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	08/06/2007 - 08/13/2007
	FEI NUMBER 3000203232

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Gary D. Osborn, RPh, CCN, CEO/Owner

FIRM NAME	STREET ADDRESS
ApotheCure Inc	4001 McEwen Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75244-5020	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

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

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, only (b) (4) from a batch of sterile injectables is sent to a 3rd party laboratory for sterility analysis, regardless of the size of the compounded batch. No pyrogen testing is conducted. Some examples of the sterile injectables include, but are not limited to, DMPS 50 mg/ml, EDTA Disodium 150 mg/ml and Polidocanol AQ 1%.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically,

a. The firm does not evaluate the Ante Room or Laminar Airflow Workbench (LAFW). The firm's SOP No. 4.06 "Laminar Airflow Hood Certification" (approved by Gary Osborn on 7/1/2007) states "The purpose of this standard procedure is to ensure all hoods used in sterile compounding are certified and that they continue to meet the requirements for a Class 100 environment." For example, the firm does not evualate the Ante Room or LAFW for airborne microorganisms on at least a weekly basis.

b. The firm's sterilization process using (b) (4) ((b) (4) (b) (4)) used for the sterilization of all glass vials, stoppers and scoops, in addition to finished injectables including, but not limited to, DHEA, Hyaluronic Acid X-Link and Sodium Hyaluronate, is not supported by documented evidence that it was validated to effectively sterilize the (b) (4) of components or drug products.

c. The firm has failed to have adequate documented evidience showing the effectiveness of the sterile filling step using a (b) (4) (b) (4) for all injectable products to include, but not limited to, Calcium-Disodium EDTA Injectable, Disodium EDTA injectable, DMPS injectable, Lidocaine Injectables, Polidocanol Injectables and Procaine Injectables.

d. The firm does not have documented evidence to demonstrate effectiveness of the cleaning regimen used to clean

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Investigator Jeff R. Woody	08/13/2007

equipment and the Laminar Airflow Workbench as decribed in ApotheCure Inc. SOP No. 8.34 "General Aseptic Procedures Used at a Laminar Airflow Workbench" (approved by Gary Osborn on 7/1/2007).

OBSERVATION 3

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, the firm does not test each batch of product, whether injectables, capsules, creams or any other drug product, to verify the acceptability of the product quality specifications such as potency and identity.

OBSERVATION 4

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, the firm's injectable drug products are not supported by actual stability studies. For example, EDTA Calcium Disodium Preservative Free 300 mg/ml Lot #20070724@42 is labeled with a Do Not Use Beyond 7/13/2009. The firm's owner stated the firm uses (b) (4) [redacted], in order to determine the "Do Not Use Beyond" dates. There are no supporting documents of these activities.

OBSERVATION 5

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

Specifically, the firm lacks procedures which address how possible sources of microbiological contamination, observed in the firm's Ante Room (b) (4) are to be controlled to avoid contamination into finished sterile injectable drug products. The Ante Room is where the firm's compound sterile injectable drugs are (b) (4) under (b) (4) Laminar Air Flow Hoods. The following possible sources of contamination observed include, but are not limited to:

a. Per SOP ApotheCure Inc. SOP No. 7.01 "Disposable Gowns, Masks, Gloves, Shoe Covers, etc" (Approved by Gary Osborn on 8/1/07), employees gown up in an uncontrolled environment and apply shoe covers, hair covers and masks outside of the Ante Room prior to entering. On 8/6/07, we observed employees gowning up outside of the Ante Room before taking

part in filling sterile injectables of Vanadium.

b. On 8/6/07, a (b) (4) Insect Trap & Monitor, was observed to be located on the floor, along the south wall of the Ante Room under a Laminar Air Flow Hood during the (b) (4) of sterile injectable Vanadium.

c. A portable radio was located on a shelf in the Ante Room, with speakers and attached wires, located on each side of the entry to the Ante Room. The Ante Room is the room where (b)(4) LAF Workbenches are housed, which are used to (b) (4) sterilie injectables drug products.

d. On 8/7/07, during the sterile (b) (4) of sterile injectable drug products, an employee with gloved hands was observed handling components in a drawer, outside of the Laminar Flow Hood, which was outside of six inches from the LAFW. The employee then returned to filling sterile injectable drug products without changing gloves. ApotheCure Inc. SOP No. 8.34 "General Aseptic Procedures Used at a Laminar Airflow Workbench" (Approved by Gary Osborn on 7/1/07) states '(b) (4) This observation was made during the process of (b) (4) sterile injectable drug vials, specifically Vanadium.

The firm does not have written procedures or validation data to demonstrate the multiple use of (b) (4) (b) (4) as a component in sterile, injectable drug products. The label for (b) (4) reads in part (b) (4).

