

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 10/30/2023-11/3/2023
	FEI NUMBER 3001581899

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Kenneth V. Meade, Senior Compliance Specialist

FIRM NAME Contract Pharmaceuticals Limited Canada	STREET ADDRESS 7600 Danbro Crescent
CITY, STATE, ZIP CODE, COUNTRY Mississauga, L5N 6L6	TYPE ESTABLISHMENT INSPECTED Contract 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**

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your firm was notified a highly pathogenic microorganism was recovered during environmental monitoring of the production area and an incident report (IR) was not initiated to conduct a documented investigation of the result. *Brucella melitensis* was recovered from an air sample taken on 08/02/2022 in Wash Up Room (b) (4) where production equipment is cleaned. Firm procedure QC-250-24 *Microbial Environmental Monitoring (EM) Program* does not require IRs to be initiated when action levels are not reached and lacks instructions to initiate an IR for pathogenic or objectionable microbial recoveries. Quality Unit personnel approved both the (b) (4) 2022 Environmental Monitoring Report and 2022 Environmental Monitoring Annual Trend Report which included the recovery of *Brucella melitensis*. The 2022 Environmental Monitoring Annual Trend Report states *Brucella melitensis* is considered non-objectionable, however the identification report from your third-party contract laboratory received by your Quality Unit on 08/24/2022 states the microorganism is highly pathogenic.

Empty space for additional observations or comments.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Kristina L Conroy, Investigator	Kristina L Conroy Investigator Signed By: Kristina L Conroy -S Date Signed: 11-03-2023 09:22:55 X	DATE ISSUED 11/3/2023