DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237 (513) 679-2700 Industry Information: www.fda.gov/oc/industry	9/6-9/16; 9/12/16; 9/14/16 & 9/26/16
	FEI NUMBER 3012729009

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Roger G. Hospelhorn, Owner/President

FIRM NAME	STREET ADDRESS
Cincinnati Specialty Pharmacy, LLC.	7731 Cox Lane
CITY, STATE AND ZIP CODE West Chester, OH 45069	TYPE OF 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) (WE) OBSERVED:

501C FD&C Act:
Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. Specifically,

Observation #1:

(a) Your firm released two finished drug products to patients that were 10 times less potent for Liothyronine (T3) in the T3/T4 capsules produced at your pharmacy than what was prescribed by the physicians of the patients. The following two finished drug products contained 10 times less T3 than prescribed on the prescription and each was released to a patient:

Patients Initials	Finished Drug Product	Lot Number	Date Released to Customer	Actual T3 (grams) in Rx	T3 (grams) required in Rx
(b) (6), (b) (4)	T4 (Levothyroxine) 50mcg/T3 (Liothyronine) 25mcg capsules	07 14 2016@9	7/14/16	0.075 gms	(b)(4)
(b) (6), (b) (4)	T4 (Levothyroxine) 110mcg/T3 (Liothyronine) 16mcg capsules	07-20-2016@36	7/20/16	0.032 gms	(b)(4)

Your firm (b)(4) T3 (b)(4) (lot: (b)(4) for the T3 in the following abovementioned prescriptions on 7/6/16. Drug production records identity that your firm did not add enough of the T3 (b)(4) to the final products produced making them 10 times less potent for T3 than the prescribed dose on the prescription by the physician. The Pharmacist at your firm reviewed and approved the production records for releasing the finished drug products. Furthermore, according to firm management, the Pharmacists and Pharmacy Technicians have not been trained on how to produce (b)(4) at your facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Nicholas L. Paulin Mark Loh	Nicholas L. Paulin, Investigator Mark Loh, Chemist	9/26/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237 (513) 679-2700 Industry Information: www.fda.gov/oc/industry	9/6-9/16; 9/12/16; 9/14/16 & 9/26/16
	FEI NUMBER 3012729009

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Roger G. Hospelhorn, Owner/President

FIRM NAME	STREET ADDRESS
Cincinnati Specialty Pharmacy, LLC.	7731 Cox Lane
CITY, STATE AND ZIP CODE West Chester, OH 45069	TYPE OF 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) (WE) OBSERVED:

(b). Your firm periodically performs potency testing on raw materials in the finished drug product (b) for the purposes of testing only. (b)(4) (b)(4) Potency testing is not performed on product distributed to patients. The following raw materials tested in the finished product were out of-specification (OOS) according to the firm's potency specification of (b)(4) which were for testing purposes only:

RM in Finished Product	Date Produced	Lot number	Result	Finished Product	Comments
Estriol (original)	6/25/14	06-25 2014@45	215.6%	Cream	Failed: sent for re-test
Estriol (re-test)	7/15/14	07 15-2014@41	106.2%	Cream	Passed
Cyclobenzaprine 2% (original)	10/20/2014	10 20 2014@46	86.8%	Cream	Failed: Sent for re test
Cyclobenzaprine 2% (re test)	11/26/14	11 26 2014@10	86.4%	Cream	Failed: No re test after failed second OOS
Progesterone (original)	10/20/14	10 20 2014@32	138.7%	Capsule	Failed: No re-test after first failed OOS

Furthermore, on potency results that are OOS your firm does not have a procedure in place on how to handle these failed results.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Nicholas L. Paulin Mark Loh	Nicholas L. Paulin, Investigator Mark Loh, Chemist	9/26/16