DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Building 51Silver Spring, MD 20993 Phone: 301-796-3150 Fax: 301-594-1204 Industry Information: www.fda.gov/oc/industry	02/24/2025 - 02/28/2025* **FEI NUMBER** 3000287309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Richard Besner, President

FIRM NAME	STREET ADDRESS
Les Produits Chimiques B.G.R., Inc.	600 Delmar Ave
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Pointe-Claire, H9R 4A8, Canada	API 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) (WE) OBSERVED:

OBSERVATION 1

1. Equipment used in the manufacture, processing, packing or holding of active pharmaceutical ingredients is not of appropriate design and suitably located to facilitate operations for its intended use and cleaning and maintenance.

Specifically, your firm failed to formally qualify (IQ/OQ/PO) the (b) (4) equipment ID# (b) (4) used in the manufacturing of Active Pharmaceutical Ingredient, (b) (4) USP (b) (4) since January 26th, 2023. The following commercial lots of (b) (4) USP (b) (4) API were manufactured using this unqualified (b) (4) ID# (b) (4) and were subsequently released to the U.S. market: (b) (4) (b) (4)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Robin P Mathew, Investigator Soyinka S Eneng, Investigator	02/28/2025

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OBSERVATION 2

1. The suitability of test methods for active pharmaceutical ingredients have not been verified under actual conditions of use.

Specifically, your firm has not completed method verification studies for the following USP analytical methods that you perform in your laboratory for release testing of the active pharmaceutical ingredient (API), [(b) (4)] USP [(b) (4)], Product [(b) (4)] identification [(b) (4)] identification [(b) (4)] assay, [(b) (4)] insoluble substance, loss on ignition, [(b) (4)] substances, [(b) (4)] and microbial analytical testing methods.

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OBSERVATION 3

1. There is a failure to thoroughly review the failure of an API batch or any of its components to meet any of its specifications, whether or not the batch has been already distributed.

Specifically, investigation #2022-003, into the out-of-specification (OOS) assay result, for raw material [redacted] (b) (4) USP, lot # [redacted] (b) (4) lacked a scientifically sound root cause assessment. The original assay result was observed to be [redacted] (b) (4) % (assay specification: [redacted] (b) (4) %). The root cause of the out-of-specification was determined to be caused by the temperature of the laboratory without a scientifically sound justification for this proposed OOS root cause. This was the only OOS investigation completed by your firm since the last FDA inspection in 2019.

*DATES OF INSPECTION
02/24/2025 (Mon), 02/25/2025 (Tue), 02/26/2025 (Wed), 02/27/2025 (Thu), 02/28/2025 (Fri)

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