

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 01/13/2015 - 01/23/2015*
	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Travis A. Leeah, RPh, MBA, President/CEO**

FIRM NAME Unique Pharmaceutical, Ltd	STREET ADDRESS 5920 S General Bruce Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY Temple, TX 76502-5803	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

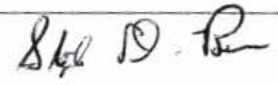
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to 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**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

- A) The investigations into two microbiological excursions during media fills above action level in the ISO 5 (b) (4) did not address cleaning processes as required per SOP #PR 8.3.3 entitled, "Out of Specification Investigation" dated 8/15/2014. The two excursions can be summarized as follows:
1. The media fill dated (b) (4) (Lot # (b) (4)) was performed in Cleanroom (b) (4). The personnel sample obtained from the gloves (b) (4) fingertip) resulted in an out of specification result of 1 CFU (Organism: *Corynebacterium tuberculo*stearicum).
  2. The media fill dated (b) (4) (Lot # (b) (4)) was performed in the (b) (4) Clean Room. The personnel sample obtained from the (b) (4) the ISO 5 (b) (4) (b) (4) glove fingertip) resulted in an out of specification result of 1 CFU (Organism: *Staphylococcus cohnii*).
- B) Your firm failed to conduct an investigation into the leakage of (b) (4) during a Media Fill performed in the (b) (4) Clean Room on (b) (4) (Lot # (b) (4)) as required per SOP #PR 8.3.3 entitled, "Out of Specification Investigation" dated 8/15/2014.
- C) Your media fills do not accurately simulate current production processes and conditions which represent the most challenging conditions. For example, your firm (b) (4) (b) (4) in the first media fill conducted on (b) (4). The same media fill resulted in an out of specification result for a (b) (4) plate in the ISO 5 (b) (4). The same (b) (4) was not used (b) (4) subsequent media fills performed between (b) (4) (b) (4).
- D) All glassware including (b) (4) used to (b) (4) is (b) (4) (b) (4) in a (b) (4). However, the (b) (4) has not been qualified to demonstrate that the unit can achieve appropriate log reduction of microbes. Your firm does not use any (b) (4) during the (b) (4) in the (b) (4).

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Stephen D. Brown, Investigator  Patrice S. Hall, Investigator Ademola O. Daramola, Investigator	DATE ISSUED 01/23/2015
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**OBSERVATION 2**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm failed to conduct surface monitoring (b) (4) (i.e. Clean Room (b) (4) Clean Room) during media fills conducted between (b) (4) and routine environmental monitoring since (b) (4)

**OBSERVATION 3**

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, dirty (b) (4) used to sanitize the (b) (4) in Clean Room (b) (4) were stored on the floor of the cleanroom during the production of sterile drug product formulations. The (b) (4) were used to sanitize the (b) (4). They were stored in the open and on the floor of the cleanroom about four feet away from the (b) (4) for the duration of production, lasting approximately (b) (4)

**OBSERVATION 4**

Written records of investigations into unexplained discrepancies do not include the conclusions and follow-up.

Specifically, your firm failed to maintain at least 20 Nonconformance Reports which were deleted from the (b) (4) between 8/14 and 12/14 with the reason documented in most cases as "Null". Some examples of the Nonconformance Reports deleted consist of the following:

1. NonConformance Record #HOMA-9M5PAR: "(b) (4) OOS" deleted on 8/11/14
2. NonConformance Record #HOMA-8L9QPN: "(b) (4) IV Bag Contamination" deleted on 9/29/14
3. NonConformance Record #HOMA-8S8LVM: "Narcotic mix-up" was deleted on 9/29/14

**OBSERVATION 5**

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

A. Video of the dynamic smoke studies conducted to demonstrate unidirectional airflow (b) (4) located in Clean

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Room # (b) (4) showed considerable turbulent airflow when a repeater pump was placed within the (b) (4) (b) (4). During the production of one lot of Succinylcholine on 1/14/2015 in the (b) (4), the technicians placed the repeater pump in the (b) (4) in a manner that creates a turbulent airflow pattern as demonstrated through the dynamic smoke study video. In the course of production, the repeater was (b) (4) (b) (4) for (b) (4) and filling of the sterile compound.

B. A telephone set placed inside the ISO 7 Clean Room (b) (4) is used for communication between cleanroom technicians stationed within the cleanroom and other staff members outside the cleanroom. A fully gowned cleanroom technician within the cleanroom was observed using the telephone on five occasions to communicate with technicians and staff members located outside the cleanroom while sterile operations were ongoing.

**OBSERVATION 6**

The separate or defined areas necessary to prevent contamination or mix-ups are deficient. Specifically, clean room design is deficient to prevent product contamination. For example, the firm maintains a plastic strip curtain separator with a length of approximately 2 feet above the floor between an ISO 7 room (Contains unclassified hood for the (b) (4) of non-sterile API and (b) (4) ) and an unclassified area. The ISO 7 room (b) (4) to the Controlled Substance Clean Room (ISO 7) which contains an (b) (4) (ISO 5).

**\* DATES OF INSPECTION:**  
01/13/2015(Tue), 01/14/2015(Wed), 01/15/2015(Thu), 01/16/2015(Fri), 01/21/2015(Wed), 01/22/2015(Thu), 01/23/2015(Fri)

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