

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 3/3,5-7,10-11,13-14,17/14
	FEI NUMBER 3005247494

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Bourjois S. Abboud, President

FIRM NAME Advanced Pharma, Inc.	STREET ADDRESS 9265 Kirby Drive
CITY, STATE AND ZIP CODE Houston, TX 77054-2520	TYPE OF 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 (I) (WE) OBSERVED:

OBSERVATION 1

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

Specifically, your firm's procedures for monitoring the ISO5 hoods are not suitable to ensure the quality of air. For example,

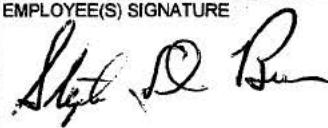
- A. During periods of production, your firm does not conduct viable air monitoring daily.
- B. Your firm does not incubate environmental samples (touch plates and spin air) at 20-25C in order to maximize the recovery of yeast and mold.

OBSERVATION 2

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

Specifically,

- A. Your media fill process simulations are not performed under the most stressful or challenging conditions. For example, your media fill for syringes dated 3/28/13 documents that a total of (b) syringes were filled. However, (b) (4) syringes/lot, were manufactured for (b) lots of Morphine Sulfate (1mg/ml) 2ml Syringe between 1/22/14 and 2/28/14.
- B. On 3/3/14, I observed operators, wearing non-sterile gowning, having their forearms in close proximity to or within the interior of the ISO5 hoods during compounding operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Stephen D. Brown, Investigator	DATE ISSUED 03/17/2014
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OBSERVATION 3

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform. Specifically, your firm utilizes non-sterile gowns during compounding operations.

OBSERVATION 4

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions. Specifically, monitoring for pressure differentials between the ISO7 and ISO8 areas is only conducted (b) (4).

OBSERVATION 5

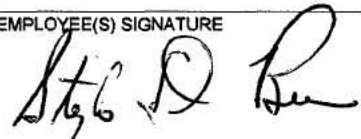
Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

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

- A) Your firm has not conducted sterility testing for approximately (b) (4) lots of (b) (4) manufactured and distributed.
- B) Your firm has not conducted any testing for endotoxin for (b) (4) lots manufactured and distributed.

Some examples of distributed lots consist of the following:

1. Lorazepam HCl 0.9% Sodium Chloride , lot # "2/27/14 10:35" (Expiration date: 3/29/14) which was manufactured on 2/27/14 and delivered to a consignee.
2. Vancomycin HCl 1.5grams in Normal Saline 250ml, lot # "2/3/14 1018" (Expiration date: 3/5/14) which was manufactured on 2/3/14 and delivered to a consignee.

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3. Propofol 1% Injectable Emulsion (USP), lot # "2/4/14 1107" (Expiration date: 3/4/14) which was manufactured on 2/4/14 and delivered to a consignee.

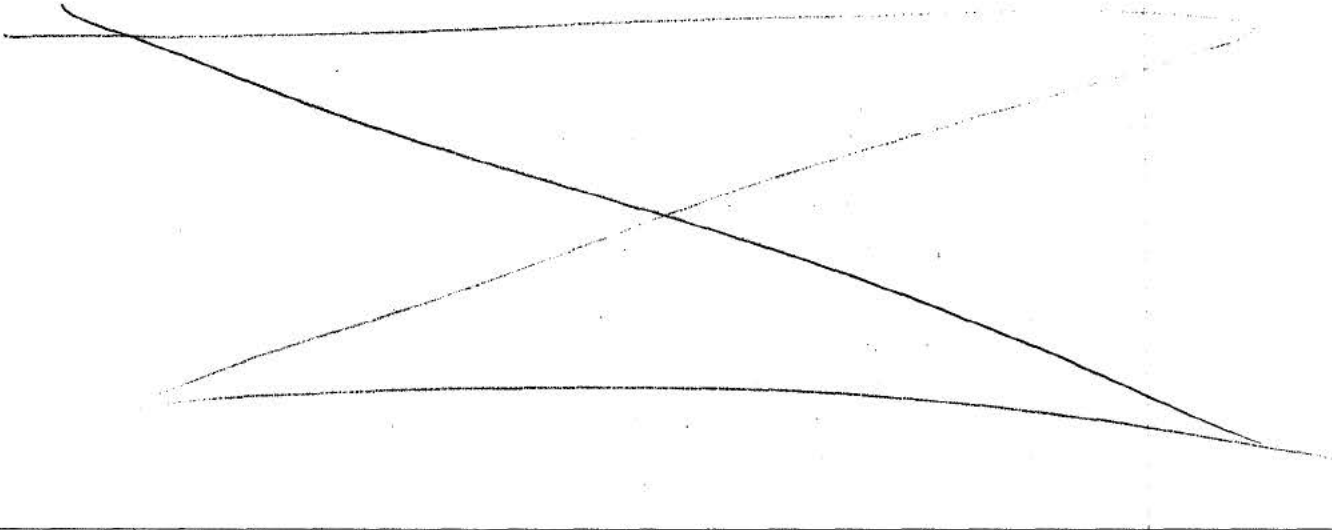
C) Your firm does not conduct growth promotion testing of incoming Tryptic Soy Broth or Fluid Thioglycollate Media.


OBSERVATION 6

The labels for the drug products, do not always contain information identified in section 503(b)(a)(10).

For example, the following drug product labels do not contain the statement "This is a compounded drug" or "Not for resale" and "office use only." *SD 3/17/14*

- A) Oxytocin 30 Units in Normal Saline 500ml, lot # "2/6/14 1545 706-50(P)" (Expiration date: 3/23/14)
- B) Oxytocin in Lactated Ringer's 500ml, lot # "1/27/14 1127 705-50(P)" (Expiration date: 3/28/14)
- C) Oxytocin 20 Units in Lactated Ringer's 1000ml, lot # "1/28/14 0914 702-99 (P)". (Expiration date: 3/29/14)



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