DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	7/6/2026-7/17/2026*
	FEI NUMBER 3015133983

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Chad R. Tinnes, Pharmacist in Charge and General Manager

FIRM NAME	STREET ADDRESS
Cascade Specialty Pharmacy, LLC	19062 State Highway 305 NE
CITY, STATE, ZIP CODE, COUNTRY Poulsbo, WA 98370-7336	TYPE ESTABLISHMENT INSPECTED ~~Manufacturer~~ Producer of Non-Sterile Drug Products LSW 07/17/2026

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

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Your firm's written procedure designates the pharmacist as responsible for ensuring the accuracy of compounding records and performing quality checks requiring pharmacist verification. However, your firm's compounding record does not specify container and closure to use to ensure they are adequate for its intended pharmaceutical usage. For example: your firm manufactured Gabapentin 100 mg/mL Suspension Stock Solution Lot 656519 that may be used in the production of patient-specific drugs. This stock solution can be stored for up to (b) (4) per the compounding record. The compounding record for Gabapentin 100 mg/mL Suspension Stock Solution Lot 656519, used in the production of patient dosage Lot 657408, does not describe the container and closure system in sufficient detail. The record states only "Bottle with Insert and Dosing Syringe," without specifying the material or type of container. This level of detail is inadequate to ensure that the selected container and closure system is appropriate for long-term storage of up to (b) (4) and does not provide sufficient assurance against degradation due to leaching, permeability, or inadequate sealing over the storage period.

OBSERVATION 2

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Lillian S Wu, Investigator Youkeun Kim, Investigator	X Youkeun Kim Investigator Signed By: 2002027774 Date Signed: 07-17-2026 11:33:01	7/17/2026

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Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

A. Amoxicillin/Clavulanate Pot 250 mg/mL Suspension Lot 657973 (RX# (b) (6), (b) (7)(C))

Your firm's compounding record does not specify the method to be used for crushing or dissolving tablets during production. The instructions for tablet pulverization do not indicate the required duration of pulverization needed to achieve a uniform particle size, nor do they specify how many tablets are to be pulverized at one time. Without these critical parameters, the production process cannot be reliably reproduced across different operators, and there is no assurance that the resulting suspension will have uniform particle size distribution.

B. Methimazole Lipo 5 mg/0.1 mL Cream Lot 654534 (RX#(b) (6), (b) (7)(C)

Your firm's compounding record instructs the operator to "Place into specified container for patient use," identified as a 1 mL syringe. However, the record provides no instructions describing how the product is to be transferred from the production container into the 1 mL syringe. There are no steps to ensure complete transfer of the product, accurate fill volume, or consistency across units.

OBSERVATION 3
Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Youkeun Kim
Investigator
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Date Signed: 07.17.2026
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Your firm has not conducted an in-house efficacy study to verify the effectiveness of the deactivating agent used for beta-lactam residue on production equipment from manufacturing and handling beta-lactam drug substances, or to confirm that the contact time employed by your firm is sufficient to achieve adequate deactivation. Instead, your firm relies solely on the manufacturer's claims to establish the suitability of the deactivating agent for its intended use. There is no in-house scientific data to support the adequacy of the agent or the contact time your firm use is adequate for the non-dedicated work area where beta-lactam and other non-sterile hazardous drugs are produced.

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

Your firm performs routine potency testing only on in-process materials for Levothyroxine Sodium and Liothyronine Sodium. Your firm does not perform routine finished product testing on manufactured drug products. For example:

A. Trilostane Capsule 58 mg Lot 660349 (RX# (b) (6), (b) (7)(C)

Your firm did not perform identity or strength testing on this finished drug product prior to release. Conformance to the labeled potency of 58 mg was not analytically verified; release was based solely on theoretical potency calculated from the quantities of components used during production.

B. Gabapentin 100 mg/mL Suspension Lot 657408 (RX# (b) (6), (b) (7)(C)

Your firm did not perform identity or strength testing on this finished drug product prior to release. Conformance to the labeled concentration of 100 mg/mL was not analytically verified; release was

Youkeun Kim
Investigator
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based solely on theoretical potency calculated from the quantities of stock solution used during production. The stock solution used, Gabapentin 100 mg/mL Suspension Stock Solution Lot 656519, itself was not tested for its potency after the production.

OBSERVATION 5

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

Specifically,

Your firm accepts the material based on the supplier's certificate of analysis in lieu of testing each components received. However, your firm does not perform identity tests each component received to ensure that the component received has purported identity. The following components based solely on the supplier's COA without performing any identity testing:

A. Trilostane powder Lot (b) (4) , which was used to compound Trilostane Capsule 58 mg lot 660349, was accepted without any identity testing. Only the CoA of supplier was used for release for usage.

B. Methimazole powder lot (b) (4) , which was used to compound Methimazole Stock solution 10mg/mL lot 647915, was accepted without any identity testing. Only the CoA of supplier was used for release for usage.

C. Itraconzole powder lot (b) (4) , which was used to compound Itrazonzole 25mg/mL Suspension lot 652087, was accepted without any identity testing. Only the CoA of supplier was used for release for usage.

In addition, your firm has not demonstrated the reliability of your suppliers' COAs through adequate validation or testing at appropriate intervals.

Youkeun Kim
Investigator
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OBSERVATION 6

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

Specifically,

Your firm does not have written stability testing program to determine the beyond use date for each drug product. Your firm assigns beyond use date based on the (b) (4) , which is based on either stability testing performed by other entity for in-process stock, or based on the dosage form and the storage condition.

*DATES OF INSPECTION

7/06/2026(Mon), 7/07/2026(Tue), 7/08/2026(Wed), 7/09/2026(Thu), 7/10/2026(Fri), 7/13/2026(Mon), 7/14/2026(Tue), 7/15/2026(Wed), 7/16/2026(Thu), 7/17/2026(Fri)

Lillian S Wu
Investigator
Signed By: 2003443287
Date Signed: 07-17-2026 11:33:29
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Youkeun Kim
Investigator
Signed By: 2052027734
Date Signed: 07-17-2026
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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."