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	2/23/2026-2/27/2026
	FEI NUMBER 3004135088

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Gokhan Ceylan, Deputy General Manager

FIRM NAME	STREET ADDRESS
Tan-Alize Kozmetik ve Temizlik Urunleri Sanayi ve Ticaret A.S.	32 Omerli Mahallesi, Uran Caddesi
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cekmekoy, Istanbul (Anatolia), 34799 Turkey	OTC 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 I OBSERVED:

OBSERVATION 1

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

Specifically, you failed to verify the identity and purity of the active pharmaceutical ingredients and packing materials that are used to manufacture OTC drugs intended for the US market. For example:

A. The firm manufactures OTC drugs including (b) (4) (b) (4) using various active pharmaceutical ingredients such as (b) (4) (b) (4) On 2/25/2026, the QC Manager stated the firm does verify the purity and strength of these APIs to what is stated in the manufacturer's certificate of analysis. The site routinely ships batches of OTC drugs manufactured with these APIs.

B. The firm uses (b) (4) (b) (4) and (b) (4) (b) (4) for primary packing of (b) (4) to pack (b) (4) On 2/25/2026, the QC Manager stated the firm does verify the identity of (b) (4) packing materials that are sourced from a 3rd party supplier. (b) (4) (b) (4) are used as primary packing materials to pack all the OTC drugs that are routinely

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shipped to the US.

OBSERVATION 2

The written stability testing program is not followed.

REPEAT OBSERVATION

Specifically, you failed to follow your Stability control procedure (FRMS_SOP_QC_023) to ensure the quality of the distributed batches for entire shelf life. On 2/25/2026, following deficiencies were observed pertaining to stability testing of OTC drug products:

A. The site approved stability study protocol for (b) (4) Lot (b) (4) on 12/9/2025 to conduct long-term (25°C/60%RH), accelerated (40°C/75%RH), and intermediate (30°C/65%RH) stability studies. However, on 2/25/2026, no sample for this batch was observed in the stability chambers intended to store stability samples under long-term, intermediate, and accelerated stability studies. On (b) (4) the firm shipped (b) (4) units of (b) (4) Lot (b) (4) to the US.

B. The firm approved stability study protocols for (b) (4) batch (b) (4) and (b) (4) batch (b) (4) on 1/12/2026 and 2/10/2026 to conduct stability studies under long-term, intermediate, and accelerated storage conditions. As per study protocols, the stability samples required to be tested as per following intervals for both products:

Product Name	Long-term testing schedule in	Intermediate Testing Schedule	Accelerated Testing Schedule

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	months	in months	in months
(b) (4)	, 6, 9. 12, 18, 24, nd 36 months	3, 6, 9. and 12 months	3, 6, and 9 months
	, 6, 9. 12, 18, 24, nd 36 months	3, 6, 9. and 12 months	3, 6, and 9 months

On 2/25/2026, I observed only two samples for each product in the stability chambers. The QC Manager confirmed the firm does not have enough samples to test for all stability intervals.

C. On 2/26/2026, the firm provided the signed & approved copy of the Stability Testing Summary Report for (b) (4) batch (b) (4) This stability study started on 3/30/2023 and ended on 3/30/2025 and involved long-term storage conditions. It was observed, the report had only the signatures of the personnel who authored, reviewed, and approved the report. The report did not have the date when it was signed off by the author, reviewer, and approver. On 2/26/2026, the firm's Food Supplement Factory Director stated she signed off this stability summary report as Approver today on 2/26/2026.

D. On 2/25/2026, I observed two samples each of (b) (4)

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batch (b) (4) batch (b) (4) batch (b) (4) batch (b) (4) stored in stability chambers maintained under long-term (25°C/60%RH), accelerated (40°C/75%RH), and intermediate (30°C/65%RH) stability conditions. However, the associated stability conditions were not documented on the sample. For example, if the samples are swapped from one chamber to the other; it cannot be detected.

E. The firm uses following stability chambers to store stability samples under various conditions:

Equipment Name	Equipment Code	Temperature	Humidity	Condition
Stability Cabinet	QA_QC_EQ_038	30°C	65%RH	Intermediate Stability
Stability Cabinet	QA_QC_EQ_046	25°C	60%RH	Long-Term Stability
Stability Cabinet	QA_QC_EQ_053	40°C	75%RH	Accelerated Stability

During the inspection of these stability chambers on 2/25/2026, the firm marked all three chambers, holding stability samples, out of order. The QC Manager stated these are out of order due to a power shutdown and these chambers are not on backup power.

