DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/28/2026-5/4/2026* FEI NUMBER 3014253278

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cheeho Choi, Chief Executive Officer

FIRM NAME	STREET ADDRESS
CTK OTC Laboratories LLC	1690 N Delilah St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Corona, CA 92879-1866	Contract 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:
QUALITY

OBSERVATION 1

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,

There is a failure to thoroughly review 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. The following bulk actual batch yields were outside the stated acceptable yield range set by the firm:

Batch Record	OTC Drug Product	Actual Batch Yield Range (%)	Calculaed Actual Batch Yield (%)
(b) (4)	(b) (4)	(b) (4)	87.70
(b) (4)		(b) (4)	88.84
(b) (4)		(b) (4)	87.42

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EMPLOYEE(S) SIGNATURE
Ngozi G Offor, Investigator

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Investigator
Signed By: 2004304335
Date Signed: 05-04-2026
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5/4/2026

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	(b) (4)		
(b) (4)		(b) (4)	90
(b) (4)		(b) (4)	90.53
(b) (4)		(b) (4)	88
(b) (4)		(b) (4)	89.84
(b) (4)		(b) (4)	91.18
(b) (4)		(b) (4)	89.42 %

The theoretical batch size for Batch (b) (4) for example is documented as (b) (4) (b) (4), yet the total net weight transferred is recorded as approximately (b) (4), representing a loss of approximately (b) (4) (approximately 13.6 %). Your firm did not complete a formal deviation/investigation report explaining the approximately (b) (4) accountable loss, determine root cause, and assess whether the loss could affect product quality or active pharmaceutical ingredient (API) concentration. Additionally, no written procedure exists about the re-evaluation and enforcement

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of yield.

B. The firm's stability program has not demonstrated that (b) (4) (b) (4) conform to established specifications through their labeled shelf life. Specifically, the firm recorded viscosity out of specification (OOS) from results received from their control testing laboratory for the (b) (4)-month (T = (b) (4)) timepoints for (b) (4) (b) (4), Batch # (b) (4) batches which were commercially distributed and remain within their expiry dating of [X]. Also, the firm recorded viscosity OOS for (b) (4) (b) (4) Batch Nos. (b) (4) (expiry date X) for the (b) (4)-month (T = (b) (4) (b) (4)) and for the (b) (4)-month (T = (b) (4)). Moreover, a specific gravity result exceeding the upper limit by 0.01 was identified at stability timepoint, T=(b) (4) for (b) (4) (b) (4) Batch Nos. (b) (4).

Batch #	Property	Test Method	(b) (4) Month	(b) (4) month	(b) (4) Month
(b) (4)	Viscosity (b) (4) (b) (4)	STB-005			405,000
(b) (4)	Viscosity (b) (4) (b) (4)	STB-005		450,000	425,000
(b) (4)	Specific Gravity (b) (4)	STB-006	(b) (4)		

No investigation was initiated for these results. The firm's quality unit has not

demonstrated that they have taken action to address the stability failures for distributed product currently within expiry.

The observation for viscosity failures was previously cited during the December 2024 inspection. The recurrence of viscosity at the (b) (4)-month and (b) (4)-month timepoints, without any intervening investigation or CAPA indicates that this deficiency remains unresolved.

FACILITIES & EQUIPMENT

OBSERVATION 2

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Your cleaning validation does not include all products manufactured on equipment #s (b) (4), (b) (4) and (b) (4). Your quality unit provided cleaning and sanitization validation report Document number RT-CV-2601-001 Ver No (#.#) 0.0 titled "Cleaning and Sanitization Validation Report for OSS01A Formula ((b) (4) Compunding Kettle)", Effective Date: 02/09/2026, that covers (b) (4) cleaning runs for three (3) compounding equipment namely:

1. (b) (4) Mixer (b) (4); Equipment # (b) (4)
2. (b) (4) Mixer (b) (4) Equipment # (b) (4)
3. (b) (4) Mixer (b) (4) Equipment # (b) (4)

These are used to manufacture CTK (b) (4) (OTC (b) (4) products). This cleaning validation, accounted for active pharmaceutical ingredients (API) of all drugs manufactured

using (b) (4) and (b) (4) and the microbial contamination. APIs tested are (b) (4) (b) (4) — all (b) (4) active (b) (4) ingredients in the formula for CTK(b) (4) .

