DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	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	STREET ADDRESS
Unique Pharmaceutical, Ltd	5920 S General Bruce Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Temple, TX 76502-5803	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 11/5/2014 (Lot #T00088342) was performed in Cleanroom (b)(4) The personnel sample obtained from the (b) (4) resulted in an out of specification result of (b)(4) CFU (Organism: *Corynbacterium tuberculostearicum*).
2. The media fill dated 11/6/2014 (Lot #T00088350) was performed in the Controlled Substance Clean Room. The personnel sample obtained from the (b)(4) the ISO 5 (b) (4) resulted in an out of specification result of (b)(4) CFU (Organism: *Staphylococcus cohnii*).

B) Your firm failed to conduct an investigation into the leakage of syringes (b)(4) during a Media Fill performed in the Controlled Substance Clean Room on 11/5/2014 (Lot #T00088344) 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) in the first media fill conducted on 11/5/2014. The same media fill resulted in an out of specification result for a contact plate in the ISO 5 "(b) (4) The same (b) (4) was not used (b) (4) subsequent media fills performed between 11/5/2014 and 11/17/2014.

D) All glassware including beakers used to (b) (4) is washed and dried 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 BI (biological indicator) during the drying cycle in the (b) (4).

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	Stephen D. Brown, Investigator Patrice S. Hall, Investigator Ademola O. Daramola, Investigator	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) (b) (4) (i.e. Clean Room (b) (4) and Controlled Substance Clean Room) during media fills conducted between 11/5-17/2014 and routine environmental monitoring since 11/2014.

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) "(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)" in preparation for the day's production. 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 four hours.

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) database 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) "(b) (4) located in Clean

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Room # [redacted] (b) (4) showed considerable turbulent airflow when a [redacted] (b) (4) [redacted] was placed within the work zones of the "[redacted] (b) (4) [redacted]". During the production of one lot of Succinylcholine on 1/14/2015 in the "[redacted] (b) (4) [redacted]", the technicians placed the [redacted] (b) (4) [redacted] in the middle of the work bench inside the "[redacted] (b) (4) [redacted]" in a manner that creates a turbulent airflow pattern as demonstrated through the dynamic smoke study video. In the course of production, the [redacted] (b) (4) [redacted] was moved within the "[redacted] (b) (4) [redacted]" to create room for [redacted] (b) (4) [redacted] and filling of the sterile compound.

B. A [redacted] (b) (4) [redacted] placed inside the ISO 7 Clean Room [redacted] (b) (4) [redacted] 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 [redacted] (b) (4) [redacted] 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 [redacted] hood for the [redacted] (b) (4) [redacted] of non-sterile API and [redacted] (b) (4) [redacted]) and an unclassified area. The ISO 7 room [redacted] (b) (4) [redacted] to the Controlled Substance Clean Room (ISO 7) which contains an [redacted] (b) (4) [redacted] (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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