

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 3/18/2026-3/23/2026* FEI NUMBER 3006185812			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Hyeoksoo Kim, COO					
FIRM NAME Dr. J Skinclinic, Inc		STREET ADDRESS 13834 Bettencourt St			
CITY, STATE, ZIP CODE, COUNTRY Cerritos, CA 90703-1010		TYPE ESTABLISHMENT INSPECTED 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: QUALITY SYSTEM					
OBSERVATION 1 Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed. Specifically, a. Your firm uses deionized (DI) water to clean and sanitize equipment used for manufacturing bulk OTC drug products. Your firm failed to assure that water used in the cleaning of equipment used in pharmaceutical production was adequate for pharmaceutical production in that the water system does not have routine testing for microbial contamination, TOC (Total Organic Carbon), and conductivity. Your firm performed TOC and conductivity testing only during the limited timeframe of August 5, 2025, to August 13, 2025. Your firm failed to provide documentation demonstrating that DI water does not require routine TOC, conductivity, and microbial testing. b. According to your firm SOP, SOP number: SOP-119, SOP Title: Water Analysis (Ver. 01, effective 12/15/2020), Section 4.3, requires testing of city water and processed water (b) (4). During review of your firm water testing folder titled "Micro Water Results Current" revealed that there was inconsistency in microbial testing and no documentation for analytical testing (b) (4) of the city water and in-house deionized water. c. Your firm's SOP number: SOP-119, SOP Title: Water Analysis (Ver. 01, effective 12/15/2020), Section 4.3.3, has established microbial limits and corrective action guidelines. Your firm failed to: a. Notify management upon reaching alert limits (b) (4)					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Navneet Kaur, Investigator Devisree P Mattigiri, Investigator Joshua S Lee, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> DATE ISSUED 3/23/2026 Navneet Kaur Investigator Signed By: 2004178854 Date Signed: 03-23-2026 17:04:41 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Navneet Kaur, Investigator Devisree P Mattigiri, Investigator Joshua S Lee, Investigator	DATE ISSUED 3/23/2026 Navneet Kaur Investigator Signed By: 2004178854 Date Signed: 03-23-2026 17:04:41
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i.79 CFU/ml on January 2, 2026
 ii.11 CFU/ml on November 4, 2025
 iii.85 CFU/ml on October 14, 2025
 iv.69 CFU/ml on August 13, 2025
 b.Take immediate corrective action upon exceeding action limits (b) (4):
 i.>250 CFU/ml on August 11, 2025
 c.According to your firms DI water test results report your firm failed to conduct investigations for deionized water conductivity failures:
 i.Conductivity failure: 1.88 µS/cm on August 7, 2025
 ii.Conductivity failure: 2.22 µS/cm on August 8, 2025
 iii.Conductivity failure: 2.34 µS/cm on August 11, 2025
 iv.Conductivity failure: 1.72 µS/cm on August 13, 2025
 d.Your firm purchases (b) (4) from (b) (4) and uses it in for manufacturing (b) (4) bulk OTC drug products - (b) (4) (b) (4) Your firm failed to conduct at least one testing to verify the purity, strength, and quality of the (b) (4) (b) (4) (b) (4)

OBSERVATION 2

Results of stability testing are not used in determining appropriate storage conditions and expiration dates.

Specifically,

Your firm manufactures (b) (4) bulk drug products, (b) (4) and distributes them to your customer in (b) (4) for filling and packaging. Your firm failed to perform active pharmaceutical ingredient (API) identity and strength testing on bulk products prior to release and distribution to your customer in (b) (4) Specifically, your firm manufactured and distributed below lots of (b) (4)

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(b) (4) and released without conducting the required API identity and strength analyses prior to release.

- i. Lot (b) (4) Date of shipping: (b) (4)
- ii. Lot (b) (4) Date of shipping: (b) (4)
- iii. Lot (b) (4) Date of shipping: (b) (4)
- iv. Lot (b) (4) Date of shipping: (b) (4)
- v. Lot (b) (4) Date of shipping: (b) (4)
- vi. Lot (b) (4) Date of shipping: (b) (4)
- vii. Lot (b) (4) Date of shipping: (b) (4)
- viii. Lot (b) (4) Date of shipping: (b) (4)
- ix. Lot (b) (4) Date of shipping: (b) (4)
- x. Lot (b) (4) Date of shipping: (b) (4)
- xi. Lot (b) (4) Date of shipping: (b) (4)

OBSERVATION 3

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically,

Your firm's quality unit failed to follow your firm's SOP Number: SOP-128, SOP Title: Annual Product Review (APR) for OTC Drugs, Ver. 01 to conduct Annual Product Review (APR) for your firm's bulk over the counter (OTC) drug products time frame 2022 – 2025

(b) (4)

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OBSERVATION 4

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,

- a. Your firm failed to establish cleaning validation to verify that current cleaning practices for shared equipment, that could prevent the cause of cross contamination. Your firm uses Tank (b) (4) and Tank (b) (4) for compounding both drug products and cosmetics. Your firm's batch records for OTC bulk products do not include the equipment IDs to identify which compounding tank was used to manufacture the OTC drug product.
- b. Your firm manufactures (b) (4) bulk drug products, (b) (4), for your customer in (b) (4) for finished packaging. Your firm failed to provide documentation demonstrating that the manufacturing process has been validated or designed to assure drug product strength and quality.

OBSERVATION 5

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,

During review of batch records with Lot Numbers: (b) (4) your employees failed to follow your firms SOP, SOP number: SOP-102, SOP Title: Good Documentation Practices; version: 01 section 4.0 – Procedure to perform corrections on errors.

Your firm's batch record with batch number (b) (4) employee (b) (4) corrected the "release#" for (b) (4) (b) (4) with his initials on the pre-weight/Work Order Picklist section but failed to add a

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correction date. Additionally, employees (b) (6), (b) (7)(C) corrected the name and quantity weighed section on PRE-WEIGHED documents; however, they failed to add their initials and correction dates.

OBSERVATION 6

Employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices.

Specifically,

- a. According to your firm's SOP-103 "Employee Training Program," Section 4.3, all employees must complete (b) (4) refresher training by (b) (4). However, your firm failed to provide CGMP training records for senior management, including the Production Director, CEO and COO since last inspection 2022.
- b. Additionally, your firm failed to review your employees' GMP training records. During review of the 2025 CGMP training folder, the GMP quizzes that your firm's employees completed on September 12, 2025, were incomplete and missing the "qualification determined by" signature and date fields.

PRODUCTION SYSTEM

OBSERVATION 7

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically,

Your firm manufactures (b) (4) bulk drug products, (b) (4)

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(b) (4) and distributes them to your customer (b) (4) These products are for to be filled and packaged in (b) (4) Your firm does not perform active pharmaceutical ingredient (API) ID and strength testing on bulk products prior to releasing and distribute to your customer in (b) (4)

***DATES OF INSPECTION**

3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon)

X Devisree P Mattigiri
Investigator
Signed By: DEVISREE P. MATTIGIRI -S
Date Signed: 03-23-2026 17:05:32

X Joshua S Lee
Investigator
Signed By: 2004943896
Date Signed: 03-23-2026 17:06:31

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Navneet Kaur, Investigator
Devisree P Mattigiri, Investigator
Joshua S Lee, Investigator

X Navneet Kaur
Investigator
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DATE ISSUED

3/23/2026

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."