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 Industry Information: www.fda.gov/oc/industry	07/14/2014 - 07/22/2014* FEI NUMBER 3010836489

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sarah A. Herrington, RN, Owner

FIRM NAME	STREET ADDRESS
I.V. Specialty, Ltd	3200 Steck Avenue Suite 330
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Austin, TX 78757	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

Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically,

Sterile garb (i.e. gowns, booties, head bonnet, facemask, goggles) is not worn during aseptic processing of sterile drug products in the ISO 5 horizontal laminar airflow (LAF) hoods. In addition, the pharmacy technician ((b) (6)) was observed on 07/14/14 and 07/16/14 to have (b) (6) hair, ears, and forehead exposed during aseptic processing of pediatric Total Parenteral Nutrition (TPN) products. On 07/14/14, (b) (6) facemask hung below (b) (6) nose and was worn backwards (white side facing out rather than blue).

OBSERVATION 2

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

Specifically, aseptic processing was deficient as follows:

a. On 07/16/14, pharmacy technician ((b) (6)) was observed to place vials in front of syringes blocking unidirectional airflow in the horizontal LAF hood during preparation of an adult TPN.

b. Your firm has (b) (4) horizontal LAF hoods equipped with spill guards where HEPA filters are raised approximately 5/8 of an inch from the work surface area(s), potentially disrupting airflow to the work surface area in (b) (4) hoods.

c. Media fills do not simulate the aseptic fill process. Media fill does not simulate production process in that media is not infused simulating the (b) (4) base solutions (b) (4)) through the sterile tubing and the (b) (4) pump into the bag. Media fill does not simulate transfer of solutions from vials with vent ports into a syringe then added to the IV bag through a (b) (4) (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lucas B. Leake, Investigator Sharon K. Thoma, Investigator Lori G. Cantin, CSO	07/22/2014

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 Industry Information: www.fda.gov/oc/industry	07/14/2014 - 07/22/2014* FEI NUMBER 3010836489

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sarah A. Herrington, RN, Owner

FIRM NAME	STREET ADDRESS
I.V. Specialty, Ltd	3200 Steck Avenue Suite 330
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Austin, TX 78757	Outsourcing Facility

d. Your firm has not conducted growth promotion of media and no certificate of analysis was on site for media used during media fills until 07/16/14 (i.e.,(b) (4) TSB Media(b) (4) mL bag,(b) mL ampule, and(b) (4) mL vial). No positive and negative controls are performed with traceability to (b) (4) microorganisms. The media fill bag is not incubated at USP recommended temperatures at 20 - 25°C and 30 - 35°C. Media fills were incubated between(b) (4) -(b) (4)°C in 2013 and(b) (4) -(b) (4)°C 2014.

e. (b) (4) used during aseptic processing have not been qualified for loss upon drug (b) (4) and interaction with the (b) (4) itself. (b) (4) are also not(b) (4) tested and lot numbers are not documented on TPN formula worksheets/batch records.

OBSERVATION 3

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

Specifically,

a. Personnel monitoring (PM) for each operator is conducted(b) (4) and not when each operator exits the clean room following preparation of sterile injectable drug products.

b. Environmental Monitoring (EM) is not performed during each processing of sterile injectable drug products. EM is performed every(b) (4), alternating testing of(b) (4) ISO 5 LAF hoods.

c. (b) (4) PM and every (b) (4) EM in each ISO LAF hood uses (b) (4) (i.e., (b) (4) which are not incubated at USP recommended temperatures. PM and EM (b) (4) are incubated between(b) (4) -(b) (4)°C. There are no established action and alert limits. Time and/or dates are not documented for when (b) (4) are placed in and removed from incubator.

OBSERVATION 4

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

Specifically,

a. Your firm has not conducted smoke studies to date under dynamic conditions for (b) (4) ISO 5 horizontal LAF hoods (b) (4)).

b. No pressure differential monitoring is conducted during production of sterile drug products. In addition there is no

ongoing pressure differential monitoring between ISO 7 (clean room), ISO 8 (ante room) and the unclassified corridor.

c. On 07/16/14, Doors to access the ISO 8 ante room and ISO 7 clean room were capable of being opened at the same time. Your firm has no system in place to prevent ISO 8 ante room doors and ISO 7 clean room doors from be opened simultaneously.

d. On 01/20/14 and 7/29/13, air differential pressure monitoring conducted by an outside source demonstrated the corridor to be more positive to the ISO 8 ante room.