OBSERVATION 6

Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically, the firm does not have validation data to demonstrate the use of (b) (4) USP, as a component in sterile, injectable drug products. We observed the (b) (4) (b) (4) label to read in part (b) (4). In addition, the firm does not have validation data to demonstrate the use of (b) (4) (b) (4) (b) (4) which was labeled as (b) (4). The firm currently uses the (b) (4) as a component in their sterile, injectable drug products to include, but not limited to: DMPS 50 mg/ml, EDTA Disodium 150 mg/ml and Polidocanol AQ 1%. The firm uses (b) (4) of (b) (4) for (b) (4) of sterile, injectable drug products.

OBSERVATION 7

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, the firm does not conduct any type of analysis on any of their active pharmaceutical ingredients received for

drug processing. Instead, the firm only accepts a Certficate of Quality or Certificate of Assurance from their supplier in lieu of testing.

OBSERVATION 8

Written procedures are not followed for the receipt and storage of components.

Specifically, the firm does not follow ApotheCure Inc. SOP No. 1.26 "Chemical and Ingredient Storage" (Approved by Gary Osborn on 7/1/2007) which states: "Place all chemicals and ingredients on shelves or pallets (plastic or wooden) that are kept (b) (4) . CAUTION: DO NOT ALLOW CHEMICALS AND INGREDIENTS TO TOUCH WALLS OR TO BE PLACED DIRECTLY ON THE FLOOR". We observed multiple bulk chemicals being stored directly on the floor in the component and bulk chemical storage area. In addition, we observed bulk chemicals being stored on top of a biohazard container in the IV Mixing Room.

In addition, the firm does not follow ApotheCure Inc. SOP 1.25 "Receipt of Bulk Chemicals" (Approved by Gary Osborn on 7/1/07) which states: (b) (4)

OBSERVATION 9

Adverse drug experience information has not been reported to FDA.

Specifically, the firm received the following complaints and adverse drug experiences, which were not reported to the FDA:

a. On 3/23/07, a complaint was received which states (b) (4), (b) had problem w/Lot #20070122@8 25 mg/ml Thiotic Acid. Said several patients have had reactions of nausea, vomitting, chills and fever (b) (4), is returning vials in this lot for retesting". Under "Additional Comments", the document states "told (b) (4), (b) possible speed of IVP".

b. On 3/8/07, a complaint was received which states "fever, body aches, chills EDTACa 2006-080420"

c. On 11/15/06, a complaint was received which states "CaEDTA, lot #2006030909, dizziness, headache, sweating

None of these complaints had documentation of reporting the adverse drug experiences to the FDA.

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Dallas, TX 75244-5020	Drug Manufacturer

OBSERVATION 10

Written procedures describing the handling of all written and oral complaints do not include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration.

Specifically, the firm's SOP ApotheCure Inc. SOP No. 9.08 "Complaint and Mishap Rectification" (Approved by Gary Osborn on 7/1/2007) does not address how to handle and evaluate complaints that could be adverse drug experiences. For example, the following complaints were received by the firm, without any further documentation or an adequate investigation:

a. On 3/23/07, a complaint was received which states [(b)(4), (b)] had problem w/Lot #20070122@8 25 mg/ml Thiotic Acid. Said several patients have had reactions of nausea, vomitting, chills and fever. [(b)(4), (b)] is returning vials in this lot for retesting". Under "Additional Comments", the document states "told [(b)(4), (b)] possible speed of IVP".

b. On 3-8-07, a complaint was received which states "fever, body aches, chills EDTACa 2006-080420"

c. On 11/15/06, a complaint was received which states "CaEDTA, lot #2006030909, dizziness, headache, sweating

OBSERVATION 11

Master production and control records lack complete manufacturing and control instructions, sampling and testing procedures, and special notations.

Specifically, the master records (blank LFW) do not describe the specific equipment and mixing instructions (such as time limitations for mixing and hold time before filling), sampling and testing procedures (such as sterility testing) nor specifications of components used in manufacturing.

OBSERVATION 12

Batch production and control records do not include the weights and measures of components used in the course of processing each batch of drug product produced.

Specifically, the firm does not record the weights and/or volume of all components used during processing of a product. The only component recorded is the active pharmaceutical ingredient used in the batch. The weights of excipients, such as water and fillers, are not recorded on the batch production record.

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OBSERVATION 13

Batch production and control records do not include a description of drug product containers and closures used for each batch of drug product produced.

Specifically, the firm does not record or document the manufacturer or lot number of containers or closures to include, but not limited to, vials, stoppers and capsules, used in the processing of drug products.

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FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Charles D. Brown, Investigator

Tricia Samaniego Martinez, Investigator

Jeffrey R. Wooley, Investigator

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