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 Industry Information: www.fda.gov/oc/industry	09/30/2013 - 10/02/2013 FEI NUMBER 3004792262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Herbert Bruce Bowman, Pharmacist R.Ph.

FIRM NAME	STREET ADDRESS
Wiley Chemists Inc.	1676 Hospital Dr.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Fe, NM 87505	Human Drug Product Producer

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

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,
Your firm does not perform finished product testing for each lot of drug product released. For example:

- Assay potency testing was not conducted on Testosterone T- 10 mg/ .1 ml cream lot 2013060309.
- Assay potency testing was not conducted on Dehydroepindrosterone (DHEA) cream lot 2013060311.
- Assay potency testing was not conducted on Estradiol E2- 1 mg/.1ml cream lot 2013062603.
- Assay potency testing was not conducted on Progesterone P4- 20 mg/.1ml cream lot 2013062402.
- Assay potency testing was not conducted on Wiley Cortisol capsules lot 2013062402.

OBSERVATION 2

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically,
Your firm does not perform identity testing on active ingredient components used in the finished drug product.
For example:

- Testosterone USP lot number [redacted] (b) (4) used to produce finished drug product Testosterone T- 10 mg/.1ml cream
- DHEA USP, Special micronized lot number [redacted] (b) (4) used to produce finished drug product DHEA-10 mg/.1ml cream
- Estradiol, USP micronized lot number [redacted] (b) (4) used to produce finished drug product Estradiol E2- 1mg/.1ml cream
- Progesterone, USP Special micronized lot number [redacted] (b) (4) used to produce finished drug product Progesterone P4- 20mg/.1 ml cream
- Hydrocortisone acetate lot number [redacted] (b) (4) used to produce finished drug product Cortisol capsules

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Erika V. Butler, Investigator Erika V. Butler Michael A. Charles, Investigator	10/02/2013

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 Industry Information: www.fda.gov/oc/industry	09/30/2013 - 10/02/2013
	FEI NUMBER 3009792262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Herbert Bruce Bowman, Pharmacist R.Ph.

FIRM NAME	STREET ADDRESS
Wiley Chemists Inc.	1676 Hospital Dr.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Fe, NM 87505	Human Drug Product Producer

OBSERVATION 3

The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary.

Specifically,
Each drug product produced and distributed is not traceable to the formulation batch. For example, such as Testosterone T-10mg/.1ml cream lot number 2013060309, this batch distribution cannot be fully determined and traced back to this lot number.

OBSERVATION 4

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,
[redacted] (b) (4) scale model [redacted] (b) (4) used for weighing active ingredients and excipients for the formulation of finished drug product is not calibrated using traceable weight standards.

OBSERVATION 5

Control procedures are not established which monitor the output and 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, process validation has not been performed for the production of Testosterone T- 10 mg/ .1 ml cream, DHEA cream, Estradiol E2- 1 mg/.1ml cream, Progesterone P4- 20 mg/.1ml cream, and Wiley Cortisol capsules.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Erika V. Butler, Investigator Erika V. Butler Michael A. Charles, Investigator	10/02/2013