DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/02/2015 - 03/06/2015* FEI NUMBER 3005623291

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jane Patel, Chief Executive Officer/Pharmacist in Charge

FIRM NAME	STREET ADDRESS
D.R. Pharmacy, Inc.	501 Andrews Highway Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Midland, TX 79701	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 WE OBSERVED:

OBSERVATION 1

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 does not conduct potency testing for any finished drug products. Some examples consist of the following:

1. BI-EST::E2:E3 2.5mg:0.25mg, lot #09152014@6 (Production date: 9/15/2014, Beyond Use Date: 3/14/2015)
2. TRI-EST 1.25mg/0.2ml Cream, lot #01092015@3 (Production date: 1/9/2015, Beyond Use Date: 7/8/2015)
3. Opium Tincture Synthetic, Deodorized, lot #02022015@2 (Production date: 2/2/2015, Beyond Use Date: 8/1/2015)

OBSERVATION 2

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

Specifically, your firm has not provided data to substantiate Beyond Use Dates of up to 180 days for finished drug products. For example, the following products are labeled with an 180 day BUD:

1. BI-EST::E2:E3 2.5mg:0.25mg, lot #09152014@6 (Production date: 9/15/2014, Beyond Use Date: 3/14/2015)
2. TRI-EST 1.25mg/0.2ml Cream, lot #01092015@3 (Production date: 1/9/2015, Beyond Use Date: 7/8/2015)
3. Opium Tincture Synthetic, Deodorized, lot #02022015@2 (Production date: 2/2/2015, Beyond Use Date: 8/1/2015)

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,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephen D. Brown, Investigator Patty P. Kaewussdangkul, Investigator Patty P. Kaewussdangkul	03/06/2015

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A. Your firm has failed to provide data to justify the use (b) (4) as a test for the homogeneity of suspensions or creams. In this case, (b) (4)

B. Your firm uses commercially available (b) (4) to reduce particle size in different products (i.e. Progesterone 100mg Suppositories and Progesterone 100mg Tablets). However, specifications for particle size have not been established. In addition, testing is not conducted to determine particle size.

C. Your firm adds (b) (4) (preservative) to (b) (4) obtained commercially which is used in various formulations. Your firm has provided no data to substantiate the 6 month Beyond Use Date assigned to the (b) (4)

OBSERVATION 4

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in processing.

Specifically, your firm documents pharmaceutical calculations needed for formulations (b) (4) (b) (4) The pharmaceutical calculations are not documented on the formula worksheets.

OBSERVATION 5

Approved components are not retested or reexamined as appropriate for identity, strength, quality and purity after storage for long periods with subsequent approval or rejection by the quality control unit.

Specifically,

A) Expired Active Pharmaceutical Ingredients were observed on 3/3/2015 near the production area. Some examples include the following:

1. Metronidazole, USP, lot (b) (4) (Expiration date: 5/2014)
2. Domperidone BP, lot (b) (4) (Expiration date: 3/1/2014)
3. Naltrexone HCl, lot (b) (4) (Expiration date: 5/14)
4. Dyclonine HCl, lot (b) (4) Expiration date: 3/30/14)

B) In addition, your firm produced three drug products between 9/2014 and 12/2014 which were assigned BUD's past the expiration of some of its components. These consist of the following:

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	Stephen D. Brown, Investigator SB Patty P. Kaewussdangkul, Investigator PPK	03/06/2015

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a) Metronidazole 50mg/ml suspension produced on 12/9/14 was assigned a BUD date of 1/8/15; however, two components of the drug (b) (4) expired on 12/10/2014 and 12/12/2014.
b) Progesterone (RDT) 200mg tablets produced on 9/4/14 were assigned a BUD date of 3/3/2015 however, (b) (4) used in the drug expired on 1/1/2015.
c) Progerstrone (RDT) 100mg tablets produced on 9/2/14 were assigned a BUD date of 3/1/2015 however, a component (b) (4) used in the product expired on 1/1/2015.

OBSERVATION 6

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 limit testing to ensure that non sterile aqueous based formulations administered orally comply with compendial requirements for microbial quality.

For example, Opium Tincture Synthetic, Deodorized, lot #02022015@2 (Production date: 2/2/2015, Beyond Use Date: 8/1/2015) was not tested for micobial limits.

OBSERVATION 7

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

Specifically, your firm does not evaluate any finished aqueous drug products administered orally for microbiological contamination.

For example, Opium Tincture Synthetic, Deodorized, lot #02022015@2 (Production date: 2/2/2015, Beyond Use Date: 8/1/2015) was not tested to ensure that it was free of objectionable microorganisms.

*** DATES OF INSPECTION:**
03/02/2015(Mon), 03/03/2015(Tue), 03/04/2015(Wed), 03/06/2015(Fri)

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