Batch No. (b) (4) that was manufactured on 2/13/2026.

OBSERVATION 6

Written procedures are lacking which describe in sufficient detail the receipt, sampling and testing of components of drug products.

Specifically, your procedure, OTC Products Sampling and Process WIPROD027 Version 12 (Issued on 11/28/2024) does not contain information about collecting a representative sample. You are in the process of vendor qualification for (b) (4) As of now you have completed the testing of (b) (4) batches of (b) (4) Batch No's (b) (4) Each batch was received as a (b) (4) (b) (4) lot size in (b) (4) bags of (b) (4) each. Your Quality Head (b) (6) stated that one sample from one of the bags from each batch was sent to the testing laboratory for full scale testing. Mr. (b) (6) also stated that ~(b) (4) sample was collected for each lot for the testing and this sampling was not recorded in the ERP system. Mr. (b) (6) also confirmed that there was no attributing document to verify that a sample of (b) (4) was collected at the site and shipped to the outside lab.

OBSERVATION 7

There was a failure to handle and store components of drug product at all times in a manner to prevent contamination.

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Specifically, on 2/16/2026 during the walkthrough of your warehouse, I saw a bag of (b) (4) Lot No. (b) (4) Mfg. date May 2025 Expiry date (b) (4) I saw the bag left open and was not sealed/secured. I also saw (b) (4) of (b) (4) material in a (b) (4) bag on top of a carton of (b) (4) (b) (4) Your Quality Head stated that the (b) (4) looking (b) (4) were (b) (4) that belonged to one of the cartons with the Lot No. (b) (4) The (b) (4) Lot No. (b) (4) (b) (4) was used to manufacture OTC drug products for the US market, e.g. (b) (4)

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