

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 4/6/2022-4/14/2022*
	FEI NUMBER 2427358

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeff Reingold, Chief Operating Officer

FIRM NAME Contract Pharmacal Corporation	STREET ADDRESS 135 Adams Ave
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CITY, STATE, ZIP CODE, COUNTRY Hauppauge, NY 11788-3633	TYPE ESTABLISHMENT INSPECTED Manufacturer
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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

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

On 4/6/2022, we observed two tablet compression dies with clean status stored in the toolroom were found to be soiled with white residue.

OBSERVATION 2

Buildings used in the manufacturing, processing and holding of a drug product are not maintained in a good state of repair.

Specifically,

A) On 4/6/2022, tablet compression room # 3P-01 had peeling paint on the wall in multiple locations. On that day the firm was manufacturing Pseudoephedrine 60mg Tablets (lot # **(b) (4)**) in this room.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Bijoy Panicker, Investigator Brandy N Lepage, Investigator	Bijoy Panicker Investigator Signed by: 2001996716 Date Signed: 04-14-2022 17 16 40 X _____	DATE ISSUED 4/14/2022

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B) On 4/6/2022, tablet compression room # 3P-03 had peeling paint on the walls in multiple locations, and had an unpainted spackled patch of approximately 3' x 1' on the wall. On that day the firm was manufacturing (b) (4) (lot # (b) (4) in this room.

***DATES OF INSPECTION**

4/06/2022(Wed), 4/07/2022(Thu), 4/08/2022(Fri), 4/11/2022(Mon), 4/12/2022(Tue), 4/13/2022(Wed), 4/14/2022(Thu)

X Brandy N Lepage
 Investigator
 Signed By: Brandy N. Lepage -S
 Date Signed: 04-14-2022 17:17:14

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Bijoy Panicker, Investigator Brandy N Lepage, Investigator	<small>DATE ISSUED</small> 4/14/2022
	X Bijoy Panicker Investigator Signed By: 2001996716 Date Signed: 04-14-2022 17:16:40	

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."