DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expy., Ste 300 Dallas, TX 75204 ph 214-253-5200 Industry Information: www.fda.gov/oc/industry	June 9-20, 2014 FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Daniel F. Volney - CEO

FIRM NAME	STREET ADDRESS
Unique Pharmaceuticals Ltd.	5920 South General Bruce Drive, Suite 100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Temple, TX 76502	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 (I) (WE) OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm does not always adequately investigate and identify corrective/preventative actions for sterility failures.

Between January 27 and March 26, 2014 your firm produced five batches of human drug product intended to be sterile that were tested for sterility and showed non-sterile results. Also, the batch of Neostigmine failed for endotoxin results. Your investigations of these failures did not extend to other possibly related batches and did not document or identify any preventative actions that address lab methods or possible environmental contaminants as a root cause for the failures. The five batches include:

Produced Date	Product	Stock Code	Batch	Location	Rejected	Expiry
3/20/2014	Oxytocin	(b) (4)	87040	(b) (4)	No	6/18/2014
1/27/2014	N-Acetyl Cysteine 20%		86513		No	7/23/2014
1/27/2014	Sodium Bicarb in D5W		86534		No	2/26/2014
3/26/2014	Neostigmine		87100		Yes	9/22/2014
3/4/2014	Calcium Gluconate		86893		Yes	8/31/2014

OBSERVATION 2

Production errors are not fully investigated.

Specifically, your firm does not always adequately investigate and document investigations of non-conformances.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Scott Ballard, Investigator Andrea Branche, Investigator	06/20/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expy., Ste 300 Dallas, TX 75204 ph 214-253-5200 Industry Information: www.fda.gov/oc/industry	June 9-20, 2014 FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Daniel F. Volney - CEO

FIRM NAME	STREET ADDRESS
Unique Pharmaceuticals Ltd.	5920 South General Bruce Drive, Suite 100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Temple, TX 76502	Outsourcing Facility

A. On June 10, 2014, we reviewed your firm's investigation (NCR #9JLFPW) related to an incident involving "normal fiber particulate (varying colors)" in Hyaluronidase vials (lot #87264, stock code # (b) (4)) manufactured on April 9, 2014. This investigation does not fully identify the particles. The investigation indicates third party particulate analysis is needed due to a lack of identification but does not extend to possibly related batches. Your Pharmacist in charge stated the third party identification has not been conducted. This batch was rejected and not distributed.

B. Also, On June 11, 2014, we reviewed an investigation (#9KCLSR) related to particulate matter found while using the (b) (4) on April 14, 2014 to (b) (4) (stock code (b) (4); batch 87253). The investigation also was not extended to related batches or retain samples thereof. This batch was rejected and not distributed according to your non-conformance report.

OBSERVATION 3

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

Specifically, the following procedures are not adequately written or followed:

A. Media fills described by (Aseptic Process Simulation - PR 8.4, effective 5/2/2014) have not yet been executed. Your firm has produced over (b) (4) different drug product batches intended to be sterile injectable human drugs since March 3, 2014. None of these product processes have been simulated by media fills.

B. (b) (4) are not qualified for their intended use. Your firm has not performed (b) (4) (b) (4) or collected data to justify the use of (b) (4) used in (b) (4) (b) (4) is used to sterilize stoppers used in the filling of human drug products intended to be sterile. The (b) (4) is used to de-pyrogenate vials and (b) (4) used in the manufacture of human drug products intended to be sterile.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	SS QAT3	Scott Ballard, Investigator Andrea Branche, Investigator	06/20/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expy., Ste 300 Dallas, TX 75204 ph 214-253-5200 Industry Information: www.fda.gov/oc/industry	June 9-20, 2014 FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Daniel F. Volney - CEO

FIRM NAME	STREET ADDRESS
Unique Pharmaceuticals Ltd.	5920 South General Bruce Drive, Suite 100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Temple, TX 76502	Outsourcing Facility

C. Gowning procedure [redacted] (PR 6.4, revision 5/12/2014) provides [redacted]. The Prep room is used to [redacted] In the past four months, you have two non-conformance reports (9HRNL5 and 9G7K9T) related to a hair found along with a rubber stopper. The [redacted] gowning requirement for [redacted] does not require full body gowning and goggles to cover the face while in this room.

D. Procedure (Preparation of Cleanroom Supplies, rev 11/1/2013) for [redacted] and bioburden reduction of [redacted] is not followed. On June 9, 2014, I observed a depyrogenated [redacted] placed into the [redacted] for Clean Room [redacted] without [redacted] or sanitizing the [redacted] after it was carried through an un-classified area (lab area hallway). I also observed the placement of a de-pyrogenated [redacted] in the Clean Room [redacted] ISO 5 area without [redacted].

E. Your practice of storing [redacted] in ISO 5 areas does not minimize risk to aseptic processing. On, June 9, 2014, I observed [redacted] in the ISO 5 areas of the [redacted] Room and the Clean Room #2. These [redacted] are located on the [redacted] tables within approximately [redacted] adjacent to where sterile drug products are [redacted] and filled. The printers use an approximate [redacted] where bags of drug product are manufactured and [redacted].

OBSERVATION 4

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically, your clean rooms are not adequately designed to prevent contamination.

There is no barrier or documented unidirectional air flow between work benches where aseptic manipulation of drug products occurs and room spaces classified as ISO 7 areas. Additionally, smoke studies conducted on [redacted] show turbulent and stagnant air within ISO 5 areas used to [redacted] and fill drug product unit containers.

Further, on June 9, 2014 we observed [redacted] readings of [redacted] air velocity in both Clean Room [redacted] and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Scott Ballard, Investigator Andrea Branche, Investigator	06/20/2014

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expy., Ste 300 Dallas, TX 75204 ph 214-253-5200 Industry Information: www.fda.gov/oc/industry	June 9-20, 2014
	FEI NUMBER 3002468086

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Daniel F. Volney - CEO

FIRM NAME	STREET ADDRESS
Unique Pharmaceuticals Ltd.	5920 South General Bruce Drive, Suite 100
CITY, STATE AND ZIP CODE Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

(b) (4) ISO 5 areas in the immediate vicinity where drug product unit containers are filled during aseptic operations.

These ISO 5 classified areas are used to hold previously sterilized drug product in large (b) (4) during filling activities for (b) (4).

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, your firm does not adequately monitor personnel and environmental bio-burden.

Your firm does not perform microbiological sampling of personnel gowns worn by pharmacy technicians that process drug products intended to be sterile in aseptic processing areas. According to Environmental and Personnel Monitoring procedure (DOC PR 8.2, effective 5/30/2014) technicians will be evaluated (b) (4) for (b) (4) that perform aseptic manipulations.

Your firm does not perform environmental monitoring of work surfaces where aseptic processing occurs at least daily during periods of production and at the end of operations. The existing monitoring procedure (DOC #PR8.2, effective 5/30/2014) calls for (b) (4) monitoring of work surfaces and (b) (4) monitoring of personnel finger-tip samples.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Scott Ballard, Investigator Andrea Branche, Investigator	06/20/2014