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OBSERVATION 3

Determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials.

Specifically, since 12/8/2025, you have not tested (b) (4) for (b) (4) On 1/10/2026, you used (b) (4) of this (b) (4) to manufacture (b) (4) bulk batch (b) (4) (Packing batch (b) (4)

On 2/25/2026, the QC Manager stated the (b) (4) equipment (equipment ID: QA-QC-EQ-011) is out of order as of 12/8/2025 due to malfunction of an electronic component. The firm raised deviation DV-25-001 to investigate the equipment malfunction and repair. The firm has not closed the deviation as the equipment repair is still pending. The QC Manager stated even the (b) (4) is not being tested for (b) (4) there is no risk to the products as they are meeting the finished product testing specifications.

Since the (b) (4) equipment failure the firm manufactured (b) (4) package batch (b) (4) and shipped this batch on two dates, (b) (4) units) and (b) (4) units) to (b) (4)

OBSERVATION 4

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not followed.

Specifically, you failed to follow your control procedure SOP-QCM-011, Microbiological Control of (b) (4) to ensure (b) (4) used to manufacture OTC drugs is free from objectionable microorganism. For

example:

Your microbiology laboratory records indicated the lab received (b) (4) samples on 2/23/2026 for chemical analysis (appearance, pH, (b) (4) and microbial analysis (Total Bacterial Count, E. coli, and Coliforms). These samples were collected from various sampling locations including (b) (4)

As per control procedure SOP-QCM-011, these (b) (4) samples supposed to be incubated to observe microbial growth. However, on 2/24/2026, none of these samples were observed in the micro lab incubators. The QC Lab manager stated these samples were not evaluated for microbial activity. (b) (4) is an ingredient used in the manufacturing of (b) (4) (b) (4) that are routinely shipped into the US.

OBSERVATION 5

The production area air supply lacks an appropriate air filtration system.

Specifically, the air supply in the core manufacturing areas used to manufacture drug products does not provide assurance that it is free from dust and/or other undesirable particulates.

For example, core drug manufacturing areas such as (b) (4) filling, and packing are shared with the areas used to manufacture cosmetic products without appropriate airlock system. The firm's QA Manager confirmed on 2/27/2026 that these areas are not maintained as classified areas and/or minimally Grade D areas. The firm's air circulation system does not provide any assurance that is suitable for intended use.

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Additionally, the QA Manager confirmed that the pressure differential in core processing aeras including sampling, dispensing, (b) (4) filling, and packing areas is not monitored to demonstrate the sweep of the air from less clean area into the cleaner areas.

OBSERVATION 6

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically, batch manufacturing and testing records are not documented/signed and/or verified at the time activity is performed. For example:

A. Equipment use logbook for balance in the sampling room indicated that the balance was used three times on 2/23/2026 to sample various material such as (b) (4) (b) (4) However, this sampling activity was not documented on Sampling Room Use Logbook as required under Raw Material Sampling control procedure FRMS-SOP-QC-019.

B. The QC Lab used the (b) (4) equipment (equipment ID: QA-QC-EQ-011) approximately eight times to analyze (b) (4) for (b) (4) between the dates of 10/14/2025 to 10/23/2025. Review of the (b) (4) equipment use logbook indicated, as of 2/24/2026, the equipment use entries were not checked/verified by the 2nd person as required under Records System control procedure FRMS-SOP-QA-003.

OBSERVATION 7

Batch production and control records do not include complete information relating to the production and control of each batch.

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Specifically, batch production and control records do not include complete information related to critical process parameters including but not limited to (b) (4) etc. for the OTC products manufactured for the US market.

Review of the executed batch records indicated that the manufacturing personnel do not document the absolute values for following critical process parameters for (b) (4) OTC drug products shipped to the US. Instead, the personnel are required to check the box if that parameter is within the range.

Final Finished Product Name	Production Stage	Critical process parameters	Criteria	Checkbox or Value
(b) (4)				Checkbox
				Checkbox
				Checkbox
				Checkbox
				Checkbox
				Checkbox
				Checkbox
				Checkbox

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(b) (4)	
	Checkbox
	Checkbox
	Checkbox
	Checkbox
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	Checkbox
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