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	3/18/2024-3/22/2024
	FEI NUMBER 3007255059

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sung-Chun Baik, CEO

FIRM NAME	STREET ADDRESS
LCC Ltd.	738-13 Samyang-Ro, Daeso-Myeon
CITY, STATE, ZIP CODE, COUNTRY Eumseong, Chungcheongbuk, 27674 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED OTC Drug 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:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Your firm manufactured and shipped OTC drug products [redacted (b) (4)] (shipped via domestic customers). During our review of product test data, we observed the following:

A. During our review of final finished drug products lots stated above, when we requested the supporting raw data for most test items, your firm's plant manager stated that the raw data and worksheets were discarded after analysts performed tests. For example, but not limited to, assay test for active ingredient [redacted (b) (4)] was not always performed for every batch, with testing for one batch [redacted (b) (4)] used in lieu of testing another batch [redacted (b) (4)] Your firm does not have any supporting raw test data or supporting incubator logbooks for microbiological testing listed on your finished product certificate of analyses; and [redacted (b) (4)] test data reported does not appear to be reliable (see Observation 4).

B. During our review of your stability study reports and recorded test results for [redacted (b) (4)] for active ingredient [redacted (b) (4)] assay test, along with other test items, were handwritten as "pass" for each stability time point; When we requested the

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supporting raw data for all test items, such as HPLC and GC chromatograms, your firm's plant manager stated that "due to misunderstanding, we just wrote pass, and did not perform the tests".

C. During the walkthrough of the inspection, we observed discarded test records in your waste bins, as detailed in Observation 4. When we compared these discarded records to the official reported records, the test data reported did not always match.

OBSERVATION 2

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

A. The firm's quality unit failed to establish specifications and conduct testing of incoming raw materials, (b) (4) within the respective USP monographs for (b) (4) Limit of (b) (4) These raw materials are received and approved for release without testing for these impurity limits. For Example, on or around (b) (4) your firm manufactured (b) (4) lots of OTC drug product (b) (4) (b) (4) which was shipped to the US Market (with arrival on or around (b) (4) (b) (4) testing was not performed for components (b) (4) per the USP monograph, nor was it performed on semi-finished products as required to be tested by your firm. In addition, the accuracy and specificity of the test methods have not been verified or validated for these components and active ingredient (b) (4)

Furthermore, your firm's response to regulatory deficiencies with respect to (b) (4) (b) (4) included your firm contracting a third-party laboratory to perform

(b) (4) testing on semi-finished product. Your contract laboratory test reports for (b) (4) (b) (4) which were provided to USFDA prior to and during the inspection lack data with respect to lot numbers tested. During the inspection, your firm's personnel stated that although there is no record showing which batch number for (b) (4) was sent for testing, they know it was lot (b) (4) from memory. Per the same personnel, they were not certain which lot number was sent for the (b) (4) (b) (4) product. Additionally, when we inquired why a lot of (b) (4) was not sent for testing, your firm's personnel did not provide an answer.

B. Your firms (b) (4) system was used in the production of (b) (4) (b) (4) (b) (4) OTC drug products. Your firm has not tested the (b) (4) to assure that the (b) (4) meets the minimum USP (b) (4) quality for (b) (4) for test items including, but not limited to, (b) (4)

OBSERVATION 3

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, stability studies in support of OTC drug products (b) (4) (b) (4) (b) (4) do not support the stated (b) (4) shelf life/expiry date. Specifically, your firm has not performed adequate accelerated and long-term stability studies in support of your (b) (4) shelf life/expiry date. During our review of your stability study reports and recorded test results for (b) (4) (b) (4) drug products, we observed that your firm did not have the supporting raw test data for stated test results for most, if not all test items. For example, test results for (b) (4) for active ingredient (b) (4) assay test, along with other test items, were handwritten as "pass" for each stability time point;

When we requested the supporting raw data for all test items, such as HPLC and GC chromatograms, your firm's plant manager stated that "due to misunderstanding, we just wrote pass, and did not perform the tests". Additionally, with respect to OTC drug product (b) (4) your firm did not provide any stability test data in support of its (b) (4) shelf life/expiry date after multiple requests for this report/data during the inspection.

OBSERVATION 4

Records associated with drug product components, production, control and distribution and within the retention period for such records, were not made readily available for authorized inspection.

