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	05/19/2026-05/21/2026
	FEI NUMBER 2027302

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mikel Gerrard Brooks Pruett, Plant Manager

FIRM NAME	STREET ADDRESS
PLZ Corp	2375 3rd St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Riverside CA 92507-3306	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:

LABORATORY

OBSERVATION 1

Equipment used in the manufacture, processing, packing, or holding of drug products is not of appropriate design to facilitate operations for its intended use. Specifically,

Your firm's purified water used to clean tanks for compounding (b) (4) and (b) (4) over-the-counter (OTC) drug products is inadequately monitored and controlled, failing to ensure water quality meets established specifications and is suitable for its intended use. For example:

a. The worst-case location after purified water has gone through the entire distribution system is not monitored on the purified water system in building 2375.

b. The purified water system diagram for building 2375 does not reflect the current system configuration.

c. Sampling and use of purified water is inconsistent among departments and purified water systems.
   I. Microbiology attaches (b) (4) and performs (b) (4) prior to sampling.
   II. Compounding uses water by (b) (4) and using the water (b) (4) for cleaning.
   III. In building 2321, the purified water system is (b) (4) for (b) (4), then sampled by microbiology.

SEE REVERSE OF THIS PAGE	Rowena S. Nguyen - Investigator Journey Marie V. Cordero - Investigator Maurine (NMI) Fadlalla - Investigator	Rowena S. Nguyen -S Digitally signed by Rowena S. Nguyen -S Date: 2026.05.21 16:25:14 -07'00' JOURNEY V. CORDERO -S Digitally signed by JOURNEY V. CORDERO -S Date: 2026.05.21 16:37:03 -07'00' MAURINE FADLALLA -S Digitally signed by MAURINE FADLALLA -S Date: 2026.05.21 16:40:08 -07'00'	05/21/2026

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FIRM NAME PLZ Corp	STREET ADDRESS 2375 3rd St
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d. Resampling for failed pH results for purified water sampling points (b) (4) and (b) (4) (b) (4)) was performed without a documented investigation into the root cause of the initial failures. Before resampling, (b) (4) is performed.

e. Total organic carbon, conductivity and pH are not monitored on the purified water system in building 2321.

f. There is no SOP established to define (b) (4) sampling locations or associated specifications.

OBSERVATION 2
Procedures describing the calibration of instruments, apparatus, gauges and recording devices are deficiently written or followed. Specifically,

The calibration of your pH meter (Equipment ID: PH01) is not adequate. From 05JAN2026 to 19MAY2026, your firm calibrated your pH meter (b) (4) times. There were approximately eighty-four results for millivolt (mV) that were out of range for pH buffer (b) (4) and approximately fourteen results for mV that were out of range for pH buffer (b) (4). Your firm monitors the pH of purified water used to clean compounding tanks used for manufacturing OTC (b) (4) and (b) (4) drug products.

OBSERVATION 3
Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. Specifically,

Your firm does not perform growth promotion testing on (b) (4) media used for microbiological water bioburden testing. Growth promotion testing is required to confirm the ability of the media to support microbial growth prior to use.

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OBSERVATION 4

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,

Your firm's quality assurance chemist has the ability to "delete" files on the computer connected to your FTIR used for identity testing of raw materials.

QUALITY

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically,

a. Document control deficiencies were identified, including specifications that are not current and procedures that lack the necessary specificity to ensure consistent and compliant operations.
   I. SOP-TM-L011, Rev. F, Effective 13MAY2024, governing (b) (4) measurement is outdated and does not reflect current practices or requirements.
   II. The (b) (4) (b) (4) trending form currently in use is Revision B, which is two revisions behind the approved version, Revision D.
   III. SOP-V082, Rev. F, Effective 02APR2024, pertaining to (b) (4) System Validation, has not been updated to reflect current requirements.

b. There were many instances observed where documents were not signed off or approved labels were not placed on approved raw materials. However, they were approved in the related software.
   I. No approved (b) (4) sticker on raw material being compounded
   II. Raw materials in QC raw material entry log not signed off as released
   III. Missing signed verification of cleaning on compounding tank P1's equipment usage and cleaning log
   IV. Change controls not signed off as completed and verified (CC-25-003 and CC-25-004)

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c. There was no change control or risk assessment performed for the (b) (4) work being performed at your facility.

d. Labels that that contain pH data, and sometimes out of specification results, are discarded daily.

e. (b) (4) stability chambers ((b) (4)) are not monitored three out of (b) (4) days a week. No alarm for notification of temperature excursion.

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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."