This cleaning validation accounted for the worse case for (b) (4) type products of only OTC drug products but does not account for all other types of products including cosmetics that are manufactured on the same equipment. The firm cannot assure that the identity of the hardest to clean or most hazardous residue is accounted for if all the products involved are not known. Additionally, the firm cannot assure preclusion of the potential risk of contamination of subsequent batches of OTC drug products by cosmetic products.

OBSERVATION 3

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

Specifically,

On 4/29/25, during the inspection of the firm's non-dedicated equipment (b) (4) Mixer (b) (4) , (b) (4) used in the compounding of OTC drug products including but not limited to cosmetic product. A compounder described the cleaning process for this equipment. The firm did not provide an established SOP that compounders follow to clean this equipment or other compounding equipment used for both OTC drug products and cosmetics.

Also, (b) (4) Filling Machine #(b) (4) was used to fill (b) (4) , Batch # (b) (4) and (b) (4) (b) (4) Lot # (b) (4) . No established SOP was used to clean this equipment after it was filled with (b) (4) , Batch # (b) (4) and before (b) (4) Lot # (b) (4) was filled. Examples of pieces equipment used for compounding both OTC drug products and cosmetics include but not limited to:

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CITY, STATE, ZIP CODE, COUNTRY Corona, CA 92879-1866	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer

Equipment/Equipment #	Model Name	Cosmetics	OTC Drug Product
(b) (4) Mixer (b) (4), (b) (4)	(b) (4)	(b) (4)	
(b) (4) Mixer (b) (4) (b) (4)			
(b) (4) Mixer (b) (4), (b) (4)			
(b) (4) Mixer (b) (4), (b) (4)			

SOP FAC-100, titled "Cleaning and Sanitization Program," lacks specific instructions for employees to follow when cleaning equipment. As a result, the firm cannot demonstrate that its cleaning procedure is robust or capable of consistently producing clean equipment.

OBSERVATION 4

Routine calibration and checking of automatic and mechanical equipment is not performed according to a written program designed to assure proper performance.

Specifically,

The firm has an SOP titled QA-115 titled General Equipment Qualification Requirement. This SOP is not followed because

A. Equipment used to test components, in-process materials, and finished products is not qualified to ensure suitability for its intended use.

1. The microbiology laboratory (Micro Lab (b) (4)) contains three (3) incubators:

- Micro Lab #(b)(4), Incubator - (b) (4) °C, Equipment #(b) (4) Model (b) (4). This is used for (b) (4). Example (b) (4) Lot # (b) (4) for Escherichia coli (E. coli) testing. Firm could not provide any raw materials, bulk or finished OTC drug product this broth was used for microbial release testing.
-
- Micro Lab #(b)(4), Incubator (b) (4) °C, Equipment # (b) (4) Model /Serial # (b) (4). This is used for (b) (4) plate and (b) (4) broth. Example (b) (4) plate Lot # (b) (4) for total yeast and mold (TYMC) test (example Lot #s (b) (4) and (b) (4) (b) (4) (b) (4)

- Micro Lab #(b)(4), Incubator (b) (4) °C, Equipment # (b) (4), Model / Serial # (b) (4). This is used for the following but not limited to (b) (4) (b) (4) plate (example Lot # (b) (4) for TAMC test used in Product?), (b) (4) plate (example Lot # (b) (4) for E.coli test, (b) (4), Lot (b) (4), used for testing (b) (4), used for testing Lot (b) (4) –(b) (4)), (b) (4) plate (example Lot #(b) (4) for Pseudomonas aeruginosa (P. aeruginosa) used for testing Lot # (b) (4)).

These are all used for microorganism cultivation, growth studies, and contamination testing of raw materials, bulk products, and finished products. These incubators lack Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) documentation. No temperature mapping studies were available for review and the firm does not have a continuous temperature monitoring program for these pieces of equipment.

2. Micro Lab (b) (4)'s (b) (4), Equipment # (b) (4), Model # (b) (4), used to sterilize culture media including but not limited to (b) (4) [y] prepared for bacterial cultivation and

contamination testing, lack IQ, OQ, and PQ documentation. No heat distribution mapping was available for review.

