Sterile Drug Products by Unique Pharmaceuticals Ltd.: Recall - Lack of Sterility Assurance

[Posted 07/11/2014]

AUDIENCE: Risk Manager, Health Professionals, Pharmacy

ISSUE: The U.S. Food and Drug Administration is alerting health care professionals, including hospital supply managers and hospital staff, not to use drugs marketed as sterile produced by Unique Pharmaceuticals Ltd., a company located in Temple, Texas, as they may be contaminated.

Health care professionals should immediately check their medical supplies, quarantine any sterile drug products from Unique Pharmaceuticals, and not administer them to patients. Administration of a non-sterile drug product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, FDA is not aware of reports of illness associated with the use of these products.

BACKGROUND: Unique Pharmaceuticals' products were distributed nationwide. Most of the product labels include: Unique Pharmaceuticals, Temple TX USA 76502.

FDA investigators conducted two recent inspections of the Unique Pharmaceuticals facility and observed insanitary conditions that result in a lack of sterility assurance of purportedly sterile drug products produced by the company, which puts patients at risk (Form FDA-483s issued April 4, 2014 (PDF - 4.28MB), and June 20, 2014 (PDF - 1MB)). These inspections revealed sterility failures in several lots of drug products intended to be sterile, recurring environmental contamination problems, and poor sterile production practices.

RECOMMENDATION: Patients who have received any drug product produced by Unique Pharmaceuticals and have concerns should contact their health care professional. The FDA asks health care providers and consumers to report adverse events or quality problems experienced with the use of any Unique Pharmaceuticals' products to the FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm

- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

[07/11/2014 - CDER Statement - FDA]

Page Last Updated: 07/11/2014
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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
Contact FDA

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 Temple, TX 76502	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

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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 (b) (4) 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 (b) (4) batches include:

Produced Date	Product	Stock Code	Batch	Location	Rejected	Expiry
[redacted]						(b) (4)

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
	Andrea Branche	Scott Ballard, Investigator Andrea Branche, Investigator	06/20/2014

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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 mix (b) (4) (stock code (b) (4); batch (b) (4)). 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. Autoclaves and dry-heat oven are not qualified for their intended use. Your firm has not performed temperature mapping or collected data to justify the use of biological indicators used in Autoclave cycles or Endotoxin ampules in the Dry-Heat Oven. The autoclave is used to sterilize stoppers used in the filling of human drug products intended to be sterile. The dry-heat oven is used to de-pyrogenate vials and beakers used in the manufacture of human drug products intended to be sterile.

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	SS AB3	Scott Ballard, Investigator Andrea Branche, Investigator	06/20/2014

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C. Gowning procedure [redacted] (b) (4) (PR 6.4, revision 5/12/2014) provides (b) (4) different gowning requirements for the Prep Room. The Prep room is used to prepare rubber stoppers and glass ware for washing and entry into the Clean Rooms. 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 lower gowning requirement for entering the Prep room 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 aluminum foil over-wrap and bioburden reduction of beakers is not followed. On June 9, 2014, I observed a depyrogenated beaker placed into the pass-box for Clean Room #2 without removing a layer of over-wrap or sanitizing the beaker after it was carried through an un-classified area (lab area hallway). I also observed the placement of a de-pyrogenated beaker in the Clean Room #3 ISO 5 area without first removing and outer layer of aluminum foil overwrap.

E. Your practice of storing weight-ticket printers in ISO 5 areas does not minimize risk to aseptic processing. On, June 9, 2014, I observed printers in the ISO 5 areas of the Narcotic Room and the Clean Room #2. These printers are located on the stainless steel tables within approximately 20 inches adjacent to where sterile drug products are filter sterilized and filled. The printers use an approximate three-inch roll of thermal paper that is torn off at the end of each batch where bags of drug product are manufactured and weight-checked.

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 April 28th and May 16th, 2014 show turbulent and stagnant air within ISO 5 areas used to filter sterilize and fill drug product unit containers.

Further, on June 9, 2014 we observed anemometer readings of 0-30 FPM air velocity in both Clean Room (b) and

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Narcotic Room 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 beakers partially covered with aluminum foil during filling activities for up to (b) (4) hours at a time.

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 gowning bio-burden on forearms and chest 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/17/2014 - 04/02/2014
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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 and followed.

Specifically, your pharmacy technicians processing drug products intended to be sterile do not always exhibit good aseptic techniques. Also, procedures for media fills and [redacted] (b) (4) tests are not adequately written and followed.

On 3/17/2014, we observed in clean room [redacted] on the work bench where aseptic processing occurs, a technician reaching over approximately forty open and previously sterilized 10mL glass vials continuously while filling a tray of approximately [redacted] (b) (4) vials for Dexamethasone Acetate 8mg/mL; lot #86972.