A. During the inspection, your firm provided a list of all OTC drug products manufactured and shipped to the US Market. (b) (4) lots, (b) (4) of (b) (4) were observed to be on this list, with manufactured date as (b) (4) Due to your firm's current Import Alert, we made an inquiry regarding the whereabouts of these lots, and on (b) (4) your firm explained that they were manufactured for the US Market, however, were shipped to a business partner, with the lots (b) (4) located in (b) (4) with no intention to ship to the US Market. On (b) (4) we observed a record which showed the end customer of these lots as a (b) (4) (b) (4) company, however before we were able to inquire about this record, your firm took this record out of the inspectional room. When we asked about the record and named the (b) (4) company we had observed, your firm initially denied what we had observed, however, shortly after admitted that the (b) (4) lots had been manufactured for a trial run with the (b) (4) company and shipped through a third-party business partner to the US market, having already cleared US customs on or around (b) (4) and stored in a warehouse ready for distribution.

B. During our walk-through inspection of your firms in-process testing laboratory on 03/18/2024 located in Factory no. (b) (4) we observed discarded (b) (4) test records, (b) (4) test printouts, and (b) (4) calibration records in the waste bin. Upon retrieving these records from the waste bin and attempting to question the analyst present regarding these records, your plant manager became visibly angry and

animated and started shouting "why are you going through trash", after which he ordered the analyst to leave the room. After notifying your firm that this could be documented as a refusal and requesting the analyst to return, the analyst returned to the room approximately 15 minutes later. When we compared these discarded records to the official reported records, the test data for (b) (4) calibration testing data, OTC drug products (b) (4) data, including OTC drug products (b) (4) (b) (4) batches (b) (4) which were shipped to the US Market, did not always match.

C. Approximately 30 minutes later, during our walkthrough of your firm's QC laboratory, we observed a full waste bin in your HPLC/GC equipment room, however, did not immediately review the contents of the waste bin, walking past this waste bin. Instead, upon our return to the same location approximately 15 minutes later, we observed that the waste bin had been emptied with no waste present. After asking your firm where the waste bag had been taken, we followed your QC personnel outside to your trash container, where we observed this individual climb inside the trash container and retrieve the waste bag. Upon return to the QC laboratory with the waste bag, our review of the waste contents found discarded records such as HPLC assay test calculations, GC performance qualification test worksheet, and sticky notes with batch numbers and (b) (4) (non-contemporaneous recording of data). When we compared these discarded records to the official reported records, the test data did not always match.

D. Investigation reports requested during the inspection were not provided at all or were not always provided in a timely manner as per detailed instruction requests provided. Per your firm, from 03/19/2021 to 03/18/2024, approximately (b) (4) batches (or (b) (4) of product) of numerous different OTC drug product batches were manufactured and shipped by your firm globally.

1. On 03/18/2024, 03/19/2024, and 03/20/2024, we requested your firm's OOS investigations for all US and non-US products with respect to (b) (4) OTC drug products on multiple occasions for the past three years. On 03/18/2024, your firm stated that your firm had no OOS

investigation for US products, however, had 3 OOS investigations for non-US products. After multiple requests for these investigations and any CAPA's, on 03/20/2024 your firm's plant manager notified us that they had been confused regarding what an OOS was and did not issue such investigations because the "manufacturing process is so simple". No OOS investigations or CAPA's were provided for our review.

2. Similarly, on 3/18/2024, we requested deviation reports from the past three years for all (b) (4) OTC drug products from all markets. Your firm failed to provide all documentation and your firm's plant manager eventually stated that most of the deviations were lost. Only one deviation was provided for 2023, two deviations for 2022, zero for 2021, four for 2020, and three for 2019.

OBSERVATION 5

Individuals responsible for supervising the manufacture, processing, packing and holding of a drug product lack the education, training and experience to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

A. Your firm identified one individual as being both the QA Manger and QC Manager, which appears to be a conflict of interest, allegedly responsible for review of testing data and review, approval, and release of OTC drug product batches. However, this individual appeared to lack the education, training, and experience to perform assigned function for either a QA Manager or QC Manager. In fact, when we asked this individual what the acronym "cGMP" stands for through an interpreter, this individual could not provide an answer. Furthermore, we observed that testing data is not reviewed by any personnel at the firm, and production batch records are allegedly reviewed and signed off by either a QC analyst who is responsible for in-process testing operations or a production team lead.

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B. Throughout the inspection, your firm personnel, including, but not limited to your plant manager, purported QA/QC Manager, and purported QC analyst did not know the meaning of common terms/activities related to pharmaceutical manufacturing operations, such as the words out of specification (OOS), Corrective and Preventive Action (CAPA), Annual Product Review, cleaning validation, equipment qualification, accelerated and long-term testing, and process validation. When we used this terminology (translated by an interpreter from English to Koreas) and requested stated records, firm personnel did not appear to understand the records we were asking for.