OBSERVATION 5

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

Specifically,

a. Wipes used in ISO 5 LAF hoods are not sterile.

b. No sporicidal agent is used for cleaning horizontal LAF hoods, walls and floors in the clean room. Your firm uses sterile (b) (4) in ISO 5 areas (i.e. LAF hoods), which is not received with a Certificate of Analysis.

c. Disinfectants used to clean floors and walls in ISO 7 clean room where ISO 5 hoods are located use tap water to mix (b) (4)

d. Materials including IV bags and packaged syringes used in manufacturing were observed to be transfered from ISO 7 to ISO 5 areas without sanitizing.

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

a. The following complaints were received by your firm and there was no investigation to determine source of contamination:

i. On 03/10/13 your firm received a complaint and determined a "small plastic floater" was found in a TPN product. No source of contamination was identified.
ii. On 11/1/13 your firm received a complaint for a Pedi TPN and determined it was a "floater". No source of

contamination was identified.

b. LAF hood certification found a leak/repair in the HEPA filter on 01/20/14 and your firm did not conduct an investigation to evaluate product impact back to the last certificate date on 07/29/13.

OBSERVATION 7

Routine calibration of automatic, mechanical, and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

a. Your firm uses a (b) (4) pump to fill base solutions for TPNs, which is calibrated (b) (4) with a (b) (4) weight that is not certified (b) (4), as recommended by the manufacturer, and to date are not traceable to a national standard. No certificates were on site for (b) (4) weights used for (b) (4) calibration of the (b) (4) pump.

b. Your firm does not calibrate the incubator thermometer to a national standard.

OBSERVATION 8

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

Specifically,

Diffuser screens covering HEPA filters in (b) (4) LAF hoods used to produce sterile drug products are not routinely cleaned and/or not documented. Brownish yellow substance was observed on HEPA diffuser screen for (b) (4) LAF hoods on 07/14/14, 07/16/14 and 07/17/14.

OBSERVATION 9

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

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

a. Your firm does not conduct finished drug product testing for sterility and endotoxins. Sterility testing only includes base solutions (i.e., (b) (4)).

b. Your firm's test method for sterility (i.e. (b) (4)) has not been validated to demonstrate it is equivalent to or better

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 Industry Information: www.fda.gov/oc/industry	07/14/2014 - 07/22/2014* FEI NUMBER 3010836489

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sarah A. Herrington, RN, Owner

FIRM NAME	STREET ADDRESS
I.V. Specialty, Ltd	3200 Steck Avenue Suite 330
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Austin, TX 78757	Outsourcing Facility

than the USP test method (i.e., Membrane Filtration or Direct inoculation).

OBSERVATION 10

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10) of the Food, Drug, & Cosmetic Act. Specifically:

Labeling does not include assignment of a lot/batch number (Lot/batch numbers are not assigned to any compounded drug products); labeling does not contain the following statements: "This is a compounded drug", "Not For Resale", and "Office Use Only"; and labeling does not contain information to facilitate adverse reporting: www.fda.gov/medwatch and 1-800-FDA-1088 <http://www.fda.gov/medwatch and 1-800-FDA-1088>.

a. For example, labels for the following drug products do not contain the above statements:
   i. TPN outsourcing for 10% Dextrose Formula 250mL, 7.5% Dextrose Formula 250 mL, 5% Dextrose Formula 250 mL.
   ii. Patient specific Rx's: Meropenem 2000 mg/NS 100 mL (AF), Cefepime 1 gm/NS 50 mL, and Vancomycin 1.25 gm/NS 250 mL.

b. Your drug product label(s) do not contain information pertaining to the established name of the drug. For examples: Remicade 900 mgs/NS 250 mL, Cubicin 500 mg/NS 100 mL (AF), Protonix 40 mg/10 mL SYR, Privigen 25 gm/250 mL, and Solu-Medrol 70 mg/NS 75 mL (AF).

*** DATES OF INSPECTION:**
07/14/2014(Mon), 07/15/2014(Tue), 07/16/2014(Wed), 07/17/2014(Thu), 07/18/2014(Fri), 07/22/2014(Tue)

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Lucas B. Leake, Investigator Sharon K. Thoma, Investigator Lori G. Cantin, CSO	07/22/2014