On 3/18/2014, we observed in the clean room [redacted] (b), a technician pull a plastic crate (filled with sterile syringe packages) from a shelf located six inches off the ground and place it on the work bench where aseptic processing occurs while preparing to process Glycopyrrolate 0.2mg/mL syringes; lot #87014. We observed the same technician (with gloved hands) pick up a hand-set and dial a hand-held phone inside the aseptic processing area during the processing of the same Glycopyrrolate drug product.

On 3/18/2014, your pharmacy technician was observed processing Glycopyrrolate 0.2 mg/mL syringes (lot #87014) [redacted] (b) (4) intended to sterilize the drug product. After the processing, the technician used a 100mL syringe with a [redacted] (b) (4) to the [redacted] (b) (4) of the [redacted] (b) (4). The technician did not record a quantitative pressure.

On 3/19/2014, your Director of Quality stated your firm has not performed any media fills to simulate the process of sterilizing and filling over 116 different drug product formulations intended to be sterile injectable human drugs. Also, there is no written procedure for conducting media fills to simulate the process of sterilizing and filling.

Your firm has not conducted an equipment qualification to show that autoclaves used to sterilize rubber stoppers and dry-heat oven used to de-pyrogenate glassware achieve appropriate log reduction of microbes or endotoxins. Your firm only conducts

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run verification for each autoclave cycle sterilization of rubber stoppers using biological indicators and verification of each de-pyrogenation cycle using endotoxin standard ampules without qualifying the equipment.

Also, materials such as aluminum foil over-wrap covering de-pyrogenated vials and steel trays holding depyrogenated vials are hand-carried through the clean room to the work bench where aseptic processing occurs without further aseptic protection.

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm produces 16 products that contain a preservative and are not tested for preservative content at time of release and includes the following products:

1. Lorazepam 1mg/mL; stock code 3927
2. Labetalol 5mg/mL; stock code 4073
3. Dexamethasone Acetate 8mg/mL; stock code 525
4. Glycopyrrolate 0.2mg/mL; stock code 4161
5. Beta-Beta with Lidocaine 5mL; stock code 3725

Also, your firm has approved and shipped the following products with potency failures outside the [redacted] (b) (4) acceptance range:

1. 5/15/2013 - Promethazine lot #83962 - 113% potency
2. 6/14/2013 - Hydrogen Peroxide 3% lot #84204 - 0.3% potency (product discontinued)
3. 6/18/2013 - Lansoprazole 3mg lot #84314 - 83% potency
4. 7/29/2013 - Hydrochloric Acid 2mg lot #84615 - 44.8% potency
5. 9/27/2013 - Polymyx/Bacitracin/Nystatin lot #82254 - 65% potency
6. 11/22/2013 - B Complex 100, lot #85230 - 70% potency

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OBSERVATION 3

Production errors are not fully investigated.

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

On 3/19/2014, we reviewed your firm's investigation related to an incident involving "dark specks" found in Morphine lot #86511 (stock code: 3937) and documented as non-conformance report #9FZTZE (dated 3/12/2014).

This report of investigation does not include microscopic examination or any other characterization of the "dark specks" found in the product that would allow for further investigation. This lot of morphine was later scrapped.

OBSERVATION 4

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your technicians do not wear sterile mouth covers and face covers while processing drug products intended to be sterile in the area where aseptic processing occurs.

On 3/17/2014, we observed your Pharmacy technicians (b) (4) and fill human drug product (Dexamethasone Acetate 8mg/mL; lot #86972) intended to be sterile on vertical flow work benches where there is no physical barrier between exposed skin on the technician's face or the non-sterile mouth covers and the open (previously sterilized, 5 mL glass vials) unit containers for drug product on the working surface in front of the technicians. Your firm also does not have a written procedure requiring sterile mouth covers or complete coverage of facial skin for technicians working inside the aseptic processing areas.

OBSERVATION 5

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

Specifically, your firm does not adequately monitor personnel bio-burden, monitor environmental bio-burden, and monitor

cascading air pressure differentials.

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. On 3/20/2014, we reviewed personnel monitoring records that include sampling of finger tips (according to Work Instruction #WI10-001.18) but no other portion of the technician (such as arms, chest, or mask) that perform aseptic manipulations. Your Director of Quality stated there are no other samples collected to monitor the microbial load of initially sterile gowns worn by pharmacy technicians in aseptic processing areas. Additionally, technician finger-tips are not tested for microbial contamination at least daily.

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. On 3/21/2014, we observed your firm's routine procedure for conducting contact plate sampling of tables, equipment, and walls in aseptic processing areas. However the last product handled in the aseptic processing area sampled was more than 18 hours prior and is separated by a disinfection of the room using (b) (4) [redacted]. The existing monitoring procedure (DOC #PR8.1) calls for [redacted] (b) (4) monitoring of work surfaces.

Your firm performs monitoring of air pressure differentials between the "clean rooms" and the "ante-rooms" by documenting that greater than zero Inches of Water (differential pressure) exist between clean room and ante-room environments. However, there is no quantitative documentation of differential pressures and there are no quantitative acceptance criteria for clean rooms during processing of human drug products intended to be sterile injectable.