OBSERVATION 6

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically, from 2021 to 2023, your firm received approximately 15 complaints regarding black particles in your [redacted] (b) (4) products. Your firm did not adequately perform investigations for root cause determination such as not establishing a cleaning procedure for your [redacted] (b) (4) [redacted] (b) (4) on all packaging lines. Per your plant manager, the reason for not establishing a cleaning procedure was due to the "process being simple." Per your firm corrective actions for the complaints consisted of refresher training for your staff with respect to assuring [redacted] (b) (4) are cleaned [redacted] (b) (4) more frequently however no training appears to have been documented.

OBSERVATION 7

The quality control unit lacks responsibility to approve all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Your Quality Unit has not been effective in carrying-out its duties of ensuring drug products are

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manufactured in accordance with current good manufacturing practices (cGMP) to ensure safety, efficacy, purity, and overall quality at your firm. This is demonstrated by observed deficiencies in your Quality Unit responsibilities. The inspectional observations listed on this form document that your firm have not performed the adequate assessments/reviews to ensure the quality of drug products manufactured and tested at your firm. For example, but not limited to:

A. Your firm's Quality Unit failed to qualify the reliability of the supplier's analysis for incoming raw materials [redacted] (b) (4) and active ingredient [redacted] (b) (4) through appropriate validation of the supplier's test results. The firm has not performed full compendial testing of components to validate the component manufacturers CoA. Furthermore, your firm has not qualified these suppliers and does not maintain quality agreements with these suppliers.

B. Your firm does not have a written procedure for performing OOS investigations, Supplier Qualifications, or Annual Product Reviews. Subsequently, during the inspection we observed that the firm has not performed OOS investigations, Annual Product Reviews, or Supplier Qualifications for related OTC drug products as of the current inspection.

C. Your firm failed to follow procedure, LCC-A-402 *Consignment Contract,* which states to conduct an evaluation for third party contractors. For instance, an evaluation was not conducted to qualify your contract laboratory.

D. Supervisory oversight over laboratory test data (static and dynamic) is deficient. See Observation 1.

OBSERVATION 8

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

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A. Your firm did not conduct risk assessment studies with respect to cleaning validation which address microbiological contamination for processes where such contamination could be of concern. Your firm manufactures OTC drug products [redacted] (b) (4) and have not performed any cleaning validation studies for any equipment used in the manufacture of these products.

B. Your firm failed to establish written procedures for your [redacted] (b) (4) on all packaging lines used to package OTC drug products after receiving 15 complaints regarding black particles observed in your [redacted] (b) (4) products as detail on their Observation 6.

OBSERVATION 9

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the manufacturing process for OTC drug products [redacted] (b) (4) including [redacted] (b) (4) operations have not been validated to show that the process operates within established parameters, can perform effectively and reproducibly to produce a drug product which is meeting its predetermined specifications and quality attributes, although the products have been shipped to the US Market.

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OBSERVATION 10

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design, of adequate size and suitably located to facilitate operations for its intended use and cleaning and maintenance.

Specifically, your firm does not have written procedures for conducting equipment qualifications such as Installation Qualification (IQ), Operational Qualification (OQ), and/or Performance Qualification (PQ) for all equipment used in the manufacture of OTC drug products (b) (4) (b) (4) During the inspection, your firm personnel, including your QA/QC Manager and Plant Manager did not appear to know what equipment qualification meant or what activities they entailed. During the inspection, we observed that your firm has not qualified the following equipment or systems: (1) Manufacture equipment such as (b) (4) filling lines; (2) stability chambers used for storage of stability samples, observed to have no monitoring for relative humidity; and (3) your firm's (b) (4) system, which your firm does not fully test to assure the (b) (4) meets the minimum USP (b) (4) quality for (b) (4)

OBSERVATION 11

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, your firm's executed batch records for OTC drug products (b) (4) (b) (4) (b) (4) lack the following information:

A. An accurate reproduction of the appropriate master production or control record for accuracy, dated, and singed. Your firm does not maintain a master batch record.

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B. Documentation that each significant step in manufacturing of the batch was accomplished, including, but not limited to:
   - Inspection of the packaging and labeling area before and after use.
   - A statement of actual yield and statement of percentage of theoretical yield at appropriate phases of processing.
   - Description of product containers and closures.
   - Examination of packaging and labeling materials for suitability and correctness before operations.
   - Records of all sampling performed.

C. Lot coding system for batch/lot numbers do not appear to be appropriate to provide unique coding for each batch/lot. For example, your lot coding system for [(b) (4)] consists of the product [(b) (4)] written as [(b) (4)] which does not account for multiple batches of the same product manufactured [(b) (4)]

X Arsen Karapetyan
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