DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Kansas City, KS 66214 (913) 495 - 5100	7/6 – 7/8/2021, 7/15/2021
	FEI NUMBER 3013446837
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jeffrey Lyons, General Manager	
FIRM NAME Accurate Rx Pharmacy Consulting, LLC dba Diplomat Specialty Infusion Group	STREET ADDRESS 103 Corporate Lake Drive
CITY, STATE, ZIP CODE, COUNTRY Columbia, MO 65203	TYPE ESTABLISHMENT INSPECTED Sterile Human Drug Producer

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

Disinfecting agents and cleaning wipes and pads used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, we observed your Pharmacist-in-Charge cleaning your ISO 5 laminar air flow hood on 7/8/2021.

A. During these cleaning activities, we observed the use of non-sterile (b) (4) wipes which were used specifically to clean the ISO 5 laminar air flow hood.
B. During these cleaning activities, we observed the use of non-sterile (b) (4) used along with the non-sterile wipes.

OBSERVATION 2

The ISO 5 classified aseptic processing areas had difficult to clean equipment or surfaces.

Specifically,

A. During cleaning, you did not clean an approximate (b) (4) radius porthole located on the right sidewall of your laminar air flow hood.
B. During cleaning, you did not clean all surfaces of the outer packaging of (b) (4) wipes residing in the laminar air flow hood.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Robert J. Ham, CSO Jill Tillman, Regulatory Officer	07/15/2021

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Columbia, MO 65203	Sterile Human Drug Producer

OBSERVATION 3

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, you did not disinfect your sterile bottle of (b) (4) before transferring from your ISO 7 room into your ISO 5 laminar air flow hood.

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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 judgment, 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."