DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	03/11/2013 - 03/19/2013* FEI NUMBER 3005364771

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Daniel P. Blakeley, R.Ph., CEO, Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Foundation Care LLC	4010 Wedgeway Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Earth City, MO 63045-1213	Producer of Sterile Drug Products

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,

a. Your media fill procedure and documentation, which are used to validate your sterile processing operations, are inadequate. You failed to a perform media fill simulation, including documenting the following kinds of information:
   1) Average and worst case processing times.
   2) Document the different kinds of interventions, along with the average and maximum number of interventions.
   3) The maximum number (under worst case scenario) or personnel in the cleanroom (Class 100 i.e. ISO 5 zone) during dynamic processing operations.

b. Your SOP 8B.16 "Environmental Testing for Cleanroom" fails to include instructions on daily monitoring under dynamic conditions (when processing occurs) in your Class 100 (ISO 5 zone) cleanroom as it instructs for monthly environmental monitoring only for equipment and air sample (viable and non-viable monitoring).
   In addition, this SOP does not include all of the equipment contained in your Class 100 cleanroom to be included in your monthly monitoring program. For example it fails to include and you fail to monitor the following (this is not an inclusive list):
   1) One (1) BAXA Pump
   2) Two (2) Chairs

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3) Fifteen (15) plastic storage bins located on the lower shelf of one of your long tables;
4) Five (5) black plastic vial racks used to hold your ampules which are passed into the heat sealer for ampule sealing operations;
5) Speaker located on the bottom shelf of your short table;
6) Door knobs, walls, and floors.

c. You failed to perform daily environmental monitoring (or when processing occurs) of your personnel. Your SOP 3C.4 "Compounding Personnel Training" instructs you to conduct annual personnel monitoring activities only. For example: ES was last monitored 10/19/2012 and CS was last monitored 10/18/2012.

d. You failed to have a smoke study procedure used to evaluate your cleanroom suite (Class 100) under dynamic conditions and employee DB stated you have not conducted a smoke study since the room was installed in 2005.
Additionally, you failed to conduct a smoke study after a new air handling unit was installed in 2007.

e. You failed to use appropriate aseptic cleaning practices as you do not always use overlapping cleaning strokes, cleaning from the top to the bottom, from the back to the front and from the inside/outside of your cleaning areas and equipment as observed on 3/12/2013.

f. Your firm has not defined a frequency or intervals where gloves must be changed out. "8B.4 Compounding Garb" only states to spray gloves with "Sterile 70% ISA". On 3/11/2013 during the fill of Hypertonic Saline 4% Lot 4HS4-130311, employee CS dropped the disinfectant bottle once at the end of processing and once during cleaning. He sprayed the bottle with Sterile IPA (Isopropyl Alcohol), placed it back on the lower shelf, continued to work and did not change his gloves. Neither pharmacist technicians changed their gloves during the process and they only wore one pair of gloves.

g. While observing cleaning operations on 3/11/2013 in the anteroom employee ES left the door between the cleanroom (Class 100) and anteroom (Class 10,000) open at least 3 times for over 5-10 second after cleaning/sanitization of the Clean Room. The door does not automatically close nor is there an airlock between the rooms.

h. You failed to follow your SOP 8B.5 "Hand Washing -Sterile Compounding". On 3/11/13 and 3/13/13, your employees ES and CS both failed to allow "water to run from fingertips toward elbows" during the rinsing of their hands as required by the procedure.

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i. There is no clock or time instrument in the anteroom to make sure employees preparing for aseptic production scrub their hands for a minimum of 30 seconds in accordance to their procedure 8B.5 "Hand Washing -Sterile Compounding."

OBSERVATION 2

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

Specifically, during processing of Hypertonic Saline on 3/11/2013 and Tobramycin on 3/14/2013 both employees ES and CS were observed with exposed skin around the neck and face. The operators do not wear the jumpsuit style but Royal Silk Surgical Gown which wraps around, ties on the side and not totally closed in the back. In addition, the bouffant cap, surgical mask, shoe covers they wear are not sterile to protect pharmaceuticals which are preservative free such as Tobramycin, Colistimethate and Hypertonic Saline. The Pharmacist-in-charge stated the scrubs worn underneath the Gown are laundered at home by the employees.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a. Potency is not performed on a routine basis. Your procedure 8B.13 Contract Laboratories & Sample Testing Frequency states "Potency testing may be done on a random basis or at the Pharmacist-in-Charge's or Quality Assurance Officer's discretion." For example:
   1) Hypertonic Saline potency was last tested in July 2009.
   2) Tobramycin potency was last tested in December 2012.
   3) Colistimethate was last tested for potency in September 2005.

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OBSERVATION 4

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

Specifically, you do not perform sterility and endotoxin test on a routine basis for Hypertonic Saline which was last tested for sterility in June 2012.

OBSERVATION 5

The records for components and drug product containers or closures do not include the supplier's lot number.

Specifically,

a. You did not document the lot number of the TPN bags used in the sterile drug process for the following but not limited to: Tobramycin Lot TA170-120103B, TA170-120327B, TA170-121211A, TA170-130312B; and Colistimethate Lot C75-120816.
b. Ampule lot numbers used in sterile drug products are not documented. Ampules used in the process are received from the sterilization company have a list of lot number on the shipping carton but do not have lot numbers on the individual bags.

OBSERVATION 6

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, there is no documented cleaning of the glassware prior to use in the cleanroom. You failed to render glassware re-used in your Cleanroom (Class 100 area) in a sterile condition prior to being introduced into your Cleanroom. This re-used glassware is located on the tables in close proximity to your processing area which includes opened ampules before sealing activities occur. Your SOP 8B.21 "Washing Glassware for use in the Cleanroom" instructs your employees to rinse the glassware using tap water, wash with liquid detergents, wipe with IPA, etc. After the washing/drying steps this SOP

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instructs them to hang the glassware "on rack to dry". This rack is located in the anteroom (class 10,000) area which does not have documented cleaning of this storage area. We observed this practice on 3/11/2013 during the cleaning process after the sterile fill of Hypertonic Saline.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

a. You have not conduced disinfectant effectiveness studies to show the disinfectants used can reduce bioburden on the different surfaces in the cleanroom (Class 100) where you produce sterile products including the following but limited to: Tobramycin, Colistimethate and Hypertonic Saline.

b. The Cavicide used to disinfect the surfaces in the cleanroom (Class 100) (where sterile Tobramycin, Colistimethate, and Hypertonic Saline are filled) is not labeled as sterile.

*** DATES OF INSPECTION:**
03/11/2013(Mon), 03/12/2013(Tue), 03/13/2013(Wed), 03/14/2013(Thu), 03/18/2013(Mon), 03/19/2013(Tue)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."