The firm has used (b) (4) culture media sterilized in these unqualified (b) (4) to conduct microbiological testing of raw materials, bulk products, and finished products, and has used those test results to support product release decisions. Batch records reviewed during the inspection, including the following but not limited to, finished OTC drug product (b) (4), Lot # (b) (4) (b) (4) Lot # (b) (4) reference microbial test results generated using media prepared in these (b) (4).

3. Micro Lab (b) (4) contains refrigerators:
   - Equipment # (b) (4), Model (b) (4), used for prepared (b) (4) and ready to make broth including but not limited to (b) (4) Lot #(b) (4) for TAMC test of (b) (4) (b) (4) Lot #s (b) (4) and (b) (4) (b) (4) – (b) (4) Lot # (b) (4) for TYMC testing of (b) (4) Lot (b) (4) and (b) (4) Lot # (b) (4), (b) (4) (b) (4) Lot # (b) (4) for E.coli testing of (b) (4) Lot# (b) (4) and (b) (4) Lot # (b) (4).
   - Equipment # (b) (4), Model (b) (4) ℃ used for example media plates (example (b) (4) plate Lot #(b) (4) for E. Coli testing of Lot # (b) (4) (b) (4) – (b) (4)), (b) (4) plate, Lot # (b) (4) for Salmonella test of (b) (4) – (b) (4) Lot # (b) (4)) and (b) (4) plate Lot # (b) (4) for P. aeruginosa testing of (b) (4) (b) (4)).

These are used to store uninoculated and prepared culture media and they lack IQ, OQ, and PQ documentation. No temperature mapping or distribution studies were available for review. Also, the firm does not have a continuous temperature monitoring program for these pieces of equipment

In the past 12 months, (b) (4) batches of OTC drug products were released to commercial distribution and

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(b) (4) media types including but not limited to (b) (4) Lot # (b) (4) and (b) (4) Lot # (b) (4) were used as part of product release testing.

4. The quality chemistry laboratory (QC / Chem) contains one (1) incubator:
   - (b) (4), # (b) (4), Model / Serial # (b) (4) SN: (b) (4)

This is used to (b) (4) bulk product samples (b) (4). This incubator lacks IQ, OQ, and PQ documentation. During the inspection, Quality stated that this incubator does not require formal qualification because it is used for viscosity testing. No written risk assessment or supporting scientific justification for this determination was available for review. Examples of physical samples and viscosity standard in this (b) (4) during this inspection include but not limited to:

- (b) (4), Formula # (b) (4), Bulk Code: (b) (4), Bulk Lot # (b) (4), MOD: (b) (4).
- (b) (4), Formula # (b) (4), Bulk Code: (b) (4), Bulk Lot # (b) (4) MOD: (b) (4)
- (b) (4) Viscosity Standard, Viscosity (b) (4), Temperature (b) (4) °C, Lot # (b) (4), Expiry Date (b) (4)
- (b) (4) Viscosity Standard, Viscosity (b) (4) Temperature (b) (4) °C, Lot # (b) (4), Expiry Date (b) (4)

On 4/28/26, during this inspection, the temperature recording of the built-in thermometer was recorded as 24.1 °C, which was (b) (4) than the temperature requirements for the Viscosity standards (b) (4) (b) (4) Viscosity Standard, Viscosity (b) (4) Lot # (b) (4), Expiry Date (b) (4) and (b) (4) Viscosity Standard, Viscosity (b) (4), Lot # (b) (4) placed in it.

The Quality Unit stated that these pieces of equipment predated their joining the firm and were unable to identify the last date on which any of the equipment had been formally qualified. The firm did not

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provide any SOP for review governing the requalification of laboratory equipment. These pieces of equipment directly impact the reliability of physical and microbiological testing data used for product release decisions.

***DATES OF INSPECTION**

4/28/2026(Tue), 4/29/2026(Wed), 4/30/2026(Thu), 5/01/2026(Fri), 5/04/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Ngozi G Offor, Investigator X Ngozi G Offor Investigator Signed By: 2004304335 Date Signed: 05-04-2026 17:17:35	5/4/2026

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 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."