

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 5/13/2019-5/17/2019*
	FEI NUMBER 3015131323

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George W. Kridner IV, Pharm.D, Chief Executive Officer

FIRM NAME California Specialty Pharmacy Inc.	STREET ADDRESS 13027 Hadley St Ste B
CITY, STATE, ZIP CODE, COUNTRY Whittier, CA 90601-4206	TYPE ESTABLISHMENT INSPECTED Producer of Non-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 I OBSERVED:
OBSERVATION 1**

You used a non-pharmaceutical grade component in the formulation of a drug product.
Specifically, your firm used components that were not pharmaceutical grade to produce drug products that included, but were not limited to, the items listed below.

A.) Non-pharmaceutical grade (b) (4) water was purchased by your firm and it was used to produce multiple nasal spray drug products. Examples include, but are not limited to, the drug products listed below.

1. Approximately (b) (4) lots of C-Ketamine Nasal Spray were produced between February 2019 and May 2019.
2. Approximately (b) (4) lots of C-Oxytocin 24 units/mL Nasal Spray were produced between February 2019 and May 2019.
3. Approximately (b) (4) lot of C-Lidocaine HCl 4% Glycerin Nasal Spray was produced in April 2019.

Your firm has not submitted any samples of this (b) (4) water to your contract laboratory to test for microbial limits and/or other analytical properties to show it is equivalent to pharmaceutical grade water.

B.) Non-pharmaceutical grade ingredient, Oxytocin, was purchased and used by your firm to produce non-sterile sublingual tablet and non-sterile nasal spray drug products. Examples include, but are not limited to, the drug products listed below.

1. Approximately (b) (4) lots of C-Oxytocin Sublingual Tablets were produced between February 2019 and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Stephanie A Slater, Drug Specialist	DATE ISSUED 5/17/2019
	Stephanie A Slater Drug Specialist Signed By: Stephanie A Slater -S Date Signed: 05-17-2019 10:39:33 X _____	

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May 2019.
2. Approximately (b) (4) lots of C-Oxytocin 24 units/mL Nasal Spray were produced between February 2019 and May 2019.

The Certificate of Analysis and container label for the Oxytocin states that this ingredient is "Not for Human or Vet use without sterile processing."

OBSERVATION 2

You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, your firm does not have cleaning procedures in place to ensure the prevention of cross-contamination of hazardous drugs. Examples include, but are not limited to, the cleaning of work surfaces, compounding equipment, and utensils, which are located and/or used to produce hazardous drug products in the non-sterile compounding room. Examples of hazardous drug products made at your firm include, but are not limited to, C-Oxytocin Sublingual Tablets and C-Oxytocin Nasal Spray.

***DATES OF INSPECTION**

5/13/2019(Mon), 5/14/2019(Tue), 5/15/2019(Wed), 5/17/2019(Fri)

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