DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	11/13/2025-12/11/2025* FEI NUMBER 3013438582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Barbara A. Knightly, RPH, PharmD, Chief Quality Officer

FIRM NAME	STREET ADDRESS
Denver Solutions, LLC	13796 Compark Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Englewood, CO 80112-7145	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 OBSERVED:

OBSERVATION 1

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

The aseptic filling process for Bevacizumab 25 mg/mL injection has not been adequately validated.

Specifically, the initial process validation was performed using a (b) (4) test method that your firm later determined was incapable of detecting the (b) (4) particulates that are a known contaminant in your process. Furthermore, after making significant changes to the process—including the introduction of a new (b) (4) test method and the implementation of a critical (b) (4) (b) (4) step per SOP-0200 (b) (4) Avastin Processing Procedure - you failed to perform a complete re-validation of the manufacturing process to demonstrate that it can consistently produce product meeting all specifications.

Since identifying (b) (4) contamination from your filling equipment, you have relied on (b) (4) - as a routine manufacturing step to bring failing product back into specification. For example, your OOS history from January 2025 to the present shows that at least (b) (4) required (b) (4) due to sub-visible particulate failures. In-process failures, even after

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implementation of an "improved" (b) (4)(b) (4) procedure per PD-25-01-RDFR-DEN-01 Bevacizumab (Avastin) (b) (4)(b) (4) Improvement Study, approved September 9, 2025, demonstrates that the process is not robust or reliable.

OBSERVATION 2

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Equipment used in the aseptic filling of Bevacizumab 25 mg/mL for intravitreal injection is not of appropriate design to prevent product contamination.

Specifically, your firm uses a(b) (4) (b) (4) (b) (4) Item#: (b) (4), as a product-contact component (b) (4) of your(b) (4) steps to (b) (4) . Your investigation into Deviation D23734-DEN and a notebook study performed by your firm, confirmed that this (b) (4) leaches(b) (4) into the product, which is one of the main root causes of recurring Out-of-Specification (OOS) results for subvisible particulates. Despite this, you continue to use this component. The selection of this (b) (4) was not supported by initial qualification studies to ensure its suitability for use with a biologic product for ophthalmic use.

OBSERVATION 3

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

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Specifically, your firm has not developed an environmental monitoring plan based upon sound scientific methods to include appropriate sampling frequency and timing. Your firm has no documentation to demonstrate that the environmental sampling performed is representative of the entire process. For example,

a) Your firm takes (b) (4) active air samples per lot depending on fill time and shift changes. Your firm has no documented risk assessment to demonstrate that the sampling is representative of the entire filling process. For example,

- Lot #2530855 of Rocuronium Bromide 10mg/mL (5mL syringe) was filled on (b) (4). Filling started at (b) (4) and ended at (b) (4) Active air samples were taken at (b) (4)
- Lot #2530869 of Bupivacaine HCl 0.375% - Dexmethasone Sodium Phosphate 0.01% - Epinephrine 1:200,000 PF was filled on (b) (4). Filling started at (b) (4) and endec(b) (4) Active air samples were taken at (b) (4)
- Lot #2531047A of Dexmedetomidine HCl (20 mcg (base) per 5 mL) PF 5mL syringe was filled on (b) (4). Filling started at (b) (4) on (b) (4) and ended at (b) (4) on (b) (4) (b) (4) Active air samples were taken on (b) (4) at (b) (4) and on (b) (4) at (b) (4)

b) Your firm has no documented risk assessment or justification for the number and placement of non-viable particle monitoring probes within the ISO (b) (4) for automated syringe filler (b) (4). Your firm has one non-viable particle monitoring probe located near the filling station.

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c) Your firm cannot demonstrate that the orientation of the non-viable particle continuous monitoring probes located in the ISO (b) laminar flow hoods (LFH) provides a meaningful sample. The placement of the (b) (4) probe is not fixed and can be bumped and moved during production and cleaning of the hoods. Orientation of the (b) (4) probe is not always directed into the flow of air during monitoring. For example, on 11/13/2025 I saw the (b) (4) probes in (b) (4) LFHs in Room (b) (4) that were tilted and not oriented into the air flow.

Since April 1, 2024, your firm has compounded approximately (b) (4) lots of sterile drug products.

OBSERVATION 4

Written procedures are not established that describe the in-process controls, tests and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically, your firm has no documented justification for the sample size of (b) (4) units no matter the batch size or the extraction of only (b) (4) of solution from each of the (b) (4) containers to perform the supplemental visual inspection of drug products where the drug products and/or the container closure system permits limited visual inspection of the contents. For example, your firm fills Ropivacaine HCl 0.2% into opaque On-Q pumps (545mL and 745mL fills). Lot sizes since April 1, 2024 have ranged from (b) (4) pumps ((b) (4) lots and sublots).

OBSERVATION 5

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

Specifically, your firm has no documentation to show the ISO(b) (4) area within the (b) (4) of the automated syringe filler (ASF-(b) in Room (b) (4)) and the ISO(b) (4) laminar flow hoods where sterile drug products are filled into various types of containers (syringes, vials, dropper bottles, IV bags and On-Q pumps) have been certified under dynamic conditions. In addition, your firm has no documentation to demonstrate that the re-certification of the ISO(b) (4) and ISO(b) (4) cleanrooms were certified under dynamic conditions per ISO (b) (4), including minimum number of sampling locations to be tested.

OBSERVATION 6

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

Specifically,

a) Disinfectant efficacy studies do not include all material from all critical areas where sterile drugs are made. For example,

- The studies failed to include the use of (b) (4)) on any surface except for (b) (4) gloves. (b) (4) is used on surfaces in ISO (b) (4) cleanrooms/areas including equipment and laminar flow hoods.
- The studies failed to include the use of (b) (4) on all surfaces in the ISO(b) (4) ISO(b) (4) areas for the automated syringe filler including the gloves and panels of the (b) (4)
- The studies failed to include the materials that comprise the floors, walls and ceilings of the ISO(b) (4) and ISO(b) (4) cleanrooms.

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b) On 11/13/2025, I observed rust and/or discoloration that appeared to be rust on the shelves of carts located in the ISO (b) (4) Cleanroom (Room (b) (4)) where aseptic drug products are filled using an automated syringe filler within an ISO (b) (4) (b) (4).

OBSERVATION 7

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a) Your firm is taping shut media plates used for environmental and personnel monitoring (completely wrapping the plate closure) which may result in a low-oxygen environment inside the plates, which in turn could compromise the growth/recovery of aerobic microorganisms.

b) Your firm is not adequately preparing product samples for endotoxin testing. For example, your firm is not vortexing the product sample before removing the test portion for endotoxin testing.

*DATES OF INSPECTION

11/13/2025(Thu), 11/14/2025(Fri), 11/17/2025(Mon), 11/18/2025(Tue), 12/11/2025(Thu)

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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."