DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	03/25/2015 - 04/01/2015* FEI NUMBER 3011432609

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Cheryl A. Estep, Co-Owner/Managing Member

FIRM NAME	STREET ADDRESS
Precision Pharmacy Center, LLC	2903 Saturn St Ste A
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brea, CA 92821-6259	Producer of non-sterile drugs

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

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

Specifically,

A. your firm does not perform analytical testing to determine finished product potency prior to distribution. For example, the following products were produced and distributed without testing for potency:

1. Benzocaine 20%/Lidocaine 6%/Tetracaine 4% PLO Gel, Lot 03192015@5
2. Progesterone SR 100 mg Capsules, Lot 03192015@9
3. Biestrogen SR 2.5 mg Capsules, Lot 03182015@12
4. Testosterone SB 25% (250mg/ml) Cream, Lot 03182015@15

B. your firm does not perform dissolution testing to demonstrate the appropriate release of the active ingredients in your modified release capsules. For example, the following products were produced and distributed without dissolution testing:

1. Progesterone SR 100 mg Capsules, Lot 03192015@9
2. Biestrogen SR 2.5 mg Capsules, Lot 03182015@12

OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm does not test your non-sterile drug products for microbial contamination. For example, the following products have not been tested to ensure that they are free of objectionable microorganisms:

A. Lansoprazole 3mg/ml in Syrup Suspension Solution, Lot 03232015@5
B. Biest 18.75 mg/ml (0.625 mg/drop) Sublingual Drops, Lot 03092015@15

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Thao T Kwan, Investigator	04/01/2015

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C. Chloral Hydrate 100 mg/ml Oral Liquid, Lot 03172015@10
D. Cocaine Hydrochloride Topical 4% Solution, Lot 03192015@3

OBSERVATION 3

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

A. your firm does not have data to support the adequacy of your blending process for encapsulated drug products. The process consists of (b) (4) [redacted]. There is no assurance that a homogeneous mixture is achieved.

B. your firm does not have a procedure in place or test performed to ensure correct particle size is achieved during production of encapsulated products. Your firm uses (b) (4) [redacted] Specifications for particle size have not been established and there is no test performed to determine the particle size.

C. your firm does not perform checks to capsule weights to ensure the targeted theoretical weight of the capsule is met.

OBSERVATION 4

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

Specifically, your firm does not have data to substantiate Beyond Use Dates (BUD) of up to 180 days for finished drug products. For example, the following products are labeled with a 180 day BUD:

A. Benzocaine 20%/Lidocaine 6%/Tetracaine 4% PLO Gel, Lot 03192015@5
B. Progesterone SR 100 mg Capsules, Lot 03192015@9
C. Biestrogen SR 2.5 mg Capsules, Lot 03182015@12
D. Testosterone SB 25% (250mg/ml) Cream, Lot 03182015@15

OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has not established specifications for microbial limits for non-sterile drugs produced and distributed

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by your firm.

OBSERVATION 6

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, your firm does not test for the identity of drug components. In addition, the Certificates of Analysis received with drug components are accepted even though your firm has not established the reliability of the supplier's analysis through validation of the supplier's test results.

*** DATES OF INSPECTION:**
03/25/2015(Wed), 04/01/2015(Wed)

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	Thao T Kwan, Investigator	04/01/2015