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	11/18/2024-11/21/2024
	FEI NUMBER 3012656014

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eun Tae Lee, Vice President/Plant Manager

FIRM NAME	STREET ADDRESS
Hankook Cosmetics Manufacturing Co., Ltd	74, Daeseong-ro 547beon-gil, Samseong-myeon
CITY, STATE, ZIP CODE, COUNTRY Eumseong-gun, Chungcheongbuk-do, 27651, Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED OTC Drug Product 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

Results of stability testing are not used in determining expiration dates.

Specifically,

Procedure QP-20-17, "Stability Test" requires long term stability studies for establishment and confirmation of the (b) (4) expiration date applied to OTC drug products. (b) (4) drug product lots had stability studies initiated between 2018 and 2019, however all of these studies were cancelled approximately three months after the stability studies were initiated. To date, there has been no stability studies completed to confirm the (b) (4) expiration date established for any drug products manufactured at the firm.

In addition, according to the reporting worksheets for drug products, informal results were recorded for 9-month and 12-month timepoints for attributes such as pH and viscosity in which several lots did not meet the established criteria. There was no investigation conducted to determine the impact of these out of specification results on those drug products which had been distributed to the US market.

Furthermore, (b) (4) unique drug products were manufactured in the year 2019, however only (b) (4) of these drug products were placed on stability.

OBSERVATION 2

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

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SEE REVERSE OF THIS PAGE	Joseph A Piechocki	Joseph A. Piechocki, Investigator	11/21/2024

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Specifically,

Records related to chemical and microbiological testing do not include all the information related to the execution of the test. For example, (b) (4) is tested for (b) (4) and microbial limits. The laboratory records do not include complete information related to the execution of the tests, including but not limited to the following:

1. The standards used for the (b) (4) analysis are prepared using (b) (4) (b) (4) There is no documentation to support the standard solution preparation, including the lot of standard used, the pipets used, and the reagent (b) (4) used to perform the (b) (4) Furthermore, there is no defined procedure for conducting the (b) (4) analysis on (b) (4)

2. The microbial limits test is conducted following QR084, which requires (b) (4) of (b) (4) be directly added to a Plate Count (b) (4) and incubated for (b) (4) at (b) (4) The documentation for testing is inadequate in that there is no record of the lot number of the plates being used for the test, the incubator ID where the plates were stored, and the times in which the plates were placed and removed for incubation. In addition, no growth promotion is conducted for any incoming lots of plate count (b) (4) Furthermore, the plate counts recorded after each pull do not have a signature and date of who performed the reading and when, each reading does not have a secondary review until (b) (4) (b) (4) and there is no documentation of the environment, including the use of a plate reader or ambient lighting, for reading of the plates.

Furthermore, additional worksheets used for documenting analyses and results, including for assay testing in finished products, does not document complete data related to testing, including but not limited to, instrument parameters, column usage, reference standard and reagent usage, and reference standard and sample preparation information, when applicable.

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OBSERVATION 3
The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. There are no written procedures which outline the process for verification by the Quality Unit of the paper and electronic analytical data to ensure that the data and the calculated test results are complete and accurate for all chemical and microbial tests performed.

B. There is no written procedure which outlines the issuance, use, and reconciliation of logbooks and worksheets used within the manufacturing area (including, but not limited to batch production records for bulk manufacturing, filling, and packaging and labeling, and equipment logbooks), and the laboratory (including but not limited to analytical raw data worksheets, equipment usage logs, reference standard logs used for documenting weight, and laboratory inventory logs).

C. According to QP-20-18, "(b) (4) Product Review", (b) (4) product reviews are required to be performed and documented for drug products manufactured within (b) (4) product reviews were not conducted for the approximately (b) (4) drug products manufactured within (b) (4) (b) (4) as required per procedure.

OBSERVATION 4
Established sampling plans are not followed and documented at the time of performance.

Specifically,

Sampling of the (b) (4) system is not adequately documented, established, or justified. For example:

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1. According to QP-14-02, (b) (4) Test Management", prior to sampling the point of use, the analyst (b) (4) There is no specific time requirement that the point of use must be (b) (4) prior to collecting the sample, nor is the amount of time the point of use is (b) (4) documented.

2. Sampling is conducted on (b) (4) points of use within the facility (b) (4) according to QP-14-02, "(b) (4) Test Management". However, (b) (4) additional (b) (4) points of use are within the facility. To date, there has been no samples or data collected to confirm that the (b) (4) meets the established (b) (4) specifications.

OBSERVATION 5

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,

A. Ancillary containers used for the dispensing of raw materials for manufacturing are not maintained in a clean state. For example, during the walkthrough of the drying room for ancillary containers on 18Nov2024, I observed containers which contained various amounts of water remaining at the bottom of the equipment, including containers that had already been labeled as fully cleaned.

B. The preparation of the detergent used for the cleaning of manufacturing and ancillary equipment used in manufacturing is not adequately documented. Your quality personnel described that the detergent used for cleaning is prepared by (b) (4) This preparation is not described in any procedure, nor is the preparation documented, including lot number of detergent used and expiration date of the prepared solution.

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C. After completion of manufacturing operations, according to QP-14-01, "(b) (4) Management", the (b) (4) remaining in the (b) (4) tank is to be returned to the main holding tank, and the (b) (4) tank is to be sanitized with the (b) (4) There is no documentation that supports this operation is conducted.

D. According to QP-14-01, "(b) (4) Management", the sanitization performed (b) (4) for the (b) (4) storage tank requires the use of (b) (4) the tank. There is no procedural requirement defining how much (b) (4) is used for this cleaning nor is there any verification that the (b) (4) is fully removed from the tank prior to resuming cleaning and manufacturing operations.

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