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	4/8/2026-4/14/2026* FEI NUMBER 3021082665

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Krutarth H. Purohit, Site Leader

FIRM NAME	STREET ADDRESS
KDC/ONE SOCAL LABORATORIES, LLC	20501 Earlgate St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Walnut, CA 91789-2909	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 WE OBSERVED:
MATERIAL SYSTEM

OBSERVATION 1

Each lot of components, drug product containers and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,

A. Your firm received multiple drums of (b)(4) but conducted identity and (b) (4) testing on only (b) (4) instead of testing each drum individually. The following (b)(4) lots were used in OTC drug manufacturing:
   1) Approximately (b)(4) lots of OTC drug products manufactured using untested (b)(4) from Lot (b)(4).
   2) Firm has used (b)(4) batch (b)(4) of OTC drug products manufacturing by using untested (b)(4) from Lot (b)(4).
   3) Firm has used (b)(4) batch (b)(4) of OTC drug products manufacturing by using untested (b)(4) from Lot (b)(4)

B. Your firm received (b)(4) drums of (b)(4) (Item #19539, Control #25-1230-1, Lot (b)(4)) but only conducted identity and (b)(4) testing on (b)(4) rather than testing each drum. This (b) (4) was used in approximately (b)(4) lots of OTC

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	Thuy Tram L Nguyen, Investigator Navneet Kaur, Investigator X Navneet Kaur Investigator Signed By: 2004178854 Date Signed: 04-14-2026 12:45:52	4/14/2026

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drug products.

In addition, your firm has no written procedure that describes the sampling requirements for high-risk components for identity testing and testing for impurities in each container you have received.

QUALITY SYSTEM

OBSERVATION 2

The written stability program for drug products does not include test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability.

Specifically,

Your firm failed to conduct ongoing stability studies for OTC drug products beyond the initial studies performed during process validation. Examples include:

(b) (4) (b)(4) - First manufactured in 2016. All (b)(4) process validation batches were placed on (b)(4) and real-time stability studies, with no subsequent batches tested.

(b) (4) (b)(4) - First manufactured in 2016. During process validation, all (b)(4) batches underwent (b)(4) stability testing and (b)(4) batches underwent real-time studies, with no subsequent batches tested.

OBSERVATION 3

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Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least (b)(4) for evidence of deterioration.

Specifically,

Although your firm maintains reserve samples for a period of up to (b)(4) years, the annual product review process includes visual examination of only (b)(4) lots of reserve samples during the (b)(4) year. Your firm has not conducted the required annual visual examinations of reserve samples in subsequent years to assess for signs of deterioration. For example, in (b)(4) OTC batches were manufactured and their retain samples were examined in (b)(4) but not in (b)(4) or in (b)(4), while the products are still within expiry date. Similarly, (b)(4) OTC batches manufactured in (b)(4) had retain samples examined in (b)(4) but not in (b)(4)

FACILITIES AND EQUIPMENT

OBSERVATION 4
Records are not kept for the cleaning and sanitizing of equipment.

Specifically,

Your firm failed to document and maintain cleaning records for non-dedicated equipment used in Over-the-Counter drug product manufacturing, including (b)(4) mixing tanks, (b)(4) (b)(4) fillers, (b)(4) homogenizers, and (b)(4) pumps. Specifically, records did not identify which cleaning method (C(b)(4) C(b)(4) or C(b)(4)) was employed during each cleaning process.

[This is a repeat observation]

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OBSERVATION 5

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

Specifically,

During the walk-through on 4/8/26, we observed mixing tanks (b)(4) (Equipment ID (b) (4)) in the compounding room displayed a sign indicating the equipment was in a cleaned status, waiting for sanitization. However, upon visual inspection of the equipment interior, unidentified white powder on the side and large pinkish clumps of residue were observed near the rim of the equipment.

***DATES OF INSPECTION**

4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue)

X Thuy Tram L Nguyen
Investigator
Signed By: Thuy Tram Nguyen -S
Date Signed: 04-14-2026 12:46:27

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EMPLOYEE(S) SIGNATURE
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Navneet Kaur, Investigator

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Investigator
Signed By: 2004178854
Date Signed: 04-14-2026
12:45:52

DATE ISSUED
4/14/2026

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."