OBSERVATION 6

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 air pressure differential between work benches where aseptic manipulation of drug products occurs and room spaces classified as ISO 7 areas.

OBSERVATION 7

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically, your pharmacy technicians repeatedly sterilize rubber vial stoppers by autoclave, but there is no procedure

that limits the number of times a stopper may be autoclaved. On 3/17/2014, we observed a technician using previously autoclaved rubber stoppers to fill an autoclave bag and re-load the autoclave. This allows for a minimum of two autoclave cycles accumulated for those stoppers used during the processing of Dexamethasone Acetate 8mg/mL, lot #86972.

OBSERVATION 8

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, your firm does not conduct certification of clean rooms under dynamic conditions.

Your firm's certification documents (Test Report #ENV1127131448RM, ENV111131117RMRev1, and ENV1211131605JQ) for work benches (inside "clean room" (b) (4)) where aseptic processing occurs, do not include an evaluation of non-viable particles in air flow during dynamic conditions. The conditions evaluated include (b) (4) technicians, but do not include moving vials, syringes, or bags and do not include manipulation of equipment such as repeater pumps and sterile tubing sets. We observed technicians processing vials, bags, and syringes on March 17th and 18th 2014 that were not represented during room certification.

OBSERVATION 9

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, given the observed inadequate environmental controls, testing is deficient in that:

Your firm does not adequately perform sterility tests according to USP Chapter 71 for invalidation of failing results, transfer of samples, and negative controls.

On 3/20/2014, your Lab Analyst stated negative controls for sterility testing are achieved by incubating bottles of media such as Fluid Thioglycollate and Tryptic Soy Broth in an incubator without any manipulation. This does not simulate the routine method of (b) (4) sterility testing of drug products used by your firm. Your written procedure for Sterility Testing (W110-001.16) section 5.3 specifies this practice.

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On 3/20/2014, your Analyst also stated that direct inoculation samples for sterility testing for products that are visually opaque (such as suspensions) are incubated fo[redacted (b) (4)] and then a[redacted (b) (4)] is transferred to a new media unit for incubation fo[redacted (b) (4)]. USP Chapter 71 calls for incubation for at least 14 days prior to transfer. Your written procedure for Sterility Testing (W110-001.16) section 4.0 calls for transfer after [redacted (b) (4)]" days.

On 3/19/2014, the Non-Conformance report #9BQGMR was reviewed pertaining to a sterility test failure for Phenylephrine 100 microgram / mL syringes; lot #85051 (BUD 11/13/2013) which was invalidated. This allowed the product to be retested for sterility, released, and distributed. Your Director of quality stated there is no environmental data or other documents available to justify invalidating the initial sterility failure. Your Director of Quality stated the test results were invalidated due to a lack of adequate unit container sanitizing prior to performing the sterility test and this is the reason for invalidating the results.

OBSERVATION 10

~~The labels of your firm's drug products do not always contain information required by section 503(b)(a)(10).~~

~~Specifically, the following labels reviewed during the inspection for human drug products intended to be sterile do not include the statement "This is a compounded drug".~~

~~1. Dextrose 5% and Sodium Bicarbonate 8.4% (stock code: 3784)~~
~~2. Labetalol 5mg/mL 4 mL vial (stock code: 4073)~~
~~3. Calcium Chloride 10mL syringe (stock code: 3942)~~
~~4. Ondansetron 50mL NS Bag (stock code: 4246)~~
~~5. Glycopyrrolate 5mL syringe (stock code: 4161)~~
~~6. Midazolam 100mL Bag (stock code: 4186)~~
~~7. Norepinephrine 250 mL bag (stock code: 4259)~~
~~8. Fentanyl 1mL syringe (stock code: 4225)~~
~~9. Potassium Phosphate 5mL Vial (stock code: 4124)~~
~~10. Oxytocin 1000mL Bag (stock code: 4271)~~

The labels of your firm's drug products observed by FDA do not contain information required by section 503B(a)(10) of the Act.

Specifically,

The following drug product labels do not contain the statement "This is a compounded drug," information to facilitate

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adverse event reporting (www.fda.gov/medwatch and 1-800-FDA-1088), and the date that the drug was compounded:

Calcium Chloride 20 mg/mL 10mL syringe
Ondansetron 8 mg in 50mL NS bag
Glycopyrrolate 0.2 mg/mL 5mL syringe
Midazolam 1mg/mL 100mL bag
Norepinephrine in D5W, 8 mg in 250 mL
Fentanyl 10 mcg/mL 1mL syringe
Potassium Phosphate 5mL Vial
Oxytocin 20 units in 1000mL LR bag
Labetalol 5 mg/mL 4 mL vial
Dextrose 5% and Sodium Bicarbonate 8.4%, 850/150 solution

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