DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place, Suite 5900 Detroit, MI 48207 Ph: 313-393-8100	03/30/2026-04/08/2026* FEI NUMBER 3014484244

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
Mr. Harvinder Dhani, Owner, CEO, President	
TO:	STREET ADDRESS
Pharmaneek Inc	7345 Woodland Dr, Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46278	Producer of Non-sterile Drug Products

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

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. Specifically,

The current cleaning process is deficient for the following reasons and does not provide assurance that hazardous drug product residue and cleaning agent residue are adequately removed from reusable glassware and utensils used in production of both non-hazardous and hazardous drug products:

- On 03/30/2026, following the production of non-sterile hazardous drug Hydroxyurea 100 mg/mL Oral Suspension Lot HU10010330260 (Beyond Use Date (BUD): 04/29/26), the reusable utensils (such as mortar and pestle and graduated cylinders) and a disposable weigh boat, utilized for production, were cleaned with (b) (4) liquid and a reusable (b) (4); No deactivating agent is currently employed to ensure the inactivation and removal of hazardous drug residue from product contact surfaces and utensils.
- The reusable washed utensils, such as mortar and pestle, and the disposable weigh boat, that were used for hazardous drug production, were subsequently observed as being placed in a shared bin containing separate utensils, such as mortar and pestle, which are used for non-sterile non-hazardous production activities.
- A technician was observed washing a disposable weigh boat that had been used to collect powder from Hydroxyurea Capsules USP, 500 mg, which was subsequently used in the production of non-sterile hazardous drug Hydroxyurea 100 mg/mL Oral Suspension Lot HU10010330260, and placing it in the same container containing utensils such as mortar and pestles used for non-hazardous production activities.
- Graduated cylinders, used during production of Hydroxyurea 100 mg/mL Oral Suspension Lot HU10010330260, were returned to storage in a closed cabinet immediately after washing, while water droplets remained visible on the cylinders.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Janet Rajan -S Digitally signed by Janet Rajan -S Date: 2026.04.08 12:10:11 -04'00'	Janet A. Rajan, Investigator	04/08/2026

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Detroit District Office 300 River Place, Suite 5900 Detroit, MI 48207 Ph: 313-393-8100	03/30/2026-04/08/2026* FEI NUMBER 3014484244
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Mr. Harvinder Dhani, Owner, CEO, President	
TO: Pharmaneek Inc	STREET ADDRESS 7345 Woodland Dr, Ste A
CITY, STATE, ZIP CODE, COUNTRY Indianapolis, IN 46278	TYPE ESTABLISHMENT INSPECTED Producer of Non-sterile Drug Products

OBSERVATION 2

Your firm failed to confirm that the quality of water was suitable for its intended use in the production of non-sterile drug products. Specifically,

The firm used (b) (4) water for the production of non-sterile drug products, including but not limited to Hydroxyurea 100 mg/mL Oral Suspension, Lot HU10010330260 (Date Made: 03/30/26, BUD: 04/29/26), Hydroxyurea 100 mg/mL Oral Suspension, Lot HU10010327260 (Date Made: 03/27/26, BUD: 04/26/26) and Hydroxyurea 100 mg/mL Oral Suspension, Lot HU10010319260 (Date Made: 03/19/26, BUD: 04/28/26). The firm had no data to demonstrate that the water used met the specifications for (b) (4) Water USP. The formula worksheet for Hydroxyurea 100 mg/mL Oral Suspension includes (b) (4) Water USP as an ingredient, but the firm used (b) (4) water.

OBSERVATION 3

Your facility is not maintained in a good state of repair, creating insanitary conditions whereby drug products may be contaminated with filth. Specifically,

On 03/30/2026, a ceiling tile in the control room where Hydroxyurea 100 mg/mL Oral Suspension, Lot HU10010330260 (Date Made: 03/30/26, BUD: 04/29/26) was produced, and subsequently dispensed to the patient, was observed to be chipped, with part of the ceiling tile missing and opened to the plenum space, potentially exposing the room to environmental contaminants.

***DATES OF INSPECTION**

03/30/2026 (Mon), 03/31/2026 (Tue), 04/01/2026 (Wed), 04/02/2026 (Thu), 04/03/2026 (Fri), 04/06/2026 (Mon), 04/07/2026 (Tue), 04/08/2026 (Wed) (8 Days)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Janet Rajan -S Digitally signed by Janet Rajan -S Date: 2026.04.08 12:10:39 -04'00'	Janet A. Rajan, Investigator	04/08/2026

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."